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

Meeting Transcript

November 9-10, 2022

Atlanta, Georgia (Virtual)

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

November 9, 2022

❖ Call to Order and Committee Member Introductions

CLIAC DFO: Good morning, everyone. It is 11:00 AM on the East Coast and 8:00 AM on the West Coast. Welcome to the fall 2022 meeting of the Clinical Laboratory Improvement Advisory Committee, or CLIAC. My name is Ren Salerno. I'm director of the Division of Laboratory Systems at the Centers for Disease Control and Prevention. I'm also the designated federal official of CLIAC, which is managed by CDC, and provides scientific and technical advice and guidance to the Department of Health and Human Services. The advice and guidance CLIAC provides to HHS focuses on issues related to improvement in 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 standards. As this is a Federal Advisory committee meeting, the Zoom chat and Q&A functions have been disabled for audience members. If you're experiencing any Zoom difficulties, please feel free to contact cliac@cdc.gov.

We want to acknowledge at the outset of today's meeting that HHS or the Department of Health and Human Services-- Health and Human Services has not yet made their final decision, and selections for new 2022 CLIAC members. As a result, we have asked some of our members whose terms formally ended in the Spring to extend their terms until the end of this calendar year. We would like to thank Dr. Susan Gross, Dr. Lee Hilborne, Dr. Lavinia Middleton, Dr. Gregory Sossaman and our chair Dr. Valerie Ng for their agreement to extend their terms and participate in this meeting as CLIAC members. We would also like to take this opportunity to thank Ms. Sarah Bennett for serving as the CMS ex officio during the April 2022 meeting and providing the CMS update. We would also like to thank Ms. Nancy Anderson for serving as the CLIAC Executive Secretary for so many years. Nancy's contributions have been invaluable to the CLIAC program, and we wish her all the best in her retirement. I would like to take this opportunity to introduce Mr. Gregg Brandush who will be serving as the new CMS ex officio. Mr. Brandish is the Director of the Division of Clinical Laboratory Improvement and Quality, or DCLIC at CMS. We welcome you to CLIAC, Gregg. I would also like to introduce Ms. Heather Stang who now serves as the Executive Secretary. Ms. Stang is the Deputy Chief of the Quality and Safety Systems Branch in the Division of Laboratory Systems at CDC.

CLIAC CHAIR: Good morning. I'm Dr. Valerie Ng. During the period dedicated to committee discussion, participation is limited to CLIAC members only. CLIAC can only accept public comments that directly relate to the topics announced in the federal register notice of the CLIAC meeting and as related to the topics.

Today, the committee will discuss and deliberate on the CLIA regulations assessment workgroup report and the CLIA certificate of waiver and certificate for provider performed microscopy procedures report. Public comment periods are scheduled at the end of each topic area for both meeting dates. Today, public comments will be limited to a total time of five minutes per individual or group. If anyone in the audience wishes to address the committee, the public comment portion of the meeting is the proper forum to do so.

Quorum-- members are reminded of the importance of remaining in attendance on both days for the full meeting and returning promptly from breaks to ensure a quorum until all matters before the committee are addressed and the meeting is adjourned. Members are expected to keep their video on during committee discussions. 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 the CLIAC and obtain a majority vote. A reminder that all CLIAC discussions and deliberations must be available to the public. The chat is not available to the public for viewing. CLIAC members should not engage in topic discussions offline to the chat. Please use the chat only to notify me of your desire to comment during the discussions or ask a question of the speaker. Draft recommendations will be discussed verbally by CLIAC MEMBERs, not via chat. An email to Heather Stang is another option to submit draft recommendations. The CLIAC recommendations table is available on the meeting website and contains a list of all past CLIAC recommendations, including information on their implementation steps.

CLIAC DFO: We will now call the roster and ask each CLIAC member, ex officio, and staff to give their name, professional title, and acknowledge their conflicts of interest. So I will start. My name is Ren Salerno director of the Division of Laboratory Systems and the designated federal official for CLIAC. I have no conflicts of interest.

CLIAC CHAIR: I am Valerie Ng. I am the chair of laboratory medicine and pathology at Alameda Health System, and I'm the laboratory director of the clinical laboratories at Alameda Health System. I have no conflicts of interest.

DR. BIRTHALE ARCHIE: I am Birthale Archie, and I'm at Bowie State University and clinical nursing practice. And I have a-- in the point of public disclosure, I have a $10 million grant with HHS ONC to educate students on public health informatics and technology. I have no conflict.

MR. MICHAEL BLACK: Hey, this is Mike Black. Good morning, everyone. I'm the vice president of laboratory operations at Ochsner Health. I have no conflicts of interest.

CLIAC CHAIR: Kim, you're on mute. You're on mute. Your mouths going but we can't hear.

DR. KIMBERLE CHAPIN: Oh, good morning. I'm trying to be extra careful with the noise around me. Good morning, everyone. I'm Dr. Kim Chapin. I'm the chief medical officer for Cepheid and also professor of Brown pathology and laboratory medicine in Providence, Rhode Island.

DR. JAMES CRAWFORD: I'm Jim Crawford, the chair of the department of pathology and laboratory medicine and Senior vice president for laboratory services at Northwell Health. My conflict of interests are I'm chair of the board of directors of a non-profit educational foundation, project Santa Fe Foundation. I serve on an advisory committee for Clarapath which is a private firm. And I'm president of an alliance with BioReference entitled The Northwell Health Genomics Alliance.

MS. HEATHER DUNCAN: I'm Heather Duncan. I'm the director of laboratory operations for ECU Health Medical Center. I have no conflicts to declare today.

DR. MARY EDGERTON: I am Dr. Mary Edgerton. I'm a breast pathologist and pathology informatician at the University of Texas M.D. Anderson Cancer Center, and I do not have any conflicts to report.

DR. SUSAN GROSS: I'm Sue Gross I'm an OB-GYN, and a geneticist, and adjunct professor at Icahn School of Medicine at Mount Sinai division of genetics and genomic sciences. And in terms of conflicts, I am the CEO and President of the ObG Project, a mobile-friendly educational site for health care professionals promoting best practices and guidelines. And otherwise, I have no conflicts to declare.

DR. LEE HILBORNE: Good morning, everybody. I'm Lee Hilborne. I'm a senior medical director in medical affairs for Quest Diagnostics. And as such, I have salary and stock from Quest. I'm also professor of pathology and laboratory medicine at-- and a medical director for care coordination for UCLA Health, which does not present conflicts.

DAVID KOCH: Looks like it's my turn. I got on just in time. Sorry I was late. And Heather, I sent you an email saying I couldn't find the link. Obviously, I found it. So I'm Dave Koch, the director of chemistry at Grady and I'm on the faculty of Emory. And also recently, I was asked to take on the role of medical director of the whole labs here at Grady, a job that I'm sharing on an interim basis for the time being.

DR. LAVINIA MIDDLETON: Good morning. My name is Lavinia Middleton. I'm a professor of pathology at MD Anderson Cancer Center in Houston, Texas. I serve on the advisory committee-- executive advisory board for Leapfrog Group. Otherwise, I have no conflict of interest.

MS. CAROLE MOSS: Good morning. I'm Carole Moss. I am CEO and founder of Niles Project. We're a patient safety public health awareness organization. I do not have any conflicts of interest. Here representing the public's voice, and looking forward to working with all of you. Thanks.

DR. NIRALI PATEL: Nirali Patel, director of molecular pathology at Tempus Labs. I have no conflicts to disclose.
CLIAC DFO: Thank you. Dr. Michael Pentella.

DR. MICHAEL PENTELLA: Michael Patella. I'm a professor at the College of Public Health University of Iowa and director of Iowa State Public Health Laboratory. No conflicts of interest to disclose.

MS. JENNIFER RHAMY: I'm Jennifer Rhamy. I'm retired. Previously, I was director of the regional Blood Center here in Grand Junction, Colorado, and I have no conflicts to disclose.

DR. GREG SOSSAMAN: Good morning, everyone-- Gregory Sossaman. I'm the service line lead for pathology and lab medicine in Ochsner Health and clinical pathologist here. I have volunteer positions with the Compass Group and the American Society for Clinical Pathology, but no financial interests to disclose.

CLIAC EXECUTIVE SECRETARY: And Dr. Tuthill is unable to join us today, so we'll move on to Chip.
DR. CHIP WATKINS: Chip Watkins-- I'm chief medical officer and lab director at NeuroLab here in Asheville, North Carolina. Also I'm a regional medical director for Community Care of North Carolina. I'm a family doc by training and an AAFP appointee to the COLA board of directors, and no conflicts of interest.

MR. ANDY QUINTENZ: Hi, I'm Andy Quintenz. I am-- I lead up a team of scientific professional affairs managers for Bio-Rad laboratories. I serve on the board of directors for the Clinical and Laboratory Standards Institute-- CLSI-- and I chair

the US technical advisory group to ISO/TC 212, which is a technical committee overseeing IVD standards and guidance documents.

DR. COLLETTE FITZGERALD: 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 this committee. I serve on the board of directors at the Clinical and Laboratory Standards Institute, but have no conflicts of interest.

MR. GREGG BRANDUSH: Hello, everyone. My name is Gregg Brandush. I'm the director for the Division of Clinical Laboratory Improvement and quality for CMS. I'm also CMS ex officio, and I have no conflicts of interest. Thank you.

DR. TIMOTHY STENZEL: Hi, I'm Tim Stenzel. I direct the office of In Vitro Diagnostics at the FDA. And for CLIAC, I'm the FDA ex officio. I look forward to this meeting. Thank you.

MS. HEATHER STANG: And I'm Heather Stang. I'm the new CLIAC Executive Secretary. I am the deputy chief of the Quality and Safety Systems Branch in the Division of Laboratory Systems at CDC, and no conflicts.

CLIAC CHAIR: Thank you, all. A few words about schedule and logistics. Copies of PowerPoint presentations and other meeting materials are posted on the CLIAC website-- that is 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. 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, please email cliac@cdc.gov. The meeting is also recorded to assist in preparing an accurate written summary of the proceedings. There will be an hour break each day. CLIAC members need to arrive online promptly to ensure a quorum so that we can begin the session. Now, moving on to the meeting. First on the agenda are the agency updates.

We will start with updates from CDC, CMS, and FDA. These are the online presentations number one, two, and three. Following the agency updates, there will be a presentation on the proficiency testing final rule, which is presentation number four. So we will turn this over to the CDC update and Dr. Fitzgerald. Go for, it Collette.

❖ Agency Updates and Committee Discussion

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

DR. COLLETTE FITZGERALD: So thank you for the opportunity to share updates this morning on our work in the Division of Laboratory Systems in 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. Next slide, please. So I'm going to start first with a brief update on CDC moving forward. Next slide, please.

In April 2022, CDC launched an effort to refine and modernize its structures, systems, and processes around developing and deploying our science and programs. The goal was to learn how to pivot our longstanding practices and better adapt to pandemics and other public health emergencies, then to apply those lessons across the organization. The effort has included a review of key workflows with a particular focus on ensuring CDC science reaches the public in an understandable, accessible, and implementable manner as quickly as possible. On August 17, 2022, our CDC director Dr. Walensky launched CDC Moving Forward, which includes four interrelated efforts that are shown here on this slide. Aim to strengthen and strategically align CDC systems and processes to drive a public health action-orientated culture at CDC that emphasizes accountability, collaboration, communication, and timeliness. These efforts include implementing changes to improve how CDC develops and delivers its data and science during public health responses as well as normal operations. Standing up new internal systems, processes, and governance within the agency to improve accountability, collaboration, communication, and timeliness within CDC and with its stakeholders at all levels of the organization. Reorganizing the agency to break down silos, elevate core capabilities, and better leverage resources, and to articulate new programs, authorities, and flexibilities that will better position CDC and public health for future response activities. We expect additional information about CDC Moving Forward to be publicly available before the end of the calendar year, and we look forward to sharing additional updates on CDC moving forward at future meetings. Next slide, please. So switching gears now to our division DLS, I'm very excited to be sharing our new DLS strategic framework with you. Next slide, please.

So this slide shows our new framework. It outlines our vision, mission, guiding principles, goals and objectives that will guide the work of our division for fiscal years 2023 through 2025. The new framework refines our vision and mission and charts our path for the next several years in pursuit of five primary goals around quality and safety, training and workforce

development, preparedness and response, data exchange and analytics, and our CDC Biorepository. In addition, there are 19 objectives in total under the five goals and 5 guiding principles-- organizational excellence, scientific excellence, partnerships, communication, and health equity. This truly was a division-wide collaboration, and I want to recognize the efforts of all of my DLS colleagues who contributed to the process as well as well as many external clinical and public health partner organizations who provided feedback and informed the new plan. A link to our new plan is shown on the bottom left hand side of the slide if you'd like to take a closer look. And as we move forward to now operationalize and implement our new plan, we look forward to continued partner engagement and collaboration to drive success forward and accomplish our goals. Next slide, please.

Moving now to laboratory preparedness and response updates. Next slide, please. As CDC's inventory of COVID-19 related work continued to expand along with the ongoing agency-wide response, it became clear that ongoing and future COVID-19 efforts would require a permanent programmatic home to sustain this critical work after the eventual stand down of the agency's COVID-19 response. CDC proposed a new division, the Coronavirus and Other Respiratory Viruses Division, or CORVD. The proposed division will be the fifth division in the National Center for Immunization and Respiratory Diseases, or NCIRD, and will focus on coronaviruses and other non-influenza respiratory viruses. The new proposed division's mission is to protect all people from illness, disability, and death from coronaviruses and other respiratory viruses through public health science and practice in the United States and globally. CORVD propose is currently in a soft launch date pending final reorganization package approval by HHS and Congress. Next slide, please.

So the lack of adequate laboratory testing capacity was evident during the response to the Zika outbreak. To address these challenges in 2018, CDC signed a memorandum of understanding with the American Clinical Laboratory Association, the Association of Public Health Laboratories, and the Council of State and Territorial Epidemiologists. The specific goal of the MOU was to prepare for and improve the implementation of surge diagnostic testing to supplement the public health emergency response system. In 2019, these four MOU partners all participated in a tabletop exercise built around an outbreak of an influenza-like illness of pandemic proportions. Although we were all challenged when we responded to the actual pandemic that presented itself less than a year later, our four organizations were better positioned for surge testing during COVID-19 than we would have been a year earlier. Leadership of these four organizations has met every week since January 2020, and the partnership continues to be extremely valuable. In May 2022, our MOU with these four partners was expanded to now include the partners that you see listed on this slide. More information about this MOU and the work of these partners on diagnostics and surge testing during public health emergencies can be found on the CDC website at the link shown at the bottom of this slide. Next slide, please.

A Clinical Laboratory COVID-19 Response calls, or CLCR calls, are now the Laboratory Outreach Communication System calls, or LOCS calls. DLS continues to convene these LOCS calls with clinical laboratories and other audiences. The calls are an opportunity for CDC, other federal partners, and professional organizations to provide updates and answer questions from the laboratory and testing community. These calls take place on the third Monday of each month at 3:00 o'clock Eastern. With the transmission of COVID-19 activities to the National Center for Immunization and Respiratory Diseases programs, DLS is continuing to provide support on updating laboratory and testing web pages and other web content. DLS has updated six COVID-19 web pages since April, including the overview of testing page, antigen testing guidance page, self-testing page, and guidelines for collecting and handling COVID-19 specimens page. DLS also recently revised the COVID-19 self-testing video series to align with updated CDC guidance. These videos are short, animated videos designed to explain the basics of COVID-19 self-tests. Next slide, please.

So since the agency was activated in June for the 2022 mpox outbreak, CDC has been working in several areas to help support clinical and public health laboratories. CDC supports testing for orthopox, viruses, which includes the virus that causes mpox, across the Laboratory Response Network, or LRN. LRN laboratories can perform up to 10,000 tests each week using the CDC developed FDA-cleared orthopox virus test. Through DLS collaborations with the American Clinical Laboratory Association, four commercial laboratory companies are now performing mpox testing with the CDC-cleared-- with CDC-developed, FDA-cleared non-variola orthopox virus test. Together, these commercial laboratories can perform up to 40,000 tests each week. Another commercial laboratory company, Quest Diagnostics, can additionally perform up to 30,000 mpox tests each week with the PCR test they developed. This means that US laboratories can perform up to 80,000 mpox tests per week. In addition to facilitating the stand up of additional testing capacity, DLS was also responsible for development of specimen handling and biosafety guidance, as well as information for laboratories on how to report results. You can find additional information on these resources at the link shown on this slide. And you'll be hearing more on CDC's mpox response efforts from Dr. Christy Hudson in tomorrow afternoon's mpox response update session. Next slide, please.

Moving next to the outbreak of Ebola virus in Central Uganda, there are currently no cases of in the United States, but CDC and partners are taking steps to shore up domestic preparedness. Laboratories that are members of the Laboratory Response Network and special pathogen treatment centers are standing up tests to rule out Ebola. Specimens from any suspect patients will need to be shipped to these locations or CDC. CDC's OneLab Network hosted two recent Ebola-

focused webinars, one on packaging and shipping of suspected Ebola specimens on October 27 and another on November 3 on what to do next when specimens-- when receiving samples from patients suspected to be infected with Ebola. DLS has sent out five LOCS messages since October 28 related to Ebola, including clarifying the shipping of specimens and clarifying department of transportation and select agent regulations. We're also working with AdvaMedDx and manufacturers to prepare for any questions about instrument decontamination. Next slide, please.

So moving next to laboratory, quality, and safety updates. Next slide, please. The proficiency testing, or PT, final rule was published on July 11, 2022. This final rule implements revised regulations that CMS and FDA proposed-- sorry, CMS and CDC proposed in 2019 to update clear PT regulations related to analytes and acceptable performance. High-level details of what is included in the final rule are shown on this slide. Ms. Sarah Bennett will be providing a more comprehensive overview of the final PT rule later in this session this morning. CMS and CDC will be working together to develop resources for both surveyors and the clinical laboratory community. These include frequently asked questions, surveyor trainings, specialty, specific one-pagers, and a new CDC-developed proficiency testing online course. Next slide, please.

I shared a brief update on our Next Generation Sequencing, or NGS, Quality Initiative at the Spring CLIAC meeting. CDC, the Association for Public Health Laboratories, and state and local public health laboratory partners are collaborating to harmonize quality standards for next generation sequencing across public health and provide laboratories with confidence in reporting results. Since 2019, the initiative has published over 91 free tools and resources to our web page, including resources for wet and dry events personnel and leadership, and over 20 more products are in development. Bench-level professionals, bioinformaticians, quality managers, and laboratory leaders can currently access customizable ready to implement products, which include guidance documents, SOPs, and forms. Through our outreach efforts with the Association for Public Health Laboratories subcommittees and professional organizations, we have engaged and continue to engage with the public health laboratory sequencing community regarding the benefits of a strong quality foundation. We want to understand their needs and remain cognizant of how the initiative's products are being used and implemented. And we'll soon be conducting a survey of CDC and public health laboratories to identify both successes and where products can be improved. Next slide, please.

To improve accessibility to resources, the NGS Quality Initiative has updated its QMS tools and resources web page with search functionality and filters that produce results specific to your laboratory's quality needs. The redesigned web page makes it easier for your laboratory to filter tools and resources by sequencing platform, laboratory role, the quality system essential building block, or your QMS status, or by using a keyword search. In addition, eight new products are now available to download, including resources for NGS equipment selection, inventory management, and implementation of bioinformatics tools and software. Next slide, please.

At the last CLIAC meeting in April 2022, we presented to the committee CDC's plan to examine the intersection between diagnostic excellence and laboratory testing to examine how laboratory staff can engage with their clinical counterparts to reduce the incidence of diagnostic errors. Our goal is to leverage clinical and public health laboratory capabilities to reduce the incidence of diagnostic errors associated with death or severe disability by 10% from baseline for conditions most likely to be misdiagnosed among ethnic, racial, or other disproportionately affected groups. We are launching a study to add a laboratory outreach component to the million hearts quality improvement preventing heart attacks and strokes project. Evidence suggests that many patients having severe hypercholesterolemia are neither diagnosed nor prescribed guideline recommended statin therapy, particularly those that reside in medically underserved communities. In working with the CDC Division of Heart Disease and Stroke Prevention, the Million Hearts Initiative and the National Association of Community Health Centers, we're engaging federally qualified health centers, centers designed to serve medically underserved communities, and clinical laboratories to prototype and evaluate a process for clinical laboratory outreach to clinicians and patients to improve guideline recommended statin therapy. This brings the laboratory into the strategy to address a significant health issue among those residing in medically underserved communities in the United States. We look forward to sharing updates on this project at a future CLIAC meeting. Next slide, please.

The National Quality Forum submission on blood culture contamination is a collaboration with the CDC Division of Healthcare Quality Promotion, or DHQP, and is designed to foster collaboration between hospital antibiotic stewardship committees and the clinical laboratory in order to reduce the number of blood cultures contaminated with skin and environmental contaminants in adults over 18. This will bring all health care institutions up to the same recommended best practice for blood culture collection guidelines. The primary measure is reduction of blood culture contamination, and the secondary measure is reduction of blood culture single sets. The blood culture contamination measure was submitted to the National Quality Forum, or NQF, as a patient safety measure in April 2022, and NQF staff and the standing committee review voted in favor of endorsement and submitted for public comments. After the public comment period ended in September, the Consensus Standards Approval committee reviewed the comments and will formally vote to endorse the measure in December 2022. If no appeals are made, the blood culture contamination measure will become a national quality measure. We look forward to the committee's decision and sharing updates with you on next steps at a future meeting. Next slide, please.

On June 24, 2022, DLS hosted a town hall in collaboration with clinical and public health laboratory partners and instrument manufacturers. The purpose of this meeting was to provide an overview and discussion on laboratory biosafety when using laboratory instruments to test human and biologic specimens. Over 200 attendees joined the town hall to hear discussions from biosafety experts and industry representatives. Highlights from the discussion included the need for risk assessments for manufacturers and laboratories that take into account the possible presence of high-risk pathogens, and the suggestion that instrument manufacturers have readily available instructions for biosafety measures for each testing stage. Additionally, panelists shared that it is important to remember the humanity of laboratory professionals and the fact that there are legitimate safety risks in the workplace. You can review the presentations from the meeting at the link shown on this slide. CDC, CMS, and FDA have agreed to convene a CLIAC workgroup to continue addressing the issues raised during the town hall, and we look forward to sharing updates from the workgroup at a future meeting. Next slide, please.

So DLS, in partnership with the Eagleson Institute, the American Biological Safety Association International, the American Association for Laboratory Animal Science, and the Association of Public Health Laboratories hosted the 17th CDC international symposium on biosafety in Atlanta in August 2022. More than 180 laboratory professionals from around the world attended the event, which began with pre-conference workshops offering participants professional acknowledgment for continuing education or PACE credits. Sessions included presentations and engaging discussions on a range of topics geared towards animal science and clinical participants. The next CDC international symposium on biosafety is scheduled to take place in February 2024. Next slide, please.

DLS will launch a new biosafety ECHO program in January 2023. The purpose of the program is to develop and engage a biosafety community of practice based on the Extension of for Community Healthcare Outcomes, or ECHO, approach to address biosafety challenges in clinical and public health laboratories. This program builds upon the pilot ECHO project, a model for diagnostic excellence that was launched by DLS in 2020. The first session of the biosafety ECHO program will be led by Dr. Anthony Tran, director of the San Francisco laboratory of the Office of Regulatory affairs at FDA. Dr. Tran will share his perspectives on public health laboratory professional burnout and its effect on safety. Next slide, please.

Moving next to laboratory informatics updates. Next slide, please. Public health laboratories conduct specialized and critical testing for the clinical partners and have made advancements in overall data exchange with their healthcare partners when ordering tests and reporting results. However, some gaps remain, and manual processes are still used by some facilities or for some tests. CDC is providing resources to public health laboratories as needed to help ensure they implement an electronic system for test ordering and results reporting. And we're working to enable all state public health laboratories to have the same capabilities. This project is referred to as the Public Health Laboratory ETOR, or Electronic Test Orders and Results. These resources include providing technical assistance, coordinating with partners, and developing infrastructure and funding when possible. You can visit our website. In the link at the bottom of this slide to learn more about this activity. Next slide, please.

It is essential to harmonize the laboratory data exchanged between healthcare systems and public health so that the data is unambiguous and has shared meaning for everyone who has access to it. CDC collaborates with several partners, including FDA, the Association of Public Health Laboratories, and developers for public health laboratory orders and results reporting to create standardized codes for diagnostic tests. Logical Observation Identifiers Names and Codes, or LOINC, is a standard that facilitates the exchange of results and is useful for aggregating data in response and surveillance activities. Tools that help improve the quality, interoperability, and portability of In-vitro Diagnostic, or IVD, laboratory data between laboratories and health care systems such as through the development of LOINC IVD, or LIVD test code mapping tools can assist with seamlessly reporting laboratory data. We provide LOINC codes to laboratories and test developers through the LIVD tool, and we promote the use of these codes through our email messaging and national calls with the clinical laboratory community. LIVD mapping tools have been developed for COVID-19 and mpox diagnostic tests available under FDA emergency use authorization and are available at the link shown on this slide. These files can be very beneficial in reducing inaccuracies and time spent on the import of laboratory test results sent through the laboratory information systems. They may also serve as a template for creating future LIVD mapping tools for FDA-approved diagnostic tests for other important diseases. Next slide, please.

The specimen Cross Mapping Table, or CMT, developed by the CDC and the Association of Public Health Laboratories is intended to improve the standardization, completeness, and understanding of specimen details for health care providers and clinical laboratory professionals. The specimen Cross Mapping Table is a tool consisting of a knowledge base that starts with a preferred specimen term mapped to all of the details needed to properly describe that specimen coded in SNOMED CT. The Association of Public Health Laboratories is in the process of putting the Specimen Cross Mapping table through a thorough review process with professional laboratory organizations. We look forward to seeing the results from pilot testing of the specimen Cross Mapping Table once this review process is completed. Next slide, please.

Moving next to laboratory training and workforce development. During tomorrow's session on efforts to address public health and clinical laboratory workforce challenges, you will hear an overview and update on all the components of one

lab from Dr. Kelly Winter. But this morning, I want to highlight some exciting new partnerships. In September, CDC initiated a three year cooperative agreement to support the OneLab Initiative. We are funding four recipients shown here on this slide to provide technical assistance to CDC and to collaborate with CDC on the creation of training resources and workforce and training assessments for laboratory professionals. They will also help amplify our marketing and promotional efforts by sharing updates on new OneLab training resources through their organization's communication channels. We're very excited to be working with these partners and look forward to seeing the outcomes from their projects. Next slide, please.

OneLab REACH is a new Learning Management System, or LMS, that provides laboratory professionals with a one-stop shop to access all of CDC's free laboratory training resources. The acronym REACH is short for Rapid Education And Capacity-building Hub. We tailored OneLab REACH to the needs of the laboratory community and built a user-friendly LMS that allows you to save courses for later, download job aids without logging in, and quickly navigate to your PACE certificates. We held a live soft launch of OneLab REACH on July 28. 135 network members attended this live demonstration. As of October 1st, OneLab REACH has about 500 users. Our full-scale promotional campaign will kick off next month. We wanted to ensure that the LMS is stable and ready to handle a large volume of users before we started ramping up promotion. In the meantime, we've continued to add more courses and features. You can sign up to access and view these free laboratory courses at the link shown on this slide. Next slide, please.

In partnership with the Association for Public Health Laboratories, CDC is helping to expand the laboratory workforce pipeline through a large fellowships and internship program called Career Pathways in Public Health Laboratory Science. In addition to creating a new competency-based curriculum, CDC set a core health equity goal for the program that centers on increasing diversity within the applicant and selection pools by 40% by 2025. CDC is committed to fostering a more diverse and well-trained public health workforce. Recruiting and developing public health laboratory scientists and professionals from the communities we most need to reach will ultimately help us achieve a more sustainable and more equitable system of care. Next year, DLS will collaborate with 10 to 20 Subject Matter Experts, or SMEs, from academic institutions and organizations that serve underrepresented students. CDC is seeking SMEs in 3 fields-- laboratory science, health equity, and diversity, equity, inclusion, and accessibility. SMEs will collaborate with us to identify barriers to participation in laboratory fellowships and internship programs among underrepresented groups and communities. Via the Intergovernmental Personnel Act, CDC expects to fund 5% to 20% of each SME salary proportional to their role in the workgroup. Those interested should email lab training at cdc.gov to find out more information. Next slide, please.

And moving lastly to partnership communication and outreach updates. Next slide, please. So we continue to use CDC's Laboratory Outreach Communication System, or LOCS, to communicate important diagnostic and testing information to the clinical laboratory and testing community. Today, there are over 104,000 subscribers who receive LOCS messages directly from CDC. It is still one of CDC's top 10 subscribed e-newsletters. We have sent 276 LOCS messages to the community since the beginning of 2020. If you have not yet subscribed, it is easy to sign up. You can send an email to locs@cdc.gov. The LOCS calls that I mentioned earlier in the presentation continues to also be an important forum to engage and communicate with the clinical laboratory community. Next slide, please.

We also want to highlight that DLS celebrated public health laboratory appreciation month in September, which is an Awareness month started by the Association of Public Health Laboratories to celebrate public health laboratory staff. DLS's post was recently featured as CDC's program post of the week, having some of the best performing posts that week, which received more than 354,000 impressions and more than 2,800 engagements. Next slide, please.

Finally, we've started attending and exhibiting at conferences in-person again, which has been a really wonderful opportunity to meet our partners in real-life again and share the work and resources from our division to those who may not be familiar with our division. This year, we've attended and had a booth at the following conferences and meetings that you see listed on this slide. We've even hosted hands-on demonstrations of our virtual reality tools as seen in the third picture from the left. We'd welcome your feedback on all the ways we can continue to outreach to the laboratory and testing community to share information on what we do and the resources that we develop. You can reach out to dlsinquiries@cdc.gov if you have suggestions, and we appreciate the feedback. Next slide, please.

And lastly, I'll just finish by taking the time to first thank our partners and all of the clinical and public health laboratory and testing 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. So thank you.

CLIAC CHAIR: Wow, thank you Dr. Fitzgerald. I feel like we've gone a millennium in six months from the last CLIAC meeting. All of this forward progress is unbelievable and so welcome. Thank you. We have about 16 minutes for questions for Dr. Fitzgerald. Are there questions? [CLIAC MEMBER].

CLIAC MEMBER: Thank you. Thank you. Thank you, Collette, for that excellent presentation. I wanted to ask you some more about the Specimen Cross Mapping Project. It sounds like a very exciting project, and wanted to know will this make

it easier for public health labs and clinical labs to connect electronically so that we can more easily report results?

DR. COLLETTE FITZGERALD: Yes. So I think it's not necessarily about being able to connect laboratories between public health and the clinical laboratories. It's more about making sure that we're improving the completeness and understanding of the specimen details that are associated with the specimen. So that without that comprehensive specimen information, it's really difficult or almost impossible to initiate appropriate laboratory testing, and that can result in delayed results and challenges in appropriate test interpretation. I would think our ETOR-related activities are more connected to improving interoperability between health care and public health.

CLIAC MEMBER: Thank you.

CLIAC MEMBER: Yeah, that was a great and comprehensive tour of everything that's been going on, so I congratulate my-- congratulate you as well. I just want-- this was really more of a comment, but as you were talking about the Million Hearts campaign and all the work that's being done in engaging laboratory medicine with the FQHCs and so on, I reflect back to several years ago probably at the beginning of the pandemic when we talked about how important the social determinants of health were. And this is a perfect program that shows the input in the link of laboratory medicine to improving engaging with social determinants. And so as we move forward, I would really love to see this as-- more that umbrella of engaging the laboratory more in driving social determinants to be a key theme that goes across the efforts.

DR. COLLETTE FITZGERALD: Thanks for that feedback.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. [CLIAC MEMBER] and then [CLIAC MEMBER]. If you still if you have another question, we'll come to you next.

ADVAMED LIAISON: Thank you again, Dr. Fitzgerald. It was a whirlwind review in a number of initiatives that took note to take back to our own company about. The one that I have a question on-- probably not surprising-- you mentioned a workgroup forming around lab biosafety and use of laboratory instruments. Did I understand correctly that-- did you say that you're going to be directing a CLIAC workgroup or is this a CDC workgroup?

DR. COLLETTE FITZGERALD: So this will really build upon a lot of work that's happened since the 2016 CLIAC recommendation. We have the publication that was published a few years ago that highlighted the instrumentation component to be an important piece, which is why we moved into then having the town. And so that will all be all-encompassing and will result in the establishment of a CLIAC workgroup.

ADVAMED LIAISON: I want to just add that there were-- the report-- or excuse me, the paper that was published on this also called out a number of other areas that need to be delved into as well, and it may be good for the workgroup to look at a couple of those others as well.

DR. COLLETTE FITZGERALD: Yeah, absolutely. It's my understanding that the workgroup would be broader-- the scope of that workgroup would be broader. But I think that charge is being defined as we speak, so we welcome that input. Thank you.

ADVAMED LIAISON: Thank you very much.

CLIAC CHAIR: Very quiet group today. I see no more hands up, no more comments or requests. We are a little bit ahead of schedule. As CMS, Mr. Brandush is scheduled to go at noon. I'd look to Ren and Heather-- I would like to pause for others who might be dialing in and adhering to that schedule.

CLIAC DFO: Heather, I'm comfortable with moving forward. Are you?

CLIAC EXECUTIVE SECRETARY: Yes, I think we can go ahead and move forward.

CLIAC CHAIR: OK, Greg, it's you! I'm sorry, let me be more formal. We are very pleased to welcome Mr. Greg Brandush, our CMS representative. He will give us a CMS update. Thank you.

Centers for Medicare & Medicaid Services (CMS) Update
Gregg S. Brandush, RN, JD, CMS EX OFFICIO

MR. GREGG BRANDUSH: So thank you. My name is Greg Brandush, and I'm the director of the Division of Clinical Laboratory Improvement and Quality with CMS. And I just want to say I'm really excited for this meeting. This is my first CLIAC meeting, so I'm really looking forward to the information and dialogue that this meeting offers. The agenda that has been developed looks really excellent. And in this presentation-- my component of this-- I'm going to provide an overview of some of the significant changes and accomplishments that the CMS CLIAC program has achieved over the past year.

First, I have to give my standard disclaimer. My staff makes me say this every time I do any presentation. The key-- I'm not going to read this because it's mind-numbingly boring, but the key point of this disclaimer is that the presentation is for informational purposes only. Any errors are mine and do not represent official CMS policy. All official guidance and policies are available on the cms.gov web page, and I've provided direct links in this PowerPoint to the memos and some of the flexibilities that I will be discussing.

During this presentation, I'll be providing an overview of how CMS CLIAC is organized because we've undergone some changes recently. I will address our priorities for the next year, share the updated enrollment numbers, review significant CMS policy memos that came out this year, and discuss some of the flexibilities that will continue after the conclusion of the public health emergency. I'll then conclude by providing a very brief regulatory update.

So let's start with our organization and leadership. I think this has been shared previously in this meeting, but because there have been subsequent changes, I wanted to address it again. So in October of 2019, CMS underwent a realignment that included the CLIA division. So formally, CLIA survey and certification activity was a component of the 10 regional offices, and the policy functions were part of central office in Baltimore. The two divisions had separate and distinct leadership chains. Following the reorganization, the Division of Clinical Laboratory Improvement and Quality-- DCLIQ-- was moved entirely within the Quality Safety and Oversight Group which is QSOG. This streamlined our reporting structure. I think it was a really good move for the agency to make. So where we are now-- DCLIQ now has five branches. There are two policy and three operations branches. The policy work is primarily located in CMS Baltimore-- it's what we call formerly the central office. Each policy branch has a technical advisor that is part of the DCLIQ leadership team. The two technical advisors are Sarah Bennett who will be speaking later today and Scott Stacy. Sarah is our programmatic and policy technical advisor, and Scott is our technical advisor responsible for data analysis. The three operations branches are subdivided into the 10 former regional offices. So the CLIA federal surveyors are in the operations branches, and most of the enforcement action and state oversight activities are handled in those branches. We also have an almost entirely new management team within DCLIQ, which is really exciting because there's a lot of opportunity for change and to reevaluate how we've been doing things. As I've said, I'm in my first year in this position, and four of the five managers have been in their position for two years or less. Angie Daubert and Raelene Perfetto are the two policy branch managers. Dan Hesselgesser is the branch manager for the southern operations branch, which includes the CMS Atlanta and Dallas locations. Josh Cohen is the branch manager for the northern and Midwest operations branch, which includes CMS Boston, New York, Philadelphia, and Chicago locations. And then Karen Fuller is the branch manager for the Western and Central operations branch, which includes Kansas City, Denver, San Francisco, and Seattle.

In terms of our priorities over the coming year, the two top priorities center around improved national consistency and increased engagement. On the consistency front, we are looking for areas where we can be more effective in uniform and applying CLIA regulations. For example, we want to make sure that we are imposing sanctions in writing citations consistently regardless of location so that the same non-compliance is cited the same way regardless of location and the enforcement remedies imposed also align. In our efforts to foster this consistency, we're collaborating with our state agencies through quarterly calls in which we are both informed of concerns the states are facing and made aware of areas in need of further clarification. Similarly, we hold regular meetings with our accrediting organizations and exempt state partners for a similar exchange of ideas. A second major priority is stakeholder engagement. We are increasing our outreach activities to reach our external stakeholder public. Our goal is to support the CLIA program by strengthening stakeholder engagement and improving awareness and compliance with CLIA regulations and guidance. We'll achieve this goal through the use of broader listserv communication. We'll be enhancing our stakeholder outreach to increase the number of subscribers that receive information from our listserv. This is an excellent means for us to reach out directly to the lab community. We also will continue to work with our state agencies, accrediting organizations, and exempt states to improve consistency and in overall laboratory oversight processes. On the federal action side, we continue to work to strengthen our relationship with the CDC and FDA as part of the tri-agency partnership that implements the CLIA program. And then finally, we will be increasingly focused on engaging with professional organizations to promote ongoing communication within the laboratory community. One of the communication enhancements that we just released this month is the revived CNN-- the CLIA Network Newsletter. And this is an informal and engaging and more conversational means to share CLIA updates and clarification. I was really excited that we were able to revive that to enhance communication. Also towards the modernization end, we are looking towards modernizing the CLIA program through issuing electronic certificates in the next year, and that is an additional area I'm really excited about.

Let's look at some numbers. This table shows the CLIA labs as of October 2022. As you all know, the Certificate of Waivers, or COWs, are our largest certificate type of the 320,000 total labs. 244,000 roughly are Certificate of Waiver labs. Approximately 27,000 are Provider Performed Microscopy labs, or PPM labs. And the number of Certificate of Compliance labs versus Certificate of Accreditation-- slightly more compliance, but they're fairly equivalent.

And this is a visual representation of the same information on the last slide. This really illustrates the number of COWs that we have in the CLIA program. As you can see, 76% of these labs are Certificate of Waiver labs.

In the past year, there have been four major policy releases that I would like to discuss. They address the PT rule, surveyor guidance, survey prioritization, and temporary testing sites.

The PT rule is easily the biggest announcement made in the past year. As we are all very aware, PT is crucial to maintaining the quality of laboratory testing because it independently verifies the accuracy and reliability of laboratory testing, including the competency of testing personnel. I'm not going to discuss this in much detail, because as Collette mentioned earlier and I'll repeat again, Sarah Bennett has an excellent in-depth presentation devoted to this later today. I hope we're not building it up too much and putting too much pressure on her, but I know Sarah will rise to the occasion as she always does. I will say, though, that this is one of the accomplishments in the past year that I'm most proud of. These recommendations came directly from CLIAC, and this rule was a great example of how our combined efforts can improve quality testing and, ultimately, lead to better outcomes for patients. The two major components of the rule-- the updated PT requirements themselves-- have an effective date of July 11, 2024. And the component of the rule that is related to waived testing was effective August 10, 2022. Again, as this is really significant and a great reflection of our combined efforts, we thought it appropriate to have a dedicated presentation on these new requirements.

With respect to survey or guidance on reporting requirements, this memo on the screen reflects an evolution in terms of what data we need. So as we all know and lived through, on March 13, 2020, the president declared a national emergency in response to the COVID virus. Congress then passed the CARES Act that required that every laboratory that performs or analyze a test that is intended to detect or diagnose a possible case of COVID shall report the results to the Secretary of Health and Human Services as required. As a result, CMS made modifications to the CLIA regulations to require laboratories to report COVID tests in a manner and frequency specified by the Secretary. Early in the pandemic, there was a tremendous need for information related to COVID testing. The first iteration of the QSO 20-10 memo required that all COVID test results had to be reported. Over time, CMS was able to relax the requirement somewhat. And in April of this year, QSO 20-10 was revised. The new guidance updated the reporting requirement to make reporting of some results optional, and what is now optional is reflected on the chart on the screen. This memo also provided clarification on the use of multiple sites. For each certificate type under the CLIA regulations, some exceptions allow a laboratory in specific circumstances to apply for a single certificate for multiple testing sites. Specifically, the regulations allow laboratories that are not at a fixed location, such as mobile units, health screening fairs, or other temporary testing locations to be covered under the certificate of the designated primary site or home base using its address. At the beginning of the public health emergency, many laboratories expanded testing to additional temporary sites to keep up with testing demand. This memorandum clarified that a temporary testing site is an entity that is not at a fixed or permanent location, these sites include but aren't limited to parking lots, schools, pop-up sites. And all the work performed at these temporary testing sites fall under the primary sites certificate and laboratory director. And then finally, the memo will also clarify the actions that a lab should take where required reporting elements such as negative results are not accepted by a state or local health department. In these cases CMS would expect the laboratory to have documentation of the attempt to report. If the laboratory has documentation that the state does not require or cannot accept negative results, there's no need for the lab to continue to attempt to report the negative results. That documentation that they maintained will establish compliance.

With 22-14, the guidance provided for surveyor prioritization followed a similar, if more complex, path to the reporting requirements guidance. So to show where we currently are with survey prioritization, we need to go through a little history. So early on in the public health emergency, CMS took steps to allow states to focus their emergency response on efforts at controlling the spread of COVID by limiting survey activities. In August of 2020, CMS prioritized these survey activities in the QSO 20-20-ALL memo, and the guidance in this memo focused on Immediate Jeopardy or IJ situations. These situations are those in which immediate corrective action is necessary because of a laboratory's noncompliant, has caused, or was causing, or is likely to cause serious injury, harm, or death to individuals served by the lab. The memo also clarified that any pending enforcement actions that the state had, they were suspended except for those actions related to an unremoved immediate jeopardy. Subsequent to this, in QSO 20-35-ALL, that memo provided revised guidance on survey activities and resolving these backlogged enforcement cases. In November of 2020, CMS issued QSO 21-04-CLIA which gave state service agencies the flexibility to perform on-site surveys and conduct optional remote CLIA recertification surveys for laboratories that met specific criteria, which brings us now to 22-14. With the 22-14 memo that's addressed in the slide, CMS provided the direction that state survey agencies may fully resume CLIA survey activities in accord with the state operations manual subject to state discretion and within their applicable COVID restrictions and safety precautions. The memo directed the state agencies to investigate complaints in accord with our normal policies and requirements, and to prioritize laboratories who have complaints pending when scheduling their regular certification surveys. The memo clarified that all initial surveys that were not completed before the public health emergency should be prioritized to ensure laboratories comply with CLIA regulations. The memo communicated the resumption of the usual process for recertification surveys. State agencies were again required to conduct recertification surveys to determine whether or not a laboratory meets the CLIA requirements. State agencies were instructed to prioritize labs that had not been surveyed in the past two years. The memo instructed the states to resume validation surveys to the extent possible to ensure consistency in the oversight of laboratories by accreditation organizations.

Specifically, the memo directed that if the accreditation organization survey was performed on-site, the state agency surveyor should plan to also conduct an on-site survey. The state agency was allowed to conduct a remote validation survey for any accreditation survey that was performed remotely by the AO. State agencies were instructed that they should prioritize the initial complaint or recertification survey workload, and then to incorporate these validation surveys using the most efficient means possible for them. The memo authorized revisits for all surveys that identify non-compliance and for which a revisit was needed to ensure compliance. And it clarified the 5% expectation for COW and PPM labs. For the duration of the public health emergency, aid agencies are required to survey 5% of a combination of the COW and PPM laboratories. This equals about 1.6% of the total COW and PPM labs for each year. However, state agencies were directed that they should prioritize the initial complaint or recertification survey workload, and then incorporate these special surveys using the most efficient means possible. And then lastly, with respect to any new and pending enforcement actions and PT desk reviews, state agencies were directed to proceed as usual for the state operations manual in chapter 6, and agencies should make every attempt to balance their workload to reduce the number of pending surveys.

The final memo I would like to discuss provided expanded guidance for temporary testing sites under the multiple site exceptions. So CMS issued this memorandum to provide guidance for CLIA surveyors and laboratories regarding the notification requirements for laboratories operating temporary testing sites. The regulations allow laboratories that are not in a fixed location, such as mobile units providing laboratory testing, health screening fare's, other temporary testing locations to be covered under the certificate of the designated primary site or home base using its address. At the beginning of the COVID public health emergency, many laboratories expanded testing to additional temporary testing sites to keep up with the testing demand. For the purposes of this memorandum, temporary testing site is where, at various intervals of time, an entity is not at a fixed or permanent location and is performing laboratory testing. So these sites include, but aren't limited to, parking lots, schools, pop-up sites. All work performed at the temporary testing site falls within the primary site certificate parameters. Additionally, the memo provided guidance on remote review of clinical laboratory data results in pathology slides. Recognizing the urgency of the public health emergency and the need to promote innovative uses of technology to increase capacity to avoid exposure risk to health care providers, patients, and the community, CMS exercised enforcement discretion to ensure that pathologists may review pathology slides remotely. Under this discretion, CMS decided that we will not enforce the requirement to have a separate certificate for laboratories that are located at a remote testing site provided that the designated primary site or home base has such a certificate and the work being performed in the remote testing falls within the parameters of the primary site certificate. So a pathologist home may be the remote testing site under this discretion. It's important to note that this guidance does not apply to pathologists who have already obtained CLIA certificates for their home or other site separate from the primary testing site.

So the CMS CLIA program doesn't have 1135 waiver authority. Consequently, we needed to rely on enforcement discretion in order to provide flexibilities that were necessary during the public health emergency. In our review of these practices, we've identified some flexibilities that we will allow to continue after the PHE ends. As noted earlier, CMS has exercised enforcement discretion to facilitate pathologist's ability to review pathology slides remotely without the need of a separate CLIA certificate for the remote location. This enforcement discretion is not contingent on the PHE authority. CMS will continue to exercise enforcement discretion that allows pathologists to examine digital images and laboratory data at remote locations. CMS expedited CLIA certificate application review and processing to ensure that laboratories located in the United States wishing to perform COVID-19 testing are able to begin testing as quickly as possible during the public health emergency. CMS must have determined that at the end of the public health emergency, our regulations will allow us to continue to allow for expedited lab certification by allowing the lab to begin testing as soon as they receive a CLIA number and pay the laboratory fee. CMS has allowed laboratories within a hospital or university hospital campus to hold a single certificate for the laboratory sites within the same physical location or street address. CMS has determined that at the end of the public health emergency, the regulations will allow CMS to continue to allow for labs within a hospital to hold a single certificate for the laboratory sites within that same physical location or street address, and this is expressly authorized in the CFR. CMS has clarified that alternate specimen collection devices and media may be used to collect and transport COVID-19 samples. The CLIA regulations really aren't prescriptive about the type of transport device. CLIA requires that the laboratory follow manufacturer's instructions. So if a laboratory modifies the manufacturer's instructions, the laboratory then is required to establish performance specifications and validate the assay prior to performing patient testing. We are also not prescriptive as to how the study is performed, so the laboratory director is responsible for defining the validation parameters. Similar to everything else I've said here, CMS has determined at the end of the PHE, the regulations will allow CMS to continue to allow the use of alternate specimen collection devices and media under the existing regulations. So the labs either have to follow the manufacturer's instructions or establish those performance specifications.

Regulatory update-- so this is going to be really brief. So for the fourth time now, I think to say that Sarah has an excellent presentation on the PT rule, so I won't talk about that any further. In terms of the other major rulemaking effort, the notification of proposed rulemaking for fees with the compatibility personnel and alternate sanctions for certificate of

waiver labs generated a tremendous amount of interest. So much so that we extended the comment period for that NPRN by 30 days in response to numerous requests.

On this slide, you will see the links that I discussed in this presentation, as well as that last one there will take you to a document that was published-- that discusses our flexibilities and other flexibilities that are going to continue within CMS. And if you don't have it and you need it, this is my contact information and the primary email for any CLIA inquiries that you have. This brings me to the end of my presentation. Thank you very much.

CLIAC CHAIR: Thank you very much, Mr. Brandush. That was very informative. Are there questions? [CLIAC MEMBER], go first.

CLIAC MEMBER: Yes, could you please explain what you mean by issuing electronic certificates? Because the pathology LISs have not had to require electronic certification as the EMRs have. And so--

MR. GREGG BRANDUSH: Yeah, we just are intending to transition from a paper certificate to an electronic equivalent of the exact same thing. That's-- it's nothing major. It's just recognizing that we live in a more electronic age and paper's a little outdated.

CLIAC MEMBER: Got it, got it. So you're not certifying the laboratory information system. It's you're issuing a certificate. Got it.

MR. GREGG BRANDUSH: Yeah.

CLIAC MEMBER: Yeah, hi. Thank you, Greg, for that report and it's nice to meet you sort of. If we were in-- if we were doing an in-person meeting, I'd catch you in the hall during a break and ask you this question, but we're not, so I'll ask you this way. As the new director of CLIA for CMS, tell us a little bit about your background, please.

MR. GREGG BRANDUSH: Oh, certainly. So my background-- I've been in health care for more than 30 years. I originally was a nurse. I worked in a variety of settings, including two years in the Peace Corps in West Africa where I ran a health clinic where we literally had no running water, we had no electricity, we had no gloves. And we had a handful of-- a scant number of medications. The syringes we had to give shots were those old metal ones that you had to screw in, which was terrifying because we didn't have any way to sterilize them-- any real effective way to sterilize them. So it was an interesting experience. And one of the things that I like to talk about with-- when I talk to CLIA staff about just lab testing and how primitive lab testing was in that environment with how amazingly advanced it is right now. And I'll give you an example of what we did. We had-- occasionally, patients would come in and they would be talking about thirst, and they would have signs and symptoms of perhaps hypoglycemia. And what we would have them do is place some urine on the ground and see if the ants flocked to it. And we had a number of people that were like, oh, my God, look-- the ants above this person's urine. So we knew we needed to refer them to a way more advanced medical facility than I had there. And if you take that view of the most basic fundamental on-the-ground type of lab versus the really advanced stuff now, it's a little mind-boggling. So in addition to my background as a nurse, I retired my law license, so I can't call myself an attorney. I guess a recovered attorney is the way I would describe it, but I have a law degree.

CLIAC MEMBER: Good for you.

MR. GREGG BRANDUSH: I've been with CMS-- yeah. I've been with CMS for 12, 13 years. And prior to coming to CLIA, I was the division director for CMS Chicago. And in that capacity, I oversaw the implementation of the CMS regulations for essentially every provider type except for CLIA. And so I've moved over to CLIA now, and I will tell you I love this program. I think if you are working with any federal agency, CLIA is the group to work with-- that it's the fairest. It's, in my mind, most reasonable, and we are very open to communication and to work things out. So I'm really excited to be part of this team, and been good so far.

CLIAC MEMBER: Great, thank you. And the use of the ants as a reagent, that takes us way back. That's the history of the laboratory. That's how laboratory medicine got started. So anyway, thank you.

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

CLIAC MEMBER: That is a fascinating story to even try to follow with a follow-on question. But there is an elbow around my question to public health, and that's something that struck me in your slide about mandatory versus optional reporting for SARS-CoV testing, because for both waived as well as moderate and high complexity laboratories, serologic testing for COVID is optional both positive and negative. And with the CDC also in this meeting, the CDC has been heavily engaged in sero-surveillance studies for serology for COVID. I myself am involved with the SeroNet consortium funded through the NCI. My question to you is has the serologic aspect of COVID public health come to-- been visible to you?

Because ultimately, there are practice of medicine guidelines or not which have not matured for COVID serological testing. And I'm just wondering if this is something that's on your radar screen. It's very much on my mind.

GREGG BRANDUSH: Yeah, I will tell you it's on-- I can say it's on the radar. We've had discussions with CDC. We rely really heavily on the CDC for the technical guidance on those aspects. But unfortunately, that's about all I could say on that front. I am aware of it and we do rely heavily on CDC for guidance on what our policies should be with respect to that.

CLIAC MEMBER: Because where my question is coming from is really how to build better data systems so that we can inform not just public health, but also the translation of emerging information into medical practice as well. And the right people are on the line in this phone call-- CDC, CMS, FDA, and hopefully, laboratory experts around the country.

GREGG BRANDUSH: Yeah, again, all I can tell-- all I can really say is that we're aware of it and are exploring our options.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you, [CLIAC CHAIR]. Greg my question is, during the pandemic-- and we're both in environmental and clinical laboratory, so we had inspectors from environmental accrediting agencies doing virtual inspections and sharing documents electronically to get that accomplished. Has CMS considered moving more to a virtual inspection environment? It seemed to be very productive from my experience.

MR. GREGG BRANDUSH: Hey, it's an interesting point. And one of the things that has been, I guess, the positive of public health emergency-- the public health emergency forced us out of our comfort zone in a lot of ways and it mandated things like remote testing. So to the extent that remote testing, if we can show that it's as reliable as an on-site test and we can depend on the results being similarly-- it's more efficient, it's more cost effective. So that is something that we will continue to evaluate and make a determination if that is something that can be expanded.

CLIAC CHAIR: Gregg, I have this one zinger question that, if we were in-person, like [CLIAC MEMBER], I would have sidebarred you in the hallway. But I was curious if you were able to succinctly state what the status is around SARS-CoV tests for asymptomatic individuals reporting to CMS-- the recension of a recension of something. I am confused where we are in that 360 circle.

MR. GREGG BRANDUSH: Yeah, the recension-- basically, if you want to look at what was happening in September, that's where we are. Yeah, I don't want to get too much into the background of that memo being rescinded, but the bottom line is that there is no change to what was occurring prior to the memo that came out rescinding it that we subsequently rescinded.

CLIAC CHAIR: So if-- I do apologize catching you off guard. So is the summation, we are allowed to do SARS-CoV testing on asymptomatic individuals?

MR. GREGG BRANDUSH: Yes, sure.
CLIAC CHAIR: Thank you so much. Are there more questions for Mr. Brandush? That was a wonderful update and it was-- it's so gratifying to see so many of the recommendations from CLIA coming to fruition into revisions of CMS practice, so thank you. We are three minutes ahead of schedule, and I'm just going to move forward. Our next presentation is an FDA update from Dr. Tim Stenzel. Tim?

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

DR. TIMOTHY STENZEL: Thank you. I think my slides are going to be pulled up as they're being pulled up. I just want to state that I have no conflicts of interest. And there we go. You can go to the next slide.

So many of you aware that Congress did pass MDUFA at the end of September. This does reauthorize for another five years the medical device user fee program. This program allows device developers through fees to pay for additional FDA headcount in order to ensure timely review of applications. There is a new element that was included. It's called TAP for short, but long version is Total product lifecycle Advisory Program. This is a new program that is designed to engage with developers early on in the development process all the way through past FDA authorization and assisting interactions with insurers as well. This is primarily designed for those entities that may not have extensive FDA or development experience.

We at the FDA did experience a lot of new developers coming to the FDA for COVID tests. We had over we engaged with over 1,000 distinct test developers for COVID tests, and I would say about 80% of them or more and did not have any prior experience with the FDA. So this program is designed to assist those who are unfamiliar with the FDA processes and procedures and also to assist them with things that aren't necessarily entirely within the guardrails of the FDA. Next slide, please.

We are in attempt following the pandemic response over the last 2 and 1/2, going on three years to get back to normal, so to speak. As of June this year, we have accepted all regular submissions. These are non-COVID regular submissions. We had paused a few categories in order to deal with the surge and more than 6,000 applications for COVID tests that the FDA received. We are now back to normal, although the review times are-- up until perhaps a month ago-- were still for applications that had been received prior to then were still undergoing review at slightly extended review times. So we're back to normal, so we're now accepting all applications that we accepted prior to the pandemic. And we're attempting to get to our statutory declared review times. And we do believe that for the fiscal year 23, which we began on October 1st, that we will get back to those normal review times for all applications. Next slide, please.

I wanted to briefly touch on COVID 19 and mpox. You'll get a more thorough update on mpox tomorrow by Toby Lowe from the FDA. Next slide, please.

So we do continue to accept some applications for COVID tests, but our primary focus now is to finish the reviews of submissions that we had received, including laboratory tests developed submissions. All laboratory developed tests that adhered to the November 15, 2021 policy and followed that notification policy are under review unless a decision has been made, and they're still allowed to be on the market and perform COVID testing until we complete our-- at least until we complete our FDA review. We have hired a third party review organization, and they are doing the lion's share of the LDT reviews. And so we are monitoring their progress. When they make a decision, they forward that decision to the FDA for review, and the official decision does come from the FDA. Next slide, please.

We have seen such incredible innovation which we have welcomed. It did require us to be very creative in our regulatory authorities. Because of the EUA authorities and the statute, it allowed us to lower the bar for what was required to prove that a device was safe and effective relative to our normal processes and procedures. And so this allowed very rapid development of novel devices. So we were very grateful to the Ebola authorities to allow that. Next slide, please.

We are also very grateful for our partnership with other agencies, including the NIH, NIH RADx program and the NIH ITAP program. So RADx was designed to fund innovative projects to be able to address the COVID needs. The ITAP program was developed as an independent testing assessment program. So in this, the NIH took over the complete validation of tests that they selected and funded this effort for. And you see on this list here the fruits of that labor. It was a very important to assure the American public and clinicians and laboratories that tests were performing as intended. Having that independent review-- or assessment rather and then review of that by the FDA was a very important advancement. And we're looking-- we're very supportive of this kind of program going forward, even for non-pandemic targets. It has been expanded for mpox, and it is likely to be expanded for other analytes in addition to COVID and mpox. For COVID, it does include multichannel tests that can test for flu as well as RSV. So we're still very active in our interactions with NIH. And together, we've clearly had a very successful program. This program had allowed the development and manufacturing at peak production within a month of nigh on a billion tests per month. So without this program, I don't believe we would have been able to achieve that all with the FDA reviewed and authorized products. Next slide, please. This lists all of the over-the-counter EUA requests that have been authorized. We see that both-- there's three molecular tests on this list. The rest of them are rapid-- actually, four molecular tests and the rest are rapid antigen tests. And so a tremendous effort by the developers, NIH, and the FDA to get these onto the market. And we continue to monitor their performances as well for all the variants that are still coming at us in the-- and as well as with the molecular test. Next slide, please.

There was a recent policy update on September 28. We are trying to get back to normal. An assessment was made by the US government that we had achieved our targeted aim of having sufficient authorized tests on the market to meet the needs of the pandemic. We then moved in this policy update to try to focus our attention on the conversions of those tests that the FDA had authorized into full authorization Unfortunately, we expect that COVID will be with us for a very long time. And the continued access to testing is very important, so we have encouraged all EUA test developers, particularly the manufacturers, to convert their test to full authorization. And that's where our efforts are. We are going to continue to allow some categories of test development, particularly those that are government sponsored that are novel or that are-- may in the future-- now or in the future meet very specific needs to responding to the pandemic, as long as we have the emergency authority to do that. Next slide, please.

So here are the current then EUA review of priorities. They are focused on any new tests to be ones that are likely to significantly benefit the public. They employ new technology, I would say. There's a novel category of tests called breath tests which we authorized one. But if they end up being something that are proven to be a very solid performers, we

would certainly want them to be part of our armamentarium for pandemic responses going forward if, as I said, it fulfills an unmet need. Say we need to identify specifically a new variant in order to properly treat a patient, then that would be important. Supplements-- these are minor changes usually to authorizations, adding, say, new features. But we will continue to allow those modifications under EUA authorities if they significantly benefit the public health. And finally, as I said, any test requests supported by US government stakeholders, then we will continue to work with those US government agencies to achieve new test authorizations. Next slide, please.

Some of the creative novel tests are listed here, and the first one is a breath test that I mentioned. More recently, we're grateful for developers that have been able to get authorizations for genotyping assays. There continue to be challenges with various therapeutics. We're aware of the evasions of vaccines by some of the variants. So understanding this on a patient-to-patient basis continues to be important. And so we're appreciative of those developers and their success in the program. Next slide, please.

A couple of safety communications-- we've issued so many of them, but these are more recent and are important to update. So there were some developers that looked for mpox that looked for not looked at non-lesion swab samples. For the most part, those non-lesion samples have not been proven to be as reliable as lesion-based sampling, so we did want to alert clinicians and the public and laboratorians about that. We're still open to non-lesion swab submissions, but they do need to prove that they're equal to the lesion-based testing. And then as far as at-home COVID antigen tests, we have even a more recent update than this. I'll just speak to that. But we did express back in August the importance of doing serial testing both for symptomatic and asymptomatic patients using COVID rapid antigen tests. And in fact, this applies not just to over-the-counter, but also point of care and central lab antigen tests. They just do not appear to be sensitive enough as single tests or even for asymptomatic patients even to test to detect 80% or more patients who have active infections. We have subsequently come out more recently in recent days stating that we are going to work with all the developers to update their labels to their instructions for use to have these factors expressly stated in their instructions for use. All of this update on serial testing is based on seminal work that we did with NIH as a collaboration with NIH. NIH funded a very large more than 7,000 patient study looking at detection primarily in the asymptomatic population. We ended up getting significant data in the symptomatic population as well. That data, some of which has been published-- more will be published forthcoming-- showed the importance of serial testing both in symptomatic and asymptomatic populations. It was very significant and it led to this policy update by the FDA. Next slide, please.

And so this just goes into more of the update. Announced November 1st that I was talking about-- I'll skip through this. You have access to that. But by and large, for symptomatic people, you should test twice if your first test is negative and test within-- two tests within 48 hours. And if you're asymptomatic-- you don't have symptoms, and your first one-- and then your first and your second test are negative, then go ahead and do a third test if you want to be absolutely sure you don't have COVID in the window of time that you're concerned about. Next slide, please.

Mpox-- so we worked very closely with the CDC in real-time every day-- weekends too-- to expand access to mpox testing. Of course, the CDC had a clear assay. We worked with them to clear additional reagents and automation. Once we had data in hand prior to the formal decision on those additions to the assay, we did provide enforcement discretion and written form to the CDC that was then communicated to any labs that were using the CDC reagents to allow them to expand testing to additional reagents and automation. This did allow a great expansion of the throughput within those labs. We also proactively work with the CDC to expand access of the CDC kits to five major reference labs, which also expanded access to testing. That moved the needle significantly. And unfortunately, with those additions, the capacity of the nation in just the LRN labs and those five reference labs was more than sufficient as far as being able to test all the needed samples in the United States. However there still was an issue of turnaround time, which I'll deal with later in a subsequent slide. Next slide, please.

So these are the lists of currently FDA cleared in the EUA authorized mpox test. Of course, the CDC and the updates to the CDC test the FDA has authorized Quest Diagnostics because they have a multi-site system that more than one site that was testing within their system for mpox with their LDT. And the Abbott molecular Alinity system is the first kit manufacturer to get authorization. It's a high throughput instrument. It allows ability for any lab that has the Alinity system to bring on mpox testing and do it in a very efficient non-labor intensive manner. Next slide, please.

Then we're continuing to review mpox EUA submissions, and there will be additional ones as well even though we're glad to see that the cases of mpox in the United States and worldwide have really come down significantly. And we did issue mpox guidance on September 7th. I'm not going to go into the details today because Toby will go into all those details tomorrow, except to say that in the very beginning of the mpox outbreak, the FDA made clear that laboratories could develop LDTs and offer them without even notifying the FDA. When the emergency for IVDs was declared, the FDA at that point wanted to continue that enforcement discretion-- enforcement policy for a select group of LDTs, mainly PCR-based lesion swab samples that were performed at a single site laboratory. And that enforcement policy has continued to date, and we don't see any reason at this point to alter that policy. Next slide, please.

Through all of this, from the very beginning of the COVID pandemic through till today-- in fact, there is another mpox town hall call as we speak right now, which I wasn't able to be on. I try to be on most of these, but we've now held 99 virtual town hall meetings with tens of thousands of participants. These are with all sorts of developers. We record these calls now. Transcripts are available online for all of these calls all the way back to the beginning of the COVID pandemic to make access to the FDA's current thinking available to all. We do try to get these transcripts out and recordings out now as rapidly as possible so that if you didn't make a town hall session, you can just check the FDA website and see that. And we've continued to provide facts, frequently asked questions, safety communications-- I mentioned a couple of recent ones-- online resources for patient health care providers and developers. And we are currently still maintaining our COVID as well as mpox diagnostic and analytes. Next slide, please. And that's the end of my update. Thank you so much.

CLIAC CHAIR: Thank you very much, Tim. Are there questions? [CLIAC MEMBER]?

CLIAC MEMBER: Yes, I know there's been a lot of chatter about the VALID Act in the pathology community, and I wonder if there's any anticipation of how that might affect FDA approval of LDTs?

DR. TIMOTHY STENZEL: So the VALID Act is in the hands of Congress right now, and we all look to them to determine the future of the current legislative actions or proposals. And the FDA is on long-term record now saying that we would prefer that this be resolved in legislation to make it clear for all.

CLIAC CHAIR: I have two questions for you, Tim. The first is related to breath testing. When the FDA evaluates this, do they evaluate the bio safety concerns related if you're analyzing breath, how it gets exhausted and the risk of aerosol transmissible infections?

DR. TIMOTHY STENZEL: Absolutely, absolutely. So both the user interface with the patient-- we want to make sure that patient-to-patient, there is no transfer of potential infectious material. It's primarily designed to look at passing COVID infection. Although, since that is so infectious, it's probably a good surrogate for almost anything. But we look at not just design, but actual testing as well. And then we look at the operator safety as well. So what happens to that breath and how does the operator who is in charge of operating that instrument-- and all the safety features around that. And then we do look at within the instrument itself, not just the interface with the patient. We don't want to see any carryover from a positive patient to a negative patient that would yield a false positive result. Yeah, so we had all those concerns. We communicated with developers and what we expect to see. All that testing for the authorized device looked just fine, and so that was an important feature. Thanks for that question.

CLIAC CHAIR: Thank you. That's so reassuring. You're ready for my second one. As RSV is starting to raise its head and there's a lot of demand for testing, I noted that there are some multiplex platforms that received EUA. And I note that the various rapid tests prior to the pandemic going through the usual FDA process had populations that were restricted and, therefore, designated as the test group-- those under two and those greater than 60. I don't see that age discrimination in test systems that have gone through the EUA process. And so the question that's popping up everywhere is, are we allowed to use a prior approved FDA test method for all ages?

DR. TIMOTHY STENZEL: So if there are age restrictions in any sort of authorization from the FDA, there could be multiple reasons. The most likely reason is we don't have sufficient data to say that the test is safe and effective in that age group. But for anything that is a central lab test for anything that is a CLIA-waived test-- I mean, clinicians have the ability to use that test. For COVID and for the multi-analyte test that included either flu and/or RSV plus COVID, if they're in the point of care or central lab, we did not restrict access at that point. So I think you bring up an important factor. As long as the test is shown to be effective and safe in patients below 2 or whatever age group that's not included, the FDA is open to additional requests to expand those claims very clearly. But I personally trust clinicians to make the best decisions with the tools they have.

CLIAC CHAIR: Questions from others? I can't believe no one on this group has more questions.

DR. TIMOTHY STENZEL: I didn't do that good a job. So-- but thanks.

CLIAC CHAIR: OK, thank you so much. We will move on, and our final speaker for this session will be our beloved Ms. Sarah Bennett who will be talking to us about the proficiency testing final rule. Sarah?

Proficiency Testing (PT) Final Rule, CMS-3355-F
Sarah F. Bennett, MT(ASCP)

MS. SARAH BENNETT: Thank you, Dr. Ng. I did want to say this final rule represents years of collaboration and teamwork between the CMS and the CDC. And as [CMS EX OFFICIO] said, it's a wonderful example of our partnership. I did want to add you guys have really been set up for this presentation. And so I really wanted to say that I can't guarantee

that you're going to be on the edge of your seats. However, I can promise that there's going to be lots of details about the final rule. Next slide, please.

This is the same disclaimer that [CMS EX OFFICIO] used that I'm also required to use. And [CMS EX OFFICIO] already covered it, so let's go to the next slide, please.

So after this presentation, these are the areas that I'm going to talk about so you'll be able to understand the effective dates the rule, which [CMS EX OFFICIO] has already covered a little bit. And then these are the other areas that I'm going to be talking about-- the microbiology changes, the non-microbiology changes, testing of samples for referral for waived testing, and PT program changes. And as you know and as [CMS EX OFFICIO] said, that there are two different effective dates in the final rule, which I will cover shortly. But you don't have to worry-- there is no quiz at the end of this PowerPoint. Next slide, please.

These are just some general places that you can find information about the PT final rule. As [CMS EX OFFICIO] said, it was published on July 11th, which I will tell you is my mother's birthday, so I was very excited. She really didn't care, but it was exciting for me. And it's easy now for me to remember the date that it was published. If you're ever bored and have nothing to do, you can go to the general federal register link which is on the slide. But if you want to go directly to the PT final rule and read the over 100 pages of it, that is the direct link to the rule. We also published a fact sheet, which is just a summary of the changes in the final rule. And we also announced the publication of the final rule in this policy memo, QSO 22-21-CLIA. And the memo is CMS's official memo announcing the publication of the final rule. Next slide, please.

So I wanted to put this slide in here because I want you all to understand that rulemaking is not a quick process. I'm sure having been on CLIAC for some of you for many years, that this is something-- as you can see, CLIAC first made their official recommendations to HHS back in 2010. That doesn't mean it's the first time that CLIAC talked about it or that stakeholders talked about it, but this kind of marks the official beginning, and we are now 2022. So you can see the long period of time that sometimes it takes to get these important rules out. As I said, CLIAC made their recommendations in 2010. After they made their recommendations, CMS and CDC formed a team to determine how we were going to implement those recommendations and what process we wanted to use. Because we really wanted to make sure that it was a scientifically-based process so that moving forward, there's something for those who come after us to be able to use a process to make a determination about adding, deleting analytes, looking at acceptance limits. And then once we got all of that in together, we actually engaged with the PT programs. We sought feedback from the PT programs on what analytes should be included or added, what should not-- what should we consider removing, their thoughts about peer grouping. And then after we got all of that settled, then what we did is we ask the PT programs to run simulations on data that they currently had from PT events in the past to figure out what our target acceptance limits should be. Next slide, please.

And here's another slide on the effective dates. I'm sure by now, you all can tell us exactly what the effective dates of these rules are. The majority of the rule, as Greg pointed out, will be effective July 11th, 2024. We are working, as [CDC EX OFFICIO] said, with the CDC on rolling this out for 2024 to come up with surveyor training educational documents for laboratories and any other types of information that will be helpful so that it will make the transition to the new regulations easier for both the laboratories and the surveyors. The portions of the reg that are now in effect are those related to laboratories that perform moderate and high complexity testing, but they also performed waived testing. Before this regulation, those types of laboratories were exempt from PT referral adverse actions for the waived testing. So we have now included, because the statute-- and I'll talk a little bit more about this later-- the statute talks about any certificate is subject to sanctions for PT referral. So we wanted to make sure that we made sure that the statute and the regulations were aligned. So next slide, please. The finalized requirements fall into these categories. And I'm going to talk about all of these categories, so next slide, please.

Let's start with the microbiology PT changes. I'm not going to-- I'm a big believer in not reading all of the words on the slide. So you all have the slides, so I'm just going to cover some of these things very generally. We really believe that the revised micro-PT requirements better reflect the current practices in microbiology by replacing the list of services with broader categories of organisms. Currently, there are five types of services listed from just doing gram stains, primary inoculation, and sending out cultures all the way up to a full-service micro lab. This change was due to a CLIAC recommendation. This is a recommendation that CLIAC made that we did incorporate into the final rule. The third and fifth bullets really are clarifications. These requirements were really already there, but there was some confusion about them. So what we did is in the regulatory language, we clarified exactly these two-- the third and the fifth bullet-- so that the laboratories and the PT programs would know exactly how the grading should occur. Next slide, please.

More changes in bacteriology. And you will see some commonalities as we go through the microbiology changes throughout the subspecialties. But this, again, is-- rather than have a list of specific organisms like they are now, we revised the reg to include a more general list based on what the PT programs determine need to be in there, but they

must include the different groups of organisms. And we also added morphology to gram stains. Next slide, please. So-- oh, no. Back one, please. There we go. Thank you.

The last change in microbiology is-- and I wanted to talk a little bit about the reason why we removed resistance testing. There was some confusion about the interpretation of resistance testing and that it may not be clear. And in some cases, the resistance testing may be determined as part of identifying an organism, so we did remove the resistance testing. But just to set your mind at ease, if a lab is doing resistance testing separate from bacterial identification, they're still required to perform the twice annual accuracy-- what we call alternative PT. So there still is that requirement. It just isn't going to be in subpart I. Next slide, please.

And as I said, we'll probably go through these fairly quickly-- the rest of microbiology, because you can see we've changed it to the general list of organisms. And for anything that is not in subpart I, as you all know, the twice a year verification of accuracy is still required in the regulations. So if it's not captured in subpart I, then there is, in subpart K, that separate requirement. So this is mycobacteriology.

Next slide, please. Mycology-- and we do-- have included direct antigen testing in mycology. Next slide, please.

Also in parasitology-- and you can see we've gone to the parasitology samples have to include intestinal, blood, and tissue parasites if they're appropriate for the sample source. And again, direct antigen testing. Next slide, please.

And the same with virology. A general list of organisms and then the direct antigen testing. OK, next slide.

Now, we'll get into the non-microbiology PT changes. Just some general information. We added 29 analytes and we deleted 5, and we're going to talk a little bit more. There's a chart later on in the presentation that includes all of these analytes, and there's a couple that I want to talk about specifically. We also clarified what the PT programs have to do before designating a sample as ungradable. They have to use-- they have to attempt to grade both the participant and the referee laboratories before-- this wasn't necessarily always done by everybody the same way, and we're just clarifying that this is how it must be done so that everybody is on the same level playing field. A couple of-- the next few slides are going to-- this slide and then the next few slides are going to talk about some specific changes we made in the non-microbiology PT. The first one is chemistry. We just made a technical change to CK-MB isoenzymes, because we wanted to make sure that we captured criteria for acceptable performance for other and different methodologies. Right now, the regulations only say presence or absence or plus or minus 3 SD, so we wanted to make sure that we captured the new technologies that are being used for that like-- well, electrophoresis, isn't new, but direct mass determination. So next slide, please.

Hematology-- for prothrombin time, we-- so prothrombin time is actually the analyte and INR is just a way to report the PT. So we wanted to make it clear that laboratories who are performing prothrombin time, if they report out a PT in seconds, then they need to report out the seconds. If they report it out by INR, they need to report it out by INR. If they report both, they need to report both. This was just a way-- there are so many devices out there that don't actually report out the seconds anymore. This is kind of a nod to new technology where you are-- the devices only report out or give you a response for the INR. So we wanted to make that a way that those prothrombin times officially could be reported. Laboratories that perform both cell counts and diffs, they have to enroll and participate in PT for both. And I don't know about you, but this third bullet, it always confused me when I was in the lab about PT. We changed the cell identification criteria from 90% to 100%. I don't know how anybody could ever get 90%. If you have five samples and you miss one, you're at 80%. So really, 100% is where you had to be or you had to do-- it was unsatisfactory. So this just aligns the five samples with the 80% like the other analytes that have 5%-- I mean, have five samples. Next slide, please.

Toxicology-- we found that PT programs tended to send the majority of the samples within or close to the therapeutic range to-- for proficiency testing samples. So as of the July 2024 effective date, we're requiring the toxicology samples cover the entire reportable range from low to high, and they need to cover the clinically significant levels. In other words, you want to see something that's really-- they're supposed to be taking it, but they're not all the way up to the other end where you have a toxic level. We want to make sure that laboratories can measure the entire reportable range for those toxicology analytes. Immunohematology-- we changed the criteria for acceptable performance for unexpected antibody detection from 80% to 100%. As you all know, unexpected antibodies is something very important, especially when you get into transfusions and transfusion reactions. You want to make sure that the accuracy is really good for detecting those antibodies. Next slide, please.

We added three definitions-- acceptance limit, peer group, and target value. Next slide, please.

I'm not going to read these to you. We have made it clear that the PT programs should assign peer groups based on their own policies and procedures and not based on directions or recommendations from manufacturers. We wanted to make sure that the PT programs are the ones who are actually doing that. Target value-- we removed the reference to NRSCL,

and we also revised this to be in a more readable format. I don't know-- if you go to the current regs now, it's like this long-- it seems like this long run-on sentence about what target value is, and it's very confusing. And so we tried to take the confusion out of it by setting it up the way that other regulations are so you could more easily read it. We're going to continue to allow peer grouping for the evaluation of P2 results. And we really don't expect that there'll be a change in how peer groups are identified by the PT programs. And so-- or how the target values are determined at all. So next slide, please.

Now, let me talk a little bit about what criteria we use. And this goes back to where I was talking about we came up with-- the CMS and CDC came up with a process that hopefully can be used in the future, but that we use. So that there was really-- it wasn't like, oh, yeah, this one looks good-- let's add that to the list-- oh, we haven't heard about this for a while-- let's take it off. We really wanted to come up with a very deliberate process on when we were adding, or deleting, or revising analytes. And so the first criteria that we used was the availability of the PT materials. And what basically our line in the sand here was we wanted to ensure that at least three PT programs offered the analyte we were considering. But the next criteria that we used is how many of the tests were being performed nationwide. We used data from Medicare data for this. That was what was available to us and our-- we considered a national volume-- the national volume of testing, and we used 500,000 as our cutoff. So where 500,000 or more being performed or 500,000 or less being performed. The next criteria that we used was impact on patient health or public health. This particular criterion can be very challenging, because there's really no standard way to look at impact. So what we did is we reviewed lab practice guidelines, critical values, and FDA categorizations to help us with this criterion. Finally, we looked at the cost and feasibility. We looked at how much it would cost the lab and how practical it was to implement. We considered the stability of the materials when developing samples and shipping samples. So if-- and we also considered whether a test methodology was sufficiently standard. Vitamin D is a really popular test right now, but at the time we were writing the rule, it was really, really challenging to come up with how we could identify a standard methodology that we could cover in-- useful in PT.

Next slide, please. These are the lists. These are the added analytes. And I did want to call out two in particular. The first one is CEA-- Carcinoma Embryonic Antigen. We realized after the final rule published that the units were incorrect. Somehow, they got-- we don't know. But anyway, we are in the process of trying to get that corrected. The final rule published as nanograms per deciliter-- it should be nanograms per milliliter. So we are in the process of getting that corrected.

The other one-- I'm sure that you all can probably guess what the other analyte is that I'm going to talk about. Hemoglobin A1C-- far and away the most public comments were submitted for the proposed rule surrounding the criteria for acceptable performance for hemoglobin A1C. We really believe that there was some confusion from the public related to this as opposed to the precision stated in the manufacturer's instructions that the labs are required to verify. The commenters were concerned that if we had a 10% criteria for acceptable performance that the manufacturers would follow suit and make their tests less precise. We do not share that concern. As you know, the precision for most hemoglobin A1C tests is about 3% to 4%. And so I think there was some confusion, which we really tried to talk about in the final rule in the comment and response portion of that rule. We-- the clarification that we provided was that verifying performance specifications is for a specific laboratory-- that one laboratory is performing the test. So if the manufacturer says that there's a 3% to 4% precision, that's what the laboratory should get. That is completely different from criteria for acceptable performance when you're talking about aggregate data that covers many laboratories, which is what PT it is. However, based on the comments, we did ask the PT programs to rerun simulations with lower acceptance limits. And as a result of that, the proposed criteria for acceptable performance was 10%. And when we finalized it, we lowered it to 8%. That, from the simulation, seemed to be the best range for that. Next slide, please.

This is just more of the test that we added that will be effective. And then these are the five tests that we deleted from subpart I. I do want to say that it doesn't mean that these tests are not important. However, they did not meet our criteria for retaining them in the regulations. Next slide, please.

Well, one of the big changes we made in the final rule was changing most of the criteria for acceptable performance from standard deviations to percentage-based limits. There are some advantages to doing this. Some of those include that we can-- the results can be tied directly to an objective goal like analytic accuracy. It's a constant in all PT events and it doesn't vary due to statistical randomness. It ensures the same evaluation criteria for all the PT programs which discourages participants from shopping around for a PT program that might have less stringent criteria. And it also-- it doesn't unfairly result in tighter effective acceptance limits for peer groups based on the listing of analyzers and tighter analytic precision. But as you all know, in the lower ranges for some tests, percentage might be overly stringent. So in those particular analytes-- the examples here-- we also included fixed concentration units. So you will see in the final rule that there are some that have just the percentage, and there are others who could be affected by this increased stringent limit that we also included-- the fixed concentration units. So there will be a combination there. Next slide, please.

Back to the PT referral for waived tests. As I said, it aligns the law with the regulations. I do want to make very clear that those tests-- those labs that are performing moderate and high complexity tests and also performing waived tests are not required to enroll for their waived tests. That is not what this requirement changed. What this requirement changed is that if they do enroll, they are held to the same requirements for testing of PT samples as the moderate and high complexity testing as well, which means that if PT referral occurs, then there will be sanctions associated with that PT referral. Next slide, please.

The last few slides that I have are related to the changes to the PT programs. We are requiring now that when PT programs-- not now-- July 11, 2024-- when PT programs reapply for their approval which is an annual process-- PT programs have to apply every year for re-approval-- that they must have a minimum of 10 participants in order to enter the re-approval process. We were finding-- one of the issues we were finding was that there were some PT programs that had less than 10 participants, and as a result of that, there was no consensus. So many of their challenges were ungraded, and that's not helpful really to anyone. So we want to make sure that they have 10 participants when they seek re-approval. We also clarified that the technical and scientific responsibilities must be performed by a private nonprofit organization. We've always required this, but we did some clarification about what we mean by that. So technical and scientific responsibilities include things like selecting and determining the target values-- the appropriate target values for challenges in grading, reporting the scores to CMS, selecting the organisms for microbiology PT. Those are all things that would fall into the technical and scientific responsibilities and must be done by a private nonprofit organization or federal or state agency. Any one of these things in the second bullet. A non-technical and scientific activity would include things like obtaining and manufacturing PT samples, acquiring and labeling the PT specimens, long-term storage of the samples and distribution and mailing of the samples. Those do not have to be performed by a private nonprofit organization. And we just wanted to make sure that was clear, because there was some confusion. Certainly, FedEx is not nonprofit and they do a lot of the mailing of the samples and the delivering of the samples, so we wanted to make sure that could continue. And so we just provided some clarification.

We also added a requirement that we may do an on-site visit for all PT programs. We did not have this really in our regulations before. We just wanted to put it there. Not that we've had any issues. I want to make you all rest assured, we've not had issues. But we wanted to have the ability should something happen that we have the ability to go on-site and that it's very clear in the regulations. Next slide, please.

The other thing that we-- another thing that we wanted to clarify with the PT programs-- and we added this requirement-- is that if a program-- it may require them to reapply for approval using the initial application process, if we find that there are problems with their renewal process. To date, we have not had an issue, but we this is something that we felt like we really needed to have in here should it happen at some point. We also will notify the program of withdrawal of approval in certain cases. That would include if they don't meet any of the PT criteria, like criteria for acceptable performance, number of samples, those types of things. And that if they provide us false or misleading information, then we may withdraw their approval. Next slide, please. Oh, That's it. That is the end of my presentation. You all can sit back, relax. You don't have to sit on the edge of your seats anymore.

CLIAC CHAIR: That was fabulous, Sarah. This group is so detail obsessed, and you are perfectly pitched. The hands are already up. [CLIAC MEMBER] first.

CLIAC MEMBER: Yeah, good report. As one of the people on this committee that's oriented towards clinical chemistry, I have a couple of questions. The first one concerns CK-MB. I can see why the CLIAC back in 2010 made their recommendations, but today, it's 12 years later. You might find that CK-MB satisfies your criteria to be removed.

MS. SARAH BENNETT: It could be, but we don't know that-- it would be considered the next time we update the PT regulation. But the data that we had when we wrote this, it was still included.

CLIAC MEMBER: So there's no plans to take any tests away from the PT requirements at this point?

MS. SARAH BENNETT: No, not until we would update the regulations the next time, and we don't know when that is.

CLIAC MEMBER: Well, we might consider that as CLIAC. The second question concerns phosphorus, and you put-- you added that, and that's a good thing. Phosphate is one of the key clinical chemistry analytes that's often ignored or forgotten, but it is phosphate. And why do we keep using phosphorus instead of phosphate, I really can't describe it. It's just historic, but it's inaccurate. Phosphate is what circulates in the blood. That's what we measure. Inorganic or elemental phosphorus is not what we measure and it should be changed to phosphate.

MS. SARAH BENNETT: We can certainly take that under consideration.

CLIAC CHAIR: We love our chemists. [CLIAC MEMBER], did you-- are you done with your question?

CLIAC MEMBER: Yes.

CLIAC CHAIR: [CLIAC MEMBER].

CLIAC MEMBER: Yes, thank you. And I want to also thank you for an excellent presentation. My question relates to the program being approved and re-approved. And you talked about the fact that it requires a minimum of 10 participants. Is that so that you can obtain a high level of validity and reliability? And if so, what is that CI-- what is that Confidence Interval?

MS. SARAH BENNETT: Well, the reason why we added that is, like I said, we found several programs who had less than 10 participants. And what happens in those particular cases is many times, the challenges are ungraded because they can't come to consensus. And 10-- in our regs, we had 10 before, but we wanted to make sure that in order to be re-approved that they had those 10 samples. Because we see that-- I mean, 10 laboratories-- because we see once you have the 10 laboratories, it's easier for the PT programs to come to consensus and actually give you the values that are acceptable as opposed to not.

CLIAC MEMBER: Is there a particular range for the values that are acceptable that fall into a high level of confidence or validity or reliability? In other words, is there a reference that says you must have-- that you believe that at this level that one would be approved or not approved? What are those parameters? I'm looking more at research. I'm going for the-- I do research. So--

MS. SARAH BENNETT: Right. So we had some references to 10 laboratories in the previous. And based on the re-approval process, that determination was made that 10 really needed to be the cutoff for re-approval in order to be able to have PT that was meaningful for the laboratories.

CLIAC MEMBER: OK, thank you.

CLIAC CHAIR: [CLIAC MEMBER], you had your hand up briefly?

CLIAC MEMBER: Yes, I did. And Sarah, this was an excellent presentation. I do want to comment-- and maybe you could expand a little bit more-- one of your slides talked about a very deliberate plan for addition and deletion criteria, and you went into that a little bit. Could you share with us how the group developed that criteria? What did you use, because there's not much out there on that kind of protocol, and that certainly is needed.

MS. SARAH BENNETT: For when the CMS and CDC group got together, we tried to figure out what would be the best things to look at in order to come up with a good solid plan that we could use this time and if we decide to do it in the future. And these four elements are after looking at multiple different areas and having lots of discussions, these were the four areas that we determined we could use to ensure that we were including those analytes that needed to be included and perhaps deleting those that were no longer needed to be in the regulations.

CLIAC CHAIR: [CLIAC MEMBER], your hand is still up.

CLIAC MEMBER: Oh, I will take it down. That's just a-- my question was answered. Thank you.

CLIAC CHAIR: I see no more hands up, which means Sarah has answer our questions. And it is 10:30. And I don't see hands for either [CLIAC MEMBER] or [CLIAC MEMBER], so I am going to end the session. We are now going to have a one hour break. CLIAC members, please ensure you are on mute and your video is off during the break. Please return promptly at 2:30 East Coast time, 11:30 West Coast, and somewhere in between wherever you are. I will see you in one hour. Thank you very much.

❖ Presentations and Committee Discussion

CLIAC Workgroup Reports

CLIAC CHAIR: It is 2:30, and the meeting already got off to a great start with [CLIAC MEMBER] educating us around phosphorus versus phosphate. And now, we're going to go into the controversial subjects. This afternoon, we will be talking about the reports from two ongoing CLIAC workgroups. We're going to start with the CLIA regulations assessment workgroup report presented by the workgroup co-chairs, doctors Kim Chapin and Greg Sossaman. These are presentations 5 and report 5a. after the presentations, we will have time for committee discussions. If you wish to provide

a 5-minute public comment, please email the cliac@cdc.gov. We have three public comments lined up. One is from the American Clinical Laboratory Association-- will be presented by Adam Borden. One is from the College of American Pathologists to be presented by Dr. Joseph Saad, and one is a written comment for the National Center for Health Research. Given that, it is time to start, so I'm going to hand it off to Kim and Greg. Go for it. [CLIAC MEMBER] has his hand up.

CLIAC MEMBER: Just a quick question-- and this may answer it. I just want to confirm-- this is an interim report-- correct-- that the workgroup is going to continue?

DR. GREGORY SOSSAMAN: That's correct.

CLIAC MEMBER: Or is this-- thank you. It helps form my thoughts as you're talking.

CLIA Regulations Assessment Workgroup Report
Kimberle C. Chapin, MD, ABMM, FCAP
Gregory N. Sossaman, MD

DR. GREGORY SOSSAMAN: Yeah. No, thank you for calling that out. And so Dr. Chapin is traveling. And so I know she was still on the call as a minute ago, so I'm assuming she'll chime in as necessary. But I'm going to try to carry some of the presentation piece. So you see the first slide. And as was pointed out, this is an interim report from the workgroup. And as [CLIAC CHAIR] said, there is a meeting summary report that's on the CDC website, and this workgroup will continue on.

Next slide, please. So as was mentioned, Dr. Chapin and I are co-chairing. This is a very large group. And the workgroup charge with this workgroup was established to provide input to CLIAC to this group for deliberation on how specifically CLIAC might be updated considering and integrating the reports from several other workgroups, including the personnel regulations, the nontraditional workflow models, and the next generation sequencing workgroup. So a lot of people involved in this group, which we'll see on the next slide. And our charge was, again, providing advice to this group. We're not doing anything other than providing advice to CLIAC. And CLIAC, of course, makes recommendations to HHS. Next slide, please.

So considering trying to integrate all of those workgroups together, you see what we narrowed down or tried to focus on the topics to present in front of the group around the total testing process and review of that. Data as a specimen, digital pathology, analytic testing specifications and histopathology were within our purview. Other things we considered out of scope and didn't consider. This is what we focused on. Next slide.

As I mentioned, it is a very large workgroup. Dr. Ng was on the workgroup with us. Mike Black, who is on CLIAC here, Dr. Hilborne, and we have a number of just really experts in the fields. I'd particularly like to call out Dr. Funke and Dr. Carter for doing tremendous presentations for us on NGS and helping us understand bioinformatics, and really went into quite a bit of detail around the informatics piece and the sequencing piece. So appreciate the input from those individuals. And again, just tons of expertise in this group. Next slide, please.

So what we're going to go through are the agreements. We've had five meetings-- multi-hour meetings where we've gone through lots and lots of information. And we've narrowed down-- at least, at this point, as was mentioned, an interim report-- the current workgroup agreements around the total testing process, status of specimen. I'll talk about this later-- the possibility of a new CLIA certificate type if it's needed. Remote testing, at-home specimen collection, personnel, and then we've lumped some of the things we've agreed on as to-- and other areas, and so we'll go through that. Next slide.

So as far as the total testing process-- and again, considering-- you have to consider what this workgroup was focused on-- next-gen sequencing, nontraditional digital pathology-- one of our agreements-- the workgroup's agreements is that laboratories requirements under CLIA should start when a specimen arrives in the laboratory for testing. Lots of discussion around clinical decision support, helping to ensure clinicians ordering the right tests, those type of things. But really, the majority of the group felt like-- but as CLIA has written it, really specifies when a specimen arrives in the lab is really when we have responsibility for that. And though that responsibility should continue through the total testing process, including data interpretation and reporting even when that interpretation, or analysis of data, or manipulation of data would occur off-site, it should still be part of-- should still be regulated under CLIA. Next slide.

So data as a specimen. And I'm sorry for-- we're sorry for the denseness of the slides and the presentation. I'm unfortunately going to be reading off of these slides quite a bit, but there's a lot of information to convey here to you. Again, this is all on the presentation on the CDC website, so if there's anything I skip or you want to go back to later,

please do that. But I'm going to I'm going to try to get through some of this in the interest of time. So they recommend that-- the current CLIA definition includes the terminology materials derived from the body. And the workgroup felt that derived should apply to images and data as that is a derivation of material from the human body. And that the term materials should be defined in CLIA as the patient specimen, including data derived from patient specimens such as, again, those images, genetic protein sequences, omics, anything that's used for the purpose of providing information around a diagnosis, prevention, or treatment of disease. And so that term materials is not currently defined in CLIA as such, and so this is a recommendation to be defined that way. There is a definition for test system in CLIA, but the workgroup felt that that should be modified to include all of the instructions, instrumentation, everything-- including software algorithms, data analysis procedures, and other components needed to perform an assay to generate test results. So really, that software algorithm and data analysis piece would be new-- a modification to that definition test system. So next slide, please.

And in light of this, there was some discussion around if a new CLIA certificate may be necessary. So the workgroup worked hard on the wording for this. And you may see some of this in previous iterations of recommendations from CLIAC, but the first piece of advice is around if an entity is manipulating information, performing data analysis, those types of activities received from a clinical lab and returning it to that clinical lab for inclusion in a patient report or for other-- or interpretation, then that entity-- again, this outside entity needs to have the appropriate CLIA certificate. Again, recommending-- as part of the total testing process, it needs to be regulated under CLIA. And so then under that CLIA certificate, they would be subject to the same patient confidentiality and requirements of the referring laboratory. And so just to be a little bit more specific about that, entities that perform that informatic analysis-- and again, interpretation or manipulation of this laboratory data should be certified under CLIA. And that's where the idea of perhaps a new type of CLIA laboratory designation beyond compliance or accreditation may be necessary. And the thinking around this specifically was using NGS as a case example where data from a sequencer is then sent through to an outside-- to the cloud to an outside bioinformatics company to a bioinformatician that would manipulate that information and then send it back to the referring laboratory. And that was the reasoning for the wording of the entity, because we're not specifying exactly what that is. Next.

So as far as remote testing, this has already been discussed at previous CLIAC meetings, and there's even been recommendations about if-- we saw this earlier in the CMS report-- a pathologist is reviewing images at home-- that that continues under the enforcement discretion. But we expanded-- the workgroup expanded the wording on this a little bit. So if a laboratory employee works out of their home or in another remote location doing data analysis or interpretation associated with that lab, then again, those activities are covered through an extension of the laboratories CLIA certificate. So again, not just a pathologist, but could be any laboratory. And under a distributed model, though, where a lab performs the wet laboratory work, and then another entity performs the data analysis or interpretation, those two sites should have separate and distinct CLIA certificates and proficiency testing required for both of those. So that hearkens back to the previous recommendation where, again, data manipulated at an outside entity needs to have its own CLIA certificate. The CLIA regulations should be revised to allow remote analysis for any CLIA specialty or subspecialty-- again, not just digital pathology. Whether it be something related to toxicology, or NGS, whatever it happens to be, we would advise a revision of those regulations. And that a laboratory's CLIA certificate covers the qualified laboratory personnel-- again trained in competence under that laboratory-- that that certificate covers them when they're using, say, a VPN type interaction or VPN type connection to review and report cases remotely. So multiple-- kind of went through multiple iterations of that-- different ways of saying various very similar things. Next slide.

Now, again, this is more of the nontraditional workflow. We talked a good bit about that home specimen collection piece. And this really hit home-- it was new to us and brought up from the pandemic, where we had lots of at-home specimen collections. And again, laboratory testing really begins-- the quality begins during the specimen collection. But it's really difficult to inspect that if it's collected at home. So where does that responsibility begin and end with that at-home collection-- the packaging, transport, those kinds of things. So a couple of recommendations for consideration for CLIAC regarding vendor own responsibilities. That the vendor should perform studies, including stability around transportation, those type of things, on at-home collected specimens and provide that information as part of their FDA approval process, so when they're submitted for clearance or PMA. And they should include that stability information. The FDA should possibly consider requiring a human adequacy control for detection in a specimen for at-home collection. Specimen collection devices should have internal controls to ensure that the patient-- the specimen was collected, and monitor the specimen's integrity during transport to the laboratory. For instance, things having to do with temperature exceeding certain limitations, or on temperature, things like that. Those type of internal controls are very valuable. And that if a lab chooses to use an at-home collection device that's not been cleared for use or is modified, they will need to submit to the FDA their own studies for review and approval. And the laboratory should have policies in place to accept or reject specimens collected outside of their laboratory, including some of these verification processes. And if a laboratory chooses to test the specimen falls outside of those-- the device manufacturer's instructions, then the lab needs to provide performance studies that show that that modification is acceptable and valid. Next slide.

So around personnel, workgroup members felt that CLIA should look broadly at new personnel roles involved in the bioinformatic data analysis variant classification, variant analysis. Again, had wonderful presentations from experts in the molecular area and really delved into what does this variant classification look like, what does that bioinformatics work look like? And it looks very different from a lot of the traditional laboratory roles. And that CLIA should encompass training and competency assessment for those staff, such as pathology assistants, image technicians, cytotechnologist, and others that are involved in digital pathology and digital-image analysis. Again, it's something new, outside of the traditional laboratory norms. And this may require establishment of a new personnel category in CLIA, or adding competency requirements to that. And that a new specialty is probably needed to accommodate the post-- this is a little bit of a-- non-sequitur post-analytic analysis of laboratory data. So what happens in the laboratory, again, using that example, next-gen sequencing, sent to an outside entity, manipulation of that data, and then comes back. Next slide.

I'm trying to get through this material and make sure I leave time for Dr. Chapin to chime in if she wants, and of course our questions, which I think I'm doing pretty good. So in other areas, this was the catchall for miscellaneous-- thank you, Dr. Hilborne-- this is the catchall for some of the other things that we talked about, that are somewhat tangential to the main topics. We did talk about automation quite a bit and how AI and automation should be handled, and really felt that robotics and automation should fall under CLIA because that's part of the responsibility of laboratory personnel, and that those aspects of that need to be included in the validation and establishments of performance characteristics. For a digital-data, laboratories should have a policy or procedure to ensure specimen integrity throughout that whole process. So again, it's of paramount importance, in a laboratory, to maintain proper identification of the specimen. And for images, things like that, that's new. And we need to have policies and procedures established for that. And so number three is similar. Any device that's storing data should have an identification number for that image, a patient identifier some other kind of institutional identifier, to ensure that quality. And then this was a point I think brought up by Dr. Carter and others, that laboratories must implement software and devices which are compliant with the components of the HIPAA final-security rule, and that the laboratories must ensure that these devices don't impose a significant risk to the safety and security of the patient data that's stored, and that FDA must ensure that the software and the systems of the test devices that they approved are HIPAA security-rule compliant. So sometimes the laboratories are put in the position of bringing in software and hardware that are not compliant with this rule. And that's the end of the presentation. I ran through that very quickly. I understand, again, presentation's present on the CDC website. A little dense. I apologize for that. I know we have some public comments but I think we should have lots of time for discussion and questions on this. And Dr. Chapin-- I'm trying to see if she's still on.

DR. KIM CHAPIN: Yep, I am. Thanks, Greg.

DR. GREG SOSSAMAN: Yeah, please do.

DR. KIM CHAPIN: Sorry. I had to move around because of noise in the area where I am. But thank you for doing that. I know I asked him to fill in, last minute, to do the whole thing. So lots of room for discussion.

DR. GREG SOSSAMAN: And I don't know if you have anything to add or-- I'm sure it would have been much better if you had done this.

DR. KIM CHAPIN: I'll do it next time.

Public Comments

CLIAC CHAIR: Thank you both. That was a huge amount of work. And that was a lot of effort in trying to summarize and to reach agreement on what you presented today. Before we have committee discussion, I'd like to hear the public comment. And first up, we have Adam Borden, representing the American Clinical Laboratory Association. Adam?

MR. ADAM BORDEN: Great. Thank you so much for the opportunity to address the committee today-- I certainly appreciate that-- and to the presenters from this morning, a lot of great, great information shared. So again, my name is Adam Borden. I'm the senior vice president of Policy and Strategy at the American Clinical Laboratory Association, or the ACLA. I'm speaking today, representing our members, who are the nation's leading clinical laboratories, regarding the topic of CMS's enforcement discretion for CLIA certificate requirements, for remote sites during and after the COVID-19 public-health emergency, an issue that was just addressed in the workgroup's report.

So as you know, early, during the pandemic, CMS had issued guidance to states to exercise enforcement discretion, to ensure pathologists may review slides and digital data remotely, at alternative sites such as the home. This enforcement discretion also extended to other laboratory professionals-- this was just discussed as well-- such as cytogenetics, laboratory technologists, and others, to review those digital images, slides, and laboratory data, from again, a remote site.

We at ACLA are appreciative that CMS has proposed to continue that enforcement discretion for pathologists after the end of the public-health emergency. And we thank the agency for releasing that information in advance of the eventual expiration of that PHE. However, we were disappointed to learn from the agency that the enforcement discretion is not proposed to extend to other laboratory professionals, beyond the pathologist. And so as the workforce environment has changed during the pandemic, and essentially before the pandemic, we're concerned that proposed policy could exacerbate current workforce issues that laboratories are currently experiencing. So we thank the CLIAC for, again, the previous recommendations from November 2019 and April this year, most recently supporting that laboratory practice, over the last couple of years and during the pandemic, has really demonstrated the success of remote analysis and interpretation of digital data securely, and recommending that HHS codify that the primary or home-laboratory certificate covers the employees when they are interpreting digital data from a remote site. Now given the current workforce challenges with recruiting and retaining laboratory employees, we believe that it's critical for labs to be able to continue offering remote working capabilities without the need for additional regulatory requirements that can often be difficult to operationalize, especially coming out of the pandemic, when so many individuals and laboratory professionals were hired or had moved to a home working environment.

Again, requiring those CLIA certificates, after the end of the PHE, for non-pathologist lab professionals, would create unnecessary administrative and expense burdens. It would hinder recruiting efforts during this time of, again, significant staff shortages in the laboratory environment. So we really just wanted to request that the CLIAC continue to reiterate the call for codifying this change that would establish the home-laboratories CLIA certificate as overseeing remote work from any laboratory employee, pathologists and non-pathologists. And thank you very much. Certainly appreciate the support for laboratories and professionals that really work hard to bring these essential services and information to patients and providers. Thank you again. I appreciate the opportunity to comment.

CLIAC CHAIR: Thank you very much, Mr. Borden, to you and ACLA. Our next public comment is Dr. Joe Saad, representing the College of American Pathologists. Joe?

DR. JOE SAAD: Thank you, Dr. Ng. My name is Joe Saad. And I'm a practicing pathologist in Dallas, Texas. I'm here representing the CAP to speak to CLIAC on the report from the CLIAC CLIA Regulations Assessment Workgroup. Thank you for the opportunity to speak. The CAP Laboratory Accreditation Program serves clinical laboratories, providing leading-edge science and technology while ensuring clinicians and patients receive accurate laboratory testing. The CAP finds that CLIAC continues to provide an adequate baseline to ensure the accuracy and reliability of clinical laboratory results.

At the same time, we recognize that specific updates to CLIA are needed to address changes in practice and technology, to adapt to evolving practice models. Hence, the CAP offers the following comments regarding CLIAC regarding remote work and revamping the proficiency-testing requirements to address the total testing process.

With regards to remote work, many pathology practices have the infrastructure to support remote sign out. In March of 2020, the CAP strongly advocated to CMS to exercise regulatory flexibility, to allow remote sign out because its benefits during the COVID-19 pandemic far outweigh the risks. The public-health-emergency policy allowed for pathologists to review slides, digital images, and electronic data from a temporary site, provided that the remote site or home base is not used as a designated primary site, and work performed in the temporary site falls within the parameters of the primary site's certificate. The CAP supports the continuation of the remote sign-out waiver for the duration of the public-health emergency. However, we recommend that CLIAC examine potential unintended consequences that could cause patient-safety and testing-quality issues. The primary-site certification was required by CLIA to ensure quality testing and safety of patients, by providing greater oversight for gynecologic cytology laboratories. In recent years, we have similar quality concerns with regards to specialty physician groups, using the in-office ancillary services, exception for anatomic pathology. Removal of the primary-site CLIA certification allows for slides to be read at various locations other than the physician's practice, potentially increasing the volume of slides read and decreasing oversight.

While the CAP recognizes the benefits in continuing to allow remote work, we strongly recommend closely monitoring for the following, remote sign-out usage to determine the settings, personnel qualifications, and documentation of compliance with primary-site policies and procedures, to ensure CLIA assures quality for all testing settings, and to prevent potential fraud and abuse. The CMS, prior to any rule making, should collect and report on the above to CLIAC for at least one survey cycle after the PHE declaration ends. Therefore, the CAP supports continued enforcement discretion following the expiration of the public-health emergency while the practice and regulatory implications of remote sign-out policy are further evaluated. In addition, the CMS should remove the pathologist's home address from the CLIA certification. Testing sites prior to the PHE declaration were required to obtain a CLIA certificate that included home addresses. Since the beginning of the pandemic, health-care providers have been attacked with higher frequency. We must protect the health and lives of health-care providers. As such, the CPA recommends that CMS remove the home address for read-only sites from the CLIA certificate, and creates an alternative mechanism for identifying these testing sites.

With regards to future requirements for the total testing process, distributive testing occurs when clinical laboratory testing is performed on a specimen or aliquot thereof, and requires sharing between two or more laboratories to obtain the necessary data in order to complete an interpretation or calculation and provide a final test result. When such testing occurs at locations with different CLIA certificates, it is considered distributive. An important quality metric in determining when a clinical laboratory, testing accuracy and reliability, is proficiency testing. Laboratories should perform by observing the same process that they do for patient samples. Doing so should not constitute intent to commit proficiency-testing referral. The CAP launched, in 2015, PT for NGS that can test wet and dry bench components of NGS testing. Currently, clinical laboratories are unable to test the entire system if a portion of the test is performed in a distributive-testing model such as bio informatics-and cloud-based software computing. This makes it difficult to assess the complete process, pre-analytic, analytic, and post analytic, and is an insufficient quality indicator.

In conclusion, the CAP supports CLIAC's efforts to examine the CLIA regulations in determining modifications to ensure that the regulations accommodate advances in clinical laboratory practice. However, any modifications should assure patient access to quality testing. CLIA is a very important tool that can ensure the integrity of clinical laboratory testing. As clinical laboratory testing continues to involve the CMS and interests of stakeholders, such as the CAP, need to work closely to ensure appropriate regulations and policies. Thank you very much for your time and attention.

CLIAC CHAIR: Thank you very much, Dr. Saad and the College of American Pathologists. Again, we have a third written comment from the National Center for Health Research. It's on the website if you'd like to pursue that.
We have hands up in the air. So folks are ready to talk. So [CLIAC MEMBER], you were first. Go for it.

Committee Discussion

CLIAC MEMBER: Thank you. And excellent presentation. I have a comment and a question. The comment is, thank you very much for thinking of non-pathologists in your recommendations because I definitely see a role, with the limited resources and laboratories, for centralized blood bankers, for example, to read panels offsite. And so I think that that's an excellent recommendation. My question is on histotechs. You mentioned that a recommendation to define the role for histotechs with digital pathology. But it's my understanding that histotechs have never actually been recognized in the CLIA regulations. So are you going to also go back and define the role of histotechs in all of their various laboratory responsibilities?

CLIAC CHAIR: This is for Greg and Kim.

CLIAC MEMBER: Yes, I'm sorry.

DR. GREG SOSSAMAN: Kim, I'll take a stab at that. So this workgroup would not be-- that would be outside of the purview of this workgroup, to go back and do that, but certainly, in my opinion, would not be outside of the purview of CLIAC to consider that. Kim, did I say that the right way? You're on mute.

DR. KIM CHAPIN: Sorry. Yeah, no, I agree. I do believe that we have some other workgroups that are addressing some of that as well. And I did have a follow-up question for--

CLIAC CHAIR: Back on mute.

DR. GREG SOSSAMAN: Back on mute, Kim.

DR. KIM CHAPIN: Hold on, I'll-- sorry, I'll raise my hand.

CLIAC CHAIR: Get in line.

CLIAC MEMBER: I'm getting in line. I'm getting in line, sorry.

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

CLIAC EXECUTIVE SECRETARY: No. I just want to address that question. So when we presented at the last CLIAC-- and I can share this but you can go back to our last CLIAC meeting-- you will see a list of all the topics that were discussed. And in fact, it was on one of the earlier slides. We do have histopathology as a topic area for future discussions. And one of the questions that CLIAC will be considering is should CLIA recognize the role that histotechnicians, histotechnologists, and pathology assistants play in the total testing process? So while we have not specifically addressed that in this interim report, we still that have that full topic area as part of the discussions coming up for the workgroup. And hopefully we'll have the next report and that information available in April.

DR. GREG SOSSAMAN: Thank you, [CLIAC EXECUTIVE SECRETARY]. That was a better answer, [CLIAC MEMBER], to your question, that-- not yet. I'm not sure where the work will begin. The workgroup will consider it. Not sure what advice will come out of it. But certainly, again, would still be within the purview of CLIAC to talk about it.

CLIAC CHAIR: Thank you. [CLIAC MEMBER].

CLIAC MEMBER: So I have a couple of questions. One is, I commend you for-- regarding digital pathology data as a specimen and requiring appropriate identifiers. So knowing that commercial entities are using digital-pathology data to create AI-based prediction algorithms, say, to predict a diagnosis from an image-- and this may be more for the FDA-- are CLIA-covered digital images being required to develop those algorithms, in other words, to be part of the training set?

CLIAC CHAIR: So [CLIAC MEMBER], did you direct that question to [FDA EX OFFICIO]? Because if you did, [FDA EX OFFICIO] raised his hand.

CLIAC MEMBER: I think [FDA EX OFFICIO] should answer it because I think it comes out of what we just heard but goes back into how the FDA is regarding that data.

CLIAC CHAIR: Mm-hmm. [FDA EX OFFICIO], it's yours.

FDA EX OFFICIO: Yeah, to me. We have a collaborative community around digital pathology. And they're working towards a framework. But in all likelihood, those kind of images will be important to assess a digital pathology, algorithm.

CLIAC MEMBER: Yeah, I think it would be important to have some process of certifying that they did come out of a CLIA laboratory with appropriate identification. I've just recently encountered the topic of data poisoning as a means of cyber attack. And while it's usually seen more often in national security, if one remembers the Tylenol poisoning, which was a disgruntled employee, one could imagine that there could be someone playing with the data. I do have another question if that's all right?

FDA EX OFFICIO: Yeah, just let me follow up on that. So we do request and get information of the source of every sample that is used in a clinical study for FDA review and decision. And our team looks at every line listing of every sample and looks at things like identity. So we do we do a thorough, careful job.

CLIAC MEMBER: OK. So I was recently introduced to some very interesting results from in-vitro microscopy and ex-vivo microscopy. And this usually uses a different light pattern, either Raman spectroscopy or is it optical or coherence transmission. And there's a very interesting machine being marketed for community hospitals who don't have a neuropathologist on staff, in which you can perform a brain biopsy, put it into one of these machines, generate an image that then gives you a probability of what type of brain tumor this might be and so on. Now these are performed in the procedure room. There are similar things for endoscopy. These are performed in the procedure room. And to what extent does this become a test that needs to be covered by CLIA and to have a pathologist involved?

CLIAC CHAIR: That's for [FDA EX OFFICIO].

CLIAC MEMBER: I guess that goes back to [FDA EX OFFICIO] also.

FDA EX OFFICIO: The question for me would be, would it be something that's FDA regulated? And then a separate question might be to, same as CLIA, how they would inspect such services.

CLIAC MEMBER: Right.

FDA EX OFFICIO: So I don't know that I know enough. Is the instrument itself doing analysis of the specimen in deciding whether it's a brain tumor or not and then what subtype of brain tumor? Or is it simply capturing an image? Or is it more like a standard pathologist's light microscope and the pathologist is looking down the scope, either remotely or in the room, and making a pathologist's determination? So how you answer that question is important.

CLIAC MEMBER: I think-- I can't remember the order of the options. But you did mention an option. The machine is actually generating an image and generating at least a probable diagnosis. So it's not a pathologist generating the diagnosis. And it's not simply generating an image. It's generating an image, and an AI routine is saying, most likely glioblastoma, less likely, high-grade glioma.

FDA EX OFFICIO: Yeah, that is a regulated product. And so if it is introduced into commerce and not just used at one site, it would be something that would regulated.

CLIAC MEMBER: OK, Thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

ADVAMED LIAISON: Yeah, kind of keeping with the mode of questions for [FDA EX OFFICIO], the idea of data as a specimen seems to me, while I understand the concept of it and the value or the need for dry labs to be under the purview of CLIA, I wonder if this might have unintended consequences if patient data is declared to be a specimen, for example, IRB review or within an institution where a laboratory or researchers may want to use data obtained to improve an algorithm or something like that. It's minor, saying there was a proposed rule for new informed consent that could also, if data is a specimen, could also be very wide, have a wide impact on how informed consents are utilized and needing to go back, when you have a certain amount of data that you want to then crunch for another purpose but that's not been permitted or informed. Do you have thoughts on that?

FDA EX OFFICIO: So I think you're asking your question, if it's outside of clinical use, more for a research question.

ADVAMED LIAISON: Well, maybe I should have said research but sometimes that research is used-- sometimes a company is gathering all this genomics data to improve their algorithms.

FDA EX OFFICIO: Right. So if the data is to be used in an FDA submission, for our review. And you define it-- well, whether you define it as a patient sample or not, it is clearly covered by the IRB rules that are important for the FDA. Whether it's-- because it is data generated off a patient-- data is generated off of a patient sample. So it's a derivative of the patient sample. So I don't think it adds any additional layer of risk from an FDA-review standpoint. I do see how it just clarifies if there's one lab that generates sequence data and there's another lab that does bio informatics and readouts, I just-- I see that as helpful to the community, to define it as such. But I don't know, at this moment, that it adds any additional risk for FDA review.

ADVAMED LIAISON: Yeah, thank you.

FDA EX OFFICIO: They would still treat all-- from the beginning of the original sample processing, is that covered appropriately, if needed, to generate the sequence data itself. Hope that's helpful.

ADVAMED LIAISON: Yes, thank you. And then I have one other question for Dr. Sossaman. In the total testing process, you stated that they believe CLIA, the laboratory's requirements should start when the specimen arrives. But later, in at-home collection, you talked about the laboratory's requirement, if they want to use a device, and at-home collection specimen off label, that they then have their requirement to submit to the FDA for that purpose. Do you envision, or are you envisioning, that some sort of separation of sample collection and some of the requirements around that to be totally outside of the laboratory's clear requirements going forward?

DR. GREG SOSSAMAN: You know, [ADVAMED LIAISON], the conversation, I think-- and Kim, remind me if I'm wrong-- the conversation around this occurred in the workgroup around FDA approval of collection devices. And that is a separate FDA approval process. And if a lab chose to use a sample-collection device different than intended, that was then an off-label use of that and they would have to prove those validation requirements as part of their-- you couldn't just consider this an LDT and not have the data on that. You'd have to-- if you modified that collection device, then you'd have to have the data to show that it performed in your laboratory as specified. And that was the conversation in the workgroup. But if that doesn't answer your question, let me know and Dr. Chapin will come up with the right answer.

ADVAMED LIAISON: No, I think that does. What you hit on there was it's ultimately the lab's responsibility to validate that that's going to work. And I was confused by the requirement to submit it to the FDA if it's just for their own purposes.

DR. GREG SOSSAMAN: I think if you modified it, then you may need to submit that. I think is what the conversation or someone from, I think, one of our ex officio members mentioned. But we can go back and review that again and look at those notes and make sure we're on point with that.

DR. KIM CHAPIN: Yeah, so one of the issues that had come up was the fact that a lot of tests are FDA cleared for collection of a specimen in a clinical setting. And so with COVID, obviously we had a lot of things that were collected at home, performed at home. And there are clearly specimens that are collected at home and then sent to a laboratory. I think the point was is that laboratory has to have some process in place to assure that the quality of what they are getting-- but a lot of people were like, that's not the lab's responsibility. So I think there was-- but if that's how they're going to use it, that was not the intended use. So it is literally that piece is not part of what the original FDA intent was for the approval of the specimen-collection device and/or the test kit, potentially. And at-home collection and at-home testing is not the purview of CLIA because it's not in a lab.

ADVAMED LIAISON: OK, thank you. And again, I echo everyone else about the amazing amount of work and of pulling things together. I was very pleased to review the slides in advance and to hear this summary.

CLIAC CHAIR: [CLIAC MEMBER]? [CLIAC MEMBER] and then [CLIAC MEMBER].

CLIAC MEMBER: Yeah, I agree with that last comment. But I also wanted to get some embellishment on this question of samples being collected at home. So if the device is FDA approved for that purpose and the lab is not modified it in any way, what are we supposed to do with those kinds of samples, anything?

DR. GREG SOSSAMAN: So [CLIAC MEMBER], you're saying, if a lab is using an FDA-approved device as intended, then--

CLIAC MEMBER: For samples collected at home.

DR. GREG SOSSAMAN: For samples collected at home, I think that's--

CLIAC MEMBER: It's mentioned in your comments, which is very appropriate, that if you can't observe it, how do we know that it's really accurate? And quality starts at the sample collection.

DR. KIM CHAPIN: Right. So I think one of the things that-- this has come up for at-home testing. Does an at-home testing device need a sample adequacy control to know that it's actually a human specimen? So I think it's those controls in place. But because CLIA is only over the purview of what is done in the laboratory, I think this is where we get this-- here's the modern way, the way we're doing things, versus here's what's actually happening. And I don't think that we have a clear answer, to be perfectly honest, about where that at-home collection piece exists. I think when it's tied to a device or a testing component, there are things that can be put in place to make sure you're getting a good-quality specimen, such as a specimen adequacy control or the fact that we-- often, many of us in laboratories get specimens shipped to us from outside, from point-of-care sites, let's say, and we assure those regulatory requirements. We make sure the box is the right temperature that they get shipped in. We make sure they get up to the lab and they're processed within a certain amount of time. The lab does take responsibility if they have that oversight of that point-of-care setting, let's say. But it's not the same thing as a person who goes to the drugstore, buys a specimen-collection device, and then maybe sends it into the lab. So I think that's one of the differences.

CLIAC MEMBER: OK, that's well said and very honest. But I think it's time that we, maybe CLIAC or the FDA, CDC tackles this because this is becoming increasingly common.

DR. KIM CHAPIN: Yeah.

CLIAC MEMBER: There's no stopping them.

DR. KIM CHAPIN: That's the discussion that we had is does FDA oversee, in some way, that home-collection piece because-- it was a discussion. We weren't really sure where to go with it. So I'm glad [FDA EX OFFICIO] here. What do you think, Tim?

FDA EX OFFICIO: So legally, home-collection devices are products that are regulated by the FDA. And so when we do review those submissions, prior to re-authorization, we ask a lot of the questions that you're concerned about sample stability, sample integrity. We concern ourselves with is there a control for the sample being adequate. Some technologies don't allow you to do that and we have to deal with that. But usually, molecular technologies allow you to have a human-control gene to make sure that the sample is a human sample and it wasn't degraded via storage or transport to the lab. So those are all things that the FDA looks at in its review of these collection devices for a specific test.

CLIAC MEMBER: OK, Thank you.

CLIAC CHAIR: [FDA EX OFFICIO]?

CLIAC MEMBER: And the prior moments of an-- anticipated my question, which was the human internal control, because for a molecular test, that can be envisaged. And it's both a adequacy as well as a specimen-integrity exercise. Thinking from an organic-chemistry standpoint, conceivably, you could think of other internal controls, which would at least be specimen integrity if not adequacy. I do muse about the age-old problem of drug and substances of abuse testing where the issue is chain of custody. And I'm not hearing that this discussion going into chain of custody. But as I say, the prior moments of discussion anticipate this human internal control which really is a molecular statement and doesn't apply to other specimen collection.

FDA EX OFFICIO: Yeah, the chain-of-custody topic is very timely because right now, for COVID, someone tests positive at home, an at-home test, for example, and as a positive result, many times, if not most of the times, they're required to go get another test to show they're positive before they can report. And it would be really nice, for FDA-authorized products, that they're performed and you get a valid result and it's positive, that you not have to delay while you wait for another test. But I don't know how to solve that problem. It's really not within the purview of the FDA.

CLIAC CHAIR: But I'd say, at the forefront the incentive is to get a negative result, testing by yourself.

CLIAC MEMBER: Unless you're malingering.

CLIAC CHAIR: Well, no, that way you can come back to work, right. At any rate, I see no other hands up. And I want to let this group know the workgroup has presented a number of agreements and recommendations to CLIAC. They cannot move these recommendations forward but CLIAC can. So if you are in agreement, I would like to revisit their agreements and see if CLIAC will endorse them and move them forward. If you object violently, let me know. But I would ask [CLIAC EXECUTIVE SECRETARY] to put up the first slide, please. Thank you.

CLIAC EXECUTIVE SECRETARY: So I put them up as a Word doc, just in the order that they were presented. So if we want to start looking through them, just let me know where to go. And of course, these are just the workgroup agreements. And we are able to wordsmith, if needed, too.

CLIAC CHAIR: And as [CLIAC MEMBER] brought out, the workgroup work is not yet done. These are the interim recommendations. However, since this workgroup of 30-plus people got to this point, it might be the time where CLIAC is ready to debate and decide which ones we'd like to move forward. So with your indulgence, I'd like to start with, do we agree that the laboratory's requirements should start when the specimen arrives for testing? Kicks out all that home stuff, [CLIAC MEMBER].

CLIAC MEMBER: Yeah, I guess that does take it out of our purview.

CLIAC CHAIR: I see this hand floating through. I don't know what that thumbs up-- I don't know who owns that thumbs up or why it's floating through. And please don't tell me I'm the only one who sees it.

CLIAC MEMBER: I tried to do a thumbs up and it went floating up. I don't know why. But I think that might be mine, which was just to say I agree. But why it's doing that, I don't know.

CLIAC CHAIR: So--

CLIAC MEMBER: That was a hard one.

CLIAC CHAIR: Yeah, I'm easily distracted. So I would recommend, would you please stay away from those things?

CLIAC MEMBER: Yeah, yeah, it's never done it that way before but definitely, I agree.

CLIAC CHAIR: The second item under this is a laboratory's requirement should continue through the total testing process. Is there discussion around this point?

CLIAC MEMBER: So this is [CLIAC MEMBER]. Oh, sorry.

CLIAC CHAIR: Go ahead, [CLIAC MEMBER] You start and then we'll get [CLIAC MEMBER].

CLIAC MEMBER: Yeah, so as far as-- and again, I do like this statement. I just-- and I don't want to cripple us with the nuance. But in reading the supplemental materials, I do know that the workgroup had talked about handoffs between, say, labs that might be doing the wet lab and labs that might be doing the informatics component, for example, for that. So I think that as long as that is not contradictory to this, I think that I would be in support of this as the total testing process that is occurring in your lab.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I agree with-- [COUGHS] --excuse me. I agree with number two, that it should continue through the total testing process. But I think it conflicts somewhat with number one. Even if you're talking about transmission of data to a laboratory, I think the laboratory has responsibilities on receiving that data so that is accurate. So I'm not on board with number one. I have problems with that one.

CLIAC CHAIR: Do you elaborate or consider in a revision of the wording?

CLIAC MEMBER: I can consider a revision of the wording. Maybe if we had some more information of what it included, that would be helpful.

CLIAC CHAIR: So I'm going to come back to you and ask you to concretely suggest a revision. And while you're thinking, we'll hear what [CLIAC MEMBER] would like to say.

CLIAC MEMBER: So you can interpret data from the data analysis. And since the bio informatics is actually the data analysis and the analysis might go back to a pathologist in the mother lab for interpretation, should we say data analysis and interpretation? And I don't know if we need to add something about verification of transmission with integrity. So I transmit my data to you for analysis. What's to say that data wasn't corrupted during the electronic transmission?

CLIAC CHAIR: And that echoes [CLIAC MEMBER] comment around the hand offs.

CLIAC MEMBER: Yes, which-- and thank you. That inspired me to add that.

CLIAC CHAIR: I think [CLIAC MEMBER] was kind of hinting at that too. But [CLIAC MEMBER], you-- [CLIAC MEMBER] --

CLIAC MEMBER: Yes, thank you. Number one brings up some interesting points in that, have we ever really considered specimen collection under CLIA regulations? We don't have phlebotomists as a role under CLIA. We don't-- and I agree, garbage in, garbage out. I'm not saying that the sample collection isn't important. I'm just wondering what makes this different than other laboratory samples where we really don't have a lot of CLIA regulations surrounding the pre-analytic process. Just some food for thought.

CLIAC CHAIR: I do know, through the workgroup, there was a discussion that we could not own the world for home collections. And this was how this wording came about. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, and I think in regards to, especially with the at-home collection, time of collection for some of our chemistry activities is very important. And I think, being very mindful of the validation requirements, knowing that once a specimen is in the laboratory, that's really all that can control for, I think CLIA does do a good job spelling out what the validation requirements are. And therefore, collection times or if someone leaves their saliva sample out for a week and then ships it and we have no visibility into that, I do think-- I think as [CLIAC MEMBER] was saying-- we do have those internal-lab quality processes that are part of the intake approval for those samples, as appropriate to our assays. So that is why I think number one does need to be reiterated because a lot of our work reports say you need to specify date and time of collection. And we often have no ability to get that from our patients. It's really best-assessment within ordered date or something like that. So I think given the expansion of where specimens are being collected, I do think it is right to clarify where CLIA ends. That doesn't mean it doesn't need to be changed or it doesn't need to come under someone else's purview, but to just reiterate where the labs responsibility really does start for this testing.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: So if one reads right to me, I think we're all in agreement. And it's not just biochemistry, a viral specimen collection, any microbiology is the same issue. It doesn't matter what it is. We don't control it until it hits the door. So why is-- so somebody can elucidate for me why one is an issue? It sounds like it's addressing that problem. It will start when the specimen arrives in the lab. And we've always had to deal with quantity. If we don't have the information we need, that is our responsibility to say, we don't have the information we need. We cannot give you a report. So somebody can just explain to you why we don't like one. I'm missing something. I'm sorry.

CLIAC CHAIR: I call on Greg, who maybe might have an answer.

DR. GREG SOSSAMAN: Yeah, thank you. I raised my hand just to bring up a couple of points from the workgroup discussion, that we did talk about, that we really were trying to define, again, when did the labs responsibly start as far as CLIA was concerned? There was discussion that the lab, of course, is responsible for having a adequate specimen-collection manual that specifies what type of specimens are acceptable, time frame, submission requirements, all those kind of things. But that wasn't all under-- just as, for instance, clinical decision support, helping to ensure that you have the right test menu or helping physicians arrive at the right test order, was not necessarily within the purview of CLIA, but for CLIA purposes, we should consider when a specimen arrives in the laboratory as that's what we should look to regulate under in CLIA. It still could be the responsibility of the pathologist or laboratory professionals to advise, again, on decision support, those kind of things, but is not really under the purview of. CLIA so those were the-- looking at my notes, those were the conversations at the workgroup.

DR. KIM CHAPIN: Yeah, and I would just add, as to [CLIAC MEMBER] point, it is good laboratory practice to provide those expectations of what specimen-collection guidelines should be. And again, if we're getting specimens brought to us by a remote transport, there are requirements, like under CAP, et cetera, about how that has to be performed. But I think what this was more referring to is, you get a specimen collection kit off the shelf and then you decided to send it to a lab in some way that we have no responsibility for that. Great.

CLIAC CHAIR: So I'm hearing some conversation around the wording. I see [CLIAC MEMBER] has a recommendation number one. And I'm thinking maybe I approached this discussion incorrectly in that the first two things we tackled are very broad and encompassing and outline the universe in which CLIA plays and what this group is delving into the detail, which is what subsequent issues will be discussing, will tail. So I'm going to come back to number one and two which I view, but feel free to disagree, as global, overarching comments about what is the universe that CLIA regulates. Number one, it's when that specimen hits the door. And number two, it's the entire testing process, all the way to the result in the record that includes all the hand offs and assurances of accuracy of those handoffs and analyses and interpretation in all those laboratories. OK, [CLIAC MEMBER].

CLIAC MEMBER: So I just want to make clear-- I think I like this but I want to make sure I understand what you're saying. So if I have a specimen collected in the OR, they should record collection time because warm ischemic time is important for downstream immunohistochemistry. But if they leave it in the OR-- and this did happen to me one time, as a resident-- for the weekend, the laboratory is not responsible because it was not in our hands. So when we say the laboratory's requirement, under CLIA, that means because it's now in our hands. But that doesn't remove some requirements around the specimen collection, wherever it occurs. Did I understand that correctly?

CLIAC CHAIR: That is correct.

CLIAC MEMBER: OK, and then I do have something to say about number two again. But if you want me to wait, I can.

CLIAC CHAIR: I just wanted to-- I spoke quickly, just wanting to flesh out that comment. Laboratory's responsible for making sure the end users understand the requirements around specimens and specimen submission, including date and time for-- called ischemic time-- and its impact on downstream things. Lab usually partners with the submitting sites to ensure that these things are adhered to. We certainly cannot own the operations of outside units. But that would be an expectation of the laboratory because we would be doing the testing. And many systems, when these are fallouts, such as the specimen left all weekend, those become unusual-occurrence reports for process improvement for the system. OK so I'm going to move on to [CLIAC MEMBER] and then [CLIAC MEMBER].

CLIAC MEMBER: Well, just as a follow up to [CLIAC MEMBER], I think it's a good example, [CLIAC MEMBER], that could occur into a hospital. And typically, I would say that under my requirements of accreditation, I can't accept that specimen. But if I don't have some requirements to point to, that's more national, then it's pushed back to me that that's my personal requirement and I'm not able to enforce it because then it becomes a political issue instead of what's the best for the specimen. So I worry that, by negating that front end from clear responsibilities, we don't give laboratories the opportunity to stand up for what's right in these situations.

DR. KIM CHAPIN: I don't think it negates the fact that the laboratory can provide guidance for non-laboratory providers to ensure specimen integrity, so what was written, yeah, what we had put in. I mean, that would be remiss of us. We need to be able to reject a specimen that doesn't have the right stuff. We'd never process a specimen that sat in the OR over the weekend.

CLIAC MEMBER: I might add, on the other hand, there is such a thing-- we actually did process the specimen-- there is-- it was a complete thyroidectomy. And how are you going to say what might have been in the thyroid if you never even looked at it? And I know that there are-- in specimen rejections, you have to take into consideration how difficult it is to replace the specimen for reanalysis. But I think that's all actually encoded already in terms of guidelines for specimen rejection. So I'm happy not to go into the weeds, here.

CLIAC CHAIR: And I will call on [CLIAC MEMBER].

CLIAC MEMBER: OK, thank you. I have some questions related to number two, where it talks about a laboratory's requirement under CLIA should continue, et cetera. That focuses on the test itself. And my question is, is it understood that qualified personnel is performing the test? I know we've had some dialogue on this before. So I'm saying, do we need to consider not only that the test is performed, but that qualified or certified or persons who are performing those tests meet some criteria as well? Or is that inherited in there.

CLIAC CHAIR: So I think you're referring to personnel requirements?

CLIAC MEMBER: Yes.

CLIAC CHAIR: Am I hearing this correctly?

CLIAC MEMBER: Yes.

CLIAC CHAIR: So personal requirements, in my mind, is one piece of CLIA and that these broad-based statements are referencing all of CLIA. I'm going to--

CLIAC MEMBER: OK.

CLIAC CHAIR: That's probably why it wasn't broken out. But we do have a personnel-specific thing later on. So--

CLIAC MEMBER: Oh, great, great.

CLIAC CHAIR: OK.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: OK, [CLIAC MEMBER].

CLIAC MEMBER: So it after data-analysis interpretation and reporting, or maybe this is included in reporting and I don't know if it needs to be spelled out, but validation of accurate data transmission. So there are actually little routines that are supposed to say, yes, what you sent me is what I got. And we should have that in place if you're going to be receiving data to analyze and return a clinically-actionable result.

CLIAC CHAIR: OK, so I think you and [CLIAC MEMBER] are both mentioning the handoff. So I would suggest the phrasing should be including data exchange, comma, analysis and interpretation and reporting. So I want to bring the group-- and thank you. I want to thank the group. It's better than that thing that's going across my screen. OK, I want to bring the group back--

CLIAC MEMBER: And I was just going to add, if you could take out that one "and," exchange. Yeah. OK, comma, and then interpretation and reporting even when formed remotely.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. We count on you for this.

CLIAC MEMBER: No problem.

CLIAC CHAIR: So again, this part of the work-group agreement is just simply to define the total testing process. Is the recommendations that came forward from [CLIAC MEMBER] and [CLIAC MEMBER] really relate to the pre-analytical before it arrives in the lab considerations, which would be outside the total testing process, as my very parsed-out brain thinks about it. So my thought is, is there a motion to approve these recommendations for the definition of the total testing process? [CLIAC MEMBER] has her hand up. [CLIAC MEMBER] is her hand up. [CLIAC MEMBER] her hand up-- his hand. I don't know if you're asking questions or if you're motioning or seconding.

CLIAC MEMBER: I'm seconded, [CLIAC MEMBER].

CLIAC CHAIR: OK, thank you. OK, thank you.

CLIAC MEMBER: My only comment it-- it was a comment, [CLIAC CHAIR], that-- I think there's a difference. The total testing process begins at-- you have to go back to the Joe Boone and those days begins when you think about ordering a specimen, in the pre-analytic. So the total testing process includes it. But that's why I sorted out what the responsibility was-- or that's what I was trying to do-- from the lab's requirement because you get a mess if you misalign responsibility and authority. But I don't that-- I think, whereas our responsibility in the total testing process begins when the specimen arrives in the laboratory. At least that's what I was trying to convey.

CLIAC CHAIR: Perhaps we should title this Total Testing Process dash Laboratory's Responsibility Under CLIA, to refine that for the laboratory. [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: Very briefly, recommendations-- the second two recommendations, that's one or the other. You can't have both. And to me, the second gets at a--

CLIAC CHAIR: Point of order. Point of order. The motion is for the top two. We haven't gotten as far--

CLIAC MEMBER: I wasn't sure if we were discussing. I will adhere to the parliamentary requirement--

CLIAC CHAIR: Thank you.

CLIAC MEMBER: --and withdraw my current statement.

CLIAC CHAIR: [CLIAC MEMBER] had her hand up, then it went away. And then [CDC EX OFFICIO]—

CLIAC MEMBER: It was for the same reason as [CLIAC MEMBER].

CLIAC CHAIR: OK, stay on target. Stay on point, guys. OK, [CDC EX OFFICIO] and then [CLIAC MEMBER].

CDC EX OFFICIO: I was wondering if the charge to the workgroup might be useful to add at the start of all of these recommendations that are coming down, as it relates to an overarching statement around changes to the CLIA regulations. That might be helpful so that you're directing this to HHS.

CLIAC CHAIR: That's an excellent point. Let me kick that around my brain, call on [CLIAC MEMBER], and then call on my people who do revisions quickly, like [CLIAC MEMBER] and [CLIAC MEMBER], to think about how that preference should be. [CLIAC MEMBER]?

CLIAC MEMBER: My comment was similar to [CDC EX OFFICIO], that she just made. Do we understand clearly what it means to say, a laboratory's requirements under CLIA? Is that clear? It's not really to me. I got to admit my doubts that this is clear to people.

CLIAC CHAIR: So would you propose laboratory responsibilities in compliance with CLIA? Would that be—

CLIAC MEMBER: Yeah, we need to enhance it such that that's clear. I don't--

CLIAC CHAIR: So under. You're reacting to the word, "under."

CLIAC MEMBER: Yeah, it's not clear what that means, at least not to me.

CLIAC CHAIR: So I'm proposing "laboratory responsibility in compliance with CLIA."

CLIAC MEMBER: That's better. I like that better.

CLIAC CHAIR: And at the top, too, [CLIAC EXECUTIVE SECRETARY], the bold, under-- Is there further discussion on this part? And collected, we actually-- I guess to the panel, does this make sense, in response to [CDC EX OFFICIO] comment that we might need an introductory type of statement? I'm happy with the paragraph above instead of generating a new sentence. Does that get to the intent? In my world, silence means acceptance. [CLIAC MEMBER] raised his hand.

ADVAMED LIAISON: Yeah, I guess I-- think you, [CLIAC CHAIR]. I guess I'm a little confused. What is the specific revision to the CLIA regs that one or two is recommending or suggesting?

CLIAC CHAIR: It is simply defining what our universe is. The specific recommendations to CLIA, to CMS and H-- I'm sorry, HHS, will come as we go through the very specific points.

ADVAMED LIAISON: OK, So one and two are just really--

CLIAC CHAR: Preamble.

ADVAMED LIAISON: OK. Thank you.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: You're on mute.

CLIAC MEMBER: Apologies. I'm having Zoom difficulties. I'm trying to find the lower-hand button and failing.

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

CLIAC MEMBER: Mine was a parliamentary question. The one and two are whereas, comma, a laboratory. In other words, you're just declaring premises. And [CLIAC CHAIR], from a parliamentary standpoint, I'm just trying to figure out what the parliamentary process is for the recommendations at the bottom.

CLIAC CHAIR: So the parliamentary process for the recommendations is anything that is moved, seconded, and receives a majority of CLIAC vote, moves forward as a recommendation to HHS. Did that answer your question? I don't do whereas because that's slide two, like, and that always--

CLIAC MEMBER: The reason I'm asking is, however it's phrased in the two recommendations, are those also just preamble or are they actual potential changes to CLIA?

CLIAC CHAIR: We are making this recommendation to HHS, which then will go forward to our partners for their consideration. And what we are asking is that the laboratory responsibility be defined as this universe, that the start is when the sample arrives in the lab and the end is all the way to the report. If that's not already defined in CLIA, that would be something we would ask them to consider. [CLIAC MEMBER]?

CLIAC MEMBER: I'm sorry to be still struggling with this but I'm trying to join the rest of you in this. And so my question is, if CLIA is not responsible for that collection phase at the bedside, who is? Who oversees that? Because I'm sure we all agree that impacts quality. So is there anyone else responsible for that? Or do we see that as fine that nobody is responsible for that, from a national perspective?

CLIAC CHAIR: I will jump out and take a first stab. Certainly, the type of specimen you receive is in your manufacturer's IFU, what's acceptable, temperature, humidity, additive, that kind of business. And then who collects it, depending what it is, blood, urine, stool, breath, whatever, that comes with different personnel requirements and/or certification or license to collect. And then if you collect it at the bedside, which bedside, in patient emergency, sniff, L-tech home, those would have different personnel type of requirements. And then transport. We have very specific conditions. But how it gets to you, whether or not it's a person carrying it or US mail, there's so many different ways. Laboratory would just set out expectations and if specimens do not meet those on arrival, they are rejected.

CLIAC MEMBER: We'll take the case of blood culture collection and [CDC EX OFFICIO] presentation reviewed the importance of decreasing that contamination in blood cultures. We've always been trained that it's the laboratory's responsibility to train the folks who are collecting those samples. We do-- by the way of reports and contamination. As I read that statement, it would say that I don't have to do any of that.

CLIAC CHAIR: So I'm thinking there's been so much conversation around the pre-analytical process that occurs outside the laboratory, that I'm thinking that's something we should ask the workgroup to consider and come back with a recommendation. Let's see if Kim and Greg did you fall off your chairs?

DR. KIM CHAPIN: Thank you. Slightly. I mean, I get it. I'm trying to think if there were probably prior discussions that we removed that piece from because I guess it's just good laboratory practice that, [CLIAC MEMBER], you would end up saying, this is how you collect the blood culture, this is the expectation how long it takes to get to the lab. We do follow that with contamination rates. Do we have to be more specific about a surgical specimen of blood culture-- not specifically those things, but that specimen-collection piece, why did that get dropped out in the first place?

CLIAC MEMBER: Yeah.

DR. KIM CHAPIN: And I don't know if there was history behind that, [CLIAC CHAIR].

CLIAC CHAIR: Yeah, there's a lot of opinion around that area. [CLIAC MEMBER] and then [CLIAC MEMBER].

CLIAC MEMBER: I guess I'm just going to jump in a little bit on that, going back to, I guess, to the blood-culture collection example, the laboratory provides guidance and specimen-collection instructions but is not always responsible for actually the collection piece, nor enforcing that. It's providing the collection instructions and then, again, rejection criteria if you receive blood cultures and improperly, samples that are improperly collected. So I think we're getting a little bit in the weeds of all that pre-analytical collection of whether or not-- there are a lot of various ways and methods and who may be collecting these samples. So I think if we could focus on just these broad definitions and then move a little bit further into the details of the personnel requirements and all the rest, we might be able to pull ourselves out a little bit and move along into the meat of the recommendations. But that's my thought.

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

DR. GREG SOSSAMAN: Yeah, thank you, [CLIAC CHAIR]. And to [CLIAC MEMBER], your point is exactly right. We-- the workgroup ended up in conversations. Remember, we were talking about at-home specimen collection, where the lab really has no authority at all. And so we ended up talking-- and to [CLIAC MEMBER], to your point-- in the weeds quite a bit about specimen collection and where does the labs really-- where does the lab's authorities really start from a CLIA standpoint. And so that was where we ended up with this agreement. And I will say, [CLIAC CHAIR], just to the rest of the group, these are just the current workgroup agreements on what we've really discussed. I don't think we actually put anything into a actionable language. At this point, again, most of these are just agreements from all the discussions, so that it would be up to CLIAC to make this into an actionable statement or add verbiage to do with it what you want as far as moving this along. So this is just the advice from the workgroup, again, our agreements and discussions. So again, if you want to do something different with this information, this would be CLIAC's purview.

CLIAC MEMBER: Given what Greg just said, could we make it for externally-collected samples, the laboratory's responsibility is-- that takes it outside of the facility range and looks to that.

CLIAC CHAIR: I would quibble on that but let's hear what [CLIAC MEMBER] has to say.

CLIAC MEMBER: Well, thank you. I'm here to quibble. How do you define external? Unless you have laboratory staff collecting every sample, which isn't going to happen, you've got a variety of individuals who might be within your institution, surgeons, nurses, whatever, collecting those samples. I come back to, really, all we can control is get them instructions of what a satisfactory sample is and have inspection criteria, for when they hit the lab, which meets the definition of the workgroup. And our role is, when it hits the lab is to make sure that it meets those requirements. But externally collected, I think that's hard to define.

CLIAC CHAIR: [CLIAC MEMBER], you have a chance to respond before we move on.

CLIAC MEMBER: Just made a good point. Maybe I'm trying to fill a gap that the laboratory shouldn't fill. And I think it dates back to my early training that it was garbage in, garbage out, and we were responsible to make sure that we didn't get garbage. So I'm going to go with the consensus on this.

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

CLIAC MEMBER: No, I was just going to-- just a brief statement. I definitely agree with what [CLIAC MEMBER] and [CLIAC MEMBER] stated. Total agreement.

CLIAC CHAIR: So I'm going to call-- thank you very much. I'm going to call this group back. We have an open motion. The open motion on the floor is to approve these two statements. Can we remove the red font? Is there further discussion? You've passed the seven seconds of silence. Is there any opposition? [CLIAC MEMBER]? Are there any abstentions? I'm sorry, [CLIAC MEMBER].

CLIAC MEMBER: I actually like what [CLIAC MEMBER] has written. I think that goes along with what CLIAC's recommendations are, and requirements are, for the pre-analytic testing. So I think one and two are good. But it has to add necessary guidance or instructions for non-laboratory providers to assure-- for pre-analytical requirements. So perhaps my recommendation was incorrect by saying our responsibility. But I believe that CLIA says that we should have written procedures for the pre-analytic phases. So I don't think one and two address what CLIA states, regarding the total-testing process.

DR. KIM CHAPIN: Heather? Do you have any comment on that?

CLIAC CHAIR: Which Heather?

CLIAC MEMBER: Heather Stang.

CDC EXECUTIVE SECRETARY: I guess I'm just a little confused. It sounded like we had some agreement. And I was wondering are we agreeing on the statements or making recommendations? So that was my-- maybe you just sensed my look of confusion over my face. So I think if we're wanting to move on-- because I got the sense that it wasn't a recommendation, maybe, [CLIAC CHAIR], maybe you can clarify it was just agreement on the comment. But if we're wanting to make a formal recommendation, which I think is what the goal of this workgroup is, is to-- we had this workgroup, the workgroup put together a large list of workgroup agreements that can be the starting point for CLIAC recommendations. If we're getting hung up on this one, perhaps we move down and get past this and move on to some of the next topics. And perhaps we can come back to this one once we discuss the other ones.

CLIAC CHAIR: OK, [CLIAC EXECUTIVE SECRETARY]. [CLIAC DFO]?

CLIAC DFO: Yes. I'm probably saying something similar to [CLIAC EXECUTIVE SECRETARY]. In terms of the total-testing process, bullets one and two, I think it's important for CLIAC to explain what they want the government to do with those bullets. So is it just that it is CLIAC's opinion that CLIA needs to reinforce these two concepts? Or are there specific areas of CLIA that need to be changed to incorporate these two ideas? So again, CLIAC should make specific recommendations to the government that the government can act upon. And if it's fine for CLIAC to make broad statements of principle. But if you want us to do something and make changes, in this case, to the regulations themselves, my recommendation is for CLIAC act to provide specific recommendations of what you'd like the government to do.

CLIAC CHAIR: Thank you. There's been a lot of conversation around this so as [CLIAC MEMBER] has said to me in the past, it's only half baked. It's not ready to move forward. So I would like to table this discussion. And I would ask Greg and Kim to go to the workgroup and refine this agreement with something actionable, downstream in CLIAC. And on the points to address, there's a lot of discussion around pre-analytical, outside-the-lab considerations related to specimen collection. That's probably something we need to think about. So I'd like to move on. We have 30 minutes left in this session. And we have some very specific comments. So I'm going to go the exact opposite end and focus on some very detailed things. CLIAC DFO?

CLIAC DFO: Hey, [CLIAC CHAIR], sorry. And I know this is going to sound very bureaucratic but the CLIAC workgroups are not empowered to make recommendations to CLIAC, right? And so the workgroups can only develop a report. And then CLIAC has to use the rapport and the studies and the feedback from the workgroups to develop recommendations because those recommendations have to be done in public.

CLIAC CHAIR: Thank you, [CLIAC DFO]. So in this section on the screen, the workgroup has reached an agreement about the term, "materials." the definition of materials in CLIA should be expanded. Is there a motion to support them? I'm looking at number two. --raised his hand. [CLIAC MEMBER] raised her hand. So discussion?

CLIAC MEMBER: I was going to say so moved. But I can second. If I was second to the--

CLIAC CHAIR: Both are equally responsible.

CLIAC MEMBER: There you go.

CLIAC CHAIR: So there's an open motion, discussion. The motion is to expand the definition of materials in CLIA to include this verbiage. [CLIAC MEMBER] and then [CLIAC MEMBER].

CLIAC MEMBER: So an image is-- a compiled image, it's stored as discrete pixels. I don't know if we need to say image and-- or just use digital imaging instead of images, which would imply that it's the pixel data behind it. Sometimes-- and I think this should be included in that-- sometimes people modify the digital image to do an artificial stain on it. For example, you could pull out the nuclei or pull out the membranes, and so on. I don't know that we need to go into such as digital image and their downstream, modified products because we've already talked about data and downstream data, I think, right? Like I say, I don't want to get too much into the weeds. I just want to make sure that the term we're using encompasses what we need to encompass.

CLIAC CHAIR: Greg?

DR. GREG SOSSAMAN: Yeah, thank you. So I may have misstated but the term "materials" is used several times in CLIA but there's not an actual definition. So the advice from the workgroup is to create a definition, which would, by definition, would include any data derived from a patient. So whether it be real image, digital image, genomic information, whatever, that's the advice from the group was to define materials that way.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, and I would just say that-- [CLIAC MEMBER], that would include any derivation thereof, from that original image. That would be the interpretation I make.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I struggle with where something like a digital image stops and attached metadata begin, and particularly, if we get into computers, computational pathology, artificial intelligence, assisted interpretation, where metadata is linked with analysis of a primary material to generate an interpretation. And so where I put both feet on the ground is, where is the actual analysis performed? You analyze biologic material. You can analyze data. But at what point

does pulling the patient's age and gender into a multi-algorithmic, predictive paradigm constitute material? So my question to those who wrestled with the definition of the term "material" is, should you provide indication of where you think the material stops and you then just enter into the realm of the electronic health record, which is not where a laboratory should be held responsible by CLIA?

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I'm reacting to this word, "materials." I'm looking at my book, here, trying to figure out where does the definition of a laboratory, in turn, include this terminology. And then I'm also concerned because materials apply to proficiency testing materials and linearity materials. So are we getting into trouble here by trying to define materials in a patient-specimen-only mode?

CLIAC CHAIR: Both of you have excellent points. Greg?

DR. GREG SOSSAMAN: Yeah, thank you. So we needed some definition to use as we talked about, again, derivation from a patient sample and trying to go further down the line, to [CLIAC MEMBER] point, then what would it be? Would it be age from a medical record? No, it's not derived from a sample. But it could be anything used in an analysis or interpretation that came from a patient sample. If there's a better word than materials, then we should use that. But materials was already used several times in CLIA, previously. So we were attempting to refine the use of that, somewhat, and be more inclusive of any data coming from a patient sample.

CLIAC CHAIR: Kim and then [CLIAC MEMBER].

DR. KIM CHAPIN: No, I'm just trying to read [CLIAC MEMBER] comment that you just put in. But I think as [CLIAC MEMBER] said, anything derived would include. And we actually talk about sites outside of the primary laboratory in subsequent discussion and the questions, recommendations.

CLIAC CHAIR: And then just to reiterate-- thank you, [CLIAC MEMBER] -- just to reiterate, materials is not defined now. So that's why this is-- OK, [CLIAC MEMBER]?

CLIAC MEMBER: Well, I was wondering if we kept repeating, although it is a little wordy, materials derived from the human body. So the term in-- so number two would read, the term, materials derived from the human body, should be defined in CLIA as the patient specimen, blah, blah, blah. And that way, we're not just talking about materials generically, but materials derived from the human body.

CLIAC CHAIR: Thank you. [CLIAC MEMBER].

CLIAC MEMBER: The trouble I have is cutting the diagonal when you get into a bio-informatics pipeline. I agree with the points previously made, is that the laboratory should not be held responsible for data that is generated from other sources than a specimen. My concern is, for lack of a better term, multi-analyte or multivariable algorithms which become part of a bio-informatics pipeline, that a pathologist then has to attest to before finalizing a report. And to the extent that those algorithms pull in data sources where the laboratory is not responsible, my concern is that materials needs to be limited so that we're not held responsible for metadata that we pull into our analytical pipelines. We still have to attest to the pipeline. We still have to attest that the product of the analytical pipeline. That's the diagonal that I'm concerned might get swept into this, inadvertently.

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

CLIAC MEMBER: Sorry. I meant to take my hand down. Sorry.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes. I was just going to type it into the chat but let me just share with you, where it says, in number two, that last sentence is good. It just needs to be reordered in terms of what is commonly done in practice. So it should read something like this, after the word, purpose, purpose of providing information, comma, assessment of health and well-being, with diagnosis and treatment and prevention of disease and/or impairment. So it's the order of that sentence. I can type it up and put it in the chat, put on record.

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

CLIAC MEMBER: Posterity

CLIAC CHAIR: Oh, Greg you have your hand up.

DR. GREG SOSSAMAN: Yeah, thank you. Just to address [CLIAC MEMBER] comment, and this may or may not be what you're getting at, but I think under number three, when we talk about the definition or expanding definition of a test system to include software algorithms, data-analysis procedures, may get a little bit more towards your concern and what you're looking at is inclusion. So we tried to-- we talked about expansion of that definition of a test system to include some of those-- maybe some of the things that you're talking about. It may be contrary to your opinion, but we did talk about expanding that. So anything that's under the laboratory purview and algorithm that it's used to generate something, should be under the test system. But this may be, [CLIAC MEMBER], what you're getting towards under number three.

CLIAC MEMBER: And I concur with your strategy to deal with it.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: My head is down. I'm sorry. I'll put it down.

CLIAC CHAIR: So let me bring everyone back to the middle of the motion, which is to recommend that CLIA include a definition for materials and that the definition is as stated in number two, with the revision on the second line should be defined in CLIA as the patient specimen, comma, including data derived from a human specimen. Such as-- and actually, [CLIAC MEMBER], I'm going to ask if we can take out digital, because for all we know, in 20 years, images will come in some other fashion. Genetic blah, blah, blah, and other data, blah, blah, blah as [CLIAC MEMBER] had pointed out, to just restructure that long phrase to match that that is above, highlighted, for the purpose of providing information for the diagnosis, prevention, treatment of any disease or impairment.

CLIAC EXECUTIVE SECRETARY: And I'm typing it. So give me just a minute.

CLIAC CHAIR: See open motions.

CLIAC MEMBER: Get rid of the comma at the bottom of the last sentence.

CLIAC CHAIR: Discussion? Hearing no discussion, I'm going to call the vote. Are there any opposed? Hearing no opposition, are there any abstained? Thank you. This motion passes.

CLIAC MEMBER: [CLIAC CHAIR], you have to do some wordsmithing on that second line, including data derived from-- sorry, it just moved.

CLIAC CHAIR: Yeah, including data derived from a human specimen.

CLIAC MEMBER: Right. Thank you. Yeah.

CLIAC CHAIR: From a human specimen.

CLIAC MEMBER: Yes, thank you.

CLIAC CHAIR: OK, the next very, I think, encapsulated agreement was to talk about the definition of a test system. And [CLIAC MEMBER] already leapfrogged us into that part of that discussion. And our recommendation from CLIAC would be a modification of the definition of test system in CLIA. Is there a motion?

CLIAC MEMBER: Yes.

CLIAC CHAIR: [CLIAC MEMBER] raises his hand. Is there a second? [CLIAC MEMBER] and [CLIAC MEMBER] both are up. OK. This motion is open for discussion. Motion is to recommend the definition of test system to be modified in this way. [CLIAC MEMBER]?

CLIAC MEMBER: The one question I would ask is whether data transmission should be included in this because I'm comfortable with [CLIAC MEMBER] comment that the algorithm pulling in data from sources the lab is not responsible for is addressed here. Does that imply or require explicit statement that you have to have accurate transmission of those data sources?

CLIAC CHAIR: And this is what [CLIAC MEMBER] was trying to get at, too.

CLIAC MEMBER: It's validation of a test system. And it's a question, not a recommendation.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Did we just call it accurate data exchange? Well, we referred to it as data exchange previously but I think-- or validated data exchange?

CLIAC MEMBER: We did write something above, [CLIAC MEMBER]. You're right. It should be consistent.

CLIAC CHAIR: Let's open number two, that we got tabled, and we punted it back to workgroup.

CLIAC MEMBER: But we have data exchange, is what we have in that number two.

CLIAC CHAIR: Do we need to define data exchange? We did not bring that up?

CLIAC MEMBER: I know you could have a sentence, data exchange is the validated transmission of data to and from a source.

CLIAC CHAIR: Let's hear what [CLIAC MEMBER] has to say first.

CLIAC MEMBER: Well, I have a different question because it seems like there's a word missing in that first line. The definition of a test system should be modified in CLIA to blank all of the instructions?

CLIAC CHAIR: The word include is missing in blue.

CLIAC MEMBER: Good. That was it.

CLIAC MEMBER: Thank you.

CLIAC MEMBER: Thank you, [CLIAC EXECUTIVE SECRETARY]. You're very fast at this.

CLIAC CHAIR: Does this group think in 10 years, the next CLIAC will be debating the definition of data exchange? Or do you think this is understandable as is?

CLIAC MEMBER: I would say that while validation of data, as it's leaving and arriving at a source, or validation of data at the source compared to the validation-- I'm sorry-- at the receiver, to the beginning, is something of a standard of practice. But I still hear people say, is there a message validator? Is there a message validator? Do we need to include one? So I would say, well, everybody knows you should have one. It's not necessarily code across.

CLIAC CHAIR: Greg?

DR. GREG SOSSAMAN: Thank you. I'm going to I'm going to rely on Dr. Chapin to help me out with this. But I think when we were-- when the workgroup was talking about this-- and Valerie, you may remember-- when we talked about test system, we were thinking in terms of what the FDA would do to validate an instrument or test on an instrument where it would not-- it wouldn't be just the hardware but it would also be the supplies, the computer that runs the instrument, the software out, everything. And so I'm not sure if we thought or talked about data exchange or data transmission in that piece. And I think we were trying to align this with what FDA approved-- clears something, approves it. In our lab, we verify those claims. So I think we were trying to align test system to be more inclusive of software and other algorithms. But I think that's how we were getting it, at that modification of that, if that makes sense.

CLIAC CHAIR: Yeah, I tend to think small most of the time. And I remember my thought about this test-system definition was small. It's the system in your lab. In terms of AI algorithms, that's how you interface with external things. And I'm not sure I would have thought of that as part of the test system. I would have thought that it's a different part of the total test process. So that being said, should we remove data exchange or should we remove the word-- should we remove data exchange? We're on the small thing but that's where that question came up. [CLIAC MEMBER]?

CLIAC MEMBER: I thought keeping it in was a good idea because next-generation sequencing is a data-exchange process. So that's why I think we should keep it.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I think we should keep it because there was quite a bit of discussion about bioinformatics being performed by a third party, outside of the laboratory. And that requires that the data be transmitted.

CLIAC CHAIR: So it sounds-- [CLIAC MEMBER]?

CLIAC MEMBER: And I think there's internal consistency with our prior discussion about specimen integrity, which is the fact that the laboratory does carry responsibility for the integrity of data used, that it imbibes, and quite honestly, transmits, in the example given, to a third-party partner who was doing bioinformatics pipeline analytics. And Wikipedia says, in a simple sense, data exchange is verification that target data is an accurate representation of source data. I think it's a term that is established.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. So are there-- so I'm hearing we leave it in, data exchange. Is there further discussion? Hearing further discussion, I would like to call the vote. Any opposed? Hearing no opposition, any abstain? Hearing no abstentions, this motion is passed. Now we have eight minutes before your probably highly-desired break time. Can we scroll down and find something that we can get done? It's not going to be the new certificate time. It's probably-- I don't think we can do remote testing in eight minutes. Maybe we can look at personnel. [CLIAC EXECUTIVE SECRETARY] has stopped. So maybe there is a thought we could do remote testing.

CLIAC EXECUTIVE SECRETARY: [CLIAC MEMBER] sent a couple of recommendations-- I'm just trying to get them pasted in here-- for remote testing. So I don't know what-- OK. So maybe if we did want to look at these real quick.

CLIAC CHAIR: Thinking we can start the discussion. If we can't reach agreement in six minutes, we can certainly continue this tomorrow. And so I'm looking for a motion to approve this recommendation, this agreement. And I'm assuming you move approved?

CLIAC MEMBER: Yes. I did also just see that. I wanted to-- recommendation number two should be-- bullet point two should actually be the first bullet point of that-- to say the CLIA regulations should be revised to allow remote analysis for any CLIA specialty or sub-specialty. And then everything else is just adding details as to the scope of that remote work. And then as far as number three, it was a minor--

CLIAC CHAIR: Heads up. We need a second.

CLIAC MEMBER: Oh, OK, sorry.

CLIAC CHAIR: Does anyone else second this motion?

CLIAC MEMBER: I was trying to second with a hand wave.

CLIAC MEMBER: Yes.

CLIAC CHAIR: OK, OK. So go, [CLIAC MEMBER].

CLIAC MEMBER: Yeah, no, I really liked this. And I think the workgroup took a lot of our discussions from, I think, it was two CLIAC meetings ago, about the remote workforce with COVID. I did just try making three. And for the informaticians in the room, I didn't want to specify just VPN because I don't know what the next policy is. So I'm just-- secured connection authorized or managed by a laboratory. So trying to make this as future-proof as possible. So welcome any changes.

CLIAC CHAIR: Thank you. So if I heard you correctly, you would like number two to be number one, and then number one becomes number two. So while we're doing that, [CLIAC MEMBER].

CLIAC MEMBER: I was just going to say, yes, I agree completely about how VPN might be altered in the future. And I like the way three is worded because as the CAP came out and said that addresses of people working from, the home address should not be publicized. However, there should be a record of the servers that you accessed and where the data went. And I think three covers that.

CLIAC CHAIR: Well, I like this one. And I'm surprised you all are lined up. So maybe you all like it too. Is there further discussion? [CLIAC MEMBER]?

CLIAC MEMBER: I do agree with it. It is well-worded and it modernizes the whole process. And I think working from home is a permanent thing.

CLIAC CHAIR: Is there further discussion?

CLIAC MEMBER: Yes.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Does this recommendation need to cover what the person from the CAP brought up about not publicizing a person's home address?

CLIAC CHAIR: Yes. That would be under number two. As I see it, it's an extension of the primary lab's CLIA certificate. That would be the address. And then number one would address the ACLA's request to have it more broad than just pathology for…

CLIAC MEMBER: Right. But do we need a phrase or a sentence in there that specifically asked that the home address not be publicized?

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: You could add, and does not require disclosure of the remote location, or something to that effect.

CLIAC MEMBER: That would do it.

CLIAC MEMBER: And I would agree with that as well.

CLIAC CHAIR: So then the phrasing would be, on number two, then those activities would be covered through an extension of that laboratory's CLIA certificate. Yeah, perfect. Perfect. Thank you. Is there further discussion? Hearing no discussion, I'm going to call the vote. Are there any opposed? Hearing no opposition, are there any abstentions? This motion passes. You all surprised me. You got that done in eight minutes.

CLIAC MEMBER: Oh, ye of little faith.

CLIAC CHAIR: One minute before the break, one minute before the break. And I would venture we can scroll through and see if there's any--

CLIAC MEMBER: Thank you, [CLIAC MEMBER].

CLIAC MEMBER: Recommendation two was actually broken off of the other one. It was subsumed under the remote work. But I felt like it called out, and it also got to the idea of the bioinformatics one that was on a different slide. So that, I don't think, will take 27 seconds. But just wanted to put that out there as a consideration for a later-- or I think it's before this, as far as recommendations are concerned.

CLIAC CHAIR: Fabulous. So by the time I finish talking, it will be 3:30-- 4:30-- whatever the time it is over there. So how about we pause here, we take a break, we come back at 4:45 East-Coast time, and that we line these recommendations up for discussion tomorrow. And if any of you so feel inclined to make other recommendations, please do so tonight. Submit to [CLIAC EXECUTIVE SECRETARY] so they're on the docket for discussion. So all of you members, turn off your video. Turn off your mic. And I'll see you in 15 minutes. Thank you.

CLIAC CHAIR: Welcome back. We will close out today with a report from the Certificate of Waiver and Certificate for Provider Perform Microscopy Procedures Workgroup Report, presented by the workgroup chair, Ms. Heather Duncan. These are presentation 6 and report 6(a). After the presentations, we will have time for committee discussions. Right now, there are no public comments that have been received at this time. If you wish to provide a five-minute public comment, please email cliac@cdc.gov. Heather Duncan, the floor is yours.

CLIA Certificate of Waiver and Certificate for Provider-performed Microscopy Procedures Workgroup Report
Heather Duncan, MPH, MT

HEATHER DUNCAN: Next slide, please. The CLIA Certificate of Waiver and Provider-Performed Microscopy Procedures Group-- this is also an interim report-- has the meeting-- I think we've had four meetings so far. Next slide, please. Our workgroup charge-- and this CLIA Certificate of Waiver and Provider-Performed Microscopy Procedures Workgroup is charged with providing input to CLIAC for consideration and making recommendations to the Department of Health and Human Services on the potential need for expanding regulatory oversight of CLIA Certificate-of-Waiver sites. The workgroup will also provide input to CLIAC on the potential need for expanded regulatory oversight of certificate for PPM procedure sites. Next slide.

Discussion topics have been divided into two broad categories, based on certificate type, Certificate of Waiver and Waive Testing, and Certificate for Provider-Performed Microscopy Procedures and PPM testing. We've completed our discussions on the Certificate of Waiver. Our workgroup members encompass both traditional and non-traditional facilities. We have several CLIAC members in the group. And I just want to thank everyone for all of the engaged discussion. It's been a really great group to work with. Next slide. There is, I think, a mind-blowing number of Certificate-of-Waiver sites. As of today, there's over 259,000 Certificate-of-Waiver locations. And as you can see, overwhelmingly, is represented by POL or Physician Office Laboratories. Next slide. The workgroup has debated and discussed a number of questions, including problems and concerns that have been observed in Certificate-of-Waiver laboratories that have that lead us to believe that increased oversight may be needed. What we feel would ensure the quality of testing at Certificate-of-Waiver sites, including laboratory directors, testing personnel inspections, proficiency testing, facility, quality system, safety issues, and following manufacturer's instructions. We also reviewed reasons that CLIA [? law ?] should be opened and opportunities for exploring quality and outreach. Next slide.

Under what problems or concerns have you observed in Certificate-of-Waiver laboratories that lead you to believe that increased oversight is needed? The group felt there may be non-traditional places that do not realize they need a CLIA certificate to perform testing. These sites may not be familiar with the CLIA regulations, including the requirement to follow the manufacturer's instructions. And there are actually a number of examples that the workgroup provided, of real-life observations. Many of the staff performing lab testing do not have any experience in a laboratory, performing laboratory testing and medical facilities. It's difficult to expect lab to understand laboratory testing if they do not have any previous experience. And it's important for staff to have the appropriate training to be able to answer questions, educate patients, and understand CLIA regulations. Next slide.

There's a need for laboratory directors or owners to have educational requirements to understand all the testing responsibilities before sites are granted a Certificate of Waiver. And this is something that the workgroup-- I think there was almost a universal agreement upon. And then having a Laboratory Director Certificate program as a way to certify-- laboratory directors may be beneficial was tied into that. There should be more pathways to obtain training. And then providing more understanding of laboratory processes to those performing the tests. And a Certificate-of-Waiver laboratory will help with the overall quality of testing.

Consideration should be given that allows surveyors to perform on-site inspections after the Certificate-of-Waiver application is received, to ensure quality testing. Next slide. The need for inspection should focus with the laboratories and sites that are not already inspected by an accreditation organization. It's unnecessary for the Certificate-of-Waiver labs associated with the hospital system to be inspected when the Certificate of Waiver is affiliated or under the umbrella of a health-care system that is already having a survey and process. And this was also something that the workgroup universally, I think, agreed upon. There should be consideration given to requiring self-inspections with a checklist or initial inspections before certificates are issued. PT for non-regulated wave tests would be considered a burden for laboratories. Partner with manufacturers as a way to educate users on perform quality testing and require the manufacturers to submit safety considerations with package insert to ensure laboratories know how to address safety issues. Next slide.

What are the reasons that CLIA law should be opened to allow changes to waive-testing requirements under CLIA's Certificate of Waiver? Certificate-of-Waiver laboratories do not have to notify CLIA when adding a new test. There's no oversight to ensure waived tests are only being used in the laboratories or sites. There is a need to update the CLIA law because non-compliance with the current law exists. And there's no required regulatory oversight. And the CLIA-- the current law doesn't allow for oversight needed to ensure compliance. Next slide.

What other opportunities could be explored now to ensure quality in the Certificate-of-Waiver sites? There's suggestions to incorporate penalties for larger health systems that have smaller clinics and have the accountability to follow the institution, and self-inspections-- to incorporate self-inspections rather than traditional inspections to ensure compliance. Next slide.

And some avenues for expanding outreach were to identify professional organizations that represent those performing Certificate-of-Waiver testing and to promote educational products, and thinking about those organizations representing nursing and some of those type of organizations, and looking back at lessons learned during COVID and how outreach was rapidly expanded. Next slide.

Workgroup agreements to date is that there's a need for specific training requirements for testing personnel in the standard training program, that PT is of limited use and not favorable due to the expense, and that the CLIA law should be opened to allow for more oversight for Certificate-of-Waiver laboratories. Thank you.

Committee Discussion

CLIAC CHAIR: Thank you, Heather. There are no public comments so this report is open for a committee discussion. See she presented some agreements in her slides, whether or not this committee wants to take on that discussion-- to me, the most impactful was the final agreement about opening the law to define waived test. The hands are up. [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: Yeah, thank you very much. Thank you, Heather. You guys have done a lot of work. I had a question back on your slide where you talked about organizations that have a Certificate of Accreditation and Certificates of Waiver, that those might-- did I understand that you all were implying that perhaps they do have oversight over the Certificates of Waiver? Because it's my experience, in my past employment, that the Certificate of Accreditation laboratories frequently will separate out the Certificate of Waivers and will not get those accredited by their laboratory accreditation organization. So in other words, they're not getting any more oversight than an organization that does not have a Certificate of Accreditation program when the Certificate of Waiver is separated out from the Laboratory Accreditation program. I hope I'm making sense. I try not to point fingers at any one accreditation organization. But there are differences in how they handle the assimilation of the Certificate of Waiver into their Certificate of Accreditation program.

MS. HEATHER DUNCAN: So if I understand you are, you saying that if the umbrella organization has a separate certificate for the waived testing, is that what you're describing, when the--

CLIAC MEMBER: Well, I guess what I'm saying is that there are some accreditation organizations that all of the laboratories-- all the certificates, whether they're Certificate of Waiver or Certificate of Accreditation, when they go into an inspection organization, they'll look at all those programs. But there are other accreditation organizations, as I understand it, that the organization can identify which certificates they want to have inspected and do not get the Certificate of Waiver programs inspected. And in those cases, then there really isn't oversight.

MS. HEATHER DUNCAN: I understand what you're saying. So the workgroup discussion was that-- during the workgroup discussion, there was discussion about the burden of how to carve out, how to separate out some of the inspection process and the burden of all the inspection, and also that there are a number of weight-- of laboratories that are being inspected and are under-- do have the oversight of that system. And so they are getting the benefit of that process. So in order to allocate resources and make sure that you have the resources allocated, that's a way to do that. And because there is an inspection process in place through that home organization, that would be a way to do so. But I understand what you're saying, that there may be not-- isn't that robust process when you have separate certificates for some of the waived locations.

CLIAC MEMBER: Yeah, well, I think in a lot of hospitals, the Certificates of Waiver are carved out because they don't want them to reflect badly on the main laboratory. And so they're orphaned as far as oversight.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]?

MS. HEATHER DUNCAN: Thank you.

FDA EX OFFICIO: Yeah, I have a question for Heather. It's a clarifying question. There was one bullet that said that manufacturers should be sure to include safety information. And I'm just wondering if you could explain in a little more detail what may be missing in current CLIA waived tests instructions for use.

MS. HEATHER DUNCAN: Some of the workgroup members felt that the safe-handling information is very hard to read, very hard to identify. It's very tiny print and it's not always very-- especially for-- in a waived location, a waived-testing location, if you're not very practiced at understanding IFU, it's not tailored for a non-laboratorian in or a non-clinical type person to really understand. And it's not very easy to read. So even identifying where it is, it's not really tailored for that type of person, in a waived-testing location.

FDA EX OFFICIO: OK, are there any particular safety considerations that you want to make sure that are understood? What are the main risks?

HEATHER DUNCAN: I don't remember any specific safety information that was called out but-- so I can take that back to the workgroup and I could provide that detail back, [FDA EX OFFICIO].

FDA EX OFFICIO: Yeah.

MS. HEATHER DUNCAN: I remember, in more broad strokes, of it being a readable, and understandable and tailored to the level of personnel in a waived-testing location.

FDA EX OFFICIO: OK, thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, thank you, Heather and the workgroup. This oversight, I think, has been necessary for several years. I have two questions. There was a statement in one of your slides that said, doing proficiency testing would be thought to be a burden on these wayward labs, something to that effect. Why did the workgroup come to that conclusion? What is going on there because if we're all about quality, wouldn't that be one way to help establish quality? So what's going on there?

MS. HEATHER DUNCAN: When the workgroup considered the waived testing and the level of testing and the locations that are performing testing and the intent of distributing out testing and the cost of a proficiency-testing program, they felt that it would limit access and it would be cost prohibitive, especially when you look at the number of locations that many of these places are distributing out waived testing to, and that when you really look at the definition of waived testing in the waived-test platform, that really is kind of overkill. And that--

CLIAC MEMBER: OK, thank you. But then you hit on the other topic I was going to ask about, which is the definition of waived testing. Did you guys consider revising that at all because I think historically-- and it's still true today, if I'm not mistaken-- waived testing, in theory, could-- anybody can do it. You're not going to mess it up. But even if you mess it up, it's not going to affect the patient. That's the classic definition of waived testing.

MS. HEATHER DUNCAN: We actually--

CLIAC MEMBER: What happened to that thing?

MS. HEATHER DUNCAN: We did discuss that if it's--

CLIAC MEMBER: This is ridiculous.

MS. HEATHER DUNCAN: --performed-- if it's performed as it's intended. I forget the exact definition. But if it's performed according to the directions. And so that is where I think you can get off-- if you stray from the manufacturer's instructions and it's not performed as intended so if you stray from the instructions and you stray from that-- and we also did, just to further-- and I'm sorry if I'm, [CLIAC CHAIR] if I'm not raising my hand. We also debated the different types of tests that are included in the waived-test systems and molecular tests and how it's really expanded beyond--

CLIAC MEMBER: It certainly has.

MS. HEATHER DUNCAN: --the way tests were. And I'll put my hand back down.

CLIAC MEMBER: Well, we need your input, Heather because-- and we're wondering what the workgroup actually discussed. And I think it's time to put this notion aside that a lab result could not do any harm if it was wrong-- to the patient. That's just ridiculous.

MS. HEATHER DUNCAN: Well, it has to be done right.

CLIAC MEMBER: Any lab test, if it's done wrong, could potentially cause harm to the patient.

CLIAC CHAIR: So [CLIAC MEMBER], we had a lot of very spirited conversation around the creation of the category called waived test. And it's a tightrope balancing act around improving patient access versus regulatory burden that reduces that access. And we talked about the first seven that came out of the gate in 1988, which has expanded tremendously, of which some of those are molecular tests, which then got into this third bullet point on the group agreement, was to consider reopening the CLIA law to allow more oversight. So it's very spirited debate. With many of the waived sites, it would be incredibly burdensome to run a PT program. And more importantly, the waived sites that are probably not doing testing correctly are in that group. They don't know what they don't know. They don't know they need a CLIA certificate, starting very basic. And therefore, they're doing testing without a CLIA certificate. And they're probably not following manufacturer's instructions, your very basic tenets.

CLIAC MEMBER: Well, I guess we've got to start somewhere. So if we're going to start on that, let's do it.

CLIAC CHAIR: I'm going to move on to [CLIAC MEMBER], then [CLIAC MEMBER], and then [CLIAC MEMBER], then [CLIAC EXECUTIVE SECRETARY].

CLIAC MEMBER: So a little bit of this has been discussed. I was wondering what the distribution was between sample point-of-care tests, glucose, and A1C or something-- which if it performed with a machine that wasn't working properly, yes, could harm a patient-- and then trying to develop some recommendations around the complexity of the test and the nearness to harm. And I think that that might help. And the other thing I would add is, as for proficiency testing being a burden, looking across the distribution of the facilities that you had, many of them require that you take basic life support every two years. So they do that for all their personnel. I would think they might be able to do something for their laboratory. It might be more burdensome on the part of the organization collecting the data because there are so many small ones. But for the organization to actually perform it, it might not be as costly.

CLIAC CHAIR: [CLIAC MEMBER].

CLIAC MEMBER: Well, I certainly want to thank Heather for the report. I know it's at times difficult, especially trying to herd a conversation like this. But I just wanted to say, I was going to comment but I think there's actually several folks that have already commented, especially on the part-- I just wanted clarification and you don't have to comment on this-- but according to your presentation, a proficiency test is of limited use and not favorable due to the expense. But then I think you'd go back to the foundation of the laboratory and in my opinion, it's quality. And I don't think it's a very good statement to say, well, we can just put out lab results whether they're good or bad. I think proficiency testing helps to determine if we're doing it right. And if we're not doing it right, then maybe we need to do something different. And I think that's-- I agree with [CLIAC MEMBER] point as well. But it's more of a statement. And I know we've talked about it. I just wanted to make that comment.

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

CLIAC MEMBER: So I'm thinking about how we've been dealing with the need to do massive amounts of testing throughout the pandemic. And I'm also thinking about what's happened to our workforce. And we all have a really good idea of what has happened to our workforce. And in working on these challenges throughout the health-care system, we've realized that the people that are coming on board to these new positions and that have begun to start doing things remotely, from home-- many people are doing that-- I think what we've learned is that when we were able to simplify instructions, in a package with illustrations, we had a better chance of having a good outcome. And we saw that with the rapid home tests. Whenever we were able to open a package and see illustrations of how to do something, you had a much better outcome. So I would just like to make a recommendation. As we start to think about the workforce and the waived facilities, that will continue to increase. That's just the way that it's going to be. I would suggest really taking a look at making sure these manufacturers are thinking differently in their instructions on how to use these tests because the workforce today, they're trained on PowerPoint. They look at pictures and bullet points. They don't read the details. And I think that's what we really need to focus on, going forward, to make sure that we have the best chance of good, quality testing.

CLIAC CHAIR: [CLIAC MEMBER]. [CLIAC EXECUTIVE SECRETARY].

CLIAC EXECUTIVE SECRETARY: So just real quickly-- and I probably should have jumped in when we were talking about the bio-safety thing. So [FDA EX OFFICIO], one of the big things that the workgroup discussed was not necessarily the safety precautions that they need to take, which was an issue, but what if, what if I have a spill or what if I have an exposure? What do I do? And that's necessarily not covered in the manufacturer's instructions. But it was potentially a discussion of educational materials that needed to be available and things that perhaps our group does, which our one lab group, which you'll hear about tomorrow, has put together some seminars and things on point-of-care testing and bio safety. So that was one of the things that they mentioned along the lines of safety. And just to put everything into perspective, nothing can be done about anything related to the CLIA Certificate of Waiver without an agreement or something from this workgroup that says that the law can change. As it states now, in the CLIA law, the only requirements of a CLIA Certificate of Waiver site is you obtain as CLIA certificate, you pay your fee, and you follow the manufacturer's instructions. So while we can suggest and make conversations around what can happen or what should happen, none of this can happen without a law change. And so if you look back at the charge of this workgroup, that was what it was, is there a need for the CLIA law to be changed? And that was really what the focus of the discussion and all the bullet points were. And so I encourage everyone on this committee to think and discuss. And if there is a need for the CLIA law to be opened in one way, shape, or form, CMS has a process for that. And so I think that-- and Greg, please speak up about misspeaking-- but I think that was the intent of this workgroup, is to gather these experts together, discuss what's been going on under-- now we're just talking about Certificate of Waiver labs. We're not talking about COCs that perform waived tests. We're not talking about COAs that perform waived tests. We're talking about just those Certificate of Waiver laboratories. So is there something else needed? And if so, the only way that can be done is with a law change.

CLIAC CHAIR: Thank you, [CLIAC EXECUTIVE SECRETARY]. If I could ask, can we pop up Heather Duncan's final slide to help guide this conversation? And then it's [CLIAC MEMBER], [CLIAC MEMBER], and Heather Duncan.

CLIAC MEMBER: Thank you. I think I understand part of why PT may not be as useful in this situation. And this is based on experience and reports in the literature. And one question I have is whether there's any sort of database that looks at harm that's caused by Certificate of Waiver. And again, you've got Certificate of Waiver within inpatient facilities that are separated out from the COAs. You've got Certificate of Waiver that are outpatient situations, that to me, are a different complexity. But what I would suggest is that the actual analytic process, as approved by the FDA, is really pretty robust. The instruments work the way that they work. They've got a lot of internal controls. Where harm has been reported has been, for example, somebody puts glycerin on the patient's hands and then collects a finger stick for a glucose test and the patient gets over medicated. Oops. Just a second. I'm sorry, Alexa just thought I said something to her. I closed-- I closed the door. Yeah, and then I've also-- for example, if somebody does a creatinine and reports it as a hemoglobin and the patient gets over transfused. So I think the pre analytic and the post analytic, particularly in the inpatient setting, are really where the biggest issues lie because they're outside of what the FDA looks at when they classify an instrument as waived. And those seem like ripe areas for discussion. Those are my comments.

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

CLIAC MEMBER: Sorry, I see [CLIAC EXECUTIVE SECRETARY] waving. Sorry. I think we need to look way into the future about where things are moving. And COVID certainly showed us that things are moving at an incredibly rapid pace. And to your point, [CLIAC CHAIR], you brought up the fact that there's molecular testing happening. But that scares me in a way because contamination is an issue in most of our-- in some of our labs for other things. And I think a lot of the waived labs don't have the right setup to potentially handle some of the kinds of CLIA waived testing that's coming about. And I think there might be some need for, what's the space requirements or how many tests are you allowed to do, before it gets to be this big, messy whatever. So I do think with where things are moving, that there probably does need to be some other kind of oversight at this point. So I agree with what Heather's workgroup has come up with here. I don't think we can just say, oh, it's just a glucose or it's just a urine dipstick. We have all this stuff that's being developed is-- we've got oncology assays that could be waived at some point. And just to go back to the package insert, I completely agree. Every point-of-care lab that I've overseen, it's pictures only because that's how people respond. But [FDA EX OFFICIO] can speak to this. For CLIA-waived, approved tests, they actually submit data with whatever that package insert or IFU or whatever it is you want to call it was used. And that's how the people perform the tests. And that was the data submitted. That is part of the FDA process, I believe. So as bad as it could be, they still can do it correctly. But I agree, Heather, it has to be much more user friendly, those components, as well.

CLIAC CHAIR: Thank you. I just want to recenter this group. I believe we are discussing bullet point number three. And so I don't know if we want to open a motion to have this discussion. If we do, will someone make the motion?

CLIAC MEMBER: I'll motion.

CLIAC CHAIR: [CLIAC MEMBER]. Is there a second?

CLIAC MEMBER: I'll second.

CLIAC CHAIR: Great. OK, now back to the lively dialogue. Heather Duncan, then [CLIAC MEMBER] then [CLIAC MEMBER].

MS. HEATHER DUNCAN: OK. Well, I just wanted to add that a good bit of the discussion around allowing more oversight and the examples provided were that labs would have a Certificate of Waiver. And then when there was some form of inspection, that they were also performing moderate-complexity testing. But without any oversight, it would never have been discovered or they had no idea that they were performing moderate complexity or there were discoveries of laboratories or sites performing testing that had no certificate or testing being performed and it was completely-- deviation from the instructions and using performing testing on samples that weren't-- and it was technically an LDT because they were not using the proper sample type. And so there were numerous examples of deviations. So I just want to say I understand that the PT bullet point is controversial. But if we could-- again, and I'm glad we moved. Just focused on this first thing, I think that opens us up to a lot more opportunity.

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

CLIAC MEMBER: Thank you. I'd like to support what Heather just shared because I was able to look at the data that they shared. And a lot of the errors that they found during the inspection were people not following the instructions that was written. And as was said and as [CLIAC MEMBER] pointed out, not everyone is good at reading the package inserts. So there really needs to be the CLIA law opened to allow for more oversight because we need to have better quality of these tests. As we have pointed out, they're increasing the number. The whole idea of making testing more available to everyone is a really good idea and will improve health care in general. So we should do our part to improve the quality of what people are getting.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes. I'm in the same area with the oversight. However, I was-- before you said let's discuss bullet number three, I was thinking about an earlier piece when Ms. Heather Duncan talked about that they self-evaluate, that they self-evaluate how well they're performing and all of that. Could you share-- is it appropriate for her to share a little more information on that or you want to stay with number three? I can wait. But that's the area. It has to do with oversight. And so maybe we'll get back to that a little later and she can give us some input on that if you want to stay laser focused on bullet number three. OK.

CLIAC CHAIR: Thank you [CLIAC MEMBER].

CLIAC MEMBER: Yeah.

CLIAC CHAIR: The reason why we're on number three is we can't do anything. We can't do anything right now under the current law. So to even get to evaluation, training, PT, we have to reopen the law because right now, we can't do anything. That's why--

CLIAC MEMBER: Yeah, I would agree. Yeah, I'm in agreement.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: So that would be the add on to the motion. And the add on to the motion, if you think about quality control and patient safety, we need people to be trained. I think it's high time that we implement and we request that a licensing-and-certification system begins for waived labs. If they want to be a part of America's diagnostic testing team, they're going to need to be trained and they're going to need to be licensed just like nurses, just like physicians, because what they produce can be deadly if it's not produced properly. So I think it's time we start licensing and certification, training-- we have everything we need to do this. Everybody is used to self-serve, I'll go take my certification training, I'll watch my videos. And everyone's used to that now. So I think it's a perfect time to really invest in safety for diagnostic testing for waived and also for other types of labs as well.

CLIAC CHAIR: And [CLIAC MEMBER]? [CLIAC MEMBER]?

CLIAC MEMBER: I keep forgetting to take my hand down. Sorry.

CLIAC CHAIR: I'm getting a sense, from the discussion, that this group seems to be of the single mind that there should be some sort of oversight of Certificate of Waiver laboratories, whether or not that being training, certification, whatever that is. [CLIAC MEMBER], before I go on.

CLIAC MEMBER: If I make a recommendation, it's that, if CLIAC is going to make this recommendation, that we have some concept of how it might be implemented. That's not our job but I do-- it's interesting to replay the tapes of our own health system, overseeing the galaxy of waived-testing sites and yes, moderate-complexity sites and the infrastructure and personnel required to do that at a health-system level, and then scaling it up to a state level, what that might translate into. And in point of fact, what [CLIAC MEMBER] said really resonated with me in the sense that a scalable, virtual mechanism for requiring certification, which actually could be filed and automated, might be the tunnel through the mountain because if we've got over a quarter of a million certificate-of-waiver locations with however many personnel would be doing that, easily 1 to 2 million people who would need to go through the system. And it's very intriguing that tomorrow we have one lab coming up, which is just that kind of industrial-scale, educational mechanism. So I think [CLIAC MEMBER] has provided some inspiration for how there might be an implementation to what otherwise would be a challenging mandate to meet. And with that grasp, that rope to hang on to, then I think a recommendation could be made in clear conscience.

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

CLIAC MEMBER: So I would like to make a motion that we, today, formulate the language to require waived facilities, laboratories, that want to participate in the US diagnostic testing will be required to be licensed and certified, and that HHS will provide training. And we'll build the system that we do in all different departments today, of the US government, replicate what we're doing and how we do it today in the census, in how we take on new health-care customers, and start today in formulating what that recommendation will look like. So I'd like to I'd like to make that recommendation for motion.

CLIAC CHAIR: So [CLIAC MEMBER], just a point of order. We already have emotion open.

CLIAC MEMBER: OK.

CLIAC CHAIR: But your discussion is right in line with that motion and it really is if we, as a committee, agree to move forward with this as a recommendation to HHS, how do we word it. And to consider everything you've brought up, do we just be simply broad based and say it needs to be open? And that's the opening salvo. And then how it gets open and implemented becomes the work of the various agencies that we would not dictate. We would just say in principle.

CLIAC MEMBER: Right, of course. Of course.

CLIAC CHAIR: I'm going to move on to [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER] and then [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Y'all will forgive me. My network is fragile today, I guess. But I was thinking if this could perhaps happen maybe a little closer to home in almost a pilot type of thing. It would still be a big pilot if you used, say, the FQHCs, which are-- answer to Department of Health and Human Services. And then maybe if we take the long view on it, maybe you do two years of research and do a comparison and then see improvements in that group. And then also, you would learn from a lot of mistakes and a little smaller deployment. So that's my idea is to maybe do it on a smaller scale by using FQHCs, learn your mistakes, and then you could scale it up from there, perhaps.

CLIAC CHAIR: Thank you. [CLIAC MEMBER].

CLIAC MEMBER: I just wanted to share that we did it-- that the workgroup has had a lot of discussion about how to scale and the sheer number of sites that would need to have-- that require oversight and how to implement and that sort of thing. And that's why there was a lot of discussion around lab director responsibility and requiring-- there needing to be a form of lab director certification because often the director for the certificate-of-waiver laboratories really has-- there's no real requirement for education or-- and then often there's someone on that, that is named but really has no real responsibility or real oversight responsibility. So it was felt that if there was an education requirement or certificate program, and that the lab director for these sites had true educational requirement, that from that, there would be much that would flow and that it would be a real trickle-down effect. And so I think there is a lot more to that. But that is a foundational element, I think, that the workgroup really coalesced around. So I did want to share that bit with the group in here.

CLIAC CHAIR: [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER]. But I want to say [CLIAC MEMBER] and [CLIAC MEMBER], if you're not going to talk, please put your hands down. Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Keeping my eye on lines of sight and actually using CLIA as the example, there are deemed organizations. There are license fees. There are CEU fees. In essence, you're recommending that we stand up a new part of the industry. And that industry has a business model. If you're going to do waived testing, there is a process by which you do it. And so I would fully anticipate that. I would ask that we be sensitive to the potential for that creating a barrier for health-care access and disparities in health care. That's one line of sight. The other line of sight is states. To the extent that states alert whenever-- certainly the state I live in, New York-- alerts whenever the topic of license and certification comes up, I think we have to be mindful of how a modification of a federal law plays out at the state level, again, with the optics of quality, yes, barriers to health care, something we should be mindful of in the recommendations we make.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. I'd like to echo what [CLIAC MEMBER] said. And that was where I wanted to go too. As I mentioned before, I think we all have personal experiences where we think harm is occurring. But in order to ramp up the training and make sure that we're covering the really salient issues, I do think that some sort of data collection to help drive where the CLIA regulations go, and where training needs to go, would be indicated. And that's something that perhaps the CDC could assist with or perhaps suggest other organizations that could assist with data collection of where the gaps are in the system for waived testing. Thank you.

CLIAC CHAIR: Thank you. In the workgroup, there were some reports from some accrediting agencies that talked about the most common defects. And they were, no surprise, not following the manufacturer's instructions and then a whole bunch of things related to quality. And--

CLIAC MEMBER: You know what--

CLIAC CHAIR: Some of you might recall way back when CMS had its 2% certificate-of-waiver audit program, where for a couple of years, they surveyed 2% of all certificate-of-waiver labs and identified the top 10 deficiencies. And those top 10 are what we learned, in the workgroup, still exist today.

CLIAC MEMBER: And [CLIAC CHAIR], I-- actually, about 10 years ago, I think I gave a presentation to CLIAC about the Joint Commission and what hospital surveyors find versus laboratory surveyors find and how those differ. But I do think that's different than collecting data on errors and where harm occurs.

CLIAC CHAIR: Yes, you are correct. That's a difficult one to tackle. [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: So I would think that if we approach this as a phased-in approach, meaning if we can all agree that it's time to hold these waiver labs accountable, then perhaps we can come to an agreement to see if licensing and certification, if it's time for them to officially be trained, and if so, then including this in the motion to HHS. Naturally, all the other parts would need to be included on how would we go about doing this. But we just need to have the OK and support to assist, if it's an agreement, assist with starting this process. And you could start really low, down the road. You need to go big and say, it's time for this to be done because I know, [CLIAC CHAIR], the first thing we talked about when I came to this committee was this. And we can just still be talking about this for the next 10 years. So I really think it's time to take a bite of the apple, here. And we need a reinvention of our healthcare system. And why not start this right, set the example, in diagnostic testing because so many things happen when it's inaccurate.

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

CLIAC MEMBER: Yes, so I have this same sentiment. This has been on the radar screen now, forever. It's the reason the workgroup came together, because this is a problem that's not spontaneously resolving and maybe getting worse. So I would agree that the first issue is, does this need to be addressed. And that, I think everybody is in agreement with. You mentioned it briefly but can-- this came up last time also, where we were unclear, actually-- or at least I was-- what is the scope of our committee because as you mentioned, it's not implementation. And there are multiple experts within the systems that are responsible for implementation. And doing-- so yes, let me stop there. If we can-- again, I can't speak for everybody, but it would help me, in terms of some clarity, as to what our role is in terms of implementation as-- I may be mistaken but I think that isn't necessarily what we're supposed to be tasked with. Thank you.

CLIAC CHAIR: I'm going to have [CLIAC DFO] jump the chain because I know he has an answer for this.

CLIAC DFO: Well, I hope I have an answer. And I'm going to repeat what [CLIAC EXECUTIVE SECRETARY] said earlier. And so we as a-- CLIAC, as a committee, can make no specific recommendations about how to fix the certificate-of-waiver process until the government is able to persuade Congress to open the CLIA law for revision. And in order for HHS to be able to persuade Congress to open the law, which means essentially, revise the CLIA law on this topic, there needs to-- HHS and the administration needs a persuasive argument. And we think that part of making a persuasive argument is a extremely clear message and recommendation from CLIAC, the nation's federal advisory committee, made up of the nation's experts in clinical laboratory medicine, that this is a major vulnerability from a quality point of view, from a patient-safety point of view. And then you can say CLIAC recommends that the law be opened to allow for more oversight. And then if CMS can persuade Congress to open the law, then that will give the government, the administration an opportunity to suggest new language in the CLIA law as it pertains to certificate of waiver facilities. So I guess-- you can make your recommendation as specific as you like, but I wouldn't lose track of the big picture here. And the big picture is what's highlighted in yellow. And I believe that the government needs a very clear, succinct recommendation from CLIAC that this is what CLIAC would like the government to pursue with Congress. And then the sort of second, third, or fourth steps would all be dependent on the success of that first step. And the second, third, and fourth steps could be what we would specifically do if we were able to open the law, such as developing training requirements or other.

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

CLIAC MEMBER: Well, I think [CLIAC DFO] just sort of spoke to what I was going to say because what's shown in yellow is fairly general, to allow more oversight. It doesn't speak to certification or accreditation labs we're talking about licensure, but we're not talking licensure here. That's a state thing. But accreditation or certification, it may not be. There may be more stringent requirements put on here. And I think the argument is-- and this argument has been going on since there were eight waived tests. At least to my knowledge, as soon as it became nine, that concern came out. So I think if we stick to the issue of opening it to allow more oversight, and then with the argument that basically the waived test environment is completely different than when it was conceived under CLIA, that then, subsequently, down the road, that then there could be a workgroup that CLIAC could get together to look at it. I mean, with the fact that we saw the statistics this morning that most of these labs are waived labs, and most of them, it's not a hospital lab, it's a physician office lab. It's a big lift. But I don't want to-- I don't think we can or should be prescribing it. So I would be supportive of us as an organization right now supporting what's in yellow, with the argument that what constitutes a waived test has changed considerably since this was envisioned.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Yes. I just wanted to-- I'm in agreement that we need to implement criteria that will ensure the integrity of any testing, and also of the personnel that is carrying out any type of laboratory testing, but want to be mindful of the fact that isn't there still a shortage of laboratory workers, and so forth and so on? And then how do we phase that in? And I've heard what [CLIAC DFO] said, as well, that we are a little bit over the line when we want to do-- require that each person be licensed and/or have a certificate, that's a second piece. We can certainly make recommendations, but I would like to see us gather some data on this so that we let the information drive our recommendations and our actions. And also, how will this impact, if at all, diversity and inclusion? Is it equity, diversity now and inclusion would be another point that I would be sensitive to. [INTERPOSING VOICES]

CLIAC MEMBER: That's it.

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

CLIAC MEMBER: So if we need to tell the story, we need to have more facts. And so what I'd be curious is to see is anyone measuring patient harm from these waived labs. And if they're not, then perhaps this is what we need to start doing, is finding a way-- it's going to be difficult because the harm often happens after you get the treatment that you shouldn't have had, or it should have been a different treatment. So I think we need to ask CMS and the CDC, is there any measuring going on right now in patient safety from these waived labs that we could use in our request to add to bullet point number three.

CLIAC CHAIR: [FDA EX OFFICIO] stuck his hand up, so I'm guessing he has--

FDA EX OFFICIO: Yeah. I think the FDA plays a key role here because we require the manufacturers to handle all complaints and any harms that are reported to the company. And also, anybody can report harms openly on the FDA MedWatch site.

CLIAC CHAIR: Yeah.

FDA EX OFFICIO: So we collect all such medical device reports and we analyze them. And so we are actively looking for harm, or potential harm. And we've taken action. I mean, we have removed devices from the market that are problematic. So that is our job. That is one of our roles, one of the hats we wear is to, once we authorize a test, that we are to monitor through various means, including required reporting from the manufacturers of any problems on market, false results or any harms to users or patients. Those are all included, so. And the data is all public, so anybody can go and look at the MDR reports once they're made public. There's a process to convert them from our system to a public system. And you can go in there and you can search. So I think we have a pretty good idea of the safety of the devices because of the requirements for manufacturers to report problems.

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

CLIAC MEMBER: Well, two questions, since [FDA EX OFFICIO] this. I'll address this first. I think one of the things-- and [CLIAC MEMBER] may have been leading to this a little bit-- is that if there's a problem with a device, it's not working, you get indeterminate, that's definitely something they're going to be able to track and send back to the FDA.
I think the more important problem is what if you report a positive or a negative and it's the wrong result and something happens that way? Those patient safety components I do not think are being well categorized. So I'm more concerned about that than a system failing because it's not doing the right thing, because I think that will be addressed pretty quickly. And then the other question was really back to [CLIAC DFO] on, if HHS needs a persuasive and clear message, do you think that bullet three is enough, or how do we create that clearer message on quality and patient safety if we don't really have any data? We may have the quality data, [FDA EX OFFICIO], to your point, about everything that's reported. I don't know that we have enough of patient safety data. I think it's just an assumption on our parts right now, because I'm not aware of it, either.

CLIAC CHAIR: [CLIAC DFO]?

CLIAC DFO: So yeah, I'll try to respond to [CLIAC MEMBER]. You know, I think obviously the stronger you feel as a committee and the more persuasive the recommendation can be, the more powerful that recommendation will be when the government or the executive tries to persuade Congress to open up the law for revision. And so I guess I don't want to tell you what to say because I'm not on the committee, but I do think, at a minimum, what's highlighted in yellow is strong. You could add to that if you had consensus around the kinds-- for example, to include personnel expectations or something like that, or-- but I think the important thing is for the committee to have a statement along the lines of what [CLIAC MEMBER] said, which is that the law-- arguably, the law was written at a time when certificate of waiver testing

was relatively limited, and that the environment has changed significantly since. And laboratory-- or quality of testing, diagnostic testing in the United States should expect a commensurate change in the oversight of this sort of testing.

CLIAC CHAIR: Yeah. OK. [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Yes. Thank you. The title of the workgroup is certificate of waiver and provider before microscopy. But we really haven't talked about provider-performed microscopy. Did your workgroup have any recommendations or thoughts about PPM?

CLIAC CHAIR: Oh, yeah. We're not ready to talk about it.

CLIAC MEMBER: Oh, OK.

CLIAC CHAIR: [CLIAC MEMBER], you're on mute, too. But [CLIAC MEMBER], you're next up. But [CLIAC MEMBER], we're not ready to go public.

[CLIAC MEMBER], you're still on mute.

CLIAC MEMBER: Well, yeah, I said we will have a lot to say about PPM when we get there. But so I just wanted to comment on gathering data for patient harm. What's difficult is it's hard to gather data on what you don't know. And a lot of what's happening in these Certificate of Labor labs is people are performing testing and they don't know what they don't know. And so these are errors for people who don't understand that they're making errors. And so I don't think any of this is going to be reported or detected. And so this necessarily-- we may not be-- and so I know lot of what we discussed in the workgroup is anecdotal. So these are simple things, people performing testing and reading the internal control line as a positive, and not understanding that's an internal control volume. These are improperly stored samples. So you have sample integrity issues. Is that patient harm? We probably will never know. They will never know. These are cross-contamination issues. Is that going to be detected? Are we going to be able to gather that data? I mean, so these are real, everyday issues. These are labs that do not have certificates. These are-- so I really urge the group to strongly consider not delaying opening this and not considering this being a deterrent to having testing open to all patients. But really, we really need to consider that we need to make sure, ensure that we have quality testing for everyone. We don't need to be restrictive about it. It's just we just-- I really, really feel that we need to have more oversight. That's all.

CLIAC CHAIR: Hm.

[INTERPOSING VOICES]

CLIAC CHAIR: --[CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: So if we think about what you just said, [CLIAC MEMBER], that helps us paint a picture that we need to add to this bullet point three. We need to paint the sense of urgency and the fact that the 257,000 CLIA waived facilities are doing, you know, shall we say millions of tests? And many of these people that are conducting these tests are not trained. I mean, we need to paint the picture of the fear of what is happening because everyone here has been talking about this for so long. So I think we need to paint a stronger picture because a lot of people don't know the information about laboratories and waived laboratories. And so we need to be very-- we need to paint the picture again, like we talked about. We need an illustration of what's happening and why we need to work on an update and modernize the CLIA law.

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

CLIAC MEMBER: Yeah, and I think [CLIAC MEMBER] and [CLIAC MEMBER] really just said what I was going to say. I don't think we should wait. It takes so long for the government to move. And if we're waiting to only realize that we don't have the ability to gather the data, then we're just putting it off, kicking the can down the road while it could be fine, it could be explosive. But it's not worthwhile taking the chance. So I think we should do something now.

CLIAC CHAIR: So we have seven minutes left on the clock. We have a statement that says the what. Do we want to craft a statement to say the why--

CLIAC MEMBER: The why.

CLIAC CHAIR: --with the recognition we cannot say the how?

CLIAC MEMBER: Yeah. The why.

CLIAC CHAIR: So do we want to-- I'm hearing [CLIAC MEMBER] wants a why. Does somebody want to propose a why? I heard [CLIAC MEMBER] say times have changed, the menu has been vastly expanded, and the risk of patient harm from an incorrect result is much greater than at the time of the original CLIA law. Beautiful. Do you want to work, or [CLIAC MEMBER], do you want to?

CLIAC MEMBER: That's what the off hours are for.

CLIAC CHAIR: So how's about we come back to this tomorrow? And everybody, if you want to write the why, submit your why to Heather so we can line them up and decide how the why goes with the what. That sound like a plan?

CLIAC MEMBER: [CLIAC MEMBER] has some great whys.

CLIAC MEMBER: And I just want to remind everybody also that there are no personnel requirements, training requirements, education requirements for not only the people performing the testing, but whoever is calling themselves the laboratory director when they apply for a certificate of waiver.

CLIAC CHAIR: This is getting scary.

CLIAC MEMBER: You just apply, you pay the fee. So when you're thinking about the why, keep that in mind.

CLIAC MEMBER: Can you have a tale?

CLIAC MEMBER: T-A-L-E.

CLIAC CHAIR: If you can pay the fee.

CLIAC MEMBER: Yeah. So [CLIAC MEMBER], we can try and draft something together if you want.

CLIAC MEMBER: Yes, no, I'm happy-- I mean, the materials are in front of us.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: That would be my second recommendation, would be the-- that was going to be my second one.

CLIAC MEMBER: There was a study in, like, 1990 something that was presented at CLIAC by CDC that showed that people who know what they're doing do a better job than people who don't.

CLIAC MEMBER: Shocking.

CLIAC CHAIR: That's a good one. And if any of you want some good reading, I recommend you go look at the CLIAC recommendation table. The first recommendations out of the gate in 1992 were around wave testing and PPM. So do we want to take action now, 30 plus years later?

CLIAC MEMBER: Yes.

CLIAC CHAIR: OK, so the motion remains open. We are going to adjourn, and we're looking for submissions tomorrow for the why. And with that, am I allowed to close this meeting? Or where's the script? Sorry. The script.
Thank you for joining day one of the Clinical Laboratory Advisory Committee meeting. We will begin promptly 11:00 AM Eastern Daylight Time tomorrow. No, it's Eastern Standard Time, right?

CLIAC MEMBER: Eastern Standard, yeah.

CLIAC CHAIR: OK, thank you.

CLIAC CHAIR: Our topics for tomorrow will focus on efforts to address public health and clinical laboratory workforce challenges and mpox response update. Enjoy your night. See you tomorrow. We've got our work cut out for us tonight. Thank you.

CLIAC MEMBER: Question to [CLIAC MEMBER]. [CLIAC MEMBER], we're not going to hear about PPM at all? It's going to be in a different report-out?

CLIAC MEMBER: Not today, no. Sorry.

CLIAC CHAIR: Not for prime time.

CLIAC MEMBER: That workgroup is ongoing, just like the other ones.

CLIAC MEMBER: I was going to say--

CLIAC MEMBER: Eventually.

CLIAC MEMBER: It's gonna be a bear.

CLIAC CHAIR: This is an interim report, remember? And the one agreement we came to is open the law, OK?

CLIAC MEMBER: Yeah. This was the easy one.

CLIAC CHAIR: Yeah.

CLIAC MEMBER: The easy part.

CLIAC CHAIR: Thank you, everybody. Bye, guys. See you tomorrow.

November 10, 2022

❖ Call to Order and Committee Member Introductions

CLIAC DFO: Perfect time. Welcome to the second day of the fall 2022 meeting of the clinical Laboratory Improvement Advisory Committee, or CLIAC. My name is Ren Salerno, director of the Division of Laboratory Systems at the Centers for Disease Control and Prevention. And I'm also the designated federal official of CLIAC. CLIAC is managed by CDC, and provides scientific and technical advice and guidance to the Department of Health and Human Services. The advice and guidance CLIAC provides to HHS focuses on issues related to improvement in 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, Zoom chat and Q&A functions have been disabled for audience members. If you experience Zoom difficulties, please feel free to contact cliac@cdc.gov. I will start the meeting this morning with the roll call. Please acknowledge a presence when I call your name. Dr. Valerie Ng.

CLIAC CHAIR: Here.

CLIAC DFO: Dr. Birthale Archie.

BIRTHALE ARCHIE: Here.

CLIAC DFO: Mr Michael Black.

MICHAEL BLACK: Here.

CLIAC DFO: Dr. Kimberle Chapin.

KIMBERLE CHAPIN: Here.

CLIAC DFO: Dr. James Crawford.

JAMES CRAWFORD: Here.

CLIAC DFO: Ms. Heather Duncan.

HEATHER DUNCAN: Here.

CLIAC DFO: Dr. Mary Edgerton. Mary, are you here yet?

CLIAC EXECUTIVE SECRETARY: Mary was in the audience. I'm promoting her now, so she'll join us right now.

CLIAC DFO: OK.

MARY EDGERTON: I am here. Sorry.

CLIAC DFO: OK. Thank you, Mary. Dr. Susan Gross.

SUSAN GROSS: Here.

CLIAC DFO: Dr. Lee Hilborne.

LEE HILBORNE: Here.

CLIAC DFO: Dr. David Koch

DAVID KOCH: Here

CLIAC DFO: Dr. Lavinia Middleton.

LAVINIA MIDDLETON: Here.

CLIAC DFO: Ms. Carole Moss.

CAROLE MOSS: Good morning.

CLIAC DFO: Dr. Nirali Patel.

NIRALI PATEL: Here.

CLIAC DFO: Dr. Michael Pentella.

MICHAEL PENTELLA: Here.

CLIAC DFO: Ms Jennifer Rhamy.

JENNIFER RHAMY: Here.

CLIAC DFO: Dr. Gregory Sossaman.

GREGORY SOSSAMAN: Here.

CLIAC DFO: Dr. Mark Tuthill.

CLIAC EXECUTIVE SECRETARY: Unable to join today.

CLIAC DFO: OK. Dr. Chip Watkins.

CHIP WATKINS: Here.

CLIAC DFO: Mr Andy Quintenz.

CLIAC EXECUTIVE SECRETARY: And he is unable--

CLIAC DFO: Oh, that's right. He wasn't going to join us today either. Dr. Colette Fitzgerald.

COLETTE FITZGERALD: Here.

CLIAC DFO: Mr Gregg Brandush.

GREGG BRANDUSH: Here.

CLIAC DFO: Dr. Tim Stenzel.

TIM STENZEL: Here.

CLIAC DFO: And Ms. Heather Stang.

CLIAC EXECUTIVE SECRETARY: Here.

CLIAC DFO: Great. Thank you very much. Members are reminded of the importance of remaining in attendance on both days for the full meeting to ensure quorum until all matters before the committee are addressed and the meeting is adjourned. During the period dedicated to committee discussion, participation will be limited to CLIAC members only. CLIAC only accept public comments that directly relate to the topics announced in the Federal Register notice of the CLIAC meeting. Today, the committee will discuss and deliberate on the following topics-- efforts to address public health and clinical laboratory workforce challenges and an update on the mpox response. Public comment periods are scheduled at the end of each topic area. If anyone in the audience wishes to address the committee, the public comment portion of the meeting is the proper forum to do so. Those who did not previously send a request for public comment and would like to participate, please email cliac@cdc.gov As soon as possible to be added to the session.

CLIAC CHAIR: A few comments about the schedule and the 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 are provided on the CLIAC website. If you are experiencing any difficulty with accessing Zoom please email cliac@cdc.gov. The meeting is also recorded to assist in preparing an accurate written summary of the proceedings. A reminder that all discussions and deliberations must be available to the public. The chat is not available to the public for viewing. CLIAC members should not engage in topic discussions offline through the chat. Please use the chat or put your hand up to notify Dr Ng, me, of your desire to comment during the discussions and/or submit draft recommendations for discussion. Draft recommendations will be discussed verbally by the committee members, not via chat. An email to Heather Stang is another option to submit draft recommendations.

The meeting agenda for today is focused on efforts to address public health and clinical laboratory workforce challenges. Our first session today is on efforts to address public health and clinical laboratory workforce challenges. We will start with a OneLab Initiative overview and update provided by Dr. Kelly Winter. The second presentation will be a OneLab virtual reality demonstration from Mr. Joe Rothschild. And Dr. Alexandra Mercante will follow with a brief update on the CDC laboratory partners forum. These are the online presentations 7, 8, and 9. After the presentations, we will have time for committee discussions. If you wish to provide a five-minute public comment, please email cliac@cdc.gov To date, we have not received any public comments. And at the end of the session, we will have a one-hour break. So we will now start. CLIAC members, please assure you are on mute. I'm sorry, reading the wrong part. We will now start with the presentation by Dr. Kelly Winter on the OneLab Initiative, overview, and update. Dr. Winter, it's all yours.

❖ Presentations and Committee Discussion

Efforts to Address Public Health and Clinical Laboratory Workforce Challenges

OneLab™ Initiative: Overview and Update
Kelly Winter, PhD. MPH

DR. KELLY WINTER: Thank you so much Hi, everyone. I'm Dr. Kelly Winter. I'm the chief of the training and workforce development branch within the Division of Laboratory Systems. And as mentioned, I will be giving an overview of the OneLab Initiative. Next slide, please.

Before we dive into OneLab, I'd like to start by revisiting the CLIAC recommendations that are most relevant to this presentation. Back in April of 2022, CLIAC recommended that CDC raise the recognition of laboratory professionals and health care through its outreach, communication, training, and guidance partnerships with the laboratory science community to increase interest in laboratory careers, work with partners to create and expand access to educational content and resources, and identify other opportunities to reduce the burden on individual training programs, including creating and overseeing programs from clinical laboratory sciences training programs. And finally, conduct a workplace survey of laboratory professionals to support and guide critical recruitment and retention activities. Next slide, please.

Back in April of 2021, CLIAC recommended that CDC develop training and education materials for SARS-CoV-2 self-testing, point-of-care testing, and follow-up care. And in November 2019, CLIAC recommended that CDC create an online library of clinical laboratory education resources for use by organizations for their own post-baccalaureate training of clinical laboratory professionals, and explore how virtual reality and simulated simulation-based training can be used to achieve competency-based outcomes. Next slide, please.

The bulk of today's presentation will focus on the OneLab Initiative. But I think it's also important to note that some other DLS laboratory workforce development activities relate to CLIAC's recommendations. As Dr. Collette Leaumont Fitzgerald mentioned yesterday, CDC is working with the Association of Public Health Laboratories, or APHL, to recruit, train, develop, and retain a diverse public health laboratory workforce through the Career Pathways in Public Health Laboratory Science Program. This program is funded by the American Rescue Plan. In addition, to creating a new competency-based curriculum, CDC set a core health equity goal for the program that centers on increasing diversity within the applicant and selection pool by 40% by 2025. CDC is committed to fostering a more diverse and well-trained public health workforce. Recruiting and developing public health laboratory scientists and professionals from communities that we most need to reach will ultimately help us achieve a more equitable system of care. Next year, DLS will collaborate with 10 to 20 subject matter experts from academic institutions and organizations that serve underrepresented students. CDC is seeking SMEs in three fields-- laboratory science, health equity, and diversity, equity, inclusion, and accessibility. SMEs will collaborate with us to identify barriers to participation in laboratory fellowships and internships among underrepresented groups and communities. Via the Intergovernmental Personnel Act, CDC expects to fund 55% to 20% of each SME's salary proportional to their role in the workgroup. Those interested should email labtraining@cdc.gov. Next slide, please.

This past September, CDC established an interagency agreement with the Health Resources and Services Administration, or HRSA, to conduct research to help CDC and laboratory partners better understand the clinical and public health laboratory workforce needs to include detailed enumeration, characterization, and comparison of the workforces, estimations of current supply and demand, and projection of future supply and demand. Through venues such as the clinical partner forum, we will ensure that our data collection efforts align with and leverage those of our laboratory partners. Next slide, please.

And now let's dive into the OneLab Initiative. In May 2021, the American Rescue Plan provided $55 million to CDC to expand the OneLab Network into a five-year initiative to bridge, train, and sustain the capacity-building community among public health laboratories and clinical laboratories and CDC. By bridge, we mean that we will seek to strengthen essential links between public health and clinical laboratories and CDC. By training, we mean that we will develop and evaluate resources with three goals- to make sure that laboratories are ready, are ready to respond, and can lead others on laboratory Systems topics. And by sustain, we mean that we will embed feasible long-term capacity-building strategies within laboratory communities. The themes of bridge training sustain not only capture the essence of this OneLab Initiative, but extend to our divisions' overall training and workforce development activities and resources. Next slide, please. OneLab now has seven components designed to culminate in an active, ongoing laboratory learning community. I will go over each component in depth over the next few slides. But at the highest level, these components are continual training needs assessment, development of resources informed by the training needs assessments.

Our OneLab Network, which is a partnership network of clinical and laboratory professionals, with emphasis on training. Our OneLab learning management system, the OneLab summit, which is a three-day virtual summit to connect the OneLab Network members and discuss what we can do together to more collectively support training needs. Our OneLab virtual reality or OneLab VR work. And finally, the OneLab test, which will be a new community of practice specifically for the testing community. Next slide, please.

As you all know, during an emergency response, it can be quite challenging to keep our training activities going full force. But we have seen how incredibly important it is to keep these efforts strong, particularly during a response. From January 2020 to April 2021, DLS experienced unprecedented increases in our eLearning course registrations. Registrations rose by 155% compared with the same period one year earlier. Connecting laboratory, education, and training professionals to each other and to CDC became an urgent priority. In February 2021, we stood up the OneLab Network so that we could collectively support training for rapid large-scale emergency responses. This was the first component of what would grow into the entire OneLab Initiative. Next slide, please.
As of November 1, 2022, the network now has over 2,650 members, representing 1,300 laboratories and laboratory professional organizations. Monthly virtual meetings focus on addressing priority training needs. New training materials developed are posted on the network's homepage and on our learning management system OneLab REACH. Next slide, please.

Thus far, the OneLab Network has held 15 live webinars to identify and address urgent laboratory training needs. Shown here are some of the topics that we've covered so far. We've actually had so many of these network meetings that this will fold on to the other slide. And participation in these live webinars is steadily growing. Next slide, please.

We've averaged about 1,200 registrations for each of the most recent webinars, with an average attendance of about 600 laboratory professionals. So next week, we will have a live webinar on how frontline facilities can safely test clinical specimens from patients under investigation for Ebola. And our most recent webinars have focused on Ebola as far as developing a plan for specimen management, and testing of patients with Ebola and other emerging viruses, as well as packing and shipping suspected Ebola specimens. And back in September, we did a public health laboratory, or PHL, 101, which was tailored to the OneLab Network, as well as participants rather in our fellowships program. So we were able to serve two common purposes with that webinar in particular. Next slide, please.

This graphic depicts the training topics that were identified through the training needs assessment conducted in 2021. So you'll see that there are three core topics in that center circle. These were divided into technical topics, crisis leadership, and emergency preparedness and operations. And then around the circle are the underlying pillars needed to support that training. So we have learning environment, centralization of resources, flexible learning modules, and cohesive messaging for the public. And you can view the entire needs assessment report on our OneLab webpage, and I'll share that URL at the end of this presentation. Next slide, please.

Based on our needs assessment findings, DLS creates training tools in a range of formats, which pivot over time based on technology trends and product priority topics identified by the laboratory community. Shown here are two of our eLearning courses. So we have the introduction to CLIA course. There's actually two CLIA courses up right now that are the beginning of our CLIA curriculum. We expect to have the third course released within the next year, likely a lot faster than that. And we actually have about 40 eLearning courses available overall, with three more in development. And the fundamentals of personal protective equipment, or PPE, course is shown here. It was tailored specifically to clinical laboratories, and served as the basis for a virtual reality training that we'll discuss later in this presentation.

And at the bottom of this slide is shown an example of promotion for our syndication service. We now offer external partners a free way to post our eLearning courses on their own learning management systems. This allows them to track metrics on their staff's course progress and completion at an individual level, while we retain control of the course content. Think of it like embedding a YouTube video on a blog. The partner can display the content. But we at CDC can push updates in real time, or even temporarily shut down the course if a major content change were needed urgently. In the past year, 50 partner organizations have begun syndicating our courses, including Auburn University, George Washington University, Texas Tech University, Cornell Medicine, Pima County Health Department, and COLA. Now that we've confirmed that the syndication platform functions well and is useful, we have transitioned oversight of this platform to one of our sibling divisions. But we remain in control of our individual courses to make sure that they are up to date and functioning properly. Next slide, please.

Early on in the COVID-19 emergency response we updated our website to make it easier for learners to quickly find all of our COVID-19-relevant courses and materials. We also created a new webpage specifically for job aids. The job aid is any self-explanatory tool that assist a person in completing work faster or more accurately. There are more than 100 job aids on this page, many of which have now been downloaded several thousand times. Two of the PCR videos on the page have been viewed over 10,000 times each. Over 80 of the resources on that page are relevant to COVID-19 in particular. And shown on this slide is our diagnostic sensitivity and specificity for clinical laboratory testing job aid, which was released months ago. Next slide, please.

We've also released two courses that leverage virtual reality, or VR, technology. VR training allows laboratory professionals to apply, assess, and improve skills in a safe, controlled learning environment. And I want to stress that we only use virtual reality for specific topics where it is appropriate to use it to build skill onto great lengths to make sure that we use that wisely. Next slide, please.

OneLab REACH is a new learning management system, or LMS, that provides laboratory professionals with a one-stop shop to access all of CDC's free laboratory training resources. The acronym REACH is short for Rapid Education and Capacity-building Hub. We tailor OneLab REACH the needs of the laboratory community, and built a user-friendly LMS that allows you to save courses for later, similar to a Netflix queue, download job aids without logging in, and quickly navigate to pace certificates. There is also an FAQ to help solve common user issues, such as retrieving lost passwords and a support ticket system so that learners can quickly receive assistance with more complex technical issues. We hold a soft launch of OneLab REACH in July of 2022. 135 OneLab Network members attended this live demonstration. As OneLab REACH has about 500 users-- our full scale promotion campaign will kick off next month, we wanted to ensure that the LMS is stable and ready to handle a large volume of users before we started ramping up promotion. In the meantime, we've continued to add more courses and features. Next slide, please.

In April of this year, we held the inaugural OneLab summit, a three-day virtual conference to connect laboratory professionals to each other and to CDC. This year's theme was Elevating Connections, Building Bridges in Adversity. Speakers included leaders from ASCLS, Guissinger Health System, ASCP San Francisco laboratory, FDA, Northwell

Health, and many more. In addition, to speakers from across the laboratory community, the sessions on training best practices facilitated by DLS health education specialists, the summit also included a sneak peek of OneLab REACH. And shown here on the slide are some metrics as far as the OneLab Summit. So 93% of participants reported that they found the OneLab Summit to be valuable to their learning. Over 1,000 people registered to attend the summit, and 90% of participants in the survey said that OneLab Summit helped them perform their job better. Next slide, please.

One of the summit sessions that received the feedback was a live discussion with all attendees to the summit on training needs, opportunities, and challenges. We invited a very talented graphic artist to illustrate participants' comments in real time to help build engagement in the discussion. Shown on this slide is the final graphic that was created during the session. We sent it out to attendees as a free digital commemorative poster to help ensure that participants engage in the next OneLab Summit. Insights from that session and the entire summit are informing training materials in development now, as well as topics for the next summit. We have not yet finalized the date for the 2023 OneLab Summit. When we do, we will update our web page, and also send out a blast email to our OneLab Network members. Next slide, please.

In September, we initiated a three-year cooperative agreement to support the OneLab Initiative. We are funding four recipients to provide technical assistance to CDC, and to collaborate with CDC on the creation of training materials and our workforce and training needs assessments for laboratory professionals. They will also amplify our marketing and promotion efforts by sharing updates on OneLab training network resources through their organizations' communication channels. Two recipients, the University of Maryland, Baltimore, and New York City Department of Mental Health and Mental Hygiene, are also developing curricula that will be shared freely to train new laboratory staff and support cross-training of existing staff. Next slide, please.

DLS also develops trainings on point-of-care testing. In early 2023, we will expand on that to create a network called OneLab TEST, which is short for Timely Education and Support of Testers. The goal is to develop a community of practice to connect those who conduct point-of-care testing in non-laboratory settings with CDC and with each other, provide them with training resources tailored to their needs, and empower them to train each other. Monthly live meetings will focus on identifying and addressing priority training needs. We will also launch a training of trainers program to prepare testing professionals to train their colleagues in the field. A new section of the OneLab REACH LMS will provide easy access to free training on point-of-care testing in a variety of formats. Later, we will establish an online discussion portal where testing professionals can share lessons learned. We're also exploring the potential for a mobile app, or application, to provide training resources for those conducting testing at non-traditional sites such as nursing homes and drive-thru sites. Next slide, please.

In a few minutes, our virtual reality team lead Joe Rothschild will give you a demonstration of OneLab VR. But I thought it important to give you a brief overview and acknowledge that this is a very large, as in 50,000-plus square feet, virtual laboratory clinical space. And there have been over 100 custom-built pieces of laboratory equipment in that space already. And the purpose of this is to create a multiplayer live environment where, over time, laboratory professionals will be able to conduct live training with their own staff. And so we're doing this in phases to make sure that the technology works correctly, and then building on that over time. Next slide, please.

The first piece of this is making sure that laboratories are VR-ready. So we are currently conducting a dissemination pilot with a goal of making sure that 40 laboratories are what we call VR-ready. So about 20 clinical laboratories in 20 public health laboratories will receive two to six Oculus Quest headsets, controllers, and cords, along with job aids to assist with setup of the materials, and an evaluation questionnaire. And I want to note that we have already distributed VR equipment to 30 laboratories as of today, and then there are about 80 virtual reality headsets out in the field in laboratories across the US. And we are actively gathering feedback from those laboratories through focus groups and surveys so that we can continue to improve our approach not only the virtual reality training itself, but how we disseminate this equipment. And all of this will ultimately inform how we conduct OneLab VR. Next slide, please.

So shown here is the website for OneLab. So we try to keep it simple. You can just go to www.cdc.gov,onelab. And that can take you across all of our different components as well, so you can read more about the OneLab Network and become a member. It's also where you can get connected to OneLab REACH, which you can also visit reach.cdc.gov. But you can also access it through this series of webpages. And for those who are interested or have questions, you're welcome to email onelab@cdc.gov. And with that, I will turn it over to our virtual reality training lead Joe Rothschild to give a demonstration of our virtual reality training. Thank you.

OneLab™ VR Demonstration
Joe Rothschild

MR. JOE ROTHSCHILD: All right, everyone. Can everyone hear me? All right, fantastic. So let me share my screen, and we will get going. All right, there we go. So yeah, good afternoon, everyone. My name is Joe Rothschild, and I work for the CDC as a health communication specialist in the Division of Laboratory Systems. But really, to be honest with you, I'm an innovator and a teacher at heart. And I'm lucky enough to be in a branch where that innovation and creative approach to learning is appreciated and utilized to train clinical and public health laboratorians is using virtual reality. As a note, I have little QR codes up in the corner of the pages that, if you want more information on that specific topic, you could use your camera to go straight there, which really brings us to the topic of this presentation of virtual reality. So let's get started.

All right, so I'm sure, or at least I hope, a lot of you are aware of the benefits of VR. I'm not really going to spend too much on this, but really wanted to put this out there that one of the great things about virtual reality is, really, it offers consistent on-demand training that, for the laboratories out there, doesn't require prepping like a physical training area. We all know stories of wanting to train in laboratories, but you have to decontaminate them and all of that.

So some background information. Our branch, the Training Workforce Development branch, we specialize in all things laboratory training-related. We have an amazing creative team, and we put as many 3D animations-- graphics, video, eye candy, all where appropriate of course, into these eLearning courses, really with the goal of making them more engaging, more entertaining, and ultimately more effective. We've been chasing virtual reality for around-- I don't five, seven years. And we finally got our chance to start developing CDC's first-ever virtual reality laboratory training course. And we piloted this course with internal CDC staff, both active laboratorians, laboratory professionals, and staff with zero laboratory experience, and really learned from that. VR was accepted almost immediately as a valid training modality. One of the really neat things was watching people in VR, for example, drop a pipette, and just instinctively reach down and pick it up. And we didn't really have to walk them through that, so that was a really neat experience. In 2020, we completed and launched a LabTrainingVR-- Biosafety Cabinet Edition, and that was put up for the HTC Vive headset, and was put on both TRAIN and the STEAM platforms. And if you have kids, STEAM, you're familiar with that. Think iTunes, but four games. We've really ramped up our VR production team and our offerings, and developed another VR course and released it on personal protective equipment, and added a multiplayer component to that, so people can see each other and interact in VR.

So in addition to that, we're in development of a VR course. Kelly mentioned it, that OneLab VR. It is designed for the $400 Oculus Quest headset. So for this one, you don't need that hefty VR gaming laptop. And we're really hoping that will help make it more available. As Kelly said, the course is going to be an open-world environment where people can walk around and interact. And also this year, we ported our original VR course on laboratory training in a biosafety cabinet to that Oculus Quest. And it is available on the Oculus Store. Let's see, next page. All right, so let's talk about this first laboratory training course that we did Biosafety Cabinet Edition. Like I said, it was released on TRAIN and on STEAM. And in it users are taught how to properly set up, work in, and shut down a biosafety cabinet. And I'm going to show you a quick little 60-second promo video that will give you a sense of it. [MUSIC PLAYING]

Welcome to your virtual laboratory. Available on both STEAM and TRAIN, CDC LabTrainingVR-- Biosafety Cabinet Edition creates a training space for learners to apply knowledge and build skills. CDC has developed this course for clinical and public health laboratory professionals. And by the end of the training, learners will be able to identify the major parts, demonstrate how to maintain positive airflow, demonstrate how to prepare for work, apply safe work practices, demonstrate how to decontaminate and shut down, and conduct emergency shutdown procedures of a class II biosafety cabinet, or BSC for short. We hope that you learn, enjoy, and benefit from CDC LabTrainingVR-- Biosafety Cabinet Edition.

All right, so as I mentioned earlier, we released a virtual reality course on personal protective equipment last year. It's another amazing VR course that we built for the VIVE headset. And in this course, users go through a museum environment. They learn about different types of PPE, when you would use them, the risks that you might encounter that would require additional PPE to be donned. And in this course, users can don and doff PPE. And I think you probably know, it's those suits with all the ping pong balls all over it. We motion-captured laboratory professionals actually working and doing things right and doing things wrong for this. So here's another 60-second short preview video on that course as well. [MUSIC PLAYING]

Welcome to CDC's second virtual reality training course. CDC LabTrainingVR-- PPE Edition takes place in a training museum, and creates a space for learners to learn about personal protective equipment. CDC developed this course for clinical and public health laboratory professionals. By the end of the training learners will be able to identify the routes of transmission of infectious agents, don and doff the appropriate PPE for daily use at the bench, and don and doff PPE during an emergency. Broken into several exhibit halls, LabTrainingVR-- PPE Edition features motion-captured laboratorians that demonstrate the correct and incorrect ways to utilize PPE and proper lab procedures in order to reduce the chances of exposure. Learners will be able to step into exhibits and practice what they've learned prior to entering a realistic anteroom and laboratory for a final exam. We hope you enjoy and benefit from CDC's latest laboratory training in VR.

All right, so last up on our current virtual reality development platter, we're calling this one OneLab VR. And so really, before we get into the details of the course itself, I wanted to let you know about some changes that we made to our VR process that I really think you'll find interesting. As I said before, our previous two VR courses were developed for the HTC Vive headset. And that system required the headset itself, which was around $800 or $900, as well as a gaming-style, really powerful computer that would run it. And those cost anywhere from $1,000 up to $3,000. So we're aware of the limited budgets for training that many laboratories have, so we decided to switch to the $400 Oculus Quest headset. It's obviously much less expensive. It's way easier to set up and doesn't require any sort of external computer. So instead of $3,000 to $4,000, you're looking at $400. And really, by moving to this more accessible VR system, we hope to further increase the reach and the dissemination of our training.

All right, so here's a sneak peek-- don't tell anyone, about our OneLab VR environment. We put it on the fourth floor of a fictitious building, and contains, as Kelly said, over 50,000 square feet of laboratories, and a really beautiful lobby. Each laboratory has a different specialty, different hardware, different supplies, all really dedicated to training the clinical and public health laboratory professional. The environment Provides a safe virtual space that includes 12 different laboratories. We're up to, I think, 250 different pieces of laboratory-specific hardware and equipment. In building, this we worked extensively with laboratory architects, designers, safety experts, and members of the clinical laboratory community to really create this virtual space that would meet really, hopefully, all your training needs. Everything in this environment, from the physical size and location of laboratories to simple things like the placement of fire alarms and sprinkler systems in the system, all of these things really have been rigorously researched, tested, and reviewed for the laboratory community.

So as you know, asynchronous and online learning is helpful. But really, nothing beats live, hands-on training with an instructor who could offer immediate feedback and guidance. So our OneLab VR product includes a multiplayer lobby, where trainers can really create their own environment, invite their own students or learners to join them in this laboratory. They could see each other. They could hear each other. They could talk to each other. We're not going to talk about throwing test tubes at each other, but you could do that, too, all together live and in real time. And so the plan, really, is to offer the option of this single-player environment or a multiplayer environment. So you could get trained potentially by CDC subject matter experts, or even your own laboratory manager. And once again, you're doing this all from the safety of your home or your home lab. So I like thinking of it this way. With OneLab VR, you could have a trainer in Germany working next to a student in Japan offering guidance on how to properly pipette in a biosafety cabinet, and actually be able to say, hey, hold on. Your elbows are blocking airflow. Or you didn't eject your pipette tip. You need to do that. And it's all live and one on one. So we're currently in the production phase of this. And everything, obviously, is subject to change. But the plan is to have this environment cleared and ready for walkthrough, I'm hoping by the end of the year. And currently, we're going to have it set up where users can walk around, do some onboarding, training, specimen handling, workflow training, that sort of thing. We're working on currently three to five-minute training scenarios inside it. Pack and ship-- packing and shipping dangerous codes, we have pretty much completed. We've started on centrifuge safety. We're going to do a short, little biosafety cabinet training course. We've listened to our end users, and they don't want hour-long training courses, so we've sort of moved them down into three to five-minute sections.

We're investigating future training courses, like autoclave safety, laboratory safety, chemical waste clean-up, a lot of PCR training, that sort of thing. So really, as we continue building and adding to this environment, we'll be loading it with more complex scenarios, organism-specific training, and really rounding out the programming, so you'll be able to train on a large variety of scenarios and skill sets. All right, I don't want to stop, because it just looks so great. But I will move on. All right, so once again, I want to remind you that if you'd like more information on our virtual reality activities, you could always send an email to vr@cdc.gov. Or even better, you could visit the VR webpage at cdc.gov/labtraining/vr.html. And yeah, with that, I'll turn it over and open it up to questions.

CLIAC CHAIR: Big, big wow. Wow. That was absolutely amazing. Thank you. [CLIAC MEMBER].

CLIAC MEMBER: Yeah, that's that was amazing, and it's very impressive. And I once said, I got a chance to try it out in real time, because it was being demonstrated at a meeting that I attended, and CDC was there. And they have a table with that on, and I got a chance to use it. And I was surprised at how fast I felt very comfortable with the technology. So it's really impressive stuff. And I'd like to take it a step further, and like to hear if it's going to go to that point. Could this these training tools, the VR and other courses that CDC has offered, be used, then, for CLIA competency requirements? Can we expect that to be a useful tool for the clinical labs to have their staff participate in, and then demonstrate to inspectors that they have been judged as competent in that field?

DR. KELLY WINTER: I'll take a stab at answering that, and then invite [CLIAC DFO] in particular to weigh in if he has other thoughts on this. There are no limitations to what topics we could cover, [CLIAC MEMBER]. I mean, anything that is needed, we certainly could. I think the biggest piece from our standpoint is having material to base it on speeds up the process of development. Whenever we have to start from scratch, and consider how to approach a course, it's going to

take longer to get that through. But if there are materials available-- it can be as simple as a handout. It can be a video of someone performing an activity in the past. But something like that that starts as a material for us to build upon would help expedite that substantially.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Oh, as a continuation of what [CLIAC MEMBER] just said, could this be used to solve a testing problem or a PT problem with labs with a certificate of waiver? This might be the solution to the problem we discussed yesterday.

CLIAC CHAIR: I'm going to assume that was a rhetorical question.

CLIAC MEMBER: Yes.

CLIAC CHAIR: Certainly, we all had that exact idea of those 259,000 labs. This is what they got to do.

CLIAC MEMBER: I was thrilled to hear of OneLab in a prior CLIAC meeting, and then to be participating in the summit that was described. But I haven't yet lobbed it into our regional discussion of training the next generation of laboratory professionals until what you said just now, which is the opportunity to have multiple people in the same virtual classroom, and to have distance with it. Because as has become painfully apparent, as we look at the New York region's ability to train laboratory personnel, the two biggest pinch points are the practical training in the educational institutions and practical training in the hospital setting. And in the first instance, the cost of training a laboratory student is vastly greater than other health professions because of the wet lab requirement. And in the latter instance, the overworked laboratory professionals already employed don't have the time to do the training. So I embrace and encourage your virtual multi-person space. And I think once you have validated and tested it, we should shout this from the mountaintops and really go to work to bring virtual classroom training into play. As one of my regional people said, we've run out of runway in terms of bringing new people into the workforce. So I applaud what you're doing, and look forward to this immediate next step with great anticipation.

DR. KELLY WINTER: And [CLIAC MEMBER], I just want to thank you for participating in the OneLab Summit. Your presentation was so helpful. And I just want to mention, since you mentioned the next generation, one of the things that we're also exploring with this technology is disseminating it through our fellowships and internships program with public health laboratories, not only to help the labs themselves be able to onboard those fellows and interns more quickly, and reduce some of that burden on the mentors and the host sites, but also to get their feedback on where they, as fellows and interns, see this technology to be useful. And also secondarily, make sure that they are, in another way, an asset to their host sites, and that they can be on-site support in helping set up these headsets more quickly and whatnot.

CLIAC MEMBER: To touch on the point that was just made about this being a mechanism for waived testing, the barrier I'm talking about with great anticipation is overcoming the person who's going to become a fully certified and licensed laboratory professional because the practicum classroom need is so great. It's a six-month, it's a one-year process. It's not just a certification, sign up once and make sure you get the certificate slip.

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

CLIAC MEMBER: OK. Good morning, everyone. This is exactly what we were talking about yesterday. The way to reach even more people, if you can envision, there are going to be areas that some of these are going to be low-income. They're going to be not able to get the virtual reality for every single person. So if you can envision these sessions going on, but then also being taped in video storage, video content, so that a person could actually just watch a live class on video. So there's a way to even distribute this more to the masses by videotaping these virtual reality classes that we can all learn from. It's wonderful. You guys have really nailed it. Thank you.

DR. KELLY WINTER: Yeah, and thank you so much for that suggestion. I will say that we are doing our best to make sure that as we disseminate the VR equipment, we are looking at resource limitations within specific laboratories, looking at rural laboratories and things like that as far as who we prioritize. But I love the idea of taping the sessions as well as just one more way to get that out.

CLIAC MEMBER: To scale. This is how you scale, and really thinking about the underserved. We've got to make sure that they get this training. They need safe diagnostic testing just as much as everybody else. So we need to bring them in, and your program that you've set up with the VR is fantastic Thanks, you guys.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. Thank you, Dr. Winter and Joe. Several things I heard him say-- that the testing is free for those who are conducting test at POC, which is excellent, because I would hypothesize that would increase the validity and reliability of those test findings. And so there would be less opportunity for misdiagnoses and harm to patients. And so that was excellent, in terms of what we went over yesterday and what we're looking at now in terms of some of the recommendations that we're planning to consider at the conclusion of our study. My comments are also based on the fact that there seemed to be very little oversight and inspection of those laboratories that have certificate of waivers. So as a matter of fact, I was reading last evening, that one particular source said less than 2% have any type of formal evaluation. So as long as we can increase the competency of those that are doing the test, I think we're headed in the right direction. Thank you.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yes. Thank you. First, I'd like to compliment Dr. Winter on your graphic. You did indeed have a very talented graphic artist. I had to blow it up on my iPad so I could read the small print. And I think you nailed the various challenges to getting people into the laboratory profession. I think VR is a useful tool for competency-- to build on [CLIAC MEMBER]'S comments, competency of those that are already in the profession. My question is if you're looking at how it will assist in finding clinical sites for those people to bring new laboratory new laboratorians in because the training is such an issue. One of the things that I've observed locally is that our local university churns out thousands of bachelor's degrees in biology. And they actually have one course in phlebotomy, because that will be the only employable skill that they will graduate with. And my question-- I'm rambling, I guess, a little bit. My question is, are you going to work with academic institutions perhaps who have biology programs to see how you could partner so that they could add a clinical laboratory curriculum, so that they have other employable skills besides phlebotomy when they graduate? And it strikes me, too, that academic organizations as partners would be able to assist perhaps in content development.

DR. KELLY WINTER: So thank you for that. No, we have not made that a specific objective. However we are partnering with academic institutions through our laboratory internships and fellowships program within public health laboratories. And particularly to your point about content that already exists, that's one of the things that we are prioritizing as far as what we get from those SMEs that are going to participate in that. And now that you've mentioned that, that's certainly something we can raise while we're in those talks to see what would be feasible. So I'm glad to hear you mention that. Thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. That was really wonderful. The first comment I want to make is, I want my lab to look like those pictures. So I think the reality of how crowded everything is where we are in our real labs is not like those. But that'll be the goal, to get to that vision. My concern is what [CLIAC MEMBER] had brought up, and other people, about the equipment. And I'm worried about, if people make this purchase, is it going to change, and all these kinds of things that happen with that kind of techie equipment? The other thing is, I do think we need to think about how do we make it more viable potentially. Like, let's say we do yearly training, and we have that capacity to do that. Can you share sets and send them to the next lab, or do something like that, so you could share costs of that. But having run a medtech program, we were the only laboratory system that was willing to take those medtech students. And to the point of [CLIAC MEMBER], it was really tough on them to continually train. And having that ability to do a virtual classroom is really a gamechanger, because other sites might be more willing to actually do that teaching component, because I don't have the physical space necessarily. So it might actually open up our capabilities of doing stuff. The other thing I think would be really cool is-- I mean, I think you've got to get to kids much earlier just to get them excited. Hey, I'd do a six grade, seventh grade workshop. And if I went in with virtual reality, they'd be flocking to lab medicine. So I think I would really like to see if that's a possibility I could do for my next volunteer lab sessions. So anyway, thank you very much.

DR. KELLY WINTER: Thank you. And I'm going to toss it to Joe in a second to talk specifically about how the technology continues to evolve, and how we're trying to make sure we futureproof that to the extent possible. But I just wanted to start by saying that we focus on those 40 initial labs that we want to disseminate equipment to. But that is not the end. I don't know that we'll ever get to every lab, but we are going to do a lot more than that. But first, we wanted to get that initial data on how well this was working, our approach to even shipping it out. And I do want to give a huge thank-you to APHL for their help in physically disseminating this equipment out to the labs in partnership with us. So this is the beginning of that part. And one of the other data points that we're going to get from this initial evaluation is how many headsets do you need in a laboratory divided across how many staff you have for this to be feasible as something that you can share and have enough for your staff needs. But with that, I'll toss it over to Joe to talk about how the technology continues to get a little bit more cost-effective, thankfully.

MR. JOE ROTHSCHILD: Yeah, and definitely, we went into this whole process knowing that-- who knows what the final VR project or VR hardware is going to be? My Spidey senses tell me, if you look at what's happened with cell phones, five years ago, you needed to download an app to do any kind of AR-- augmented reality. It was a secondary tool that you

would have to install on your cell phone. Now that capability is built natively into every cell phone. I'm thinking that the way it's going to go is VR, once phones get powerful enough, will be built into this, where you'll be able to drop it into a headset. It will have hand tracking built into it. And everyone will just be able to use their mobile devices for it. But keeping that in mind, the way we're actually building this is with a tool and a technology that, wherever the industry goes from a hardware perspective, we're prepared, we're flexible.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: [CLIAC MEMBER] has anticipated my comment, which is next Thursday, Friday, I will be co-manning one of three laboratory profession tables at the annual New York State High School Counselors Association. The 2023 American School Counselors Association in Atlanta is July 15 to 18 have a virtual reality encounter is something that connects. And this is a very robust discussion. I've been told by a school counselor, set up in a cafeteria, and you will have students come. So the recruiting potential of this technology, let alone the training potential, is something that I think can really connect.

DR. KELLY WINTER: Thank you for that. I'm glad you mentioned in particular, again, the need to inspire the youth, essentially, to get interested in this. And while that is not specifically within our purview in DLS and in TWDB. I will say that, because we have these courses available on publicly-available gaming, the STEAM site and whatnot, there's no reason, either through our website or through steam, that you couldn't direct students or suggest to students that they try it out. And our assumption would be a lot of them might already have this equipment. Over.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you, Dr. Winter, for that presentation. It was really remarkable, all the work. But I did know the involvement of different groups in here, and I didn't hear you speak much about the commercial labs' involvement, and the manufacturers' and vendors' involvement, in this effort. Could you talk a little bit about what the response from those groups has been, and what they might be working on with you and others?

DR. KELLY WINTER: So thus far, we have not had any specific partnerships with commercial labs around this. But that said, we have demonstrated this at clinical laboratory partner forum, or at least touched upon it. And it's something that surely, we would be interested in. But four years in, we've tried to prioritize what we could do quickly, and with the partnerships that we already have largely, and people who've been invested in this intellectually with us from the start. But I think that's a welcome suggestion.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: So in the business development realm for this, one of the things I would suggest is, as you think about your partners, and as you think about developing the program, if you strike up an area of health equity, and you find a way to provide incentives, for those people who are using the full program, they are rolling this out at Quest Diagnostics. And if you offer them participation in your health equity program, the taping of what they're teaching would be shared to those on video, I think that's a way to make sure you get content right away that you can start rolling this out on a secondary program. That would teach the teachers and teach more people at once in the spirit of health equity. I think that's something that would be great to start out with from the very beginning. Thank you for that.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, this is great. It has a lot of potential. And I have heard several of you talk about the fact that we need to get to the young people and get them excited somehow into the laboratory profession. And [CLIAC MEMBER], I think it was that mentioned the counselors are meeting in Atlanta? Well, that's great. Those of us that live in Atlanta should take this opportunity. I've been trying to get in touch with key counselor groups for several years to try to tell them that this is an option for their students who are interested in science, and maybe good with their eye-hand coordination. And they would be great as laboratory professionals, but nobody knows about the laboratory profession, or at least...

CLIAC MEMBER: Ours is a regional campaign right now next week. But it needs to be national.

CLIAC MEMBER: All right, and then one more comment. I'm thinking like a scientist. Has an experiment been done yet-- and this is probably for Kelly, I guess. Have any experiments been performed yet to compare those people that get trained in the traditional way with the VR training? And are they just as good, if not better?

CLIAC MEMBER: So there's a great question. We did do an initial evaluation of the effectiveness of VR training, specifically the biosafety cabinet course. So we did that with CDC employees largely because it's much quicker to do it that way. And we did find that it built not only skill among those who were novices, so we did have non-laboratory staff

from CDC participate, as well as seasoned laboratory staff. Not only did it build skill within those who were novices, but it also built confidence even in those who were very proficient to begin with in using the biosafety cabinet. So that was the extent of what we've done so far to compare it. I think once we have more equipment out in US laboratories, we could look at doing something a little bit more robust.

CLIAC MEMBER: Yeah, I think that would be great. You're getting it right away. If you can do those experiments, and show that VR teaching is just as good, then you're going to remove any skepticism that people might have. So very good.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. This question goes to Dr. Winter. And as part of your needs assessment-- we're people that are into quantification, were you able to do an assessment of what the shortfall is predicted to be of laboratorians. For example, our local VA here in Grand Junction closed to inpatients for eight months because they had insufficient lab staff to staff 24 hours a day, and could no longer operate as an acute care facility. They just were able to reestablish that by finally finding enough laboratory professionals. So with that preface, we know that it's real. We know that it can compromise health care. Do we have a sense of what the number is of laboratorians that we need to find.

DR. KELLY WINTER: So we see you see do not yet have that magnitude quantified. That is something that we're working on through that workforce assessment with HRSA, and with our clinical partners as well. I'm sure that there are other organizations that might have a sense of the magnitude so far, but I don't have any numbers with me on hand. But that is something that we hope ultimately to do with the workforce assessment that we're doing with HRSA.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I know we're talking about education here, but it was interesting, with COLA, we're looking when we're certifying labs actually using VR technology to be able to look around a lab and do your certifications virtually. I just am saying I think the future is really unlimited in terms of where this could go and how we could use these types of technologies. So it's really cool, and thanks for the lecture. It was great.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. Dr. Winter, you mentioned that one of your aims is to increase a diverse workforce. I believe you talked about DEI and inclusivity or accessibility. And you also received-- clarify if I misunderstood, some of the American Rescue Plan monies, maybe $55 million or so. And how is that being used to increase the DEI and accessibility?

DR. KELLY WINTER: I just have to start by saying it's a topic particularly dear to my heart. My PhD is an epidemiology, but it's specifically in health equity. So I'm really thrilled to help bring this approach to the laboratory space at CDC. So the $55 million was American Rescue Plan funding for OneLab. So there's that bucket of ARP funding that directly goes to everything that we've talked about as far as VR needs assessments, the network, et cetera. There's a completely separate line of ARP funding that was provided to us to do the fellowships and internships program and public health laboratories. And that was much larger. So that was $282 million. I have to make sure that everyone is aware that about 80% to 85% of that is meant for the stipends for the fellows and interns themselves-- moving expenses, et cetera.
But with that, that was our opportunity to look at diversity within the laboratory workforce. And so what we're doing is looking to increase the diversity within both the applicant and selection pools in the internships and the fellowships program. So over time, we will be working with the SMEs that I mentioned at the beginning to look at what can we do not just in terms of recruiting. Obviously, recruiting is very important and marketing, but really looking at what barriers exist to students even considering pursuing these applications. And I want to stress that we are looking at diversity across multiple dimensions-- so not only race and ethnicity, but sexual orientation, gender. We're looking at the proportion of veterans that are within the application pool and the selection pool, the proportion of students with disabilities, et cetera, and looking at what we can do to make sure that more students from those underrepresented groups and communities are compelled to apply for these programs, are clear on what the selection criteria are, are clear on what the opportunities are as far as where they might be sent to host sites. I think in particular, something that's on my mind is making sure that if I were a student who has a disability, for example, what might I have concerns about being placed in a rural area without any confirmation of what the transportation situation might look like. But really, one of the main focuses of having these subject matter experts that we're going to fund a portion of their salaries is to get their thoughts on how we can address these barriers as quickly as possible. So we're looking specifically to partner with academic professors, and also people who lead student organizations-- for instance, the head of an LGBTQ+ student organization, or the person who runs the office of reasonable accommodations in a particular place, so that we have a wide representation of perspectives of what the issues really are, and some really feasible solutions that we could implement as quickly as possible. And so we're not going to wait until we have all of those recommendations to start looking at what's possible. We're going to prioritize them

in terms of how quickly some of them can be implemented and start looking at how well they work, and then adjusting from there. So I hope that answers your question, [CLIAC MEMBER]. But feel free to make sure if I missed any pieces.

CLIAC MEMBER: That's excellent. Yes, it does. And Joe had mentioned that there's free training. Is part of that rescue fund money used for that free training?

DR. KELLY WINTER: Yes, so the $55 million funding that goes to OneLab is really to create all the free trainings. And then we are creating specific trainings for the fellowships and internships program. But out of responsibility to taxpayers, as well as just general prudence, we're trying to do what we can to make sure that anything we're developing for OneLab that is appropriate for the fellows and interns we'll just turn right around and offer as part of the competency-based curriculum for the fellows, for instance, so that we're not duplicating efforts for any reason. So a large portion of all of this funding goes directly to creating trainings, whether that's webinars, VR, eLearning courses, job aids, et cetera.

CLIAC MEMBER: Thank you very much. Excellent.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: The question was asked about what is the need in the workforce, and yesterday was mentioned the national coalition of organizations that are addressing this. I chair the Consortium of Academic Clinical Laboratory Leaders in New York State. And over the past year, this has been our top priority, working with New York State Clinical Laboratory Association, Greater New York Hospital Association. In data publicly reported at the NYSCLA September 2022 conference, a survey that was completed in September of 2022 showed that, for responding laboratories representing 19% of all FTEs in the state, we had a 22% shortfall in the number of laboratory professionals we needed. And it was very consistent across all of the reporting institutions, academic and non-academic. So as a sample of a rather substantial portion of the state of New York, that 22% would consume the entire annual production of new certificates per year, leaving the other 80% of labs without any new people. It's a very dramatic and sobering statistic.

CLIAC CHAIR: Thank you, [CLIAC MEMBER].

CLIAC MEMBER: There is more data in the survey. But needless to say, this has been our top priority in the state of New York for this academic lab consortium, and has dominated our landscape once we cleared the baffles with COVID testing.

DR. KELLY WINTER: And I will say, we would love to fold your data into what we're doing as appropriate. We never want to recreate the wheel, and we want to leverage what partners have already done in this area.

CLIAC MEMBER: I can put you in touch with the purveyors of the survey information.

DR. KELLY WINTER: Thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thanks, [CLIAC MEMBER]. That was really good information. Was that equally distributed across urban and rural areas?

CLIAC MEMBER: Yes, we had about an 80%, 20% proportion. As measured by FTE, it was about an 80% urban, which is downstate, versus 20% upstate. It was a consistent finding upstate and downstate. And the comment about training is-- and we're working with educational leaders across the state, is that students learn local and they work local. And so distance learning has its downside in that you invest in a distance, and you don't get the student because they're going to stay local. Again, very rich topic. We could go on. I'll stop right there.

CLIAC CHAIR: So I have three questions. For those of you who know me, it's a remarkable show of restraint that I made it to the end. For [CLIAC MEMBER], first I'm giving up my day job in this jail cell and I'm going to go live in that virtual lab. It is gorgeous.

CLIAC MEMBER: There you go.

CLIAC CHAIR: So I wanted to explore a little bit more. I think it was [CLIAC MEMBER], who brought up whether or not these could serve-- or maybe it was [CLIAC MEMBER], could serve for competency assessment. I'm certainly very curious how we could, not only for waive labs for training, but for moderate complexity point-of-care testing, which right now is a real labor-intensive way to assess competency. So I would just put that out as an ask. My second issue is, have we explored external agencies-- and I'm thinking about the Department of Transportation or OSHA, for certain types of training that today require in-person training? An example of that is category A shipping and packing training. Is there

some way this could substitute for an in-person, so that I can train a lot of my staff at their convenience instead of getting a live body in to do that training? And then my third-- and this is for the old-timers. There used to be a Coordinating Council for Education that CLIAC had reports from periodically. And this gets to both [CLIAC MEMBER] and [CLIAC MEMBER]'S comment about having that Coordinating Council liaison with these high school counselor things nationally to get our foot in the door way early in the training game. So that's the question. Do we still have that Coordinating Council live? And if so, do we need to make an official recommendation to have that coordination occur? Or can that happen without? So I would ask [CMS EX-OFFICIO] and [CDC EX-OFFICIO] or [CLIAC EXECUTIVE SECRETARY].

DR. KELLY WINTER: So I just want to thank you for question one, which I think was more of a suggestion, but very, very hopeful. And then as far as DRT and OSHA, we have not engaged with them yet. But that is an intriguing possibility as far as something that could be feasible long-term. And then I'll cede number three to [CLIAC DFO] or [CLIAC EXECUTIVE SECRETARY].

CLIAC MEMBER: So I can chime in on the Coordinating Council. At least from a few years ago, it was still active and still doing its thing. It frankly didn't have very much positive output. And I tried to talk to them and convince them to get in touch with the high school, and even the middle school, counselors to tell them about the clinical laboratory jobs that are available. And they weren't able to, as far as I'm aware, take action. And today, I don't know if they're still active or not. I'd be interested if anybody else knows for sure.

CLIAC CHAIR: [CLIAC MEMBER], maybe we need to redirect. Maybe the Coordinating Council is not the action point. Maybe it needs to be the front-line folks who are members of ACLA, ASM, the societies where the front line lab staff—AACC, Yeah, and they go to their community high schools and use these virtual tools to try to engage interested youths.

CLIAC MEMBER: And to that point, I did talk to somebody ASM, because I had created this whole module for seventh grade a live workshop kind of thing that was really super well-accepted by the middle school teachers. But during the middle of the day, I was asked for the whole school to do a presentation on lab stuff. And it was really super well-received. And so I think it was like, oh, could we get what you've done and use it in other places? So I think it's getting a coordinated component. It sounds like [CLIAC MEMBER] has a great setup in New York, and I just don't know how you create that component. But Ellen Jo Baron, who was still doing teaching in ASM said, oh, you've got to provide this to ASM. And I'm like, yeah, but to who, and how does it move forward? I think that's the thing. Like, it's been an impetus for individuals, but it could be fabulous if it was more coordinated.

CLIAC CHAIR: And we can build on what others have already developed. OneLab is one of them. [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: Yeah, first of all, it's fabulous and it's exciting, and I'd love to see it. I think once anybody under 15 gets introduced to this, they're going to love the lab. The other thing I would suggest is, then, we could employ those people, as we talked about, home collection. And if we have a module for home collection, this may be, as we talked about yesterday, the concerns about preanalytic components, this could be a nice opportunity to help close that gap. But it will mostly apply to people who are 20 and under, I suspect. So we're training a new cadre of lab people, and we're getting them involved right away.

CLIAC CHAIR: I would expand that larger than home collect. I want to roll this out to my OR techs, my endoscopy suite, you know, like how you label it and get it to me. So specimen collection is an obvious need. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, and just to reiterate a point I made earlier, you get them excited. They like science, they go off to college, they get a bachelor's in biology. And there's nothing they can do with it. So I really think that, as well as concentrating on high schools, we need to think about the undergraduate biology programs, and how we get those folks into a clinical training program, which as we've mentioned are few and far between. It's hard to find places that will take folks for the hands-on laboratory staffing, which is something that Dr. Winter and Joe are working on. But I also think that attention going towards undergraduate university programs would be well spent.

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

CLIAC MEMBER: OK, I was going to ask Kelly, how long does it take to build these modules? Because obviously the content is so needed, and everybody's already giving you about 10 suggestions, right?

DR. KELLY WINTER: That's a fabulous question. It used to take a really, really long time. We have improved that if we were to start from scratch, you can take a year or more. But that is actually a really important piece of OneLab VR that we didn't do a good enough job in this presentation of emphasizing. We stopped after these first two courses and said, we can't keep starting from scratch as if we're essentially building a lab. So by having this OneLab VR space, not only will laboratory staff be able to train each other in it. We can also have just-in-time modules in there that are on-demand. So by

building out that whole space now, and starting to build more and more equipment-- as long as it's equipment that we already have available and functioning in that space, it speeds it up substantially. That said, it entirely also depends on how much we have the content nailed down as specifically with the correct way to perform a particular procedure. So the more of that we have, the faster it can happen. So I would say, depending on the length and whatnot, we could find ourselves, once OneLab VR is released, in a place where it could be more like four to six months for short-term things. But really having that multiplayer live capacity, and make sure that in true just-in-time situations, trainers themselves could get in there and do the training. We just had need to continue to build out more of the equipment. And some of the pieces that you see in there are functional, but perhaps not to the extent that you would need, depending on what you're trying to train on. So it's really prioritizing how we can do that.

CLIAC MEMBER: Yeah, I think that was one of the questions somebody else asked. Have there been industry partners that could help speed up that component for the equipment that you have in the lab? And I think they would be very willing to help with that, too.

DR. KELLY WINTER: That's a very helpful suggestion. There are some challenges about how we would have to go about doing that. But it's not impossible as far as how we could look at partnering that way.
While I had the floor, just quickly, I wanted to mention-- back to the point about packing and shipping. I hope you all are already aware, but I just wanted to make sure I mentioned that we have an eLearning pack and ship course. It's not sufficient for initial certification, but it is a piece of the packing and shipping training. And we also do training of trainers virtually now, where we work with laboratory staff who are SMEs in packing and shipping out in the field to make sure that they have what they need to train their staff, and to train staff even beyond their own lab. So the people who participate in that program agree to train at least 100 staff a year in packing and shipping. So it's not a perfect solution, but we are just constantly looking at different ways to address that. Over.

CLIAC CHAIR: That is fabulous. Thank you. Well, [CLIAC MEMBER], then [CLIAC DFO]. Then we will move [CLIAC MEMBER].

CLIAC MEMBER: Two comments-- both in New York State and nationally, NAACLS-accredited training programs are undersubscribed. So this is not just pinch points of practical training, which leads to the second comment. When I say working with educational leaders, these are the associate colleges and the baccalaureate programs in our region. The Dean for the College of Health Professions of the City University of New York points out that, of her 150,000 students, only 100 per year find laboratory sciences. So we definitely have work to do at the higher level of learning.

CLIAC CHAIR: [CLIAC DFO]?

CLIAC DFO: Yeah, I just want to return quickly to the specimen collection and home collection idea in VR, and asking a question of Joe. And I'm pretty sure I remember this when I did a longer actual virtual walkthrough of the OneLab VR space, in that it's almost more like a hospital space with tons of different rooms. And as I recall, Joe, one of those rooms was a specimen collection room, and one of those rooms was a pack and shipping room. And they weren't well developed, but I think you and your colleagues had already anticipated that those would be subjects that we could build out at a later time. But I think those are great ideas. It seems to me, if we had the right SMEs, we could probably build out those pieces fairly quickly. Joe, is that correct?

MR. JOE ROTHSCHILD: Yeah, absolutely. Our whole goal was to make this an open sandbox pile of LEGOs that will provide you all the pieces, and then you just put them together in whatever fashion you want. So yes, all that sort of in place. We have phlebotomy rooms already designed, and all of that as well.

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

CLIAC MEMBER: Thank you. It's certainly an excellent presentation. So thank you for presenting. And there's been so many comments. I apologize if you've already answered this and I just missed it. So if it's a repeat, please tell me. Have you thought about, or have you already addressed, the, quote, "computer horsepower servers"? Because I would imagine, with the enthusiasm that you're seeing today, that you turn this on. Has that already been discussed or have you thought about that?

DR. KELLY WINTER: We have mentioned it, but I'll toss it back to Joe to talk more about it again. It bears repeating.

MR. JOE ROTHSCHILD: Yeah, absolutely. So by moving to the Oculus Quest headset, all that you need in order for you to access the training is the $400 headset. And then you need a mobile device for, like, five minutes that has a Wi-Fi connection. And then once you get it configured, that's it. Because basically, you need to connect your phone to the headset to say, hey, headset. Here's the Wi-Fi account I want you to connect to. And then once you do that, you can download the training from the cloud. So yeah, very little-- no horsepower needed.

CLIAC MEMBER: Gotcha. So that so this doesn't reside at a central location, correct?

MR. JOE ROTHSCHILD: Correct. Yeah, it's all downloadable through the Oculus Store.

CLIAC MEMBER: Yep. Gotcha. All right. Thank you.

CLIAC CHAIR: [CLIAC MEMBER].

CLIAC MEMBER: Hi. I just wanted to say that our laboratory has participated in the pilot program, so we have really enjoyed the experience. And I hope I'm not telling tales out of turn. But in some of the follow-ups, the packing and shipping ask was actually very much a popular ask in some of the follow-up discussions. I think that you are right on when you mentioned that. And I know that was something that I also requested, and saw that this would be an excellent use and need for in our laboratory as well. And I also saw generationally that our younger techs were really excited and jumped on. And some of our older techs lagged behind a little bit and were a little more hesitant. But then they were also-- kind of came aboard. But I just wanted to also just mention, having some firsthand experience with this, how exciting its been in its use in our laboratory. And thank you.

DR. KELLY WINTER: Well, thank you, [CLIAC MEMBER], for being a participant. And Joe tells me that the small pack-and-ship little mini course that we're going to do in VR is about 95% complete. So we hope that will be available in a few months. We're still waiting for all of the focus group data to be compiled, but I keep hearing little snippets of what's been provided from the laboratories. But it's helpful to hear directly from you that you found it helpful. And I will say, I do hope that by getting these headsets into the hands of fellows and interns, perhaps that will help with some of the generational gap that you're talking about.

CLIAC CHAIR: Thank you both again. We are awestruck by those incredible presentations. Two comments-- Joe, if you build out specimen collection in a hospital environment, make sure you build in all the distractions. You cannot get a specimen collected without side people interrupting, and that's how it goes sideways.

DR. KELLY WINTER: Great. I agree completely.

CLIAC CHAIR: Our next speaker will be Dr. Alexandra Mercante. She's been waiting so patiently. She will be speaking on the CDC Clinical Laboratory Partners Forums update. And I do want to warn you, Dr. Mercante, you can see we are all at a state of heightened excitement, so just be careful.

CDC Clinical Laboratory Partners Forum Update
Alexandra Mercante, PhD

DR. ALEXANDRA MERCANTE: Thank you so much. Good afternoon, everyone. My name is Dr. Alexandra Mercante, and I'm the associate director for communication in CDC's Division of Laboratory Systems. I'm going to speak to you today about CDC's Clinical Laboratory Partners Forum. I'll provide some background about the forum, a summary of our last meeting in June, a preview of our upcoming meeting later this month, as well as information about how you can become a member of the forum. Next slide, please.

CDC's Clinical Laboratory Partners Forum, or CLPF, was formed in 2017 to strengthen relationships among the many different professional organizations that represent the public health and clinical laboratory communities in the United States. As you can see by the logos on this slide, this network is incredibly broad, comprised of 24 partner organizations, including associations that represent hospitals, clinical chemists, clinical pathologists and microbiologists, accreditation organizations, and standards developers, associations representing commercial laboratories and public health laboratories, the nation's epidemiologists, as well as FDA, CMS, and CDC. Next slide, please.

The forum has steadily grown since its inception five years ago. The forum meets at least twice a year, and met more frequently during the height of the COVID-19 pandemic. To date, CDC has held 11 Clinical Laboratory Partners Forum meetings. The forum most recently met on June 18, 2022. 18 partner organizations were represented, and a total of 55 participants were at the full-day hybrid event. Members joined both in-person and virtually to discuss laboratory workforce challenges, like recruiting and retaining laboratory professionals, the impact that the COVID-19 pandemic has had on laboratory workforce job satisfaction and burnout, and outreach to students as early as middle and high school to foster awareness about laboratory professions. Forum members also noted that clinical laboratories have never had a higher profile and higher visibility than now. And they highlighted that this is the moment to speak with one laboratory community voice Forum members also emphasized the importance of health equity and equitable access to testing, as well as our commitment to applying lessons learned from the COVID-19 pandemic response as we tackle current public health emergencies like the ongoing mpox outbreak. Next slide, please.

One key outcome expressed by forum members was the need for focused meetings to explore topics like laboratory workforce challenges and health equity issues in more depth. Because of this, we are hosting our next Clinical Laboratory Partners Forum meeting on November 30 from 1:00 to 4:00 PM Eastern Standard Time. And the goal of this meeting is to identify synergies between workforce development projects and discuss opportunities for collaboration. During this virtual event, forum members will have the chance to participate in interactive breakout sessions where they will take a deep dive into discussing laboratory workforce topics like recruitment, training, staff retention, and career development. The breakout sessions will also allow forum members to discuss and share what they have accomplished in these spaces, what they hope to accomplish in the future, what they need to meet their laboratory workforce goals. And importantly, it's a chance for forum members to identify opportunities for new partnerships to help achieve laboratory workforce-related goals more effectively and efficiently. Next slide, please.

The clinical laboratory partners forum remains a foundational platform for CDC and partner organizations to communicate and collaborate on issues of mutual interest and concern. If you are a member of a partner organization that would like to be part of the forum, please reach out to us at CDC by sending an email to dlsinqueries.cdc.gov. And we'll be happy to include you in the forum's future meetings, as well as our email distribution list. Next slide, please. Thank you so much for your attention and time. Next slide.

CLIAC CHAIR: Thank you. Thank you very much, Dr. Mercante. Are there questions, comments? Like [CLIAC MEMBER], are you part of this forum? Are you running this forum?

CLIAC MEMBER: I was taking notes because I definitely want to figure out which organization I'm part of that can join this. I'll reach out in some fashion.

CLIAC CHAIR: Crystal clear. There appear to be no comments, so thank you very much. I would also shout out to [CLIAC MEMBER] in Atlanta. Consider the Partners Forum to help you with reaching the middle school, high school group. [CLIAC MEMBER], you know where you need to go, right?

CLIAC MEMBER: Well, that's a good comment. I will take that. Is that part of the goal of this health care forum.

CLIAC CHAIR: To have your voice heard.

Committee Discussion

CLIAC CHAIR: If there are no further questions, I just want to publicize what has been going on in the chat. There are two links that were included for the lab training website-- www.cdc.gov/labtraining. And there was a second link provided specifically for the packing and shipping training course. And then if there are no further comments on this session, our break is scheduled for 2:00 PM, 11:00 AM my time. And we're only at 9:38. Oh, [CLIAC DFO], wants to say something before I go charging off. Go ahead, [CLIAC DFO].

CLIAC DFO: Yeah, I, did just want to-- so this is our session on efforts to address public health and clinical laboratory workforce challenges. And you, as a committee, don't have to make any recommendations on this topic. But if you wanted to make recommendations for HHS, this would be the time to do that. And for consideration, [CLIAC CHAIR], if there's no interest in recommendations on this topic, we could potentially use the available time now to return to some of the draft recommendations from late yesterday.

CLIAC CHAIR: Thank you, [CLIAC DFO]. So I'm curious. Some of the thoughts I was having was, can the OneLab in some way be accepted for things like competency assessment-- so for example by CMS to meet our CLIA regulations, or the packing and shipping the DOT in OSHA collaboration, would those need to be official recommendations from this committee?

CLIAC DFO: Yeah. I mean, for instance, you could consider recommendations to ask CDC to specifically look into the possibility of using these resources for those purposes. I think it would require a lot of work across the agencies, obviously. And I'm not sure how we would go about doing that. But, I mean, that would be an example of a recommendation that you all could give us, and it would compel us to move in that direction.

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

CLIAC MEMBER: This is unrehearsed, but on the topic of potential recommendations to HHS with regards to laboratory workforce, the discussions of the last year of the New York State Laboratory Leadership Consortium have included mention of the need to communicate to public authorities-- whether it's city, state, or federal, the importance of investing in the educational pipeline. And among many topics, which are dutifully recorded in the minutes that I also do, is educational

scholarships, loan forgiveness programs, investment in health care entities that bring students into the clinical laboratory for training. So there can be, in essence, resourcing of something that has been under-resourced, and therefore closed, over the last 20 years. There is a desperate need for public funds investment in some manner in the educational pipeline. And this is a nascent dialogue, even at the level of New York City, which is investing in workforce. I would welcome opportunity to engage in dialogue at the federal level for how we could move advocacy forward in this direction.

CLIAC CHAIR: So [CLIAC MEMBER], while you mull this over, [CLIAC MEMBER], create a possible motion for us to consider.

CLIAC MEMBER: OK.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I think I'm just overwhelmed about all the resources. And so one of my recommendations would be if we could somehow get clarity how we could do that a little bit better for the purposes of education, because we've talked about funding at various different levels of scholar-- just too many resources. And I think people get overwhelmed, and then the message gets lost. So how can we target better? And [CLIAC MEMBER] you talked about-- excuse me. It was also talked about all the other things that go on that we didn't really address. Like, we're talking a lot about education. But salaries, stress, all these other components haven't really been dealt with. And we really need to understand not just attracting, but retaining. And so I'm just finding it a little overwhelming with all the possible resources. And so my recommendation would be a way to corral that a little bit better?

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. I'm struck by Dr. Mercante saying the forums have identified that this is a time of high profile for clinical laboratories and we need to speak with one voice. And yet the poster that Dr. Winter presented with all of the issues facing a lab has, like, 50 things on it. So how do we as a group narrow on the few things that we can prioritize and speak with one voice.

CLIAC MEMBER: With one voice, exactly. OneLab, one voice. [LAUGHS]

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Well, I'm going in the same direction as you folks are headed, because we need to have a synergy between CDC and HHS over workforce retention and recruitment. What we've seen this morning, with all the education and training, the virtual reality, the clinical partners forum, all these are wonderful recruitment and retention tools. And I can see CDC and HHS working together to get this information out there into the hands of clinical labs, whether they be doing high complexity or minor complexity or waive testing. So that is really a useful, available tool to everyone that people don't have to search for things. And I would like to see us make a motion that CDC and HHS just work together on competency documentation, education and training, because from what I hear from my staff, they want continuing education opportunities. And we all know that laboratories are very busy, can't travel to meetings, and there's not resources available to this. And what CDC has developed fills that gap beautifully. Thank you.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I sent a suggestion to [CLIAC EXECUTIVE SECRETARY] in an email. But basically, for education, training, and ongoing competency assessment, I sent a recommendation-- there it is, that our laboratory partners explore how to use virtual reality to do this. And I reflect on being at United's training center in Denver, where they basically clear pilots to fly on their regular ongoing competency based on their performance in a VR setting. And they have a very elaborate program, so I suggested perhaps that CDC reach out to the FAA. Yeah, actually, the Air Force-- my son is an Air Force Academy graduate and he's a pilot. And he's an instructor, and they use VR now for all of their pilot training, so.

CLIAC MEMBER: Yeah, it's truly remarkable to see what they do. So anyhow, this was my thought.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah. Thank you. I mentioned earlier, with the OneLab Initiative, involvement of our commercial partners, vendors, manufacturers. And I think this might also be an opportunity for CDC to work with-- and I think someone mentioned this earlier too, with manufacturers. We rely on manufacturers for primary training on our instrumentation when we get a new instrument. And I think they spend a lot of time, effort, and money on training, individuals from our laboratories. And this would seem to be a natural partnership, and they would welcome exploring how to use VR setups in the initial training of professionals on instrumentation. So I wonder if this is, again, another opportunity to coordinate with manufacturers on a project.

CLIAC CHAIR: Thank you. You know, I was thinking about this, and loosely associating [CLIAC MEMBER] comment about the poor man's way to do the training without an Oculus is to watch a video. And I'm struck with the whole COVID pandemic. As these 300-plus new tests came out on the market, the manufacturers often had a video that showed you how to do the testing. So that leapfrogs over the technology hurdle and distributes it to masses for the education. Now, I see [CLIAC MEMBER] nodding. The question is, did they watch it? Did they understand it? Did they pay attention, right?

CLIAC MEMBER: Well, those who care and who wanted to do something about it, absolutely. They watch it and use it. I mean, look at how many people started buying at-home tests when they were finally available. There was a waitlist, so same thing.

CLIAC CHAIR: We have two proposed recommendations on the screen. [CLIAC MEMBER], you still have your hand up. Is one of these yours?

CLIAC MEMBER: The second one is mine. Oops.

CLIAC CHAIR: So the second one deals with education primarily, and the first one deals with competency assessment. So is there a preference from the group? If there's no preference, we're going to start in numerical order to discuss number one. Speak now if you want to focus on two first. OK, is there a motion for proposed recommendation number one?

CLIAC MEMBER: I just put my hand up. "For this purpose" is appearing twice. So there's an editorial—

CLIAC CHAIR: We can't discuss it until we have an active motion. So are you moving approval?

CLIAC MEMBER: I'll move approval.

CLIAC CHAIR: Thank you. Is there a second?

CLIAC MEMBER: I'll second.

CLIAC CHAIR: [CLIAC MEMBER], OK. Now, what were you saying, [CLIAC MEMBER]? The editing?

CLIAC MEMBER: Well, I think [CLIAC EXECUTIVE SECRETARY] just did it. She's very fast. We noticed that yesterday.

CLIAC CHAIR: So I would like to expand this to say CLIA recommends that CDC and other federal laboratory partners explore how to use-- and instead of specifying virtual reality, should we be broader and refer to it as "remote learning" or some other comparable thing? And then aside from the training, assessment, and all that other stuff to meet regulatory compliance for CLIA-- to meet regulatory-- no, up, remote learning to meet regulatory compliance for CLIA, period? [CLIAC MEMBER], and then [CLIAC MEMBER]. And then [CLIAC MEMBER], your hand's still up.

CLIAC MEMBER: Oops.

CLIAC CHAIR: And then I would strike the rest of that sentence. Save it somewhere, [CLIAC EXECUTIVE SECRETARY], in case somebody wants to put it back in. Thank you. [CLIAC MEMBER] and then--

CLIAC DFO: Since you're talking about regulatory compliance for CLIA, should you consider adding CMS to the—

CLIAC MEMBER: Yes

CLIAC CHAIR: Should we just leave it at regulatory compliance? And then I would put perhaps parentheses CMS comma OSHA comma DOT. Yeah. So [CLIAC EXECUTIVE SECRETARY], it's compliance strike force strike CLIA parentheses-- strike that, emphasis e.g. comma CMS ocean dot. [CLIAC MEMBER].

CLIAC MEMBER: Yeah I think that's OK now. I was watching how it was going. So I don't have any other comment, other than since this was mine, I would accept that as a friendly amendment.

CLIAC CHAIR: [CLIAC MEMBER] just one-upped me on Robert's Rules, guys. OK, [CLIAC MEMBER]?

CLIAC MEMBER: OK. I was so impressed by the virtual reality and I'm one of these people who tunes out when people start talking. And I have to have a way to keep me in-- I mean, if you notice, I'm taking notes and fidgeting over here. And I

would like to add remote learning, including virtual reality, because I would hate for somebody to say, oh yeah, we'll make another video. I mean that virtual reality was so impressive and makes you go through the steps.

CLIAC CHAIR: So then, if I'm hearing that right, after remote learning parenthesis e.g., virtual reality-- oh, I'm sorry, including. She's already got it there. I would make it an e.g., for example, because who knows? In two years, it will be something equally exciting. [CLIAC MEMBER].

CLIAC MEMBER: It's kinda related to yesterday. I think everybody thought it was terrific. I mean, it's been used in Air Force, actually. Military got to this, possibly, first. It's obviously something we need to do. So my worry is-- and again, this is probably my last meeting. But if we ask to explore, are we all going to be retired by the time we're onto the next base? If we think it's a good thing, do we not have the mandate to say that we recommend that virtual reality-- I don't have the right words. I actually love that, the remote learning. I mean I'm a little nervous about, for example, virtual reality will drop out. Remote learning is a Zoom call. So one thing is to make very clear that we're talking about these new technologies. But can we not just make it our recommendation that this needs to happen now? Make it happen. Like, the job of these others is how you implement. Like, is our role-- I'm putting this out there as a question. It's not quite rhetorical. It's halfway rhetorical. Is our goal not to say, look, this is what we need to do? And everything, for various reasons, it takes a long time when it goes through the federal system. So I'm not saying that's good or bad, but words like "explore" aren't heavy-duty active words. And I do think we have to be very clear that by remote, we don't mean, what's happening now.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. There's a flurry of synonyms that are popping up in the chat that CLIAC [EXECUTIVE SECRETARY] is putting on the screen. But my recommendation would be to replace all of those, and the sentence to read, "CLIAC recommends that CDC and other federal laboratory partners collaborate on the use of remote learning." OK, [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: Yeah, I agree with what [CLIAC MEMBER]'S saying. And I always think about word that was even stronger. "Adopt" was a good one, or "allow the use of remote learning."

CLIAC CHAIR: [CLIAC MEMBER], I was going to suggest "implement," but I thought "implement" was way too strong.

CLIAC MEMBER: Yeah, I agree with [CLIAC MEMBER]. We want them to use it, whereas "collaborate" might also be interpreted as we've got to figure out how we work together, whatever. Yeah. But anyway, my suggestion is "allow the use of remote learning."

CLIAC CHAIR: So I'm going to wordsmith this some more. "Other federal laboratory partners implement remote learning to meet regulatory compliance." [CLIAC MEMBER] has a suggestion in the chat, another word suggestion. And the floor is yours. You flipped back to me again. There you go.

CLIAC MEMBER: As usual, I want to try making this as broad as possible. So rather than "remote" my suggestion would be "recommends that CDC and other federal laboratory partners implement and/or develop guidelines to define how alternatives to in-person learning and training can be implemented to meet regulatory requirements." And I realize I'm repeating a lot of that. Basically, CLIAC or CLIA is in-person training, hands-on training. And I think really, it is the alternative to actually watching someone at their physical bench. And I don't want to just restrict it to VR, because I do think when we do things-- like if we're going to talk about bioinformatics and dry lab stuff later, you don't actually need a virtual reality. You could technically still use Zoom or something like that. So I would really like to make it a little broader than just virtual reality.

CLIAC CHAIR: Yeah, I agree with that. And I'm going to take my red pen, which is only rivaled by [CLIAC DFO]. And I'm going to chop the sentence to say, "and other federal laboratory partners implement," and then cross everything out up to "alternatives to 'in-person."

CLIAC MEMBER: In-person training.

CLIAC CHAIR: In-person training to meet regulatory-- or in-person—

CLIAC MEMBER: Training competency something.

CLIAC CHAIR: Find a word that's all of them, that encompasses all of them OK, we can type training/learning as a placeholder.

CLIAC MEMBER: So I think it's important to have the word "competency" in there somewhere too.

CLIAC MEMBER: Yeah. I want "competency," yeah.

CLIAC CHAIR: OK, slash competency. And then strike "can be implemented." OK, [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: I'm still worried. As you heard, there's a lot of resource that has to go into doing virtual reality right. I love the idea of the broad. That was actually quite brilliant, so thank you for making the case. What we're looking at is not in person. But it's too easy, especially when resources are scarce, to fall back to Zoom. And we just heard about equity. That's what's going to happen. The places that have money are going to be on the next generation. Like, what we saw is going to be a few years from now. People are going to be very amused at the quality of it. There has to be some language-- I was thinking, including "latest technologies" or something that we want to be forward-thinking about this. Again, I love the idea that it's not in-person. But some focus on including latest technologies such as virtual reality, which is going to be around. I mean, that's going to be here. It's not going anywhere. That's the Metaverse. So I think we're talking about a focus on tech. But I just worry, just having seen this time and again, it's very easy to slip back. PDF is a digitized record. It's useless when you get 5,000 pages, but it actually technically is a digitized record. So when things aren't specified, it will always go back to the least common denominator. And we know who's going to end up with that. So just another $0.02.

CLIAC CHAIR: And think about how you would like to edit this to address that issue.

CLIAC MEMBER: Yeah, I would say "including latest technological advances in education, such as virtual reality, so it's pretty clear where we're going. So I put that out there for you guys to edit. That's what I'm thinking in terms of the editing.

CLIAC CHAIR: So I would just shorten that. And so after this three word with slashes thing that we need to find a new word for, we could put back in parentheses e.g. virtual reality. [CLIAC MEMBER]?

CLIAC MEMBER: Actually, [CLIAC MEMBER] said it for me. So I was in the process of lowering my hand.

CLIAC CHAIR: So how about-- oh, this is going to sound really unwieldy. Other federal laboratory partners implement technology contemporary alternative.

CLIAC MEMBER: Actually, it's a public meeting at the CDC.

CLIAC CHAIR: I'm sorry. [CLIAC MEMBER], did you mean--

CLIAC MEMBER: I have to-- yeah, no, I'll mute. I just--

CLIAC CHAIR: It was a non-sequitur I didn't get it.

CLIAC MEMBER: Yes, no, no, no. That was-- I'm off.

CLIAC CHAIR: OK. [CDC EX OFFICIO]?

CDC EX OFFICIO: Just a consideration for the committee. And as we've been hearing about equity, would the committee want to consider asking CDC to explore asking corporate America for free technology so that this can become available?

CLIAC CHAIR: That's a great suggestion. That would be, I would think, a third recommendation, unless we can shoehorn it into number two, the educational piece. So I'm going to go on to [CLIAC MEMBER] while I'm mulling that over. [CLIAC MEMBER]?

CLIAC MEMBER: Again, just thinking about yesterday, too, with a certificate of waiver and competencies and those sorts of things. I mean, we're talking about laboratory workforce challenges here. But could we not also make a recommendation-- and maybe this isn't the right place to do this, but in terms of incorporating this into the certificate of waiver competencies-- those sorts of things.

CLIAC CHAIR: OK. Thank you. I think this entire committee wants all the waived labs to do this. I think that's the sense I'm getting. So the question is, when we go back to that motion that is still open around reopening the law, that would be part of the how, once we get what and the why done. Back to this sentence, I'd like to wordsmith a little bit more after "virtual reality" to "current in-person activities-- to insert the "current" activities parenthesis-- oh, strike that, too, because I can say, parenthesis training comma learning comma competency assessment comma-- we probably need an "e.g." in there too, to meet regulatory requirements in parenthesis, I'm sorry, after the competency. [CLIAC MEMBER].

CLIAC MEMBER: I just want to put in one more bid for instead of using e.g., like for example, use a word like focusing on-- I know it was to shorten it up. But I still am a little bit fearful of thoughts if it would be alternatives focusing on most current, because it's really the tech piece of learning. It really is. I would like to be able to say the most current technologies, e.g. virtual reality, because then it gives a context what we're talking about.

CLIAC CHAIR: So how about this? "Partners implement technology alternatives."

CLIAC MEMBER: We don't like-- we didn't like what was in red?

CLIAC CHAIR: Well, I mean, it's, like, 10 words instead of one.

CLIAC MEMBER: Well, first of all that's just me. So I'm very happy. You can shorten it up.

CLIAC CHAIR: No, I mean, is that something that would meet your request?

CLIAC MEMBER: Yeah, I mean, I just the idea that we're focusing on educational technologies, such as virtual reality, then it's just really clear not to do a fallback.

CLIAC CHAIR: I think it's bigger than educational because I keep pushing the competencies.

CLIAC MEMBER: Oh, yeah, yeah, yeah. I know. You're 100% right.

CLIAC CHAIR: Yeah 100% right. And then whether or not-- a couple of you, [CLIAC MEMBER] and [CLIAC MEMBER] in particular, have commented the FAA has a very robust system for this type of technology learning and competency assessment. Do we want to include a sentence as an example to bolster the statement? And [CLIAC MEMBER] came off mute, so go for it, [CLIAC MEMBER].

CLIAC MEMBER: Yeah, I mean basically, that may be getting a little bit too much into the how. But that was why the recommendation of CDC reach out to the FAA, because they have done the training, the education, and the certification. And they have manuals to do it. So my only point was we don't need to start from scratch even within a federal agency.

CLIAC CHAIR: Do you want to propose a second sentence? An example?

CLIAC MEMBER: I think that second sentence that starts with "recommend." Get rid of the other stuff. "CDC reach out to-- "that's fine the way it is. Well, other people can wordsmith it. But that was my thinking because it seemed very much akin to what we're talking about. And it's very cool. I flew in 10 minutes from LAX to Hawaii.

CLIAC CHAIR: Oh, I don't want to be on your plane. So how about the second sentence recommend strike the "that." "CDC consider the Federal Aviation Administration structure," or some word, "for airline pilots. Consider the FAA administration training for airline pilots, training and competency assessment?

CLIAC MEMBER: Or "program." The national simulator program, I think, is what I got on the website.

CLIAC CHAIR: That's broad enough. [CLIAC MEMBER]?

CLIAC MEMBER: I guess I'm going to argue that it's a little too broad. Are they considering it for how they institutionalize it? Are we asking that they consider it for how they structure it? I'm a little unclear exactly what we want the CDC to do. And is it the CDC or is it CMS and CLIA that we're really reaching out to?

CLIAC MEMBER: Yeah, it's CMS. It is CMS. I guess actually, I'm talking out of turn, huh?

CLIAC CHAIR: Keep talking out of turn.

CLIAC MEMBER: Go ahead.

CLIAC MEMBER: Yeah, consider the Federal Aviation program for airline pilots as a strategy to model the programmers. I think that's what you're asking, right? It's not just--

CLIAC MEMBER: Yeah.

CLIAC CHAIR: As a model.

CLIAC MEMBER: As an example, because there's probably several examples the military test whatever, right?

CLIAC MEMBER: Is it an example of how to structure the training or an example of how to structure the regulation?

CLIAC MEMBER: training.

CLIAC CHAIR: I would say it's a model all encompassing. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I was wondering what are we going after here as well? And are we asking them to consider? Are we asking them to reach out to the Federal Aviation Administration to find out how it worked and what snags they had to overcome. Like somebody said earlier, avoid reinventing the wheel.

CLIAC CHAIR: So what we need is a synonym for "consider." We need an active verb. Who's got their thesaurus open? Three words, [CLIAC MEMBER]. One word. That's my-- that's my remote brain that's on holiday right now.

CLIAC MEMBER: Just use.

CLIAC CHAIR: OK.

CLIAC MEMBER: Or could we put model in there? Recommend CDC and CMS model, the Federal Aviation Administration program for airline training for pilots for training and regulation, or for training? But you get a--

CLIAC MEMBER: And certification because I think that's the big deal.

CLIAC MEMBER: For training and certification.

CLIAC MEMBER: It's the whole-- it's the whole regulatory piece that we talked about above.

CLIAC MEMBER: Now, folks, I don't know that we want to model that program until we know that it's worked. That's why I say reach out to. It's only two more words, come on. Reach out to them and find out more about it and what snags they had to overcome.

CLIAC MEMBER: Yeah, I would agree. I don't think it's that simple. They're still trying to implement it into training for Air Force pilots. So it's one of those things where it may be really advanced for people who already know how to fly. But if you're actually trying to train somebody, such as in Air Force students, it may be very different. So I agree with you, [CLIAC MEMBER]. I think there needs to be a little bit more investigation about what's actually happening.

CLIAC CHAIR: Would you-- I want to add a clause, which is heresy, because that adds more words. But I would say for train-- at the end of that sentence, airline pilots for training and certification as a possible model because we may end up not wanting to use the FAA model.

CLIAC MEMBER: That's-- I agree with that as well. Good additions of words that clarify is a good thing.

CLIAC MEMBER: As an example, right.

CLIAC CHAIR: And let's take that out of this.

CLIAC EXECUTIVE SECRETARY: So I can't really raise my hand when I'm sharing my screen easily. But one thing is we at CDC have-- we have the recommendation. But we also take all the conversations into consideration when we're addressing recommendations. So if you're not comfortable with this last sentence, it's still going to be captured in the meeting summary. And it's still going to be captured in the information that we use when we start addressing these recommendations. So if you would rather keep it just simple with the first sentence, just know that that information will still be captured.

CLIAC CHAIR: She just opened the gate for me. I recommend we strike the second sentence and that the five pages of single spaced capture of the discussion will be considered. Can you guys live with that? [CLIAC MEMBER], you still have your hand up?

CLIAC MEMBER: Sorry, I guess I can live with that. But who's going to read all that?

CLIAC CHAIR: I do.

CLIAC MEMBER: Implement-- you read that all?

CLIAC CHAIR: Yeah, for the minutes. But CDC is extraordinarily diligent in reviewing these minutes-- the recommendation.

CLIAC MEMBER: Yeah, I think that's OK. I mean, I think it's OK if [CLIAC EXECUTIVE SECRETARY] going-- all I want to say is there's already a model in the federal government to do this shamelessly steal whatever you can from it.

CLIAC CHAIR: Their further discussion on proposed recommendation number one. OK, seven seconds of silence. I'm going to call the vote. Are there any opposed? Hearing no opposition. Are there any abstentions? This motion passes. Now, let's go to proposed recommendation number two. Is there a motion to approve? Go on, [CLIAC MEMBER].

CLIAC MEMBER: I can motion-- approval of my own motion, I suppose. I don't know if that's--

CLIAC CHAIR: You can.

CLIAC MEMBER: Yes. Is there a second?

CLIAC CHAIR: Raise your hands-- or [CLIAC MEMBER]-- so [CLIAC MEMBER] seconded. Now, we're talking about this recommendation number two. And the question is [CDC EX OFFICIO] comment around how to fund it. Do we want that as a separate number three? Or do we want to find a way to incorporate it into number two? [CLIAC MEMBER] has-- [CLIAC MEMBER] has the word resource-- you have that word in there.

CLIAC MEMBER: And this is where I am underschooled in how CLIAC can make recommendations to HHS. The verb examine and the verb resourcing, to me, that's the crux of how this is phrased. What can we ask HHS to do?

CLIAC MEMBER: And don't want them to examine-- well, I'm sorry, never mind.

CLIAC MEMBER: Because we could say we want them to fund-- I want HHS to fund it. But is it HHS or is it Congress? And that's why I need guidance on what the active verb needs to be.

CLIAC MEMBER: That needs-- that's it, fund. That's the word.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: To fund.

CLIAC MEMBER: That's it. That's always it.

CLIAC MEMBER: Just go straight for the jugular here.

CLIAC MEMBER: Be obvious.

CLIAC MEMBER: Yeah, I'm totally comfortable with that. And I prefer an HHS mechanism over a statutory mechanism.

CLIAC MEMBER: And we have funding in the last sentence as well. So we don't want-- we want to just remove that. So it's not repetitive.

CLIAC CHAIR: And do we want to include something about the hardware or the--

CLIAC MEMBER: No, to me, the less we say, the better.

CLIAC MEMBER: Leave it open.

CLIAC MEMBER: Leave it totally open, because it's up to the educational programmers to declare what they need to resource.

CLIAC CHAIR: And so--

CLIAC MEMBER: Are we establishing educational programming?

CLIAC MEMBER: Well, see, the less said the better, because that can include establishing, resourcing existing, expanding the bandwidth of existing programs. I think the more prescriptive we become, we narrow it.

CLIAC MEMBER: But you've got funding in there two places.

CLIAC MEMBER: Yeah, but that's wordsmithing. But I want to distinguish between the student and the institution of learning. And something I didn't do in the heat of typing up the first attempt at this is hospitals, labs, or institutes are sites of learning as well. So institutions of learning and sites of clinical training, because that's, as I say, the two pinch points, the educational program and hospital laboratories, which aren't resourced.

CLIAC MEMBER: Are not resources.

CLIAC MEMBER: And so if we want to take out the second funding-- let me just look at loan forgiveness for students.

CLIAC MEMBER: Support. Support.

CLIAC MEMBER: And support. Yeah, support. I like support. I'm trying to I'm trying to make it concise and broad.

CLIAC MEMBER: Vague.

CLIAC CHAIR: So how about this wordsmithing? CLIAC recommends that HHS fund the educational pipeline, so strike "mechanisms for"--

CLIAC MEMBER: And fund the educational pipeline for the laboratory profession.

CLIAC CHAIR: Yeah. So [CLIAC EXECUTIVE SECRETARY], strike those three or four words.

CLIAC MEMBER: To include but not be limited to.

CLIAC CHAIR: And then do we need "such actions"?

CLIAC MEMBER: No. Not limited to tuition benefits and loan forgiveness. So take out "such actions as."

CLIAC CHAIR: Yeah. Delete. Delete the "ands." And support institutions of learning.

CLIAC MEMBER: Yeah, and support of institutions of learning and sites of clinical training. Yeah. Thank you. Support.

CLIAC CHAIR: Educational? That's what we took out. Did you want us to put--

CLIAC MEMBER: Well, educational institutions is redundant.

CLIAC CHAIR: OK. So we've got it really crisp right now. Did we lose your--

CLIAC MEMBER: No, actually, I think you've honed it successfully.

CLIAC CHAIR: Not me. It's, like, five people yelling at the same time. [INTERPOSING VOICES]

CLIAC MEMBER: There's no parliamentary order right now.

CLIAC CHAIR: We've totally disintegrated. [CLIAC MEMBER]l-- [INTERPOSING VOICES]

CLIAC MEMBER: Yeah, I just have a question. This print is small, so I'm squinting to try to read it. I don't know if you can make it larger. But question I have-- and those of you who have helped develop the language, you can answer this-- do we have in here, or should we have in here, some focus on aim to do inclusivity for underrepresented populations in terms of funding coming through and all of that? Do we need to look at where we could add that as appropriately-- I do recall Dr. Winter said that was a key piece in this whole rescue fund being used, et cetera, et cetera. Just asking.

CLIAC CHAIR: That's an excellent point. I'll let [CLIAC MEMBER] talk before I'll say the clause I want to add. OK, [CLIAC MEMBER]?

CLIAC MEMBER: Returning to parliamentary order here. Yes, I think it is entirely appropriate to add a clause saying, "with special attention to" and then insert the inclusivity--

CLIAC MEMBER: D&I, accessibility.

CLIAC MEMBER: Yeah. I won't be the one-- I'll ask someone else to craft that. But I think inserting a clause "with a special attention to." What I'll comment, from our New York State discussions, is despite the desperate need for training, there is only a limited number of programs and they're not near the students. They're in the middle of upstate New York and they're not in the center city. And so you can't ask a student to attend a school up in Albany. You can't ask a New York City borough student to attend a school up in Albany. You need to have a school in New York City. And so figure out four words, or five, to express that.

CLIAC MEMBER: May I follow up and say that, then, do we need to add something with SDOH, the Social Determinants Of Health, because one of those variables would be transportation, even if they were going to access--

CLIAC MEMBER: Because they can't get to the school-- the training school.

CLIAC MEMBER: Right. But that's what I'm saying. Built into the funding that would come forward, it would be a consideration for those persons who are coming from underrepresented communities or--

CLIAC MEMBER: Yes, thank you.

CLIAC MEMBER: All of these words that are popping up I think we should leave out. The HHS fund the educational pipeline for the laboratory profession including but not limited to, and then even a second sentence. A special attention should be given to meeting the educational needs of and--

CLIAC MEMBER: Individuals from-- or students from underrepresented populations or underrepresented--

CLIAC MEMBER: Separate-- yeah, so make it a separate sentence, or even with special attention to. and [CLIAC MEMBER], please insert the language right now.

CLIAC MEMBER: Are we also trying to address geographic disparity?

[CLIAC MEMBER]: Recruitment and admission of students from underrepresented populations.

CLIAC MEMBER: That could include geography.

CLIAC MEMBER: As well as students with disabilities, as was--

CLIAC MEMBER: Here, you can pile it on. We can be concise up above, but we can pile it on here.

CLIAC CHAIR: So we'll have a period after "training," and then the second sentence is what we're wordsmithing to include STOH and DEI. [CLIAC MEMBER] and then [CLIAC DFO]?

CLIAC MEMBER: Yeah, I think-- and trying to get back to the idea of making a recommendation and then having the groups that we refer it to take note of all of our conversations. I really do think that this is a strong recommendation right now. And in the interest of-- I know we have a lot of other really meaty stuff to discuss. I don't know if it would be out of order to move for approval of this now or if that's sort of out of order. I also see that not a lot of hands are up anymore. So may have been coming to a close on its own.

CLIAC CHAIR: [CLIAC MEMBER] wants to move on. And to move on, we have to have the statement we're going to vote on. And I think that's where we are. So I want to hear from [CLIAC DFO] before we go charging in here.

CLIAC DFO: Yeah, so two comments. One is similar to [CLIAC MEMBER], which is, I recommend against a lot of wordsmithing, because it will cut down the amount of time you have to address other issues. The second comment-- and for those of you who've been on CLIAC a while or before, you've probably heard me say this. The best recommendations for this committee are specific to our three agencies that are part of the CLIA program that we have the ability to act upon. As important as this recommendation is, asking HHS for funding, in all likelihood, we'll end up with a letter back from the Secretary of HHS that says something along the lines of thank you, CLIAC, for your recommendation. We've gone through that a lot. And so I think if-- I mean, I accept how important this is, and I think it's good for CLIAC to get on the record. But I wouldn't encourage a lot of wordsmithing, because it may end up with about that much of a response, whereas if you tell CDC or CMS or FDA to do something specific within sort of CLIAC's scope, that puts a lot more

pressure on the three of us to do something. And the three of our CLIA agencies are sort of accountable, from a CLIA perspective, to the CLIAC recommendations that fall within our purview. But funding educational pipelines would be outside of our purview and our existing funding. So I'll stop.

CLIAC CHAIR: Thank you. It sounds, from that, that this broad, overarching desire is probably not going to have success. So unless there's violent disagreement, it's an aspiration we all want, but this is not the right way to get it. So I would like to have that motion withdrawn.

CLIAC MEMBER: I withdraw the motion. And that's why I was asking for guidance, because CLIAC expressing earnest opinion is one thing, but functioning within the guidelines of what we can and cannot do is the guidance that's of value to me. So I withdraw the motion.

CLIAC DFO: And I don't mean to say you can't do this. You're welcome to do this. I'm just advising that it may just be sort of a statement of record.

CLIAC MEMBER: I've put my hand up.

CLIAC CHAIR: Yes, first hand.

CLIAC MEMBER: Would it be-- we have leverage if we use stats to show that the percentage of, let's say, minorities and underrepresented persons, and maybe we move down from that, but anyway, use statistics to better support our position—[CLIAC DFO], would that be helpful, or you've also received where they have said, thank you, we received it, and that's the extent of it? So it doesn't really help to build your background information in such a way that we show that there's a gap and that there's a strong need? So my question is, is it not even applicable to say, wait a minute, there's a great need here. And also, looking back at some of the information that we've shared regarding competency and integrity and the workforce and all of that, I'm just wondering if we could build our case.

CLIAC DFO: And I guess asking HHS for funding is a big ask, and it's very difficult to do. And frankly, I think using political mechanisms and political weight is going to be more effective if you're just looking for funding. But if you want-- another way is to go back to the exploring specific mechanisms. How can these benefits and loan forgiveness be specifically applied to the laboratory profession, along those lines, may have more immediate success. But again, I guess what I'm saying is, my recommendation is, the committee should prioritize how it uses its time and develops these recommendations. And as [CLIAC MEMBER] said, you have some pretty meaty recommendations from late yesterday that I don't think you've gotten to. And I'm not sure that spending a tremendous amount of time on this particular recommendation should be the highest priority, because it will be-- it's a really aspirational ask.

CLIAC MEMBER: So two very brief comments. That's why I started with examine. And the other is that, what is the value of a "for the record" statement? If we're action-oriented, then this motion should be withdrawn.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Would it be a more practical suggestion if we take HHS out of that and say that recommends that CDC look for funding sources, such as grants and other monies that could be directed to this purpose? And then we're once again directing it towards an agency that has the responsibilities. Take HHS out.

CLIAC MEMBER: Examine opportunities for.

CLIAC DFO: Yeah, I think that's fine.

CLIAC MEMBER: And then we move on.

CLIAC DFO: Exactly.

CLIAC MEMBER: So as the person who put the motion on the floor, the CD exam and opportunities for funding, and then take out sources. And then it becomes "and supporting institutions of higher institution and supporting."

CLIAC MEMBER: Third line.

CLIAC MEMBER: Yeah, supporting, and then just move on.

CLIAC CHAIR: Is there further discussion?

CLIAC MEMBER: I have just one more word to add. In the very last part of that, underrepresented populations, usually, I think the government's language is "minority and underrepresented populations." So add "minority" in front of that.

CLIAC CHAIR: Go ahead. Further comments? Hearing none, I'll call the vote. Any opposed? Hearing no opposition, any abstentions? This motion is approved. There is a third one, which is very narrow. Propose recommendation number three. Is there a motion for approval?

CLIAC CHAIR: So it's open for discussion.

CLIAC MEMBER: Would that be-- let me raise my hand.

CLIAC CHAIR: Well, [CLIAC MEMBER] was there first, so [CLIAC MEMBER] and then [CLIAC MEMBER].

CLIAC MEMBER: Now that we've changed our recommendation to explore opportunities for funding, has this become redundant, because the record in the discussion will mention the vendors as one funding source?

CLIAC CHAIR: This one is very specific for the distribution of VR technology. [CLIAC MEMBER]?

CLIAC MEMBER: I just wanted to change "pursue mechanisms" to "pursue partnerships with industry."

CLIAC CHAIR: I was going to say, I was going to replace both of them with partner.

CLIAC MEMBER: Partner.

CLIAC MEMBER: Sounds good.

CLIAC CHAIR: CDC should partner with industry to contribute VR technologies. Any other comments?

CLIAC MEMBER: To contribute or to supply to industry? To provide? Or simply to make its laboratory VR tools more widely accessible? And then you can take out the whole center.

CLIAC CHAIR: Yes. [CLIAC MEMBER], you have your hand up.

CLIAC MEMBER: Yeah, I was going to say, CDC should partner with industry and philanthropic organizations.

CLIAC CHAIR: Now we have to spell philanthropic. OK--

CLIAC MEMBER: Talk to [CLIAC EXECUTIVE SECRETARY].

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

CLIAC MEMBER: All right, I think you covered what I was going to say that the previous wording wasn't so good. So I think I'm done.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I just want to-- I think it just needs to be clear what you're asking industry to do. So for instance, when I was asking before about how do you improve that lab experience, do you need a subject matter expert from that manufacturer to come in and show you all the steps, and make sure that it's done correctly? So it's that contribution. But are you also asking for them to provide the headsets, and everything else. So I think that's sort of getting into the weeds. But if I go back and ask my companies, I'm sure they would say, I would love to do it. But how are we going to see where that moves forward? Or is it just donating money, even? But I think it would be virtual SMEs, or helping design the tool, as well as, is it to help support the headset? I don't know-- so--

CLIAC MEMBER: Yeah, I think it's SMEs as well as tools, as well as platforms.

CLIAC MEMBER: Right, OK. So again, I wouldn't waste time wordsmithing on this. Yeah. I just think you need to understand what's that broader piece. Yeah.

CLIAC CHAIR: Do we have suggested wording?

CLIAC MEMBER: I think that's--

CLIAC CHAIR: I'll throw it out. To improve health equity, CDC should partner with industry and philanthropic organizations to have VR tools more accessible to support laboratory treatment. Or replace to support with for. And do we need to put clinical in front of laboratory?

CLIAC MEMBER: Yes.

CLIAC CHAIR: OK, for clinical laboratory.

CLIAC MEMBER: I think so, for sure. It's not just laboratory training-- specifically the clinical laboratory profession.

CLIAC CHAIR: Just take out supporting. Sorry, [CLIAC EXECUTIVE SECRETARY]. OK, [CLIAC MEMBER] and then [CLIAC MEMBER]. [CLIAC MEMBER], you're staring at me. And you're on mute.

CLIAC MEMBER: I'm on mute. Sorry about that. Yes, so do we need to say-- it's obvious if CDC is working on it that this is a public health measure. There won't be any confusion that industry will just be supporting industry.

CLIAC CHAIR: To improve health equity and public health?

CLIAC MEMBER: Yeah, just something that it's-- again, it's CDC, so it's assumed that we are trying to partner with industry in order that this will be broadly available, irrespective of whether you are in industry, public health, academic, just something to make clear this is not-- because they'll say, yeah, we do this all the time for our people.

CLIAC CHAIR: And then, there's [CLIAC MEMBER] suggestion on the second line-- virtual reality tools, insert and resources. Is there further discussion? Hearing no further discussion, I'll call the vote. Are there any opposed? Having no opposition, are there any abstentions? This motion passes. Thank you. OK, it is 10:40. We break at 11:00-- that's in 20 minutes. And is there further comment on this session? Because I would love to go back to the open motion on the waived testing. No other comment on the session? Here we are with the waived testing-- remember, it is the yellow highlighted line is what we're discussing. I want to thank all of you-- I'm very grateful for your work last night and your contributions. A number have come in to explain the why. The yellow is the what, and here's all the why. And we get to discuss which of the whys you want. So who'd like to lead this off? First why is a [CLIAC MEMBER]- [CLIAC MEMBER] collaboration. I believe [CLIAC MEMBER] had one. I think [CLIAC MEMBER] may have submitted one.

CLIAC MEMBER: I just sent over a few words for the opening.

CLIAC CHAIR: So just the visual value, from my perspective, the [CLIAC MEMBER]-[CLIAC MEMBER] collaboration is the longest, and it's referenced. So it's like the law, right? And then the others capture what we were trying to get at. It doesn't have the same amount of detail. So sort of one of the questions for the committee is, how much detail do you want?

CLIAC MEMBER: Yeah, so I sent in something that was addressed that was certainly much smaller than [CLIAC MEMBER] and [CLIAC MEMBER]'S. But it did address the why-- it included the numbers of labs. But [CLIAC EXECUTIVE SECRETARY], you said you put it in somewhere.

CLIAC CHAIR: Yes, and I think [CLIAC MEMBER] and [CLIAC MEMBER] that put some of it in their revisions, too.

CLIAC MEMBER: Oh, OK. But I wanted to get at what we were talking about yesterday, that it started out with a very small number of labs and tests. And it has exploded. And that there really are none of those safeguards that we have for other laboratory testing. So I tried to be concise-- the [CLIAC CHAIR] rule.

CLIAC CHAIR: OK, [CLIAC MEMBER]?

CLIAC MEMBER: I would just take-- it's off the screen now, but I think it was-- well, I like having references, to start with. So I would take that, be it resolved statement, and make that the top statement. So that if I'm coming to this, I see exactly why this other information is there. And I know exactly what we're talking about. And that's going to make me interested in reading the rest, whereas otherwise, I'm trying to figure out where am I going, here?

CLIAC CHAIR: Yeah, I noticed on one of the earlier versions, there was a lot of, be it resolved, and a lot of whereases, which sounded like a proclamation kind of thing. So my question is, do we need to use those terms? And number two, this large paragraph, which details and captures many of your concerns around why we need to reopen the law, do we just need to preface it with a why question mark, to make it pretty clear why we have this verbiage?

CLIAC MEMBER: So this is [CLIAC MEMBER]-- I've sent over something, but I can read what I wrote, and it really is a higher level, as far as it would fit perfectly. If you want me to read it?

CLIAC CHAIR: No, we can see it, [CLIAC MEMBER]. And I love that statement as part of the why. And the question is, should we move [CLIAC MEMBER] paragraph to the first paragraph behind why? And then, the second paragraph would be the [CLIAC MEMBER]- [CLIAC MEMBER]-- the scope of testing authorized. So that we would have two paragraphs. [CLIAC MEMBER] did we miss anything in [CLIAC MEMBER]? I thought I saw something come from you. Did I miss anything? Or [CLIAC MEMBER]?

CLIAC MEMBER: Oh, I like your idea of taking out the be it resolved that, and just saying, CLIAC recommends. And that also eliminates two thats.

CLIAC CHAIR: Thank you, oh, you get a special gold star. Get rid of thats. Other comments? [CLIAC DFO]?

CLIAC DFO: Just coming back to what [CLIAC EXECUTIVE SECRETARY] said earlier, you know, I think this language is really, really helpful. I think it's great. And we can ensure that it's enshrined in the meeting minutes, but it may not be necessary to have a recommendation with an extensive why paragraph. So I don't think it's necessary to wordsmith a long, long paragraph, but just to be clear on what you're asking the agencies to do.

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

CLIAC MEMBER: What I will say is that I was [CLIAC DFO], I was inspired by your comments yesterday, which was that it was worth communicating a compelling argument. And wherever this argument lands, I'm totally comfortable.

CLIAC DFO: Yeah, absolutely. And I think it's really, really valuable, and it will be in the meeting. And I'm sure many of us will use it again. But I wouldn't want a multi-paragraph recommendation, I guess, is what I'm saying.

CLIAC MEMBER: Would it help to have almost like bullet points of just the key things, so they just stand out? And then you get the rest of the full paragraph? Like the number from initial to now, the number of waived tests from initial to now? Does that really-- and the fact that there's no competency training-- like just make it three things?

CLIAC MEMBER: Well, I think what [CLIAC EXECUTIVE SECRETARY] brought up yesterday about what is in there today? All they have to do-- like if you took my paragraph underneath it--

CLIAC MEMBER: --bullet point that said, today, all that is required is the CLIA certificate, to pay a fee, and to follow, if we put that in there, it is so logical to show--
CLIAC MEMBER: I put that in my first sentence in my paragraph, because that's what we talked about yesterday.

CLIAC CHAIR: And then, [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER], and [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, to go back to that recommendation, is it only the oversight that we're asking to be allowed, or do we want more structure, as well? So in other words, oversight--

CLIAC MEMBER: I'm sorry, [CLIAC MEMBER]?

CLIAC MEMBER: We're trying to ask them to open the discussion in the law. We need to-- and we don't need to go into all the things that we need to do. We need to get the approval and the support to get into modernizing the law.

CLIAC MEMBER: And I agree with that, [CLIAC MEMBER]. I'm just making some suggestions here that I think oversight could be interpreted narrowly. And what we're asking for is more than just that they're going in more often, or that they're paying more attention, that we're looking for more structure in the regulations. So I'm wondering if oversight is a strong enough word for us. And then, my other question was, does ensure fully capture our concern? Or should we say ensure and improve? Or just improve?

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

CLIAC MEMBER: So the sentence where we have quality and reliability, I'd like to modify that to say, oversight of certificate of waiver testing sites in order to improve-- we can still say, quality. But we also, really, in my opinion, would need to say validity and reliability of waived testing. So you have, in research, you want it to be valid and reliable. OK, so I

would say validity and reliability. Quality with validity-- quality with validity and reliability of waived testing. Oh, and then-- OK, and then, the comment that I made down there, I think it's the why, is it? Can you scroll down, please? See--

CLIAC CHAIR: First paragraph is [CLIAC MEMBER]'S, second paragraph is [CLIAC MEMBER]- [CLIAC MEMBER].

CLIAC MEMBER: I think I was number four, or whatever. Did I-- anyway, if it's there, that's fine. To me, it was mind boggling when I realized that the percentage of testing, or testing that has been done by the government, is only 2%, and from this particular source, and that the findings from even that testing has shown serious infractions. And because I'm in practice, and I'm in health care. So I'm delivering. And if we have misdiagnoses, we harm patients. So that's where I was coming from. We want to make sure that all that we do really promotes health and wellness, and minimize misdiagnosis and harm to the patient.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Yes, you're welcome.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, that was basically what I was going to try to say, but [CLIAC MEMBER] did it very well. Also one more comment, since we moved the sentence around in the proposed recommendation now has COW, we need to define that. Rather than down below.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. I was trying to make a sort of concise actionable recommendation. So in the chat, I did put in some verbiage to basically say, you know, it really does ask, like we were asking for an evaluation of the requirements for training personnel and laboratory oversight for COW sites, which is not currently in the CLIA regulations for COW labs. I don't want to define here what we think those should be, but I think that is a key component of what we are asking for. And then, secondarily, knowing that modification of CLIA's very long process, potentially, it seems as though a secondary ask could be CMS evaluating the feasibility of increasing surveys for COW sites. Because that is something more immediately actionable. And even though we don't have any, I guess, defined requirements in CLIA, going by the information we've received with that 2% of sites being surveyed, you can see if things are being grossly stored improperly, or people aren't reading directions, and things like that. So I hope that this is synthesizing all of this discussion in a slightly actionable manner.

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

CLIAC MEMBER: I was talking. I first put the comment that in order to recommend any structure, the law would first need to be opened. And so I think I just wanted to, I guess, comment that first, I think we would need to recommend that the law should be open in order to make any additional changes. So I think, first, we should make a very focused recommendation to open the law, and then we could make additional recommendations, perhaps, on any additional structure. So then, if we wanted to make any recommendations on how that structuring should be, including requirements for training, or personnel, or anything like that, increase surveys, then I think maybe we should focus those additional recommendations somewhere else. But I think that we should make one very focused structure recommendation to open the law, because that would have to be done first before anything else could happen.

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

CLIAC MEMBER: Oh, I'll take it down. I'm all set. Thanks.

CLIAC MEMBER: So I think what [CLIAC MEMBER] just said is great in providing the why. So here's the why, and here's the ask. And then all of this is back-up information.

CLIAC CHAIR: So I am-- oh,[CLIAC EXECUTIVE SECRETARY] [CLIAC EXECUTIVE SECRETARY], go ahead, [CLIAC EXECUTIVE SECRETARY] staying.

CLIAC EXECUTIVE SECRETARY: So there is a process for doing all of this. So it's not just going to be that CLIAC makes this recommendation and we're opening up the law. So CMS will actually have to complete and fill out what they call an A19 form, which is requesting the law to be open. So this was presented as an introduction during part of the workgroup meeting introductory call. But what we're looking for is that supporting evidence. So we can have just a general recommendation that says, you should open the law. Then we're going to use the workgroup report, we're going to use the workgroup presentation, we're going to use this whole CLIAC meeting presentation summary report, which will ensure

that we're capturing all of this why in there, as supporting documentation for when or if this A19 is submitted. So again, maybe we're getting a little bit too deep into the details. I think we've captured everyone's thoughts on the why, but like I think many have said, we've got to do something just to even get the law open first before we can even do anything else. And so this is the first step. As many have mentioned, I think even as we have mentioned to the workgroup participants, they are part of the workgroup now, there's probably going to be, if the law is opened, another workgroup to say, well, what does this look like now? We're able to open up the law, but what is going to happen now that it's open, and what should we do? So again, this workgroup was just getting the evidence together to support or not support opening up that CLIA law.

CLIAC CHAIR: Thank you, [CLIAC EXECUTIVE SECRETARY]. So I'm going to propose the motion being CLIAC recommends the CLIA law-- strike that, I don't like that-- and strike should-- be opened to allow-- strike more-- oversight of CLIA of certificate of waiver testing sites, period.

CLIAC MEMBER: Very good.

CLIAC CHAIR: Had so many things we wanted to put in, but this is tight, focused, and you can't get distracted reading these 15 words. I see [CLIAC MEMBER] nodding. And all this wise stuff, and all the CLIA presentations, lost. OK, [CLIAC MEMBER]?

CLIAC MEMBER: I move approval.

CLIAC CHAIR: We already have a motion.

CLIAC MEMBER: I already have a motion. It's been long since--

CLIAC CHAIR: I'm getting ready to call the vote.

CLIAC MEMBER: So perhaps call the vote.

CLIAC CHAIR: I'm waiting for more hands. I'm waiting for any more hands. [CLIAC MEMBER], yours is still up.

CLIAC MEMBER: Oh, I was just going to make a second motion to approve.

CLIAC CHAIR: We got a live motion, guys. It's like an electric wire. Hearing no more discussion, I'm going to call the vote. Are there any opposed? Hearing no opposition, are there any abstained? Thank you, this motion passes. OK, we have two minutes before our break. I don't think-- but I was surprised yesterday-- I don't think there's another thing that we can get done in two to 10 minutes. So how about we take a break. Committee members, I would ask you to look at the list that was emailed to you earlier today of all of the other ideas we have to talk about, and help me in the late afternoon to focus on which ones are of high priority to you. We are going to take a one-hour break. We will come back at 2 o'clock-- is that right? Your time, which is 11 o'clock my time.

CLIAC MEMBER: It's 2 o'clock now, in the East.

CLIAC CHAIR: I'm sorry, I'm sorry, I just can't deal with this time change. 3 o'clock your time.

CLIAC MEMBER: And which email was it, [CLIAC EXECUTIVE SECRETARY], that had all the lists?

CLIAC EXECUTIVE SECRETARY: I'll resend it out.

CLIAC MEMBER: OK, thanks, because I got so many emails from you.

CLIAC CHAIR: I love--

CLIAC CHAIR: I loved it. You were so engaged, thank you. So again, turn off your video, turn off your audio, your microphones, and I'll see you in an hour. Thank you.

Mpox Response Update

CLIAC CHAIR: Welcome back. We close out the day with an M-pox response update. We will start with a CDC response update from Dr. Christie Hudson, followed by an FDA response update from Ms. Toby Lowe. These are presentations 10 and 11. After the presentations, we will have time for committee discussions. If you wish to provide a five-minute public comment, please email the CLIAC@cdc.gov. We do have one public comment, Dr. Rick Nolte, representing the

Association for Molecular Pathology. After the session, we have time on the agenda to continue our deliberations from yesterday, and a short discussion on future CLIAC topics. Moving on to the CDC response to the M-pox epidemic, and we'll start with Dr. Christie Hudson, floor is yours.

CDC Response
Christina L. Hutson, PhD, MS

DR. CHRISTINA HUDSON: Thank you. Let me get these going. All right, can you see that? OK. OK, I'm actually going to just turn off my video because my Wi-Fi is not great, but I just wanted to introduce myself, Christie Hudson. I'm currently the lead of the Laboratory and Testing Task Force. And normally, I'm the branch chief of the poxvirus and rabies branch, so thanks very much for the invitation today.

All right, so just quickly I'll just do a very brief overview of orthopoxviruses, some of our past preparedness activities, and then a little bit on the mpox outbreak focusing on diagnostic testing, sequencing, and some of our research activities.

So many of you are probably familiar with orthopoxviruses, because of the mpox outbreak, but just to go over some of the ones that maybe you're not quite as familiar with that do cause a skin rash in humans. We have Molluscipoxvirus, which can be transmitted person to person, quite often in children. Some of you may be familiar with this one. Parapoxvirus is generally transmitted from zoonotic route, such as from cows, sheeps, or goats. We have yatapoxvirus, which is fairly rare, and can be transmitted through mosquitoes. And then finally, orthopoxvirus, which is the genus we're most familiar with, and variola virus, and mpox are both within this genus.
And when we look around the world, orthopoxviruses, although they've been identified for centuries, we're actually continuing to find new isolates. So Alaskapox, which is in Alaska, and then Akhmetavirus, which is in the country of Georgia, are two fairly new isolates. All of these orthopoxviruses are genetically very similarly related. This is really helpful when you think about cross-reaction to vaccination. And that's how, for instance, the smallpox was-- I'm sorry I'm having-- there we go. During the smallpox efforts to eradicate, we actually used vaccinia virus, which is an orthopoxvirus that is related to variola virus. It does create challenges, though, when doing, for instance, serology assays, differentiating between different orthopoxviruses that are so similarly related.

And then, a closer look at the orthopoxvirus genus, you can see that mpox and variola are the ones we're most familiar with, and of course, cause human disease. There are some orthopoxviruses that don't cause human disease, such as ectromelia, that's only in mice. And then, we actually have the orthopoxviruses split into old world and new world-- with new world including raccoonpox, skunkpox, and bullpox. And these do not cause human disease, as far as we know.

Typically, with human orthopox infection, you have a febrile rash illness, and you have systemic symptoms, including soreness at the site of inoculation, erythema, local lymphadenopathy can occur, fever, and flu-like symptoms. And you can see one picture of a human smallpox case in endemic areas. And then up here is actually a vaccinia virus within an animal and a human, and at the bottom, we have cowpox within a rat and a human.

And then for mpox, it was first described, unfortunately, in monkeys in 1958, that is how it got its name. It's actually likely transmitted in endemic area through rodent exposures. The first human cases were described in 1970, but we do think that probably mpox was circulating before then, but was mistaken for smallpox. In endemic areas, quite often, it's confused with varicella. And especially clade one does cause a smallpox-like disease where you have a systemic rash throughout most of the body. The two clades, again, clade one, has higher morbidity and mortality, including more lesions, and then the mortality rate is around 11%, compared to clade two, which has a lower mortality rate, thankfully. And that is the clade currently circulating.

And we've had an increase in mpox cases in recent years. The US, of course, had an outbreak in 2003, and we had imported cases recently. UK, Israel, and Singapore also have had exported cases in recent years.

So for preparedness activities, I'm not going through all of this, but much of the tools we're using were developed for smallpox research. And these efforts have really been a priority for the US government since 1999, when we focused on diagnostic assays in particular, and clinical guidance, training of health care professionals. And then in 2009, there was a focus on therapeutics. So this is currently what we do at CDC for smallpox research. You see that all of these are very closely related. They have to have a direct human health impact. And you can see our focus is on nucleic acid base diagnostics, including our FDA-cleared test, protein-based diagnostics are more field deployable assays, next generation vaccines, including Jynneos, and then antiviral therapeutics. And we do have a small animal model that we have characterized in recent years.

And part of our work has been to get our FDA cleared tests within the Laboratory Response Network, which many of you are familiar with. This is, of course, an integrated network of laboratories from state and local public health labs, but also federal, military, and a few international labs. And they are there to respond to bio threats and other public health

emergencies. So we already had FDA cleared test prepositioned within the LRN, including the non-variola orthopox tests, as well as variola-specific tests.

At the start of the outbreak, we relied heavily on these LRN labs to run the non-variola orthopox tests, and they were able to do around 10,000 tests per week. The laboratories would then send samples to CDC where we could do mpox-specific PCR. We have clade one and clade two PCR tests, and then we also do sequencing. And although we had enough capacity, it was clear that we really need to increase testing access. So we work with commercial labs to bring those on board to run the CDC NVO test, and so once those five labs were running mpox tests, our capacity nationwide has been at 80,000 tests per week, or more.

And these are just some recent numbers for the current outbreak. We have a total of 28,797 as of November 9. You can see the highest number of cases are in California, New York, Florida, Texas, and Georgia. And of course, the map just shows the darker blue is the more concentrated states. And this is on our CDC.gov web page and is updated on a regular basis.

We also have our testing data up on these web pages. This is a really nice way to look at the total testing numbers. Again, this is not all the testing performed across the country, this is focused on the LRN labs and those five commercial labs that are testing, but it's a good representation. And within those labs, a total of 123,809 specimens have been tested. We have a cumulative positivity rate of 27.5%. And you can see that testing numbers really peaked in August and have been steadily coming down through the week since then.
And another way we can look at this is, again, looking at total testing capacity at that 80,000 test per week. And you can see that the testing volume at the bottom, in blue, even in August, when we were at our peak, we never got anywhere close to that total testing capacity.

And so just switching gears, I just wanted to give a couple of interesting updates. So for sequencing, we have had some very interesting observations during the current outbreak. First, all publicly available mpox genomes from this outbreak have been belonging to clade 2B, which is formerly the West African clade. And it's interesting that during the outbreak, these do share a common ancestor with mpox from Nigeria. However, it's really important to note that we are missing a lot of sequencing data from surrounding countries and surrounding years. So take that information with a grain of salt. We clearly have a lot of mpox isolates now sequenced, but for previous years, we're missing a lot of data.

When we look at a genomic sequencing tree, we basically see that the mpox sequences fall into two lineages. So the red, that's the predominant lineage. Most of the US isolates, as well as international, fall into that lineage B1. But we do have this blue lineage called A2, and we actually have three US cases from the 2022 outbreak, as well as one case from 2021. So this was actually an exported case in Texas. There's been some additional sequences within that lineage. Most had travel to Western Africa or Middle East. So just very interesting, looking at the sequence information. And then, we have seen-- this is a DNA virus, so it doesn't mutate as frequently as RNA viruses, like SARS-CoV-2 or flu. But we have seen an increased mutation observed in the 2022 mpox isolate. And most of these are due to an enzyme called APOBEC3, that's a human enzyme. So in essence, this human enzyme is causing most of the mutations that we're seeing within the mpox isolates. What that means, I think, is still to be determined. But certainly, an interesting observation.

And then, we've also seen rather large deletions, around 3% of our genomes do contain these very big deletions. And these can impact diagnosis using our tests that we're using, as well as potentially therapeutics. And so, in particular, we found a deletion in a few isolates that impacted our mpox generic and clade two-specific tests, because it was in the gene that those tests targeted.

And I'll just quickly touch on a couple of research efforts. We do continue to look at transmission to animals, and thankfully so far, there has not been evidence of that. But that's something we are monitoring. We also are interested in wastewater detection, and we actually are just starting to receive that data from the company doing that testing across the country. But this wastewater scan is the site that's already up, and they started looking in California very early on. So there's some interesting data there. We also continue to screen isolates to make sure that they are sensitive to TPOXX, or tecovirimat, which is the therapeutic that is predominantly being used for mpox. And so we have to do that in our lab using culture techniques.

We wanted to see if mpox was actually circulating prior to the first confirmed case, so we've done some serologic studies, as well as looking at banked residual specimens using PCR. And then, finally, looking at prevalence of undetected mpox within higher risk populations.

So this, I think, is my last slide-- I just wanted to go over a really nice study in collaboration with the District of Columbia department of Forensic Science's public health laboratory. And our objectives were to determine if mpox DNA can be detected in specimens prior to lesion or rash. Right now, the lesion is the specimen that is used for mpox detection. It would obviously be nice if we could detect mpox before those lesions are present. So that was one of our goals. And then

we also wanted to look at the immune response after Jynneos vaccination. So visit one, we had a lot of participants, which was wonderful. You can see the numbers were fairly high for our throat swab, in particular. And we tested throat swabs, rectal swabs, as well as whole blood for viral DNA. Unfortunately, we only had positives in two of our rectal swabs and one throat swab. Which is good, because it means that hopefully we're not missing mpox cases-- the numbers were very, very low. But doesn't really indicate that one of these specimens would be good for detection of mpox before lesions form. And then we have a visit two where we collected specimens again, and those are currently-- the testing is complete and we're analyzing those results.

So in conclusion, I think everyone knows, this is the largest mpox outbreak outside of endemic areas. We have been able to use multiple medical countermeasures we developed through the US smallpox research agenda I didn't touch on all of these, but in addition to our FDA-cleared tests, we also developed tecovirimat, or TPOXX, as well as Tembexa for smallpox, and then the vaccine Jynneos.

And obviously, lots and lots of people contributed to all this. So happy to take any questions if there are any.

CLIAC CHAIR: Thank you very much. Are there questions for Dr. Hudson? [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. Out of curiosity, it looks like you had approximately 95,000 negative tests. And I heard you say that it's not particularly useful to test asymptomatic individuals. Out of curiosity, what symptoms did the 95,000 that were negative for mpox have?

DR. CHRISTINA HUDSON: That is a great question, [CLIAC MEMBER]. And I'm not an epidemiologist, unfortunately, so I don't all of that information. I will say, because they had to test the lesion swab, or there was a swab of a lesion, right, so it had to be an illness that caused some sort of rash or skin lesions that was being confused with mpox. So I do think that that's something that people are really interested in, and I've heard conversations where they've talked about was there a specific differential that commonly was confused with mpox. And so far, I have not heard a smoking gun, per se. But I think there's a couple of different rash-causing illnesses that could potentially be confused with mpox.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you for this excellent presentation. It's important for us to have tests ready. So in this case, it was very fortunate that we had a test. You said that there were other orthopoxviruses that could emerge. Do we, the CDC, looking to see if the test will work against the other strains, as well?

DR. CHRISTINA HUDSON: So the North American poxviruses that I mentioned do not-- they're not detected with the non-variola orthopox test. And Alaskapox is not, either. So we at least know that if someone happens to be infected with one of those, which Alaskapox does cause human disease, the North Americans, like I said, we don't know if it does, but this test we've shown in laboratory studies that it does not cross-react with those specific orthopoxviruses.

CLIAC MEMBER: OK, that's good to know for the future. And one question on the data that you showed from the CDC lab, 166 rectal swabs, two were positive for mpox. Were those individuals also-- did they have lesions for mpox, or were they asymptomatic individuals?

DR. CHRISTINA HUDSON: Right, thanks for that question. So we tried to screen out individuals that had lesions. But the rectal swabs were all self-collected, so there could have been lesions present that the nurse that was doing the screening didn't see, or the individual even didn't realize they had. So that is a limitation of this study.

CLIAC MEMBER: Thank you. Very interesting.

DR. CHRISTINA HUDSON: Thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you very much, Dr. Hudson, for that great information. I've had a lot of experience in the sciences and biology and genetics, as well. So I appreciate hearing. You mentioned that in 2022, that you saw mutation of the mpox virus, and that I believe you said, if I didn't hear you correctly, did you say you felt that was related to deletion?

DR. CHRISTINA HUDSON: So most-- so there's two things I talked about, and I went through it very quickly, so I apologize for that. So most of the mutations that we're seeing are due to APOBEC3, which is a human host enzyme. So when you look at the mutations across the genome, the majority of them are caused by that enzyme. And we have a paper about that, so I can put that in the chat once we get done. The other point I made was we are seeing some other interesting deletions, or rearrangements, in about 3% of the genomes-- not related necessarily to APOBEC3, that are

causing, for instance, issues with one of our diagnostic tests. So those are very, very small numbers. So not as convincing as APOBEC3 that it is something occurring within this particular outbreak. It may be something specific to those individuals, because I believe it's still at less than a dozen cases, if I'm remembering correctly, who were very immunocompromised. So for that particular deletion, it could be something more specific with those small numbers of cases.

CLIAC MEMBER: OK, then in association with that, is it your opinion that because that did occur, and that there was an opportunity for misdiagnosis and delayed treatment?

DR. CHRISTINA HUDSON: Well, so thankfully, those particular-- so first of all, our non-variola orthopox tests that is used in all the LRN labs and the five commercial labs, it's still able to detect those. The target of that test is what's called a viral essential gene. So if the virus loses that gene, it basically can't function anymore. So in theory, that gene should never have a mutation. Either way, we know for sure that test is able to detect those viruses with those deletions, and that's how it was identified. It was first tested with that test. It was positive, and then with a subsequent mpox-specific test, it was negative. And so that's when additional sequencing was done to figure out there was a deletion in that gene.

CLIAC MEMBER: OK, and you also said that you were able to collect specimens for detection prior to the onset of a rash, right? So is that DNA tested, or how was that carried out?

DR. CHRISTINA HUDSON: So in that DC study, it was DNA. But we actually were able to culture from the two rectal swabs that were positive.

CLIAC MEMBER: OK, great-- last, I notice you said that you used LRN labs and commercial labs for testing, but I didn't hear you say you use POC certificate of waiver type of laboratory. So is that-- you just wanted to make sure you stuck with the big ones? Or can you comment on that? And that's my last question.

DR. CHRISTINA HUDSON: Thank you for that. So we already had the test established in LRN labs, and we have a close partnership with them-- especially for smallpox preparedness. So we do PTs with those labs to go through our smallpox algorithm, which is both epi and laboratory-based. So they already had the test in-house. When we decided we needed to increase testing access, we basically-- and [CLIAC DFO] and Jasmine can talk more about this-- but we reached out to commercial laboratories, and we really wanted to make sure they had a very large national footprint, so that we were hitting everywhere across the nation to make sure testing access was very, very good. So it wasn't a purposeful, I guess, selection, but that was the main goal when we brought those tests-- those commercial companies on board to run our test.

CLIAC MEMBER: Thank you very much. Excellent.

DR. CHRISTINA HUDSON: OK, thank you.

CLIAC CHAIR: Are there any more questions for Dr. Hudson? Seeing none, we're going to move on to our next speaker. I'm sorry, thank you very much, Dr. Hudson. Very informative. Moving on to our next speaker, it's Ms. Toby Lowe to talk about the FDA response. Ms. Lowe, the floor is yours.

FDA Response
Toby Lowe

MS. TOBY LOWE: Thank you. Thanks for the opportunity to provide this update. And I think-- there we go with the slides. Thanks, Miranda. So I'm Toby Lowe. I am associate director for regulatory programs in the Office of In Vitro Diagnostics at FDA. And I will go through a little bit of information about FDA's response since the beginning of the current mpox outbreak. So we've been very engaged with CDC and other stakeholders since the first case of mpox was detected in the US. As Christy talked about, CDC does have a cleared, non-variola orthopoxvirus test, and we've worked very closely with our colleagues at CDC to increase the testing capacity with that test. So we cleared the use of additional regions and automation, worked with CDC to expand that testing to the commercial laboratories, in addition to the LRM labs. And we've also been working with commercial manufacturers on development of additional mpox tests. And then, additionally, there's also a number of laboratories that have developed their own tests, and we've worked with those laboratories, as well, and monitored the tests that we're aware of for safety issues. And we did issue safety communication over the summer about using lesion swabs, and not other sample types, to avoid false results. So moving on to the next slide.

I did mention that there are laboratory developed tests that have been used for mpox. And I'm sure most, if not all of you, are familiar with lab-developed tests, so I won't go into great detail. But we do have some information here on what LDTs are, and on FDA's general policy of enforcement discretion with respect to LDTs, which is generally in place except for certain circumstances, such as public health emergencies. So that came up this year, obviously, since there were a

number of laboratories testing with LDTs prior to the declaration. And then we consider whether there are various factors, such as the national testing needs and other factors to determine if we need to put into place special enforcement discretion policies during a public health emergency. So when I talk about what we've done since that declaration, I can get into those policies a little bit more.

On the next slide, we have some links here for anyone who's interested. These are all actions that took place on September 7, so that was when the 564 declaration for emergency use of IVDs for mpox was issued by the HHS Secretary. And we issued a guidance document on that same day, as well as issuing the first mpox emergency use authorization. So these steps were all important to give FDA the ability to use our emergency use authorities. And in conjunction with that, we put into place some additional enforcement policies to help streamline access to mpox testing.

So on the next slide, we have some information about what was included in that policy. So we talked in the policy about our review priorities for emergency use authorization, as well as the enforcement policies for those tests that are developed and performed in a single laboratory. And those are high complexity laboratories, which are the labs that are able to develop LDTs. We also in the guidance document provided recommendations for diagnostic test validation, and some enforcement policies for modifications to cleared or authorized tests. And enforcement policies for serology tests, since we knew that there was some interest in that area, as well. So going into the specifics a little bit more-- the review priorities that we have been focusing on are high-throughput diagnostic tests, tests with home specimen collection, and rapid diagnostic tests. And due to the nature of the outbreak, we included in the guidance that we wanted developers to inform us of their intent to submit an EUA request within 30 days of the guidance. So that was by October 13. And we used that to help prioritize which submissions we were going to review.

And on the next slide, this is specifically for those tests that are developed by commercial manufacturers-- we did expect that those developers submitted their EUA request, or a premarket submission, and receive authorization or clearance prior to offering or distributing their test. But at the same time, once the test is authorized, we indicated that we don't intend to object to implementation of certain modifications to a developer's own cleared or authorized test while FDA conducts its review. So that we tried to sort of balance out those policies to get the right level of assurances there. And then, getting into the policies specific for tests developed by laboratories, we did include a policy for those high complexity CLIA-certified laboratories, where we do not expect EUA requests for certain diagnostic tests for mpox. And we sort of laid out the parameters for that. So PCR tests using lesion swab samples, we indicated that they should be appropriately validated, and that we thought that this would be-- that we would accept notifications for 30 days after the publication of the guidance. And that we thought the need for tests would be satisfied by the number of tests that would be put into place during that time. And then, additionally, we don't expect EUA requests for certain validated modifications to a cleared or authorized mpox diagnostic test. And we did ask for notification to FDA for both of these policies.
And notably, these policies do not apply to tests with home specimen collection or at-home tests, as well as to tests that use other specimen types or technologies. So we also provided a policy for enforcement discretion for modifications, and we did provide a list here of the types of modifications and the parameters around that enforcement discretion. So I won't go through all of these, but this was to provide some additional flexibility for laboratories that needed to make smaller changes to tests to incorporate them into their laboratory workflow.

And then, in the guidance document-- we can go to the next slide-- we also included voluntary templates along with the guidance document that provided our validation recommendations. And the two templates that are currently posted are for molecular diagnostic tests for mpox. And we've also indicated that we are working on templates for antigen tests, as well. And we also, as we've done in previous emergencies, we will update these as appropriate throughout the outbreak as things evolve. So then, mpox serology tests are the last policy that we included in the guidance. And it's important to specify that these are not for the use-- for these to diagnose an active infection. And so we included a policy where we would not intend to object to the use of serology laboratory-developed tests, when they include these specific warnings in their test reports. So last, we have a list of the currently cleared and authorized mpox tests. So the CDC's test that was cleared prior to the current outbreak, and has been cleared with modifications since. Then we have issued two emergency use authorizations so far-- one for Quest and one for Abbott's.

So the last slide here has some links that include resources for developers. So we have our website that has information on our policies and the authorized tests, as well as some frequently asked questions. We do have a virtual Town Hall series that we've been doing since the beginning of the COVID public health emergency, and we've been incorporating mpox into that, as well. And we also have email lists and a mailbox, if there's any questions, we are always happy to engage through those resources. And I'm happy to take any questions, as well.

CLIAC CHAIR: Thank you very much, Ms. Lowe. Are there questions for her? I see no hands up, so it was a crystal clear presentation. Thank you very much. And I do want to comment, it is light years more nimble than at the start of the COVID pandemic. So I want to thank the FDA for such rapid pivoting. Thank you. Our next session is for public comments, and we Rick Nolte lined up on behalf of the American Association for Molecular Pathology. But I don't see him in the room.

DR. FREDERICK NOLTE: I'm here.

CLIAC CHAIR: Oh, you're right in front of me. Rick, it's all yours.

DR. FREDERICK NOLTE: I'm on?

CLIAC CHAIR: Yes, you're on.

DR. FREDERICK NOLTE: Thank you. Good afternoon. I'm here on behalf of the Association for Molecular Pathology, or AMP. And I thank you for the opportunity to provide these public comments. My name is Dr. Frederick Nolte, and I am a member of AMP. As an international medical and professional association, AMP represents approximately 2,600 physicians, doctoral scientists, medical laboratory scientists and technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics.

We are pleased that CLIAC is being briefed on policy impacting mpox response efforts, and would like to provide several insights based on our members' experiences from working in a range of settings during these public health emergencies. First, the diversity of laboratories in the United States is an enormous strength. Certified public health laboratories are essential to begin testing in the earliest stages of an outbreak, and conduct surveillance in not-emergent times. However, their limited testing capacity and lack of integration with the broader health care system limits their ability to meet the clinical testing capacity needs in the US. Especially during times of significant community spread. Community and hospital clinical laboratories are optimally positioned to meet the testing capacity needs in their local area due to their physical proximity to patients. Additionally, community and hospital clinical laboratories are often able to provide the faster turnaround times necessary to manage patients that need immediate care.

Unfortunately, AMP surveyed our members multiple times throughout the COVID-19 pandemic, and found that academic medical centers and community health laboratories were consistently underutilized and deprioritized during the pandemic, particularly regarding access to limited testing supplies, and the FDA's prioritization of review of applications for emergency use reauthorization. As these types of laboratories also showed the fastest turnaround times, this was a great disservice in the public health emergency response.

Second, laboratory-developed procedures were instrumental in our country's response to the COVID-19 pandemic. Our survey showed that laboratories frequently deployed multiple SARS-CoV-2 testing methods simultaneously, including those developed by their own laboratories, and used this redundancy to minimize the impact of the ongoing supply chain disruptions. Varied types and locations of laboratories enabled the identification and tracking of different viral strains, which has been critically important for the understanding and adapting the country's response to the pandemic over time. Further, laboratories developed and validated innovative approaches to make sure patient care was maintained despite problems with procuring certain materials and test components. For example, laboratories validated the use of saline instead of extremely limited viral transport media, and the use of saliva as a specimen type to alleviate the swab shortage. Ultimately, diversity in both LDPs and laboratory types was not only crucial for navigating the COVID-19 public health emergency, but essential for innovation and patient access. As the country's diverse laboratory community was such a unique strength in responding to COVID-19 pandemic, we hoped that the policies put into place at the beginning of the mpox health emergency would seek to leverage that strength.

Unfortunately, we have found that the FDA's most recent guidance on developing, validating, and seeking EUAs for mpox diagnostic test, repeats the same mistakes we saw on the COVID-19 response, by not utilizing or prioritizing community and hospital laboratories. And fails to allow for enough testing diversity to meet the country's capacity needs. The FDA's guidance on EUAs for mpox states that they would prioritize applications from high throughput and high capacity laboratories. With these restrictions, we are concerned that, from the outset, local laboratories will be restricted from serving their communities, and molecular professionals be restricted from being able to practice medicine. Additionally, FDA set unreasonable timelines for compliance, and this policy set by the guidance document and acknowledged in this guidance, that its thinking could dramatically shift in just a month's time, continuing FDA's unpredictable pattern or diagnostic policy setting, that AMP finds strains laboratories limited resources as they adapt to changing requirements. It is critical that the same policy failures during the COVID-19 pandemic are not repeated in this current mpox outbreak, or any future infectious disease outbreaks. All laboratory types and testing approaches are needed to ensure that the United States can adequately respond to infectious disease outbreaks, and we urge the federal government to more appropriately develop policies that bolster each segment of the laboratory infrastructure in order to better prepare for pandemics of the future. It is imperative that the CLIA program be modernized to better reflect the current state of molecular pathology, and we urge CLIAC, as experts in the field, tasked with providing scientific and technical advice and guidance to HHS, to fully consider how CLIA-based regulatory system would better support patient care while allowing for innovation.

The COVID-19 pandemic showed the entire world the importance of molecular diagnostics, but also, how quickly our health system can fail if we do not support and employ all of our health system's strengths.
Still, we are resilient. If we are to meet the goals of the recently released national biodefense strategy regarding diagnostic availability, we need all hands and tools on deck, and a regulatory system better suited to support the molecular professionals working to care for patients and contribute to the response efforts. Thank you very much for your attention.

Committee Discussion

CLIAC CHAIR: Thank you very much, Dr. Nolte. Session is open for committee discussion. [FDA EX OFFICIO]?

FDA EX OFFICIO: Yeah, I just want to add a couple of things to the record here. So it's regrettable that some in the lab community do not understand FDA policy around COVID or around mpox, so I just want to make a couple of statements to correct some potential misinterpretations. And this is despite the fact that in the beginning of COVID, we had weekly Town Hall, and lots of press releases, and for mpox, we also started with weekly Town Halls to explain the mpox guidance. For mpox, prior to the emergency declaration for IVD, the FDA made clear that our usual policy of enforcement discretion for LDTs was in place. Anyone with an LDT could develop it, validate it, launch it, as is our usual policy. However, when the Secretary made the determination there needed to be EUA authorities for IVDs on September 7th, we did adjust the policy slightly. We only allowed any LDT that had a PCR-based technology and lesion swab sampling to either remain on the market, or they could develop a test, and they simply needed to notify us within five business days if they had already launched the test, with an email, with no data-- no data review by the FDA. And then there was a window of 30 days for labs to notify us if they wished to stand up testing for mpox.

We ended up hosting more than 80 notified labs, LDT labs. All of those just notified us with a simple email, and no data submission whatsoever. So I think that contrasts greatly from what was just expressed, and I wanted that entered into the record. There is no volume limits for those labs, LDTs were not held to any volume limit. Our focus on volumes was we wanted to spend our resources on test developers who could produce tests in high volume. The other thing having to do with LDTs goes back to the beginning of the COVID pandemic. On February 29, 2020, the FDA did issue a policy that said that LDTs of any sort-- no volume restriction-- could develop a test, validate it, notify the FDA, and immediately begin testing, even before we had received any data. At that time, for COVID, we were asking for data. And that policy remained in force throughout much of the pandemic. And there was no volume limits on tests at that time. So the FDA very clearly, in both cases, was very open to the helpful addition of LDTs to both COVID and mpox. So I just wanted to make sure the committee understood that. Thank you.

CLIAC CHAIR: Thank you. Are there other comments? [CLIAC MEMBER]?

CLIAC MEMBER: I feel compelled to represent the public health lab community and make a couple of comments about our readiness to respond. Each public health laboratory is different, faces different challenges, and you're under different structures. In the case of COVID-19, we worked closely with our academic medical center here in Iowa, and we were in constant communication with them on a daily basis. They could get resources for testing sometimes when we couldn't, and vice versa. And we shared what we could. The state hygienic lab, the public health lab in Iowa, did over 1.8 million tests for COVID so far. We ramped up dramatically to become a high throughput laboratory. We had space designated for surge capacity about eight years ago that we built an additional area out to our lab. And we utilized that space, and we're still using it today. And we hired over 200 people as temporary employees during this time period. It's hard to do that, but I'm very proud of our response for Iowa. I don't know what other states did, because I haven't been engaging in those conversations. But I think some public health labs can respond to emergencies like this. When we were faced with mpox coming on board, we did a modeling exercise to see what we might need to be prepared for testing, and we never exceeded our capacity to do those tests. So it's a matter of planning and it's matter of funding, at times, as well. But I think working together, we can all meet the needs for the state.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. Other comments? Hearing no comments, I would like to close the session on mpox, and get back to what you all are waiting for, to start talking about all those workgroup agreements that were presented yesterday, and to try and prioritize what we want to try to craft into recommendations by the end of the session. So [CLIAC EXECUTIVESECRETARY] emailed you during the break the latest compilation. Green is what we passed. Yellow is, I believe, what we discussed, but we've not finalized. And then everything in white is a free for all, as to how you want to line up this for discussion. [CLIAC MEMBER] already got in the front of the line and wanted to talk about self-testing and home testing. So that's already lined up. Are there other suggestions, priorities from other members of the committee? I'll maybe postprandial, but we have time to think about that. So why don't we start with recommendation number two in yellow. Is there a motion to approve?

CLIAC MEMBER: [CLIAC CHAIR], can I ask a question? This is [CLIAC MEMBER]. I think we went to yellow on this because we were going to try and wordsmith it to be a little more clear. I think that's where we got stuck. So I was just rereading it again for the 19th time, so maybe we can just say, performed under distributive model, where one laboratory

one component, a separate laboratory forms another component, instead of being specific. That each of those parts need distinct CLIA certificates. OK, sorry.

CLIAC CHAIR: We need an open motion, right? Before we can talk? So do you want to move approval?

CLIAC MEMBER: Yes.

CLIAC CHAIR: And [CLIAC MEMBER] seconds. OK, now go back to your editing.

CLIAC MEMBER: So I didn't want to be so specific about the distributive model. So I would take distributive model where one laboratory forms one component. And then other separate performs another, period. And then take out all the rest of the other stuff, and then say, that each separate and distinct CLIA certificates would be needed. I don't think we want to specify what's getting done at each place.

CLIAC CHAIR: Yes, and I think it was [CLIAC MEMBER] who wanted to be very specific about data analysis and interpretation. So [CLIAC MEMBER], we just took that out. How do you feel about that?

CLIAC MEMBER: But I think there's a whole lot that can be added to that discussion. Like again, can we make a paragraph, Mary, that bullet points all those issues? I mean, because we had many, many discussions about the data analysis, and the two presentations that were given to us.

CLIAC CHAIR: Right, and I guess my question would be, does it need to be in? As long as data analysis is considered to be part of the testing under CLIA, then it's OK not to call it out. But if it isn't.

CLIAC MEMBER: Well, it is.

CLIAC MEMBER: And I know there was another-- yeah, I know there was this new CLIA certificate type down below. So I think including it is a--

CLIAC MEMBER: Doesn't the statement above say that? That part of the testing process-- what's included in the testing process?

CLIAC CHAIR: No, we never got approval until testing.

CLIAC MEMBER: Oh, OK.

CLIAC CHAIR: Or the CLIA-- yeah, so this was a standalone recommendation about separate CLIAs.

CLIAC MEMBER: So yeah, so see the new CLIA certificate type, if that is approved, and CLIA follows the recommendation, then I think recommendation number two would simply say all the CLIA activities.

CLIAC CHAIR: So the open motion is the discussion around distributed testing with more than one laboratory, and each laboratory requiring a separate CLIA. [CLIAC MEMBER]?

CLIAC MEMBER: Apologies for missing some of this discussion yesterday, but I think there was still an open question around whether-- and again, when we're talking about bioinformatics, and I think even the complex multifactorial AI type algorithms that might be used to engender like a clinical test, I don't personally believe that for an entity, for example, that say, my wet lab sequencers give you a BAM file, if I sent that to an entirely separate shop, and that could exist to just do the reporting-- I do not think that there is a great CLIA identifier or something for that. And so I think that that's my concern. As we move towards maybe standalone, sort of data center type companies, or industries coming up to aggregate data and make what they say is a clinically actionable result-- do we do we actually have to define how those may need to be regulated as pertains to health care? And apologies if I'm revisiting something you discussed while I was absent.

CLIAC MEMBER: But then isn't it a new CLIA certificate?

CLIAC CHAIR: Well, should somebody help-- jump in if I my memory is faulty-- but I thought we included data if it's derived from a human specimen, that it was CLIA-covered.

CLIAC MEMBER: So that would put them under the regular-- OK, thank you. Sorry for that.

CLIAC MEMBER: So I think, given that that one has passed, that this recommendation covers data analysis and interpretation.

CLIAC CHAIR: And I just want to nit-pick this a little bit, because the statement is addressing two different laboratories. But in the distributed model, you could easily have three or four involved. So do we need to say, under distributive model where one laboratory performs one component and another and in parentheses, or others?

CLIAC MEMBER: Yes.

CLIAC CHAIR: Separate entity, parentheses, I-E-S, performs others. Each of these entities should have separate and distinct CLIA certificates, and PT would be required for all. Just off the top of my head. Does that make sense? [CLIAC MEMBER] says he sent [CLIAC EXECUTIVE SECRETARY] a pithy version. So let's see.

CLIAC MEMBER: Let's see it, [CLIAC MEMBER].

CLIAC CHAIR: I feel a lot of pressure on [CLIAC EXECUTIVE SECRETARY] here. She's holding up well.

CLIAC MEMBER: We can all agree to that statement, yeah.

CLIAC CHAIR: Yeah.

CLIAC MEMBER: The only thing is that I somehow feel one laboratory performs one component, and another performs another component. There have been so many other separate-- there have been other nouns along the way that I think it's important to say what another is describing, another component.

CLIAC CHAIR: So [CLIAC MEMBER], would you want to work on that? Or think about, do you like [CLIAC MEMBER] pithy one? Where he condensed—

CLIAC MEMBER: I see, different testing components, I see, I see. I was so stuck on that.

CLIAC MEMBER: I would wonder-- I mean, I guess it would fall into this, it's like, let's say you do some IHCs in your lab, but you send another IHC that you don't have the antibody for to another lab, that would be-- I mean, you're doing the same type-- I guess that would be a different testing component then, because the antibody would be different.

CLIAC MEMBER: Different spot.

CLIAC MEMBER: Yeah, in my pithy version, that would be a different analyte, and therefore a different component.

CLIAC MEMBER: Yeah.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. So and I think the problem where you're getting at around the verbiage is what we tried to include-- the workgroup tried to include under the new CLIA certificate type number two, where we ended up with a verbiage entity, that just says, entities that perform informatic analysis, or could be data manipulation, whatever it is, another entity. So we didn't want to specify a company, a lab, whatever it happened to be that another entity that was manipulating data that was sent to it from a wet lab should be regulated under CLIA. And so that was-- I'm sorry, Valerie, jumping ahead to number two-- but I really begin to wonder if recommendation number two, is it even needed if we jump down to the CLIA certificate type and make sure the wording is tight under number one and two, do we even need really recommendation number two? Or is it kind of redundant? Because again, really, the idea was is we looked at the way data is sent out of a lab and returned to a lab, whether it's around next-gen sequencing, or image analysis, or algorithms, manipulating data, we wanted to ensure that if it's used for, and included in, an interpretation and diagnosis, that that entity then would be regulated under the same rules, for quality and things like that, as a clinical laboratory. So that's where the entity wording came from. And that may help address some of people's concerns about-- are we talking with a wet lab? Which lab are we talking about that kind of thing? I'm not sure if that helps out, but in looking at this, I'm not sure-- do we even need to right now spend a lot of time on recommendation number two? Or just move on to the other ideas?

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: To the extent the recommendation two survives the moment, where is a geographic term which I think certainly confuses me. For me, it's the circumstances under which it's-- my perception of what this is trying to get at is when do you need two distinct certificates and when do you not? And so to me, explicit is the circumstances in which

multiple laboratories performing different testing components must have distinct-- wordsmith on your own time, it's confusing to me as it is right now.

CLIAC CHAIR: I'm going to pull the committee back to saying the entity under discussion is in yellow. Y'all are talking about what's in white below, right? That's not what we're supposed to be talking about. But I would also ask you to look at the sections we were talking about, the new CLIA certificate type, and do you agree that those concepts are embodied in these pithy yellow highlighted statements? [CLIAC MEMBER]?

CLIAC MEMBER: I mean-- so I'm going to go back to the yellow-- multiple laboratories, is a laboratory defined as an independent entity? Or could a laboratory be my micro lab versus my chem lab, within the same entity? So do we need a different word to indicate that distinct institutions or entities have to have their distinct CLIA certificate?

CLIAC CHAIR: This is a lot like the point I think [CLIAC MEMBER] was trying to make, and if I were to try to compromise there, we would replace laboratories with entities.

CLIAC MEMBER: Yes.

CLIAC CHAIR: Where it says, each site, we would replace site with entity.

CLIAC MEMBER: Right.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I think when we removed the phrase, distributive model, we lost the relationship and the reason that the data, or the information is being moved from entity to entity. And so I think, for me, that's where I become confused, and where this becomes just kind of gray. And so I think it's important to keep that phrase so we maintain the relationship and the reason that this is being shared between entities.

CLIAC CHAIR: Thank you. Do you like this insertion?

CLIAC MEMBER: The only thing I would say is that second where, I would like, in which, so that we--

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you.

CLIAC MEMBER: Did you call on me?

CLIAC CHAIR: Yes.

CLIAC MEMBER: OK, I was going to say something similar. The pithy version, nice try, to try to get it short, but then it was losing the fact that these are multiple entities performing the same testing. Or they're testing on the same sample, or the same patient. And if it's multiple entities, without tying that together, we're missing what we're trying to get at here. So would you accept if we insert on the same specimen after that parentheses? From different testing components?

CLIAC MEMBER: I like that. That's what I'm getting at.

CLIAC CHAIR: On the same specimen, comma, each entity must have a distinct CLIA certificate.

CLIAC MEMBER: Right, and then that might take care of, I believe it was [CLIAC MEMBER] question about, if I have a microbiology lab and a chemistry lab and a hematology lab under the same thing, but they're all performing different testing components, they all have to have their distinct CLIA certificate, that's not what we intend.

CLIAC CHAIR: We need a comma there. [CLIAC EXECUTIVE SECRETARY], please. Other comments on this?

CLIAC EXECUTIVE SECRETARY: So does this get into-- if we put same specimen, will this cover those that are-- I mean, I think, we all got this because like I said, it was because of these people and these sites that are doing the bioinformatic data interpretation and analysis. So if we put specimen, is it assumed that it's data, too? Because there's not really a--

CLIAC CHAIR: So we have data earlier in the parentheses, data analysis.

CLIAC EXECUTIVE SECRETARY: OK.

CLIAC CHAIR: Do you think that is explicit enough?

CLIAC EXECUTIVE SECRETARY: Sure.

CLIAC CHAIR: OK. [CLIAC MEMBER]

CLIAC MEMBER: I hate to be pedantic, but my work with me may have several specimens-- should we say on the same accession? Instead of specimens?

CLIAC CHAIR: I would say are thinking too much like an anatomic pathologist. Because you have one specimen, multiple blocks, right?

CLIAC MEMBER: Yes.

CLIAC CHAIR: And one accession.

CLIAC MEMBER: But one accession and multiple specimens.

CLIAC CHAIR: Right, but on the laboratory side, it's one specimen.

CLIAC MEMBER: Well, except that much of our paraffin embedded material will go to the molecular lab, which can operate on paraffin for DNA analysis. So the AP cases would fall under a setting where data from one paraffin block may generate molecular data, or molecular data from a paraffin block may be sent to a different entity.

CLIAC CHAIR: Do you think we need to be this detailed in this recommendation?

CLIAC MEMBER: And so, like I said, I don't know if I'm being a little too pedantic.

CLIAC CHAIR: Because I would be adding five words, and you know how I am and adding words.

CLIAC MEMBER: Or just replace specimen with accession.

CLIAC CHAIR: Accession is not a term familiar or commonly used in the laboratory. So let me stew in that. [CLIAC MEMBER]?

CLIAC MEMBER: No, I think we're getting a little bit away from our real point here and may confuse people. I think we're really trying to address the data and analysis and interpretation, that we should come right out and say, those laboratories that do data analysis and interpretation must follow CLIA regulations.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I'd like to second that, because I think there's already CLIA regulations associated with the wet work, and referral laboratories. So it seems like the unique component here is the data analysis.

CLIAC CHAIR: [CLIAC MEMBER].

CLIAC MEMBER: I would just say, I don't want to box us in to the future. And is there anything else that we need to consider? I think the point was, because it was really related to data to start, is that the only thing that we're really looking at? So I would just caution about being too specific. So again, just the for example. But the distributive model was really based on that things could be done in other places, and there was no oversight of those laboratory settings. Which is what [CLIAC MEMBER] was going back to. So it seems like we have two different things, whether it's on the same specimen, the same site, or a different laboratory, like a completely different laboratory. Which isn't really a laboratory, it's just a site-- the computer.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I think I agree with [CLIAC MEMBER], because as of right now, like I say, you might send some of your work to a reference lab, and they have to have their own CLIA certificate. So I would think that some of this wet bench testing, or all of it, is already covered. And that this is actually introducing data analysis and interpretation as needing

coverage. And so maybe it would help if we saw recommendation number one again, if we could scroll down enough to see it.

CLIAC MEMBER: No, below. The number one-- number one.

CLIAC MEMBER: Well, but that's explanatory notes. That's not the actual recommendation. The new CLIA certificate type, is that a recommendation? Or is that explanatory notes?

CLIAC CHAIR: It was a workgroup agreement. And it was a workgroup agreement that these different entities should be regulated by CLIA. And then it raised the question, do we need a different type of CLIA certificate? Which addresses sort of like secondary, tertiary analysis of things generated from a primary lab.

CLIAC MEMBER: So if we go back up to what we already said about data and passed-- should be-- OK. So once materials from the human body includes data, and data analysis--

CLIAC CHAIR: Which it does.

CLIAC MEMBER: Then the entity performing the data and data analysis is doing a test on material from the human body. So it seems to me that would already imply that they need a CLIA license.

CLIAC CHAIR: So is this motion a redundancy?

CLIAC MEMBER: I'm thinking that it is, although, certainly in our minutes, we should mention that that's what we meant by that.

CLIAC CHAIR: I want to comment in the chat, [CLIAC MEMBER] an noted she liked keeping the phrase, distributive model, because that's sort of what drove this conversation. But then [CLIAC MEMBER] popped up saying that Google doesn't think distributed model is a common term in the laboratory. So it's a term we've been using in CLIAC, but I don't know how widely it's recognized. So the questions for the group, is this duplicative?

CLIAC MEMBER: Maybe we just need to say that we need the new CLIA certificate to go with that data analysis component. Because we have it above.

CLIAC CHAIR: But above, when we have materials defined, it's automatically included.

CLIAC MEMBER: But weren't we saying that maybe it would be a different type, like--

CLIAC CHAIR: Well, that's different. That's different.

CLIAC MEMBER: OK, all right.

CLIAC CHAIR: This one is different. And so if you want to, we could say, this one possibly is-- this is redundant, so we're going to stop discussing. And then we can move to the new CLIA certificate type. Do you need a different type of certificate? That's one option. There may be others.

CLIAC MEMBER: [CLIAC MEMBER], what do you think? This was our product, just not clear.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, thank you, [CLIAC CHAIR]. Yeah, no, I agree. I think, again, to point out that what you're seeing is recommendations from the workgroup, was an iterative process. And so these recommendations-- or not recommendations, I'm sorry, these workgroup agreements were derived from a series of conversations. So what you're seeing is what we eventually arrived at, is agreement from the workgroup. So I agree that the change in the language implies that data analysis is now covered as part of testing, and a CLIA certificate would be required for those entities. I think the workgroup agreement was just trying to make that extremely clear. And say, yeah, this is a list of things that we've agreed on as we've talked about this. And then, the next piece was the derivation of the new CLIA certificate type. So again, it was iterative, and so some of this may be repetitive, these agreements. And so then, it would just be up to this group to decide what do we want to pull out from all of these agreements and put into a recommendation that goes back to HHS? So I agree that the next step would then be, yes, it should be covered under CLIA. And what's needed under CLIA? It's likely a new certificate type that would cover that type of activity under binding entity. I hope I said that well.

CLIAC CHAIR: So then, it sounds like we want to stop talking about this, that it is redundant. Do you both agree, as the workgroup co-chairs?

CLIAC MEMBER: I agree that that's where we would end up from the workgroup standpoint, yes.

CLIAC MEMBER: And I agree.

CLIAC MEMBER: The next piece that we got to, which is more actionable, would be the new coverage under CLIA from a certificate aspect.

CLIAC CHAIR: Let's hear from [CLIAC MEMBER] and then [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: And I agree with what [CLIAC MEMBER] has said in the sense that these two statements, the one we've been working on and the new CLIA certificate type, concatenate together. And what I would ask is that the focus be on the certificate type, but declare where one CLIA certificate ends and the other one begins. And that may simply be geographic, non-contiguous, or it may be some functional statement, but I think there should be guidance on when a single activity-- because data analysis can be part of the test system-- when that separates into two CLIA certificates. Hopefully that can be stated simply.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, just sort of food for thought, but do we need a new certificate type? Because it strikes me that we're still in high complexity testing, and is what is needed is a new specialty category? So just like you've got blood bank, which has its own specific personnel requirements, and whatnot, is data-- is what is truly needed is something that are high complexity that's data analysis, and describes the requirements for data analysis. And would that make life easier for CLIA? Don't really know. But anyway, food for thought that it may not be a new certificate type, so much as a new specialty.

CLIAC CHAIR: [CLIAC MEMBER]? Or actually [CLIAC MEMBER]?

CLIAC MEMBER: Thank you, just to answer that a little bit more directly, I think the conversation can-- correct me if I'm wrong-- at the workgroup level was because this entity, if it's just handling information, was not handling biologic or chemical materials, may not need to be regulated quite the same way as it is as a clinical laboratory that's handling those materials. And so maybe the safety requirements may not be as applicable, or some of those kind of things may not be quite as applicable. And that CLIA, or CMS may need to look at would there need to be a new CLIA certificate type? Because certainly not every parameter that a clinical laboratory needs to accommodate to handle biologic samples would be necessary for a company that just does data analysis. So that was some of the conversation at the workgroup. We certainly didn't get down to the detail of saying this is what every aspect of should it should be covered under a new CLIA certificate.

CLIAC CHAIR: And to cross reference [CLIAC MEMBER] comment, if we scroll down to personnel-- so while we're talking about a new certificate type, there is an agreement number one, that CLIA should define new personnel rules. And there we have variant classification now.

CLIAC MEMBER: Right. It was really more that, and also the security of transmitting the data, and the interpretation of the data. And the people were appropriately trained to do that. So it is sort of this iterative process on how to get there.

CLIAC CHAIR: So do we want to continue the conversation on a new CLIA certificate type? [CLIAC MEMBER]?

CLIAC MEMBER: Oh, I would say, yes. I would not continue the conversation on that yellow part, and I would do it on the new CLIA certificate type. I did have a side conversation, or someone in listening, one of the guests, who's in informatics. And I did go look and see if data exchange was defined by NIST, N-I-S-T, whose definitions we regularly use for security of data and various computer guidelines. And in fact, data exchange is not defined in NIST. Although, I think it [CLIAC MEMBER] who found a definition of it. And I did find, I think, some statistical organization defined it as including end to end validation of the messaging. While NIST talks about end-to-end validation, they do not call it data exchange. So I just want to make sure that somewhere in our discussion, data exchange is defined as independent end to end validation of a message.

CLIAC CHAIR: So if the minutes are reviewed in conjunction with that recommendation of the definition of materials, which included data, perhaps the actual authoritative body definition of data exchange could be included. I'm thinking it might be those Reagan's-- whatever that German name was-- that entity that does--

CLIAC MEMBER: I actually found it. And I can put that link in the chat.

CLIAC CHAIR: And I'm going to have [CLIAC MEMBER] talk while you're doing that. [CLIAC MEMBER]?

CLIAC MEMBER: OK, just a word-- where the word, they, I was going to ask, should we have another word-- let me see. It was the one that you just had up. OK, right here. Under this CLIA certificate, they are subjects, which it should be they replaced by?

CLIAC MEMBER: The entity.

CLIAC CHAIR: [CLIAC MEMBER], you broke up, we think you said they should be replaced by the entity? Is that what you were trying--

CLIAC MEMBER: I put entity just to be consistent with the top.

CLIAC MEMBER: Right.

CLIAC MEMBER: I concur, yes. I was just saying that, for us to reflect on changing that. So that's good.
Are you able to hear me OK?

CLIAC CHAIR: So when we talked about this is a new CLIA certificate type, there were some comments around these type of entities just manipulating data would not be held to the same biosafety requirements, or other things that right now CLIA covers. Do we want to have a statement in there that addresses that? And I look to the workgroup co-chairs, [CLIAC MEMBER] and [CLIAC MEMBER].

CLIAC MEMBER: Yeah, so sorry, [CLIAC CHAIR], go again. What--

CLIAC CHAIR: So entities that manipulate information only, right, are typically not exposed to--

CLIAC MEMBER: No, I agree, I agree with all that. That's why we said, do we need a new certificate type? But I guess I wasn't-- what was part two of that?

CLIAC CHAIR: Yeah, so do we need a new certificate type, and then what would it be? Because another option is to take CLIA, and just say, those entities when you do your risk assessment, or your annual, semi-annual evaluation, to say those sections are not applicable under the existing CLIA.

CLIAC MEMBER: But I think it was more-- so you're saying that these sites that just do informatics would still be under CLIA, but that these sections do not apply?

CLIAC CHAIR: Certain sections within CLIA today would not apply, yeah. And therefore, we would not need a new certificate type.

CLIAC MEMBER: We would just have to say what's excluded and that could get messy.

CLIAC CHAIR: Yeah-- I would just say, we would recommend what's on the screen right there. And then let our partners figure out how to write that into the survey manuals.

CLIAC EXECUTIVE SECRETARY: So I think from the workgroup, the direction that we went with needing this new certificate was because these people, or these entities, are only doing data analysis, they would have a hard time finding and qualifying as a certificate of compliance or accreditation, based on the fact that they would not have the typical laboratory director--

CLIAC CHAIR: Requirements, right.

CLIAC EXECUTIVE SECRETARY: The requirements or the qualifications. So as the workgroup really got down into the types of facilities that are already doing this now, do not have a CLIA certificate, there's no way that they could right now get a CLIA certificate without doing high level recruitment for a laboratory director. But we were also not saying that the qualifications for a laboratory director for this site should be the same as a certificate of compliance or accreditation. It's kind of a completely different beast. And so that's why the workgroup went the direction of there may be a need for a different CLIA type of certificate to cover these sites that are just doing that manipulation of data, or exchange of data, or whatnot.

CLIAC CHAIR: Thank you, [CLIAC EXECUTIVE SECRETARY]. I'm going to have [CLIAC MEMBER] and then [CLIAC MEMBER], your hand is still--

CLIAC MEMBER: I'm sorry, I'll take it down. So thank you.

CLIAC MEMBER: Would this be a new CLIA category?

CLIAC CHAIR: What I'm hearing based on [CLIAC EXECUTIVE SECRETARY] bringing up the background, I think this is, in the words of [CLIAC MEMBER], half baked. I think we need to go back to the workgroup and talk about what we would ask as a qualifications for a lab director, for lab personnel, all that stuff. It's too, I think, premature to talk about a new certificate type without having some detail behind that.

CLIAC MEMBER: So I have a question related to that, [CLIAC CHAIR]. If this is the qualifications are of such, and people who are sending all their stuff out for NGS interpretation, what are the qualifications that you are expecting? Because one of my concerns is, we can say we recommend this, and how many years is it going to be before these sites actually are held accountable for what they're doing? So I'm concerned about that. But is there something that we could add such that it's not half baked. And I don't know the answer to that, per se. But this is where Karen Kaul, and the people that are doing all that stuff now-- [CLIAC MEMBER], as well.

CLIAC CHAIR: I don't have an answer right now. So let's hear from [CLIAC MEMBER].

CLIAC MEMBER: Just a question, just the whole idea of manipulating data and whatnot. I mean, do we need to put anything in there about HIPAA regulations or certain types of security so that the data is protected? I mean, it's not-- that we need to think about?

CLIAC MEMBER: Well, that was part of the discussion, [CLIAC MEMBER], you know, like that's the reason that we want to make sure that they're regulated. So that all of those sort of safeguards for HIPAA and everything else are in place. It was just all the other pieces that go along with that certificate, like

[CLIAC EXECUTIVE SECRETARY] was saying, that don't quite fit.

CLIAC MEMBER: But something specifically here? Don't we need to write something in?

CLIAC CHAIR: Well, the question is, do we have enough to make an official recommendation, or does it need to go back to the workgroup to reach an agreement, then bring back to us? [CLIAC MEMBER] and then [CLIAC MEMBER]?

CLIAC MEMBER: Oh, I see other areas.

CLIAC MEMBER: Be happy to bring this back to the workgroup, I think, along with our colleagues, ex-officio colleagues on the workgroup from CMS and others that can help advise. I think one of the things-- and [CLIAC CHAIR], you are on the workgroup, you could chime in on this, too-- that if we're modernizing CLIA-- that terminology has been thrown around a couple of times-- if we're modernizing, maybe it needed to be a new CLIA certificate type to start-- kind of start over rather than trying to retrofit into what already exists. It may be more efficient and expedient to start with a new CLIA certificate type. So that was also part of it, too. But we certainly, as you said, could bring it back to the workgroup and defer to our colleagues from CMS on what they think would be the best route to get this done most efficiently.

CLIAC MEMBER: That would be part of the why. It's more, what's the requirement? What's the actual recommendation?

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

CLIAC MEMBER: I, taking [CLIAC MEMBER] point, that things happen slowly, and bioinformatics analysis is ongoing and affecting people's lives, I kind of like the item number two, the last sentence that says, this may require a new type of CLIA laboratory designation beyond certificate of compliance or accreditation. In my mind, that leaves it open to have a different designation that indicates that no, you may not have to wear PPE, but you have to have the right personnel. You don't need a lab manager, as defined by CLIA, but you have to have someone who is in charge of all your bioinformatics algorithms, and make sure that everything is working. So the job descriptions would be different. And I guess, and I'm going to shorten my statement now, I think this comes-- that this is covered by that last sentence.

CLIAC CHAIR: Yeah. [CLIAC EXECUTIVE SECRETARY]?

CLIAC EXECUTIVE SECRETARY: So again, it kind of ties in a little bit to what we were just discussing about certificate of waiver. Now, granted, we're not trying to open up the law, but we're trying to get-- workgroup felt something else was

needed. And if you're modernizing, the charge of this workgroup was to look at the entire CLIA regulations and see what needs to be updated. We have this going on now, where data is being sent out to sites that are not under any type of CLIA certificate, they're doing data analysis, interpretation, and sending it back to the laboratory. These sites should have some form of oversight. Is without a recommendation saying that CLIAC believes that something is needed, to take this back to the workgroup and start discussing personnel qualifications on something that-- I don't think that we can do that at the workgroup level without saying that, yes, we need something different. And what would that be, and what would that look like? So if the committee feels that a change is not needed to CLIA, then I don't think it's going to be worth the workgroup's time to start looking at what new director qualifications should be and revising and editing CLIA. So that's just kind of where the workgroup was thinking, was that, first of all, we need to get buy-in if something like this is needed, and then, we can add to our agenda, after subpart K, and after histopathology, for more conversations on personnel.

CLIAC CHAIR: Yeah, thank you, very helpful. [CLIAC MEMBER] and then [CLIAC MEMBER].

CLIAC MEMBER: I'm trying to digest what just said to us, because I agree with [CLIAC MEMBER] that there is a matter of time here, and we need to be addressing this quickly. Because there's a lot of this going on. And how is this impacting quality in these laboratories? And we need to have some input on that. On the other hand, I don't see where you wouldn't have to open a law again to get these changes made that we're talking about. And wouldn't it be easier to include them in the existing law than to set out changes into the law, and to place-- that would take a lot longer. So maybe it's a two part-- we would either do this, or include it in to the existing standard. So maybe we have to look at it from that perspective.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. In the report that you turned out, and I'm reading it specifically, it says, CLIA should require training and competency assessments for staff, such as pathology assistants, image technicians, cytotechs and histotechs performing digital pathology. So exactly how does that relate into the current discussion about the separate certificate type? With that expansion of personnel assessment, is that in a different part of CLIA? Is that something that you see that as being part of this new certificate type? But I wondered if you could share, [CLIAC MEMBER] and [CLIAC MEMBER], if you could share with us exactly what your vision was for those other personnel.

CLIAC MEMBER: Well, I'll say that I think that conversation came about for clinical laboratories that are already doing anatomic pathology, have a high complexity, considered high complexity, and planning to bring in digital pathology. And it would be that for those people who are involved in digital pathology, they need to have training and competency. So it would be a separate issue than an outside entity that needs to be covered under CLIA. So two different issues.

CLIAC MEMBER: OK, so what do we need to be addressing that issue? Or is that work to be developed by the workgroup?

CLIAC CHAIR: This is an agreement, right? This is an agreement that the workgroup brought forward to us. And so if CLIAC wants, it is our opportunity to make this a recommendation. Back to [CLIAC MEMBER].

CLIAC MEMBER: So many perform digital pathology, in that they operate the machine that captures the image. I don't know that they perform, as a group of physicians just described, actually perform digital image analysis, unless it's just a submit to that program button. So I would think that anybody who is creating digital image analysis tools needs to have an informatics competency.

CLIAC CHAIR: So I see these as overlapping circles. The thing we were talking about is a new type of CLIA certificate that would address laboratories that manipulate information only. And the overlap is some of these people were talking about, meeting personal requirements, would fall under that. You could simply, and as [CLIAC EXECUTIVE SECRETARY] said, add a new subpart to address the different personnel types. But I'm starting to hear that we probably should recommend a new CLIA certificate type to address this new type of analysis. That is what that motion, the open motion is about, if we can scroll back up. So perhaps it should be CLIAC recommends a new CLIA certificate type for the following-- and then we get rid of if. Get rid of-- so it would say an entity manipulating-- get rid of the its. So it sounds like this is the building-- the foundation building block, before we can start talking about the components of that new certificate type.

CLIAC MEMBER: After the comma on the second line, an entity manipulating information, blah, blah, blah, needs to have the appropriate CLIA certificate. Needs to have that new type of certificate. But I don't think you have to say that entity, because you took--

CLIAC MEMBER: --the beginning of the sentence here.

CLIAC CHAIR: Yeah, so you just remove entity, right?

CLIAC MEMBER: Then wouldn't we lose the comma, too?

CLIAC CHAIR: I think so. To have the appropriate CLIA certificate, whatever this new one looks like. So what do you all think about that? Further comments?

CLIAC MEMBER: Well, if we remove that one comma, then we don't need the first line comma.

CLIAC CHAIR: Go [CLIAC MEMBER], go [CLIAC MEMBER]. So remove the comma after information.

CLIAC MEMBER: And then, in the bullet point underneath, under that CLIA certificate, under this new CLIA certificate, the entity is subject to--

CLIAC MEMBER: [CLEARING THROAT]

CLIAC CHAIR: Yes, [CLIAC MEMBER]?

CLIAC MEMBER: Sorry, I was clearing my throat. But I was going to raise my hand. So I don't think you need the-- in the after one, after patient care, I don't think you need-- needs to have the appropriate certificate. Because the header already says there's a new certificate for this.

CLIAC MEMBER: I agree, yeah.

CLIAC MEMBER: And you don't need number two anymore, because you've incorporated that in number one.

CLIAC CHAIR: Yeah, so we can remove those seven words, beginning with needs.

CLIAC MEMBER: Patient care-- no, you want care, want patient care.

CLIAC CHAIR: And we can go up and remove the colon, and move the and. I'm sorry, recommends a new certificate type for an entity.

CLIAC MEMBER: And then--

CLIAC CHAIR: Do we have to add the patient confidentiality?

CLIAC MEMBER: It seems to me that they're conducting a HIPAA transaction, and therefore, it's covered. But I don't think we need to-- I think it's--

CLIAC MEMBER: I think it's one of those things that it doesn't get done now. So I think it was just the fact that we called it out. But it doesn't need to be here. It would be part of the-- assumed to be part of the certificate, right?

CLIAC CHAIR: I'm sorry, [CLIAC MEMBER], you had your hand up?

CLIAC MEMBER: It sounds like a bunch of mics are open now. I was going to say the same thing, that that's the point, right? These are all the elements that will be expected. HIPAA is one thing of multiple
issues.

CLIAC MEMBER: Multiple.

CLIAC CHAIR: Exactly.

CLIAC MEMBER: So calling that one specific thing out doesn't make--

CLIAC MEMBER: Yeah.

CLIAC MEMBER: And is HIPAA even CLIA, or that's a whole different regulatory body?

CLIAC CHAIR: It's a different regulatory body.

CLIAC MEMBER: But also, HIPAA, it's one of those things that if you are transmitting medical information, if you're using software, that's already built in. Like it's hard to imagine that they would be using any portal. Again, this is one of the

reasons we're recommending this, because maybe somebody's sending an Excel spreadsheet over their personal email. But barring that, if they're using any portal system, a lab can't accept information that somebody sent from a personal email. So certainly, if they're going be sending it to a CLIA regulated lab, those portals-- the health care clouds are built out now for whether it's Amazon, Microsoft-- they're all built. So that should work, I think.

CLIAC MEMBER: This is probably in there, because that doesn't always happen. I'm trying to recollect the discussion, but it was specifically around that confidentiality that they probably weren't using the correct portals.

CLIAC MEMBER: If they're not, then that's the least of their problems, actually. That's such an obvious one. So that would be part of how it's mapped out.

CLIAC MEMBER: I don't think--

CLIAC CHAIR: [CLIAC MEMBER] has her hand up.

CLIAC MEMBER: Yes, I was just going to say, it looks like that's what, interoperability? And when you are engaging at that level, do we want to be safe than sorry? To say that we do need to have HIPAA there? Or do you think it's overkill?

CLIAC CHAIR: I think because HIPAA is a separate entity, not part of CMS or CLIA, I think we should state it. And I was going to suggest the wording, CLIAC recommends a new certificate type and HIPAA compliance for an entity manipulating information.

CLIAC MEMBER: Perfect.

CLIAC MEMBER: That's right, it's perfect.

CLIAC MEMBER: Don't assume.

CLIAC CHAIR: Yeah, don't assume. [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, and I just come back to HIPAA-- I think that's a point that [CLIAC MEMBER] made. There's other regulatory issues associated with a safe and secure mode of data exchange, data transfer, all of which need to be rolled into regulations when this new certificate type is developed, which CLIA will do. But I think it's broader that they need to be compliant with all regulatory requirements for patient data transfer.

CLIAC CHAIR: And so Heather, it's HIPAA.

CLIAC MEMBER: I do the same thing all the time.

CLIAC MEMBER: Every single time. Yep.

CLIAC MEMBER: You're in good company.

CLIAC MEMBER: But I love that idea, that it's all the regulations. That is-- that is just one little piece. There's multiple issues.

CLIAC MEMBER: Yeah, I mean, it needs to comply with interoperability standards.

CLIAC CHAIR: So how about CLIAC recommends a new certificate type and compliance with all security regulations, parenthesis HIPAA, comma, interoperability, comma, in parenthesis, whatever.

CLIAC MEMBER: Because a big piece is, is that any time that the patient's information is being transferred anywhere, he or she needs to be aware of that transaction about to occur, and give tacit permission for it to take place.

CLIAC CHAIR: And I just want to read [CLIAC MEMBER] comment, because I don't understand it. And you cannot run through a red light on the way to the office, but by definition, this is a covered entity and must comply. Not to be contrary, but I don't think we need a comment on this.

CLIAC MEMBER: Sorry if I'm being obscure. But there's all kinds of laws and regulations, and this one is important, and you have to comply in your covered entity if you're involved in this activity. I just don't think we need to comment on it.

CLIAC MEMBER: I feel strongly that putting that in there may-- it just, I think, it will distract. I don't think it will help. I think it would obviously have to meet all regulatory requirements. And it's--

CLIAC CHAIR: So I'm hearing two members recommending we strike the phrase that starts with and compliance. New certificate type for an entity, back to where we were. Is there further discussion?

CLIAC MEMBER: Yes, I'll raise my hand here. Just a point of clarity-- so we're not putting anything in there for HIPAA. And again, back to the fact that-- and I'm OK with either way, that when you're doing any type of transfer of patients' data that relates to interoperability, using any of those software systems, it's been my experience that you have to make sure that it's clear. But what I may be missing is that we're saying maybe we're saying it's clear, but not at this level, is that right? That's why we don't need it here? OK, if that's the case, you're saying that there's a prerequisite step that has occurred. And when you get to this level, it is not necessary, because regulatory guidelines have been addressed. OK.

CLIAC CHAIR: I understand [CLIAC MEMBER] comment about the red light. There's a whole bunch of things that cover you if you're doing anything with human stuff-- part of that is CLIA. But then other parts include various other entities. And so we're attacking the CLIA part, but the others would also be implied.

CLIAC MEMBER: OK, thank you.

CLIAC MEMBER: Sorry, the red light issue was just a--

CLIAC CHAIR: Threw me for a loop, [CLIAC MEMBER]

CLIAC MEMBER: Sounds like you've gotten a ticket before.

CLIAC MEMBER: I appreciated it, [CLIAC MEMBER]. I thought it was well said.

CLIAC CHAIR: [CLIAC MEMBER] got it. I was sitting there thinking, what does the red light have to do with HIPAA? But OK.

CLIAC MEMBER: So the rest of this whole statement then goes.

CLIAC CHAIR: So the recommendation on the table is that single sentence. [CLIAC EXECUTIVE SECRETARY], if you could just make it yellow, so folks can focus on it. Are there other comments about this recommendation? Hearing no comments-- oh, sorry, go ahead.

CLIAC MEMBER: I was just going to say, you know how I am, it's a little bit of wordsmith, not perfect, but the word it and returning it-- and so is it returning the specimen to the laboratory for--

CLIAC MEMBER: Information, yeah, data.

CLIAC MEMBER: It's the information or the data.

CLIAC MEMBER: I mean information.

CLIAC CHAIR: Why don't we make returning instead be returned, because we see from a clinical laboratory, and return to the laboratory. Actually, you could make it even shorter-- receive from and return to the laboratory.

CLIAC MEMBER: --is a derived product, not what was sent.

CLIAC CHAIR: Yeah. You're right.

CLIAC MEMBER: OK, thank you.

CLIAC CHAIR: Are there other comments?

CLIAC MEMBER: I don't think you need a comma after et cetera anymore.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. Hearing no further comments, I'm going to call a—

CLIAC MEMBER: Did we say we didn't need two clinical laboratories?

CLIAC CHAIR: I want to say, eliminate the first.

CLIAC MEMBER: Right.

CLIAC CHAIR: You see, from, and then return to—

CLIAC MEMBER: The first one.

CLIAC CHAIR: Yeah. And then, yeah. Any other comments?

CLIAC MEMBER: Well, yes, because if we say a clinical laboratory, it doesn't refer to the clinical laboratory. It could be any laboratory if it says a laboratory. Does that make sense? OK, let's see.

CLIAC CHAIR: Are you recommending we replace "a" with "the"?

CLIAC MEMBER: Right, return to the laboratory. Rather than a laboratory. It could be the laboratory across the hall, across the room. It would be a laboratory.

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

CLIAC MEMBER: I am just having a little problem with manipulating information, performing data analysis, et cetera.

CLIAC MEMBER: Et cetera.

CLIAC MEMBER: And so that takes it-- maybe it's not something with data, once you add et cetera.

CLIAC MEMBER: Yeah, I know, I asked that--

CLIAC MEMBER: When it says "et cetera," could you say, or similar activities? No-- and similar-- but I would just say, manipulating information.

CLIAC MEMBER: Yeah, I agree.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: Or you could say, yaddah, yaddah, yaddah.

CLIAC CHAIR: I think someone's going to throw—

CLIAC MEMBER: It's late in the day. We're getting punchy.

CLIAC CHAIR: Someone's going to throw rotten fruit at us for this kind of nickel and dime-- hey, let's go to [CLIAC MEMBER].

CLIAC MEMBER: I was going to suggest we just say, and other activities for the conclusion of testing.

CLIAC MEMBER: I like just manipulating information, because other activities could be a--

CLIAC MEMBER: That's again—

CLIAC MEMBER: Supposed to be wet lab activities.

CLIAC MEMBER: Good point.

CLIAC MEMBER: So this is specifically manipulation of information.

CLIAC MEMBER: Yeah, this is pretty simple. It takes a village to cut down 14 lines.

CLIAC CHAIR: Are there any other comments?

CLIAC MEMBER: [CLIAC MEMBER], you OK with this?

CLIAC CHAIR: You have your hand up.

CLIAC MEMBER: Well, I'm-- oh, [CLIAC MEMBER], sorry.

CLIAC CHAIR: No, [CLIAC MEMBER], it's you. [CLIAC MEMBER] hand is always up.

CLIAC MEMBER: Oh, no, sorry. I was going to say, I'm sorry. I'm just butting in at this point, sorry.

CLIAC MEMBER: There could be a third laboratory. I don't-- and I was almost thinking in the shortened it and just returned for inclusion in the patient report, or for patient care. It's just a thought. I don't know that it matters where you send it to. It's just this entity does something with it, and then they return a product that's going to be used for patient care.

CLIAC MEMBER: Well, if I may speak-- would we say then the pertinent medical lab-- laboratory?

CLIAC CHAIR: The suggestion is just to be very broad-- received from and returned--

CLIAC MEMBER: Returned to the permanent lab-- laboratory?

CLIAC MEMBER: Of the designated?

CLIAC MEMBER: It may not be returned to the laboratory. It could be reported to an EHR-- a hospital EHR.

CLIAC MEMBER: So could it be the designated?

CLIAC MEMBER: Well, that's why I wanted to leave it--

CLIAC MEMBER: Area, clinical laboratory?

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

CLIAC MEMBER: I'm going to channel [CLIAC DFO] and [CLIAC EXECUTIVE SECRETARY] at this point and say that I think our partners understand our intent with this. And if this is close enough--

CLIAC MEMBER: Is it good enough?

CLIAC MEMBER: They'll help us figure the rest of it out.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: I was going to agree, and I was also just going to mention, I thought it was important to maintain that it's a clinical laboratory, and if we stray too far from that, we're going to move into the research realm. And I don't think we want to do that.

CLIAC CHAIR: So it sounds like we want to leave, to the clinical laboratory, in, and it sounds like we're ready to perhaps vote, because we're torturing our partners with this wordsmithing. Are there any further comments? Some hands are still up-- did you want to talk? [CLIAC MEMBER]? If there are no further comments, I'm going to call the vote. Any opposed? Hearing no opposition, any abstain? This motion passes.

CLIAC MEMBER: Give it the green, [CLIAC EXECUTIVE SECRETARY]. And then, we're getting rid of everything underneath that.

CLIAC CHAIR: Yes. It's only the green goes forward on this document.

CLIAC EXECUTIVE SECRETARY: The red stays for all of our notes. The green is the only official.

CLIAC CHAIR: Right. Now earlier, when the session started, I commented that [CLIAC MEMBER] had asked that we consider options-- let me just read it exactly-- at home testing should include self-testing as a broader term. I think either both this should be prioritized for this afternoon's discussion. But what [CLIAC DFO] has very clearly told us is neither of these activities are covered by CLIA.
CLIAC MEMBER: Right.

CLIAC CHAIR: In which case, we should not--

CLIAC MEMBER: And Nancy kept going back to us many times saying, this is not covered by CLIA. Because I brought it up all the time.

CLIAC CHAIR: I know, I know. [CLIAC MEMBER] is agonizing over at-home collection. You can hear it in every sentence.

CLIAC MEMBER: So I'm just raising my hand real quick here, if I could.

CLIAC CHAIR: You could.

CLIAC MEMBER: OK, good, raising my hand. I'm just curious-- I know that FDA does approval in vitro, but I think many of us would like to know where does that responsibility lay in an organization like this one? Is there somewhere that there are experts discussing and helping to make decisions on self-testing? I think that's what we would all like to know so that we can work with them, as well.

CLIAC DFO: So if I could clarify just quickly, at-home collection is definitely within scope. OK.

CLIAC MEMBER: It's not at-home testing.

CLIAC DFO: But not at-home testing. Does that make sense?

CLIAC MEMBER: So that's what we need to know. For self, at-home testing, what is the group like this one that we--

CLIAC DFO: There isn't a federal advisory committee for at-home testing.

CLIAC MEMBER: And there's nobody covering it, other than the FDA.

CLIAC DFO: I said, there's no federal advisory committee for self-testing. There are multiple agencies that work on different pieces of self-testing. FDA has obviously the most important role, which is to authorize the tests for use and sale and distribution. But there's no federal advisory committee, and this is a federal advisory committee. But at-home specimen collection is definitely part of CLIA. And I think it was a great discussion yesterday about where does that fit? And should this committee make specific recommendations about that relative to CLIA?

CLIAC CHAIR: And I see [FDA EX OFFICIO] hand is up, and perhaps he wants to respond to [CLIAC MEMBER] question.

FDA EX OFFICIO: Yeah, just wanted to provide some information. So while there's no federal committee, there are FDA committees, advisory committees, that aren't specifically focused on home tests or home collection, but broadly are responsible for that. That's in addition to the work that FDA does to review home collections, and authorize them, and home tests and authorize them.

CLIAC MEMBER: So do any of them need expertise of those people on this committee? Could they use input from experts on this committee?

FDA EX OFFICIO: Well, the FDA, for its advisory panels, has experts that are relevant to an area. So we would actually divide up the categories of testing, and if it's like a home diabetes test, there is a separate committee than, say, another type of home test. So we have microbiology panel, so they are disease-specific focused, and they cover all sorts of testing within that disease category.

CLIAC MEMBER: OK. Is there one that works on antibiotic resistance and antibiotic stewardship?

FDA EX-OFFICIO: Yes, the microbiology-- the FDA microbiology advisory panel. Yes.

CLIAC MEMBER: OK, great.

CLIAC MEMBER: So [CLIAC CHAIR], I do have my hand up for real.

CLIAC CHAIR: But [CLIAC MEMBER] in line in front of you.

CLIAC MEMBER: OK, I just want you to know that it's for real.

CLIAC CHAIR: OK, got it, got it. OK, [CLIAC MEMBER]?

CLIAC MEMBER: Yes, [CLIAC DFO] actually anticipated my first point, is that at-home testing is not, I think, the discussion, it's at-home collection. And I also think it should be broader because self-collection is not necessarily in a domicile. It's in essence outside a health practice site. I sent a proposed recommendation to [CLIAC EXECUTIVE SECRETARY] at 3:55 PM-- we've been keeping her busy in the prior discussion. And what I attempted to do in the draft recommendation was to navigate a diagonal between yesterday's conversation about, is the laboratory responsible for specimen quality. And something that I think has been highlighted during the pandemic, but is by no means limited to it, which is the ability of a patient to self-collect a specimen outside of a clinical practice specimen, is a very important part of where medicine is moving. And I think that this is an opportunity to make a statement about that. And my parochial issue is that New York State has very strong feelings about the fact that this cannot be done. And I think federal statement, in some fashion, would be extremely helpful for achieving a standardization. So here's my recommendation-- and again, what I'm trying to do is split the diagonal between the workgroup's statements about specimen integrity and human controls, to state that this is self-collection, involving a collection device. I didn't mention the FDA, but clearly the FDA plays-- at least my understanding is the FDA comes into play with the device. But to basically say, to put this all together and say, we should make a statement about how the laboratory receives a specimen, and I included the workgroup's comment that if a laboratory chooses to test the specimen that falls outside acceptance criteria, that you have performance criteria. I did not explicitly move all of their language here, because I was concerned about overstating what the laboratory needs to do. Anyway, this is my attempt to say this is important, and to state where CLIA can help the laboratory and yes, the patient access have the specimen integrity that we require.

CLIAC MEMBER: Yeah.

CLIAC CHAIR: OK, [CLIAC MEMBER].

CLIAC MEMBER: OK, so yeah, I agree with that completely because right now, we have a lot of specimens that are self-collected, and FDA cleared as self-collection. But they have to be, quote, in a clinical environment, where when we found COVID, basically, the clinical environment ended up being the home. So I think it's just it is more the self-collection component-- if we can qualify that, then I think that is important. So I agree with how this is stated. I think it's really important to differentiate.

CLIAC MEMBER: And I tried to make it as simple as possible.

CLIAC MEMBER: Yeah. And so my question for [FDA EX OFFICIO], then, would be, if self-collection is something that is part of an FDA cleared product, does that open up the ability for that home collection, or somewhere else-- the CVS Pharmacy, whatever it is-- is that allowed, then, based on their…

FDA EX OFFICIO: So yeah, so we've cleared a number of, say, STD tests to have self-collected urine, sometimes self-collected swabs. If you move it from a healthcare setting, or going into the clinic, or the hospital's laboratory to collect the sample and then bring it back and give it to a healthcare worker, there's more strict chain of custody, and making sure that sample is handled properly, and stored properly, transported properly. When it goes to the home, then there are additional considerations to make. So one of those is the shipping of that sample back to the lab. So if you ship that, say, during the winter, and/or you ship that during the summer, what are the effects of ambient heat or cold on that sample? And what is needed? So for example, I was involved with an assay that was a wholesale assay-- it could be collected in the physician office and then shipped, even, not even from home. But it needed to be shipped on ice during the summer. So those are the additional considerations when you have a home collection, or even a remote collection. So when the FDA reviews a submission from a manufacturer who wants to do any of these kind of collections, we include looking at how that specimen is collected and how it's transported, and what safety features there are in place to make sure that that sample is not harmed in any way by time or temperature or transport, before it gets to the lab. To help ensure that the lab gets a quality sample that then can yield a quality result.

CLIAC MEMBER: And to that, that's why we didn't want the lab to be responsible for that home collection. That's why they said, the stuff starts when the specimen gets to the lab.

FDA EX OFFICIO: Right, but it's sometimes important to know when the sample is collected. So I believe for all the COVID home-collection submissions, we did want the users to record when they collected the sample, so that when the lab received it, they would know how old that sample was, and they could use that information. We would still encourage testing with it, but if it's outside the stated claim of how long ago that sample was collected, then the lab can note that in their report, and protect themselves, should labs be inspected, and whether they're following everything. So thank you.

CLIAC MEMBER: Thanks, that's helpful.

CLIAC CHAIR: I'm so-- this topic is on self-collection-- I realized we have not opened it as a motion formally for discussion. Do we want to? If so, can I hear a motion to approve?

CLIAC MEMBER: So moved.

CLIAC CHAIR: So I hear-- and I hear the second. OK, now, [CLIAC MEMBER]?

CLIAC MEMBER: Yes, I approve. I just have another comment after this.

CLIAC CHAIR: We're ready for your comment.

CLIAC MEMBER: OK, what I was going to say, it's a whole different piece, though, it has to do with the instructions for collections. And the fact that some of the literature is very difficult to see and read. Like I have one sheet here, and I won't mention to whom I received it from, but it's so light. And then I have another one that is nice and colorful, and you can easily read it. So just maybe do I need to write something in reference to the literature, the educational piece? Or is that for another day? Because this one, I end up not using, although I have not needed it. But--

CLIAC CHAIR: So it sounds like you're talking about the instructions for how to do the self-collect.

CLIAC MEMBER: Correct.

CLIAC CHAIR: And how that could be improved. And right now--

CLIAC MEMBER: Absolutely.

CLIAC CHAIR: Right now, that's not included in this verbiage. So I will think about how to insert it.

CLIAC MEMBER: OK-- or did you want it to be a standalone?

CLIAC CHAIR: No, I think we can group them all together.

CLIAC MEMBER: OK.

FDA EX OFFICIO: This is [FDA EX OFFICIO] As long as it's something that is FDA approved or cleared, the FDA tests those instructions. They ask the company to use it with typical users and show that it works. But anybody who sees a problem with any part of a product can report that to the FDA. I just want to alert that. So there is a mechanism for this committee to report certain issues to the FDA that is then the FDA's responsibility to take a look into it and take action, if needed. So it's just one outlet for potential issues, you might say. I just to make sure that was clear.

CLIAC CHAIR: Yeah, thank you. [CLIAC MEMBER] and [CLIAC MEMBER], if you still want to talk?

CLIAC MEMBER: No.

CLIAC CHAIR: OK. So then we're to [CLIAC MEMBER] and [CLIAC MEMBER]. [CLIAC MEMBER]?

CLIAC MEMBER: Thank you. I'm still a little confused what part of this is not currently covered by FDA or CLIA. And I guess my question goes mainly to Tim that, I thought-- we're seeing that the CLIA regulations would specify vendor requirements, but isn't that something that's included in the FDA approval of the device? And when analytically possible, inclusion of adequacy control and internal controls, again-- that almost sounds like how the FDA approves devices in the first place. And then, I thought requirements for acceptable samples and rejection of samples was currently in the CLIA regs. So I was hoping to get some clarification on that.

FDA EX OFFICIO: Yeah, they're shared-- they're shared responsibilities. So the FDA looks at it from a device safety and effectiveness standpoint, and we typically ask for integrity control and adequacy controls, where the technology allows. Sometimes that is not something that a technology can do, and so you try to control and mitigate the risks in different ways. And then, we ask the developers to test those mitigations to make sure they're—But yeah, it's definitely shared. In labs, if they receive a sample, say, the consumer at home didn't tightly seal something and there's been leakage, that's clearly something where the lab would note that that was a problem. Certainly either there's a problem with the collection device, it wasn't properly manufactured, or the home user didn't shut the device thoroughly. But that's just a very clear example of where there is a shared responsibility. It's important that the FDA determine that users know how to use the device and close it and ship it, and we do record problems-- have the test developers record problems such as they didn't

shut it and it leaked. We get all that annotated in a clinical study. So we know whether or not the instructions are adequate enough to ensure, in most cases, an accurate test, and a good sample that the lab receives.

CLIAC MEMBER: Yeah. So I guess going back to my question, then, so you've already got regulations and processes that you follow to ensure that some of these things are getting performed. Again, it's my understanding that we already have requirements for sample acceptance. So what I'm trying to get at is, where is the gap that we're trying to get to with this recommendation?

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. That's for the committee discussion, we're not going to put [FDA EX OFFICIO] on the hook for that. [CLIAC MEMBER]?

CLIAC MEMBER: I'm going in the same direction. Instructions, that's like home testing. We're back to the-- I'm a little confused because it's a little bit back to the home testing arena. And a lot of these aspects [INAUDIBLE]

CLIAC CHAIR: Well [CLIAC MEMBER], we were having trouble hearing you and now you disappeared. Are you back? OK, now you're on mute, and we're—

CLIAC MEMBER: I'm back.

CLIAC CHAIR: OK.

CLIAC MEMBER: Yeah, so-- yeah, so-- yeah, I'm sorry, I'm just repeating what [CLIAC MEMBER] said. What is the need? Because it sounds like if you're testing at home, it is FDA-- is that's the purview there, including the instructions. Right down to the instructions, and there's a mechanism to report issues. So in our discussion, maybe this all was addressed, and then maybe we'll focus needs to be discussed.

CLIAC CHAIR: Sue, you are breaking up, but I think your comments are along the lines of [CLIAC MEMBER]. What's the gap?

CLIAC MEMBER: Yes. [CLIAC MEMBER] I'm not sure [CLIAC MEMBER] breaking up, [CLIAC MEMBER] thank you.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: So I appreciate this discussion. My attempt was to distill into a recommendation that could be discussed the working group's prior agreements, I think, [CLIAC MEMBER] is calling them, about what should be done, and I am recalling yesterday's conversation where this committee expressed concern that lab was or was not held responsible for specimen integrity when the specimen was collected outside the lab. If, indeed, this committee's discussion with input from all quarters is that this is not a gap, then CLIAC can observe that, this motion-- this recommendation does not move forward, but instead, as I listened to the discussion, CLIAC said this is covered. And laboratories should not have to worry about being exposed to absence of regulation. And I think we have to be careful. It's not home testing, it's self-collection. There's a big difference. But if, indeed, between the FDA and the current CLIA regulations there is no gap, then I think laboratories should be able to operate with confidence in the space. The reason why I asked [CLIAC EXECUTIVE SECRETARY] and [CLIAC CHAIR] to bring this forward for discussion is that in our own local efforts to advocate for non-supervised self-collection as a regional laboratory, there are headwinds. And my parochial perspective is that guidance to laboratories and working with regulatory agency about unsupervised self-collection I think is something that needs to be grappled with and hopefully there be in place guidance so that we can adapt to where American health care is going.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: So I'd like-- well-- OK, sorry. It sort of goes along with that, is that I think a lot of times if you're doing a home collection, you're also doing the testing. And so it's not always one thing or the other. It's often paired. And so I think to Jim's point, that is where, as a regional lab, if I want people to do home collection at their convenience bring it to wherever, that that would not apply based on how-- I don't know of a specimen collection device that just has FDA clearance for home collection. Can you give me an example where a-- say a regional lab may not have validated how that gets shipped to them separately. So I guess that's my question. So if [CLIAC MEMBER] wants to go back to his New York State, bless you, and say, this collection device is FDA-cleared for self-collection, but that-- I don't know that that's separated. It's usually paired with the test system itself. What-- can you give me an example of that, [CLIAC MEMBER]?

CLIAC CHAIR: So I just want to say-- this conversation's around self-collection wherever that happens. So let's just move home testing off to the side and let's have [FDA EX OFFICIO] tell us what happens.

FDA EX OFFICIO: Yeah. The FDA can review self-collection devices, or they can be FDA-regulated. But when we authorize a collection device for a specific purpose, we need to link that up with a specific test. And we just-- for example, we just authorized the test for liver disease that was a saliva self-collection at home that gets sent into the lab. And so we evaluate, is that collection device, does it work well with the specific test and for the specific disease? And then they are a linked system. I was going to go back to say, though, that-- I mean, as far as the FDA is concerned, if the laboratories are using an FDA-cleared or approved product that includes a home collection and the laboratory is following the instructions of the test as it's authorized, as far as the FDA is concerned, the lab is following proper protocol, I don't-- I wouldn't see why the lab would get dinged for what happens outside of the lab. But when the sample is received by the lab, then that's where CLIA regulations, I would guess-- I know because I've run clear labs. That's where your responsibility-- so if you see there's no sample in the container, then there's-- because it was leaked all out, then that's a problem, the lab has responsibility at that point. But the lab doesn't have responsibility in my mind when it's FDA-cleared for the purpose and the collection is at home and sent to the lab. Thanks.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: The irony is through this whole discussion, I'm thinking about 24-hour urine collection, because if ever there was home collection, that's a 24-hour urine. My reflection on this discussion is that this topic is covered and that to the extent that there is assurance given to laboratories, then the appropriate checks and balances are in place for self-collection.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. My perspective on this, the gaps that I see, no matter where that sample is collected, I don't have any internal control to tell me it's from a human, and I don't have any internal control in most cases to tell me it's adequate. So if that's the gap, do we want to make a recommendation to the FDA to include those specific elements be included in the evaluation of a self-collect that will drive up the cost of the test? Because it'll drive up the cost of your collection.

CLIAC MEMBER: That's what we talked about in the workgroup. It was like, where are those clarity points needed? And that's exactly the point, Valerie, is how do we know it's a good specimen if it's not in a clinical setting, right?

CLIAC CHAIR: And there were three things. How do we know it's good? How do we know it's human? And how do we know it was within the right environmental conditions? There's no temperature and humidity gauge on these things. [FDA EX OFFICIO]?

FDA EX OFFICIO: All right.

CLIAC CHAIR: OK.

FDA EX OFFICIO: And I totally understand your concerns, and we share those concerns when we evaluate home collection. And we try to mitigate all those risks to the extent possible to a given technology. So any helpful hints you have for us on how we can improve things are welcome.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I would agree with that suggestion, [CLIAC CHAIR]. When we can integrate internal controls or human sampling controls into our molecular tests, we can, but that is not always possible. And that does also complicate the test or also drive up the cost of the test and we are developing a test and how. So I would agree with that suggestion.

CLIAC CHAIR: And then, to-- thank you. And to respond to [CLIAC MEMBER] comment in the chat about are people really sending animal samples? That certainly was postulated early in the COVID pandemic because the incentive was to get a negative result so that they could continue working.

CLIAC MEMBER: Or someone else's sample.

CLIAC CHAIR: We have no way to prove that.

CLIAC MEMBER: So I could sample my dog and send it in?

CLIAC CHAIR: Yes.

CLIAC MEMBER: Yep.

CLIAC CHAIR: People did. You are not alone. So then, given that, do we want to reword this recommendation? That CLIAC recommends that FDA--

CLIAC MEMBER: Consider.

CLIAC CHAIR: Include, whenever possible, inclusion of specimen adequacy, comma, environmental monitoring and human source verification for self-collect specimens as specimen adequacy control, comma, human origin and environmental monitoring for self-collect specimens. [CLIAC MEMBER], then [CLIAC MEMBER], then [CLIAC MEMBER].

CLIAC MEMBER: Forgive my ignorance, but I don't know how I would verify human origin. What tests would I use? Anybody know?

CLIAC CHAIR: Well for human genes, right? If you're doing nucleic acid testing, there's some housekeeping genes.

CLIAC MEMBER: OK. Because I don't currently do that.

CLIAC CHAIR: Yeah, yeah. This would be a big deal. [CLIAC MEMBER], then [CLIAC MEMBER].

FDA EX OFFICIO: Yeah, the CDC-- the CDC COVID assay which a lot of people copied in various forms has a human RNA control gene in it. So and that did prove very useful for verifying, especially in review of test results, if samples were adequate prior to reauthorization.

CLIAC CHAIR: [CLIAC MEMBER]? Oh, she muted.

CLIAC MEMBER: I'm good, yes. Thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: And I applaud this. I think the simplicity and the directionality is appropriate. I don't want you to get tangled up in the fact that the human origin control can also serve as a specimen adequacy control. So I might invert the sentence to say, whenever possible, controls for specimen adequacy, human origin, and environmental monitoring. And that way, you're not obligating yourself to three controls and can get away with two.

CLIAC CHAIR: Nice.

CLIAC MEMBER: Yeah.

CLIAC CHAIR: Nice.

CLIAC MEMBER: Thank you. I was going to say the same thing.

CLIAC CHAIR: Nice. So further discussion?

CLIAC MEMBER: Let's see. Hold on, just-- I just have a question. I was just reading and see if it was applicable here, but as I was thinking, it would be great in terms of instructions and all of that if-- when a consumer purchased a kit, a self-kit, if there was a QR code that would allow them to touch a link and have a video. So a QR code would really be great-- again, I'm back to this bad piece of literature that is difficult to read, but QR codes are so popular. Everybody-- even if they-- nosy people just want to see where it goes. So they'll be click, click, click and find out. So anyway, maybe that's for another piece, but I would like for you to just reflect cognitively on is there a way for us to recommend that that would have a video. Thank you.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: The noun may be wrong. Specimen devices. Is it a platform? Is it a technology?

CLIAC CHAIR: Oh, yeah.

CLIAC MEMBER: But the specimen itself is not what you're regulating, you're regulating the mechanism to get the specimen. So self-collect devices or something like that.

CLIAC CHAIR: Yes. You're even using the word that FDA uses.

CLIAC MEMBER: I'm learning.

CLIAC CHAIR: [CLIAC MEMBER], I just want to comment, many of the IFUs, Instructions for Use, in many of the assays point of care way that I use today do have QR codes. And I do know when I was looking at my home testing COVID, that I couldn't read the 2-point font. I just took a picture and went to the web and read the directions so I could do the test.

CLIAC MEMBER: But it may not be for all. So we want--

CLIAC CHAIR: Yeah, it's not--

FDA EX OFFICIO: No.

CLIAC MEMBER: No--

FDA EX OFFICIO: It's not-- it's not for all. It's not-- it's not an FDA requirement right now. Certainly the FDA has been encouraging this to help people understand how to do the test properly.

CLIAC MEMBER: OK, thank you.

CLIAC CHAIR: So further discussion?

CLIAC DFO: This is [CLIAC DFO], I have a question. Maybe this is for [FDA EX OFFICIO]. Should this recommendation say for authorization of self-collection devices or approval or--

FDA EX OFFICIO: Yeah, for authorization. It is very hard once the FDA has made a decision on a device and it's already been cleared or approved to go back and say, oops, you need to do something else. So it would be a forward-looking recommendation. And I'm fine to receive this. It is our goal to, whenever we look at these things, is to try to make this possible, and it's certainly something we did routinely for home collection and COVID, which we authorized, I don't know, more than 80, if not more than 100 home collection devices for COVID.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I was going to say something similar to what [CLIAC DFO] just added, but I'm also wondering, what do we mean by this phrase "environmental monitoring?"

CLIAC MEMBER: Yeah. I was just going to ask the same thing, yeah.

CLIAC CHAIR: Temperature and humidity. Do you want to just say temperature and humidity?

CLIAC MEMBER: In other words, a urine specimen to avoid the possibility that the patient tampered it?

CLIAC CHAIR: I'm thinking more like COVID. Our antigen test kits are like 15 to 30 degrees, but twice a year, it gets 35 degrees in our area. And so we can't use a specimen that exceed it at a temperature excursion. So if it went through the US mail to get to me, how do I know it stayed below 30 degrees?

FDA EX OFFICIO: And there are devices that you can package and even strips that you can package. What the FDA does has the developers bench test. Collect-- have a sample-- usually it's a contrived sample that mimics an actual patient sample. And then we have them bench-tested for the period of time of shipping that they claim. So say shipping could be 24 to 48 hours, then we have them tested at various temperatures and show that the result is still accurate. We have them dilute a positive or control down to near the limit of detection and then we have them do this bench testing to make sure that temperature extremes that are expected during winter and summer are not going to negatively impact the result.

CLIAC MEMBER: So we don't really need to say anything about environmental controls, then, because again, that's under your purview?

CLIAC CHAIR: And maybe it's already happening. That's what I'm hearing.

CLIAC MEMBER: Right.

FDA EX OFFICIO: Well, yeah, the sample adequacy control and the sample integrity control, you don't have sample adequacy here. So that's, did they-- for example, in a nasal swab, did they-- are there human cells in that sample? Let's say they collected a human sample. So the adequacy in the human origin could be in one. But then in addition, we want to

know that that sample remains intact. Now if it's an RNA control and it remains intact through shipping at the level expected, then that also is assurance that the sample has remained intact through shipment. So it's a little bit difficult to put all of these things into words, but we usually divide them at the FDA into specimen adequacy and specimen integrity. That's we're both-- we're testing both those things. The human control part of it is interesting because some developers don't test for the fact that it's a human sample. They can create other sorts of methods of measuring sample integrity. So if that's important to the CLIAC membership, they should include human in it, too.

CLIAC CHAIR: [CLIAC MEMBER], did that answer your question? So I would reward this-- I would reward this, it recommends that FDA include, whenever possible, controls for specimen adequacy, comma, integrity, comma, and human origin or authorization of self-collection devices.
Yeah, and take the environmental monitoring out of--

CLIAC CHAIR: --environmental out.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: That's good. That's what I was wondering about. Call on [CLIAC MEMBER].

CLIAC MEMBER: This is a question, not a recommendation. Does the CLIA requirement for laboratories to have criteria for specimen acceptance or rejection require any statement here that the lab needs to know what the device specifications are? In other words, if you're doing RNA, I think it's self-evident, but if there is some added analyte or some strip that's on the inside of the container or something, does any statement need to be made about the laboratory actually knowing how this device works? I think not, but since it was a concern of this committee yesterday, I'd like to make sure that no statement needs to be made.

FDA EX OFFICIO: Yeah, the regulations aren't that prescriptive.

CLIAC CHAIR: So [CLIAC MEMBER], where we got hung up yesterday was discussion of where the total test processing starts for a lab under CLIA, right?

CLIAC MEMBER: That's why I'm asking the question.

CLIAC CHAIR: OK. And so there was a group saying it's only when the sample hits the lab, but there's another group saying, but wait a minute, what about specimen collection? And there was a conversation that the labs should be recommending the collection device and know the information around that, and that's what they accept. But maybe we need to have more workgroup discussion.

CLIAC MEMBER: Well, I immediately think of pap tests, because the appropriateness by which the pap test sample is obtained is something the lab definitely reacts to. And however that's regulated, the lab has a very active role in working with the clinical site in this case that obtains the pap test. So we may be swirling in the teacup here, but again, I think not having to say anything is preferable, but if this committee thinks something needs to be said, this is the place to say it.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: So I think [CLIAC MEMBER] points are exactly, at least in my memory, what came up in the workgroup person comments, in that there was not, I guess, a total awareness of what was being done on the FDA side when something was cleared for self-collection as to what went into validation of that sample integrity or specimen integrity or environmental testing. And then you would need to pair that up on the laboratory side with ensuring that we knew what happened on the outside and that we could perform appropriate-- or ascertain that the specimen still maintained that integrity on the lab side. So I think the intention-- it was stated earlier, this is a cooperative where the FDA has its role and the laboratory under CMS has its role. So I think those need to be paired up. And what I hear with Jim, if FDA is testing these devices more extensively than the laboratory knows, there needs to be some way that the laboratory is aware of what kind of conditions the device was tested under. And so some of that can be incorporated into quality checks within the laboratory. I believe that was the conversation at the workgroup if I'm stating that correctly, [CLIAC MEMBER].

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: Yes, thank you. I've been reflecting on the word "integrity," and I wondered if a better word could be "specimen quality" versus "integrity." Because quality gets into QI, QA, and a benchmark that would determine something that we could measure by. So I would suggest switching "integrity" to "specimen quality."

CLIAC CHAIR: Any objections from the committee? And [FDA EX OFFICIO], is "integrity" a word that FDA uses to mean "quality?"

FDA EX OFFICIO: "Integrity" refers to the sample stays intact from collection to receipt at the laboratory. That's what we're measuring. "Quality of sample" in FDA terms would be-- could impact in a different areas, but I would immediately think they-- relative to COVID, was it a good enough collection of a sample? Was it a good enough nasal swab to be able to detect positives? Or was it-- but that's where a sample adequacy control-- both of these are quality measures. When the sample-- when the lab receives it, is it enough of a sample to make the diagnosis? And is the sample intact as well to not have false negatives in both cases? So those-- but that's how we define them. They're all under the rubric of sample quality. We also look at sample storage because if you collect a sample, we say-- in the instructions for use in the device, in the test or in the collection device, we'll say collect it and then transport it within so many minutes at room temperature, or if it's needed, ship it on ice, sometimes sipping on dry ice. It's all dependent on the sample. But it all comes from testing-- not done at the FDA, by the way, but done by the test developers to show the FDA that their mitigations or their test system ensures a good quality sample arrives at the laboratory.

CLIAC MEMBER: I will yield to you as to whatever is consistent with the nomenclature.

FDA EX OFFICIO: You can say "ensure quality sample gets to the laboratory" in so many words. Including measurements of sample adequacy and integrity and whatever other characteristics you have.

CLIAC MEMBER: OK.

CLIAC CHAIR: So my sense-- and [CLIAC MEMBER], you can debate this with me, is that the existing wording captured that. Quality has many components. The FDA already looks for many things, but the gap that we think exists is not all self-collection devices have a mechanism to assess for adequacy, integrity, and human origin. The stress test tests for the environmental conditions and other things are part of the existing--

CLIAC MEMBER: Yes. He actually explained it to me that it's broader than what I was thinking. And so I'm comfortable with that. Thank you. We could move forward.

CLIAC CHAIR: So I would like to call the vote on this. Is there any objections? Hearing no discussion, are there any opposed? Hearing no opposition, are there any abstain?

CLIAC MEMBER: [CLIAC CHAIR], I was just wondering, do we need two commas? It's getting-- it's kind of nit-picky, but-- so CLIAC recommends that FDA include, comma, whenever possible, comma, controls for specimen adequacy.

CLIAC CHAIR: Sure. I mean, I'm not the grammar person, so yes. So are there any abstentions?

CLIAC MEMBER: Boy, that really did it.

CLIAC CHAIR: Hearing no abstentions, this motion is approved with the appropriate commas included. Thank you, [CLIAC MEMBER]. It is now 5:40 your time. And I believe there's no way we're going to get through another agreement to reach a recommendation. So with that, I would like to conclude the discussion on the workgroup agreements. I would like to open the floor for suggestions for future CLIAC topics. Who would like to talk about what?

Future CLIAC Topic Discussion

CLIAC MEMBER: I have one.

CLIAC CHAIR: Just start talking. Go, [CLIAC MEMBER].

CLIAC MEMBER: I have a request from one of my HLA colleagues that we review the HLA decisions that apparently were made by CLIAC back in, I think, 2014. And there's been some changes and-- I'm sorry I wasn't-- I-- didn't review his request adequately to give you any more details than that, but I can give you more details in the next couple of days.

CLIAC CHAIR: So maybe modernization of HLA CLIAC issues.

CLIAC MEMBER: That would be a good phrase to use at the moment, yes.

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

CLIAC MEMBER: A rapid point-of-care testing for outpatient facilities to bring in some of the technology that we've learned from COVID on rapid testing point-of-care to help empowering those doctors' offices so they have as many tests as they need at a reasonable price for their clients. And if we can include antibiotic resistance-- a test that exists in other countries that you can test to see if it's a bacteria or if it's a virus. These are things we are missing out on, and we're overusing antibiotics and it's detrimental.

CLIAC CHAIR: So perhaps antibiotic stewardship on top of testing, yes.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: Yeah. We talk about host response markers.

CLIAC CHAIR: Response markers.

CLIAC MEMBER: That is FDA-cleared here. We have some.

CLIAC MEMBER: Can you add sepsis to that as well, [CLIAC CHAIR]?

CLIAC CHAIR: Yes.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: Sepsis is a very broad category. Do you mean testing?

CLIAC MEMBER: for sepsis.

CLIAC CHAIR: OK, got it. OK. [CLIAC MEMBER]?

CLIAC MEMBER: Question. Just looking at my notes from November 4 of last year, continuous monitoring devices was raised as a potential topic. And the question that I would ask is, this is analyte-directed, not oxygen pulse telemetry-directed, I assume. This would be the reason to bring this forward.

CLIAC CHAIR: Yes. Well, because pulse ox is light waves going through your finger, and there's no--

CLIAC MEMBER: So it's a continuous monitoring-- yeah, exactly.

CLIAC CHAIR: It's a glucose.

CLIAC MEMBER: It's an analyte-- this is an analyte-oriented topic, not a telemetry-oriented topic.

CLIAC CHAIR: OK. [CLIAC MEMBER], your hand is still up.

CLIAC MEMBER: Oh, sorry.

CLIAC CHAIR: Others? [CLIAC MEMBER]?

CLIAC MEMBER: It just tacked on to what [CLIAC MEMBER] said. There's a lot more remote patient monitoring going on, and certainly in primary care. And I don't know the regulations quality of those types of instruments, anything along those lines in terms of making sure that the integrity of those numbers is good. So remote patient monitoring stuff.

CLIAC CHAIR: Yes. [CLIAC MEMBER], your hand is up, but I just want to say, [CLIAC MEMBER] sent me a chat, and he says, there's been some great presentations today on workforce training, virtual reality, et cetera. However, I think we have to continually raise workforce development pay, et cetera, up in our discussion. In my opinion, we are in a crisis across laboratories concerning workforce. So I think we would add laboratory workforce, again, as a future topic.

CLIAC MEMBER: I would concur with that.

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

CLIAC MEMBER: You think I would learn this by now. So I would definitely support ongoing discussion of workforce. And on the molecular-- on molecular microbial resistance testing, just to further support that, there's been a lot of discussion on

the AMA CPT side about what to do about it. So I think that there could be some favorable reaction to discussing that and providing input that can inform the industry.

CLIAC CHAIR: OK. [CLIAC MEMBER]?

CLIAC MEMBER: Yes, I thought the discussion from the CDC about efforts to look at laboratory medicine integration with patient care and patient outcomes was very interesting. I'd like more updates on that. And also discussion of other possible avenues such as anemia screening I think would be valuable.

CLIAC CHAIR: Thank you. [CLIAC MEMBER]?

CLIAC MEMBER: I would be interested in more information on mpox testing, especially as it relates to some of the information that Dr. Hutson talked about today. So anyway, mpox testing.

CLIAC CHAIR: Thank you. [CLIAC MEMBER].

CLIAC MEMBER: Along the lines of the molecular testing, it might be a good idea to partner with the advisory committee called PACCARB. They are addressing the antimicrobial resistance and have continuously been highlighting the need for rapid testing. And so it might be great to partner with them, to get information from them. They have done a lot of studies, and then for the experts on this committee to be able to provide their input.

CLIAC CHAIR: Thank you. And I would actually think about [CLIAC MEMBER] and [CLIAC MEMBER] comments around antibiotic resistance. We did have a talk about culture-independent diagnostic tests which are really starting to make a major play in clinical microbiology. And as you separate the traditional serial way of doing microbiology testing, how is this impacting the workflow and therefore possible accuracy of diagnoses? I say that because what if you did a molecular resistance test but you don't know what the organism is? And how do you interpret that without putting it in the right context? [CLIAC MEMBER], your hand is still up, and then [CLIAC MEMBER].

CLIAC MEMBER: Oh, I'm sorry, I'll take it down. Thank you.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: So I think that all falls under the diagnostic stewardship component where I think we're taking many different pieces of information in the laboratory and how can we do that better? But I think for all of the diagnostics that we've done in our labs, how do you make that health economic outcome data stick such that we can justify, what is better for us to do for patients? And so how do we maybe get at that those questions better? So in the lab, somebody goes, oh, you can't implement a $250 test. I go, yeah, but at the other end, if I can save $10,000 and get the person out of the ICU faster because I identified her sepsis quicker, then that might be a good thing. So I think there's lots of examples that have started to come out with that. Is there some kind of guidance for laboratories to look-- how do they make those cases? So I think diagnostics stewardship work gets infection control, it gets antimicrobial stewardship, it gets the lab, it gets the ID people. That component-- and we have many people on this call who have already done that within their institutions. I think it's harder for smaller entities to be able to make those inroads for good diagnostics, let's say, that might make a difference for patient care. So maybe we can have more discussion on that.

CLIAC CHAIR: And this-- your comments align nicely with [CLIAC MEMBER]'S around the lab integration with patient care outcomes because if we can demonstrate that, that's a no-brainer. And you're right, the cost in the lab is, what, 2% of what the actual-- and yet we face the biggest budget fights.

CLIAC MEMBER: But we can do performance parameters very easily. This is faster than that. But the real issue for a lab being able to implement differentiating technology is where else does that affect downstream? And how does that message resonate better? So some of us are very vocal and very involved. We could get good technologies, I think it's just harder for other health systems sometimes.

CLIAC CHAIR: Are there more suggestions?

CLIAC MEMBER: I would-- let me just raise my hand here.

CLIAC CHAIR: That's [CLIAC MEMBER], it's OK.

CLIAC MEMBER: OK. I would be interested in finding out more what can the government do to increase DEI and inclusivity in the workplace as it relates to this particular topic.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Laboratory staff workforce.

CLIAC CHAIR: [CLIAC MEMBER]?

CLIAC MEMBER: I believe it was [CLIAC MEMBER]. I think that is fantastic, that this is actually critical. There are some fantastic diagnostics available that a lot of labs just simply don't have access to because lab directors don't like the way the finances work out even though there's no question we're talking life-saving and actually cost savings, we can't get these new diagnostics into place. Now who-- so I just want to second that, that I think that is critical. We're doing things in some labs that really are potentially out of date, are not in any way doing best by the patient. So I just wanted to give a big shout-out to [CLIAC MEMBER] for bringing that up. And a question-- and the question is, I guess that would be for the follow-up discussion about how even to implement something like that. But yeah, again, I don't think I'll be back for the next meeting, necessarily. So aside from just thanking everybody tonight, and it was just a great two days, but I think that's fantastic, that that should not be put on the back burner, because everything we create, everything we do, if you can't actually get it into patient care, it really doesn't matter. So thank you, [CLIAC MEMBER], that was fantastic.

CLIAC CHAIR: Yes. And for the future group, when this discussion occurs, the typical ROIs, Return on Investment that laboratories do are not accepted by organizations if we're bringing in patient outcome and save dollars. So how do we move past that to look at populations and have our ROIs include that information and strike a chord with our administrators? Any recommendations are welcome. It is 5:52. We end at 6:00. I want to acknowledge-- it's in the chat, thank you, [CLIAC EXECUTIVE SECRETARY]. But I want to acknowledge [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER], [CLIAC MEMBER], and myself for hanging on for one more session. In the immortal words of the Terminator, to paraphrase, we will not be back. And so I just want to comment, our next meeting date is--

CLIAC MEMBER: You've said that before.

CLIAC CHAIR: I know, I know, I know, but it's going to be for real this time.

CLIAC MEMBER: Those last words.

CLIAC MEMBER: We mean at this time, right?

CLIAC CHAIR: Yeah. So the next meeting date is April 12 through 13, 2023. A hybrid meeting is-- option in Atlanta. Information will be provided on the CLIAC website. Please email all CLIAC topics, suggestions, or suggested member candidates to cliac@cdc.gov. Yeah. And [CLIAC MEMBER] has noted, I didn't take a picture this time because I'm a retread and I don't think I need to take a picture to memorialize this. So with that, I am going to adjourn this meeting, and thank you all.

CLIAC MEMBER: Bye.

CLIAC MEMBER: Thank you, [CLIAC CHAIR].

CLIAC MEMBER: Thank you, [CLIAC MEMBER].

CLIAC MEMBER: Thanks, [CLIA MEMBER].

CLIAC MEMBER: Thank you, everybody.

CLIAC MEMBER: No group picture--

CLIAC MEMBER: --healthy.

CLIAC MEMBER: No group picture taken this time? That's been one of your hallmarks.

CLIAC MEMBER: Bye-bye, everybody. Thank you so much.