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

Meeting Transcript

November 6-7, 2019

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

November 6, 2019

❖ Call to Order and Committee Member Introductions

CLIAC DFO: I'd like to welcome you to the November 2019 meeting of the Clinical Laboratory Improvement Advisory Committee. My name is Ren Salerno and I'm the director of the Division of Laboratory Systems here at CDC, and I also serve as the Designated Federal Official for CLIAC. We're very pleased to have all of you here today. We expect this will be a great meeting, and we're very excited about the next two days.

My first order of business is to introduce to you the new Chair of CLIAC. I am extremely privileged and very honored to introduce Dr. Valerie Ng as the new Chair of CLIAC. Dr. Ng's numerous professional responsibilities and activities include Professor Emeritus in the Department of Laboratory Medicine at the University of California San Francisco, where she had a 17 year academic career. Currently, Dr. Ng is the Director of the Clinical laboratory and Director of the Transfusion Service at Highland Hospital in Oakland, California, a part of the Alameda Health System, which is recognized as a world class patient- and family-centered system of care, and promotes wellness, eliminates disparities, and optimizes the health of diverse communities. She serves on several medical and academic committees, and has authored numerous scientific articles. This is Dr. Ng's second term on CLIAC. Her current appointment to CLIAC began in September 2016, and most recently in December 2013, she served as the chair of the Nontraditional Workflow Model Workgroup, and presented that work group's report to CLIAC during the April 2019 meeting, resulting in three CLIAC recommendations.

Please join me in welcoming our new Chair.

[APPLAUSE]

CLIAC DFO: And I get now to turn the microphone over to you, Valerie.

CLIAC CHAIR: Thank you, Ren, and good morning.

AUDIENCE: Good morning.

CLIAC CHAIR: Thank you, can I hear it louder? Good morning.

AUDIENCE: Good morning.

CLIAC CHAIR: Thank you. It is my deep pleasure and honor to serve as the Chair of this committee, I'm looking forward to a lot of forward motion over the next couple of years and meetings. That being said, it's time to do our usual diligence with our introductions to each other, which will also serve as our roll call. Since we are seated alphabetically, we'll go alphabetically around. I would like you to please tell me who you are, where you work-- briefly-- and if you could let us know your conflicts of interest. We have three new members we are absolutely delighted have joined the panel. Birthale Archie and Carole Gross, and who am I missing? I mean-- Carole Moss and Jennifer, of course, she's dead center. And you three get a little bit special extra time to introduce yourselves to the other panel members, so that we can work well together. So with that said, Birthale?

CLIAC MEMBER: Thank you, Madam Chair. I have no conflict of interest. OK are you able to hear me now? OK. I said thank you, Madam Chair, I am Dr Birthale Archie, and I have no conflict of interest in serving on this Clinical Laboratory Improvement Advisory Committee. I'm a registered nurse, nurse educator, and Assistant Professor in the Graduate Nursing Program, and the immediate past interim Chair of the Department

of Nursing at Bowie State University in Bowie, Maryland. Some of the major courses that I've taught there are Advanced Nursing Research, Theory and Curriculum Development and Design, Role of the Nurse Educator, Transition into Nursing Practice, just to mention a few. And I have extensive experience in clinical practice in hospital and other settings, and also in academia. I reside in Columbia, Maryland, I have and hail from the great state of Michigan-- go blue! [LAUGHS]

I did my preceptorship at University of Michigan for my doctorate, have served two terms as a second Vice President of the National Black Nurses Association located in Silver Spring, Maryland, served five years as the Chair of the health policy for the National Black Nurses Association, and spoke on violence in a White House briefing. Member of the International Sigma Theta Tau Nursing Honor Society. I hold a Biology degree and a minor in Chemistry from Aquinas College, Grand Rapids, Michigan. Master's degree from Wayne State University in Community Health, and a Doctor of Nursing Practice from Case Western Reserve University, a Carnegie One University in Cleveland, Ohio. I have engaged in research on sickle cell, and more recently on medication adherence. I'm the author of the medication adherence algorithm that is copyrighted, it is also in the Library of Congress in Washington, DC.

I am pleased to serve on this great committee with a number of outstanding professionals to address laboratory improvements and regulations. This is also an opportunity for me to obtain greater insight into the operations of the clinical laboratories, and also to use that information to improve nursing practice as pertinent. And I'm a member of Mount Pisgah AME church in Maryland. Thank you.

CLIAC MEMBER: Marc Couturier, I work for the University of Utah Department of Pathology. I'm also a consultant for Area B Laboratories as a Medical Director, which is commercial non-for-profit National Reference Laboratory owned by the University of Utah. My spouse works for and receives income from BioFire Diagnostics, so as such, I have a financial conflict of interest with that entity. And I receive research reagents from [INAUDIBLE] Diagnostics Tech Site, BioFire, and Meridian Diagnostics.

CLIAC MEMBER: Good morning, I'm Keith Davis. I am Board Certified in Family Medicine, practicing in rural slash frontier Idaho, where I'm the owner, CEO, and Medical Director of a private independent rural health clinic, including being the Medical Director of a Physician Office Laboratory there. My conflicts of interest continue to be that I serve on the Board of Directors for Cola, a laboratory accreditation organization, where I serve as Treasurer, and I also serve on the Board of Directors of Cola Resources Inc, an educational organization where I serve as the Vice Chair.

CLIAC MEMBER: Good morning, I'm Lee Hillborne, I'm a pathologist. I am a past President of ASCP, my main conflict of interest, among my many areas of employment, is I am employed by Quest Diagnostics, and as such I obtain both a salary, and have some stock in Quest Diagnostics. I'm also a Professor of Pathology Laboratory Medicine at UCLA, and have a-- I'm Medical Director for Care Coordination, and do some health policy research at Rand. I think that's it, and I can say go blue, too, because we're blue.

CLIAC MEMBER: I'm Brad Karon. I'm a Clinical Pathologist at the Mayo Clinic in Rochester, Minnesota, Professor of Laboratory Medicine and Pathology there. Employed by Mayo Clinic and currently serve on the Council on Accreditation for the College of American Pathologists, and the Clinical Chemistry Committee for the College of American pathologists.

CLIAC MEMBER: Good morning, I'm Tom Lorey, I'm a pathologist by training, I currently serve as the Regional Medical Director of Lab Services for the northern California region of Kaiser Permanente. Let's see, I'm an Associate Editor with the Journal of Applied Laboratory Medicine, I have no conflicts of interest, financial or otherwise.

CLIAC MEMBER: Good morning, I'm Sharon Massingale, and I currently serve as a Laboratory Director for Public Health for the state of Alabama. And a conflict of interest might be considered that I am a member of the Association of Public Health Laboratories, and I'm also serving on the Workforce Development committee in that organization. I'm Certified by ABB, and I also serve as a Southern-area Representative to the Board.

CLIAC MEMBER: Good morning, I'm Lavinia Middleton, I'm a Pathologist by training. I currently hold the title of Deputy Division Head for quality at the University of Texas M.D. Anderson Cancer Center, and I have no conflicts of interest.

CLIAC MEMBER: Good morning, I'm Carole Moss, I'm happy to be here. I do not have conflicts of interest. In 2006, I lost my 15-year-old son Niall Calvin Moss in a war I never knew existed. The war of hospital-acquired infections and sepsis. The availability of rapid, accurate point-of-care diagnostic tools and the mandate to use them could have significantly changed the outcome. Niall would be 29 years old today. Not today, but this year, and that would be awesome for him to be here. Niall was one of the two-million people that contract preventable hospital-acquired infections. In that year, he contracted MRSA from unclean services from an MRI at the top Children's Hospital in Orange County, California. He contracted days later-- so days after his MRI, he began to have flu-like symptoms, and several pediatricians did not take his signs of sepsis seriously. They tested Niall for strep throat. After a negative culture, they handed me a prescription for strep throat antibiotic, and I spent the last three hours of my son's life in public, waiting for a useless antibiotic.

Instead of following urgent sepsis protocols, they handed me this antibiotic, and the next morning we rushed my son Niall to the hospital. And there were more delays. I watched my son suffer to breathe for more than 12 hours without one single drop of antibiotics. Niall died an hour after the MRSA test was taken. It took three days for the emergency doctor to call with the results of the test, to discuss MRSA and what that was. I'm so honored to be here with you working side to side. I've spent 13 years, My husband and I have really wanted to understand how this could happen and how we could prevent it from happening for others. And so my work began, making nine appointments at the CDC to understand why aren't you educating us? And it's been a great 12 years of relationship building with the many hardworking people at the CDC. We've worked with CMS. We started a nonprofit called Niall's Project and we are an awareness organization that educates the public. We work with health care workers, and we find a way to update policy and share personal stories that actually really do make changes. So I'd like to say that I've spent 12 years on the Hospital-acquired Infection Advisory Committee for the state of California as a public member, voting for 9, and for the remaining I've been subject matter expert for Antibiotic Resistance. I worked on the very first state to have the Antibiotic Stewardship and Environmental Cleaning subcommittees. I continue to share what we've learned-- what I've learned from experts like you-- with the public and policymakers. And I'm honored to work side-by-side with all of you to help improve CLIA outcomes and diagnostic testing that will implement rapid change and make sure that diagnosis are improving outcomes. Thanks so much.

CLIAC MEMBER: Good morning. Good morning, My name is Katherine Perez. I'm an Infectious Diseases-trained Clinical Pharmacist with Houston Methodist Hospital System. I lead the Antimicrobial Stewardship Program across the eight-hospital enterprise, and I work very closely with our Pathology Department in incorporating rapid diagnostics with our stewardship initiatives. Additionally, I hold an appointment with the Department of Pathology and Genomic Medicine at our institution, and I'm also faculty with the Houston Methodist Research Institute.

CLIAC MEMBER: I'm Jennifer Rhamy. I'm a medical technologist, specialist in blood bank, and hemapheresis practitioner. I am currently the Director of the Blood Center at St. Mary's Regional Hospital-- Medical Center in Grand Junction, Colorado. We serve 18 hospitals across Western Colorado and eastern Utah, primarily rural, and I have learned a lot about rural health care in the years since I've been there. My hospital is part of an eight-hospital system, and I lead the Patient Blood Management Collaborative for those eight hospitals, as well as

chair the Best Practices team for the Transfusion Services of all eight hospitals. I previously was Executive Director of Laboratory Accreditation at the Joint Commission, and have spent a number of years in leadership positions in hospital transfusion services, blood centers, and the medical device industry. And I have no conflicts and I'm here today because I have a passion for improving health care through high-quality diagnostics and laboratory services. Thank you.

CLIAC MEMBER: Good morning, I'm Bonnie Rubin from the University of Iowa State Hygienic Laboratory, currently practicing retirement from the State Hygienic Laboratory. I am also currently an Associate Professor at the College of Public Health at University of Iowa, therefore in keeping with the other people-- Go Hawks. And the only conflict I have is that I'm on a regulatory committee for the Clinical Laboratory Management Association.

CLIAC MEMBER: Good morning. I'm Greg Sossaman, I'm a clinical pathologist. I serve as the System Chairman and Service Line Lead for Pathology and Lab Medicine at Ochsner Health System, which is a large integrated delivery network based out of New Orleans, Louisiana. Since we're in Louisiana-- we're no Atlanta-- I won't mention anything about the Saints this year. I have no financial conflicts of interest, but I do serve on the ASCE Board of Directors.

CLIAC MEMBER: Good morning. I'm Cindy Wilkerson. I just retired a month ago from my last position as the Senior Director of Laboratory Medicine Department at Memorial Sloan Kettering Cancer Center in New York City. Prior to that, I did serve 30 years in the United States Navy. My last position was as the Director of the Center for Lab Medicine Services for the DUD. I've been a Med tech for almost 40 years now, so I'm excited to participate in this committee, and I have no conflicts.

CLIAC MEMBER: Hi, My name's Tom Williams. I'm a pathologist by training, Anatomic and Clinical support in Chemistry. And for 20 plus years, I was a Laboratory Medical Director and Chair of Pathology at Methodist Hospital in Omaha, and I also directed the Chemistry sections at Methodist, and also Children's Hospital across the street. I retired from that position in 2016, and took another position as the State Health Officer and Director of Public Health for the state of Nebraska, which I served for two years. And retired from that late last year, and now I'm doing some consulting, primarily in public health, and also emergency preparedness. And I have no conflicts.

CLIAC MEMBER: Good morning. I'm Donna Wolk. I'm the Director of Molecular Microbial Diagnostics and Development at Geisinger Health, an interdisciplinary health network in the health laboratory in central Pennsylvania. We cover 44 counties and 10 standardized hospitals and 13 affiliates. I'm an editor for Elsevier, which is a financial disclosure. I'm an Adjunct Professor at Wilkes University. I lead the American Society of Microbiology laboratory medicine best practice for rapid diagnostics for bloodstream infections, and the same topic for a non-profit called Project Santa Fe. I have current research grants from BioFire, Cepheid, OpGen, DiaSorin, and Safeguard Bioscience, all in the realm of rapid diagnostics and clinical outcomes.

ADVAMED LIAISON: Good morning. My name is Andy Quintenz. I lead the scientific and professional affairs group for Bio-Rad Laboratories, quality systems division. I am on the corporate advisory board for the American Association for Clinical Chemistry, on the board of directors for the Clinical and Laboratory Standards Institute, and chair of the US technical advisory group for ISO technical committee 212.

CLIAC EXECUTIVE SECRETARY: Good morning. I'm Nancy Anderson. I'm the senior advisor for clinical laboratories in the division of laboratory systems here at CDC. I'm also the executive secretary for CLIAC. I'm also on the board of directors for the Clinical and Laboratory Standards Institute, and have no conflicts.

CDC EX OFFICIO: Good morning, everyone. My name is Collette Fitzgerald. I'm deputy director for science in the Division of Laboratory Systems here at CDC. I'm the CDC ex officio for CLIAC, and I have no conflicts of interest.

CMS EX OFFICIO: Morning. I'm Karen Dyer. I'm the director of the Division of Clinical Laboratory Improvement and Quality at CMS, and I have no conflicts.

FDA EX OFFICIO: Good morning. I'm Peter Tobin. I'm a chemist in the Division of Program Operations and Management in the Office of In Vitro Diagnostics and Radiological Health at FDA, and I have no conflicts of interest.

CLIAC DFO: Just for the record, Ren Salerno from the CDC and I have no conflicts of interest.

CLIAC CHAIR: And I'm Valerie Ng, and I'm professor emeritus at University of California San Francisco, and currently chair and laboratory director for the clinical laboratories in Alameda Health System. I am a director of the board of directors for Alameda Health Partners, which is a wholly owned physician organization of Alameda Health System. I am a member of the Hospital Laboratory Workforce Initiative, which is sponsored by the California Hospital Association.

I have served in the past, and I think I remain on the roster for the FDA Microbiology and Hematology Devices panels. I serve as the editorial review chair for Doughty Enterprises in the laboratory medicine specialty, and I've been advisors to the Betty and Gordon Moore Foundation and CARB-X. Those are my conflicts.

So thank you. A couple housekeeping tools-- I want to remind all the members of the importance of remaining in attendance on both days for the full meeting, to ensure a quorum until all matters before the committee are addressed and the meeting is adjourned. And then for those of you who want to know these facts, the quorum is 13 members, including the ex officios but not including the industry liaison.

CLIAC DFO: Official CLIAC recommendations are those related to an item on the meeting agenda that are put forward as a motion, seconded by another CLIAC member, voted on by CLIAC, and obtain a majority vote.

CLIAC CHAIR: During the period for a committee discussion, participation is limited to CLIAC members. However, public comment periods are scheduled at the end of each topic area today, and we will have an extended public comment session tomorrow. Today's 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.

For those of you who are planning to provide a public comment, please fill out a speaker information form, located at the registration desk and at the back of the room. Tomorrow, we will have an extended public comment session on emerging technologies in the clinical laboratory. All public comments are available on the CLIAC meeting website and in the member folders. Please note that not all comments will be provided orally tomorrow. We would ask that you please review all comments tonight, and be prepared to discuss tomorrow.

So for scheduling purposes, may I please have a show of hands in the audience for those planning to give public comment on today? One, two-- so two people today. OK, one today. And the other person, would you please let us know on what topic you are planning to issue your comment? Workforce at 1 o'clock. OK, thank you. So schedule and logistics-- the copies of all the PowerPoint presentations and other meeting materials are posted on the CLIAC website. At the start of each presentation, I will announce the presentation number to assist you in locating the correct electronic file. The blue number on your agenda next to the presentations indicates what the presentation number is.

CLIAC DFO: Just a reminder, this meeting is being webcast and recorded. We welcome those who are viewing the meeting remotely. Links for accessing the webcast are provided on the CLIAC website. As I said, this meeting is also being recorded to assist in preparing an accurate written summary of the proceedings. Be sure to speak into the microphones, and keep in mind that all of your comments are being recorded and will be posted for the public. There will be morning and afternoon breaks. Food and drink items may be purchased in the CDC cafeteria downstairs, which is open until 1:30 in the afternoon. Take the elevators across from the auditorium to the basement level, turn right, and proceed past the guard.

Please wear your CLIAC badge at all times while in this building to prevent delays when entering and exiting the cafeteria. After the cafeteria closes, vending machines that provide water, soft drinks, and snacks are available on this floor. Restrooms are located down the hallway adjacent to the meeting rooms on both sides. If you purchase that cadence lunch online from Which Wich, your order can be picked up at the registration desk during the lunch break. The meeting cannot begin without a quorum present, so for non-committee members attending the meeting, there are also several dining options directly across the street from CDC's campus at the Emory Point development. We are scheduled for lunch at 12 o'clock, but I believe immediately before lunch, we will ask all CLIAC members, our AdvaMed liaison, and our ex officios to gather immediately on the stairs opposite the meeting room for a group photo.

CLIAC CHAIR: This meeting is also audio taped to assist in preparing an accurate written summary of the proceedings. A reminder again, please be sure you speak into the microphones. Please restrict sidebar conversations to outside the meeting room, and please silence your phones and other electronics. Dinner reservations are tonight at 6 PM at Cafe Lily near the Courtyard Hotel. If you would like to participate but have not already done so, please sign up at the registration desk before noon.

We're done with housekeeping. Moving on to the meeting. We will start today with our much-awaited anticipated updates from the CDC, CMS, and FDA. The online presentations are 1, 2, and 3 on the website. And as a reminder to our speakers, please avoid the use of acronyms. An acronym reference is provided on the website with the presentation for those of you who need some help. So now, we will move on to the CDC update, and that will be given by Dr. Collette Fitzgerald, and that is presentation number one.

❖ Agency Updates and Committee Discussion

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

CDC EX OFFICIO: Thank you. So good morning, everybody. Thank you for the opportunity to share some updates from our work in the Division of Laboratory Systems in the Center for Surveillance Epidemiology and Laboratory Services here at CDC. So in the Division of Laboratory Systems, our vision is that exemplary laboratory science and practice drives clinical care and public health. Our mission is to improve public health surveillance and practice as well as patient outcomes, by advancing clinical laboratory quality and safety, data and repository science, and workforce competency.

Our mission of work focuses on supporting the 260,000 CLIA-certified laboratories and testing sites in the United States in four priority areas-- quality laboratory science, highly competent laboratory workforce, safe and prepared laboratories, and accessible and usable laboratory data. Today, I will focus on sharing updates on some of our DLS activities in three of these four goal areas.

So starting with quality laboratory science, CMS and CDC issued a proposed proficiency testing rule in the Federal Register back in February of this year. This rule proposed to revise the proficiency testing regulations under CLIA related to required analytes and microbiology subspecialties, and their associated criteria for acceptable performance.

The comment period ended on June 4th, 2019, with more than 100 comment letters submitted by individuals and organizations. CDC and CMS are now analyzing comments, and gathering data needed to finalize the rule. Moving now to a project that I first mentioned at the last CLIAC meeting, we have performed a scoping literature review to look for opportunities for laboratory engagement to improve diagnostic excellence. The initial search strategy looked at publications from the last five years, from 2013 to 2018, and identified 1,392 articles, of which 116 were relevant to our project.

This box on the far right hand side of the slide highlights some of our observations and findings from further analysis of these 116 articles. Few studies used a definition for laboratory related diagnostic quality, safety, or error to drive the study design. 35% of the 116 articles were research, and 65% were commentaries. Studies developed to measure laboratory-related errors, processes, or changes in practice applicable to reducing diagnostic errors rarely included patient outcomes data. And lastly, there was a focus in these articles on the pre- and post-analytical phases of testing issues.

So there are local and national initiatives that are not described in the published literature that provide guidance and recommendations for laboratory practice supported by studies that link to patient outcomes. Identifying and sharing knowledge of these initiatives may advance the continued need to bridge laboratory and patient care settings to advance diagnostic excellence. So we need to conduct more outcome outcomes research that demonstrates the value of laboratory medicine, and to share unpublished findings, practices, and protocols.

So based on the findings from the scoping review, we at CDC now plan to develop a laboratory community of practice on diagnostic excellence based on the Project ECHO model. The purpose of this pilot will be to connect laboratory professionals, clinicians, and leaders in laboratory and health care, with a goal to engage laboratory expertise to capture innovative use of data and promote data driven processes, and to share best practices. We look forward to sharing updates on this project as it develops at a future CLIAC meeting.

This next slide shares an update on the Clinical Laboratory Partners Forum. Participants in the forum meet twice a year. The full meeting occurred on September 10th at the Association of Public Health Laboratories, or APHL, in Silver Springs, Maryland. 35 individuals representing 15 organizations participated.

Presentations and discussions focused on current priority areas that were identified by the group, which included workforce training needs and biosafety. Updates were shared on a number of topic areas, as shown on this slide, and included updates on the APHL Training Needs Assessment, workforce assessment of laboratory competencies, biosafety outreach from public health laboratories to clinical laboratories, preparedness training priorities for clinical laboratories, and a discussion on using data to describe the clinical laboratory community.

The next meeting of the clinical laboratory partners forum is scheduled for May 13th, 2020, here at CDC in Atlanta. So if there are any partner or professional lab organizations who are not currently part of the clinical laboratory partners forum, but are interested in joining, please contact Nancy Anderson from our division here at CDC.

So moving now to safe and prepared laboratories, in collaboration with the Center for Preparedness and Response, our division led a laboratory preparedness tabletop exercise on May 23rd, 2019, in Atlanta here at CDC. The purpose of this exercise was to assess the utility of a newly-created laboratory task force guide, and to review the processes for commercial laboratories to provide diagnostics surge testing during a public health

emergency. This was the first exercise to evaluate CDC's activation of surge laboratory testing support provided by commercial clinical laboratories.

So to build upon the Spring tabletop exercise I just mentioned in the last slide, and recognizing the need to take a look at the broader clinical laboratory community, we are beginning a multi-year study to assess the possibility of collaborative partnerships with other clinical laboratories and regional laboratory systems that may reliably offer high-volume and high-throughput testing to meet surge demands doing a public health emergency. The goals of this study include evaluating the capacities and capabilities of clinical laboratories that are non-public health laboratories to relieve the burden off of public health laboratories; to assess the ability and willingness of laboratories' participation during an active emergency, as well as identifying potential challenges with participation in surge testing due to biosafety, liability, and financial concerns; and finally, determining how to strengthen and steer these public private partnerships so that we are better prepared as a unit for the next public health emergency.

Shifting now to biosafety, we are collaborating with the Association of Public Health Laboratories, or APHL, who held a series of biosafety listening sessions in Minnesota, Hawaii, North Carolina, and California, between October 2018 and April 2019 with an objective to review public health laboratory outreach efforts to clinical laboratories, and to identify clinical laboratory biosafety needs. The summary reports from these listening sessions should soon be available from APHL, but some of the high-level findings from these full listening sessions are listed on this slide.

Identified gaps included leadership engagement. There was a lack of biosafety buy-in reported. Clinical laboratories reported a lack of leadership support related to biosafety issues due to various factors, and to a lack of data related to safety issues that would support investment in biosafety. Training and resources-- there was limited opportunities for training of laboratory staff as it relates to biosafety, and especially risk assessment, reported. Clinical laboratory staff identified risk assessment as an unmet training need.

For workforce, an absence of dedicated biosafety officers was reported as a gap, and for laboratory infrastructure, the gaps included outdated equipment and lack of sufficient laboratory space. Needs and some proposed solutions discussed at these meetings included engagement with academic institutions; the need to build biosafety curriculum and develop educational forums for young laboratory professionals, so that they can gain basic knowledge of biosafety before they enter the laboratory workforce; the need for evidence-based biosafety to capture data on laboratory-acquired infections, and to show the value of investment in biosafety, so a proactive rather than a reactive approach; and lastly, a need for additional training and resources, including a standardized approach to risk assessment and biosafety and biosecurity.

The APHL Biosafety and Biosecurity Committee will continue to collaborate with our division to address these identified gaps and needs moving forward. Moving now to a highly competent laboratory workforce, DLS continues to work closely with partners to develop and release training and workforce development resources to the clinical and public health communities to strengthen the laboratory workforce. This afternoon, in the clinical laboratory workforce update session, you'll hear from Senia Wilkins, chief of our training and workforce development branch in our division, about workforce activities we have been working on in FY19, and the new and exciting plans they have for FY20.

Our division is happy to make you aware that we have also ventured into the world of incorporating virtual reality into our e-learning courses. In a previous meeting, some of you may have participated in a VR demo that we provided. That VR demo was very general, and more about experiencing the technology. Today, we're excited to share a preview of our first-ever virtual reality laboratory course that is based on setting up a biological safety cabinet.

Senia Wilkins will also be sharing more updates about this project later this afternoon in the Clinical Laboratory Workforce Updates session. But please be sure to check out the demo during one of the breaks. The demo is set up right outside the door on the left-hand side, or to the right if you're next to the registration desk, so please check that out.

So my final slide this morning is to let you know that the CDC's 16th International Symposium on Biosafety will be held here in Atlanta, February 29th through March 4th of 2020. This will be the first time our division is responsible for leading and coordinating the meeting in partnership with the Eagleton Institute and the American Biological Safety Association, or ABSA International.

The purpose of this symposium is to promote the principles and practices of laboratory safety, with a focus on the needs of the biosafety community at large. The overall theme of this meeting will be the power of risk assessment, the importance of risk assessment, and making risk-based decisions related to the implementation of biosafety and biosecurity best practices within the clinical and diagnostic laboratory community. And with that, I'll finish, and I'll take any questions the committee might have. Thank you.

CLIAC CHAIR: Thank you, Dr. Fitzgerald. Are there questions?

CLIAC MEMBER: So I think, as I comment, I was very interested in your assessment of the link between laboratory quality and outcomes and so on, and for those of us who have found this elusive for decades now, and the challenges with linking our proximate outcomes with ultimate outcomes and so on, I'm wondering whether-- have you approached arc in the evidence-based practice centers to actually drill in, and actually engage one of their EPCs in trying to answer this question to work collaboratively?

CDC EX OFFICIO: Not specifically, yet. But we are hoping, through establishment of our ECHO community, to reach out to multiple stakeholders within the community to participate in bringing everybody together to think through how we make those connections.

CLIAC MEMBER: OK, because I think that would be a good connection. They're obviously part of you because they're part of HHS, and also, that's what they do, and they've got people set up. So I would strongly encourage, as ECHO moves, to really do that.

CLIAC MEMBER: I just came from a two-day symposium in Chicago with Clinical Laboratory 2.0 initiatives and Project Santa Fe Nonprofits Foundation, and this past meeting was a roadmap for laboratorians to describe exactly what you're doing-- experimental design, the PICOT format for experimental design, the CDC's analytical framework leveraging the CDC laboratory medicine best practice. And so they would, I'm sure, welcome any discussion and the meeting materials, or even something that maybe I could get them to share, just kind of by way of what was discussed at the meeting.

CDC EX OFFICIO: Terrific. Thank you, [CLIAC MEMBER]. Yeah, so we're familiar with their project activities and have had engagement with them, and we'll continue to do that.

CLIAC MEMBER: Yes, as a non-microbiologist, could you define the scope of "biosafety"? I mean, are we talking about emerging pathogens of public health concern, safety from strep in the lab, or what basically is the scope of interest in investigation in this area?

CDC EX OFFIOCIO: Do you want to take that one, [CLIAC DFO]?

CLIAC DFO: I think when we use the term "laboratory biosafety," we're talking about the prevention of accidental infection in the laboratory, as well as the prevention of accidental dissemination or release of an

organism from the laboratory setting beyond the laboratory. You know, it obviously has a lot of relationship to infection control, sort of in the broader health care environment, and a lot of laboratory biosafety practices can be applied to advance infection control.

But I think the terms that, in the work that we're doing in laboratory biosafety, is primarily focused on reduction of infections inside a laboratory setting, and the prevention of external release of organisms from the laboratory.

CLIAC CHAIR: Are there any other questions? Thank you, Dr. Fitzgerald. We're going to take a slight break, and give a warm welcome to Susan Gross. Susan, if you'd just please quickly introduce yourself, and declare your conflicts of interest.

CLIAC MEMBER: Apologies for being a little delayed. My name is Dr. Susan Gross. I'm an OB/GYN medical geneticist. I'm a professor in the Department of Genetics and Genomic Sciences at the Icahn School of Medicine at Mount Sinai. I am the medical director of the genetic laboratories at Sema4, which is a venture of Mount Sinai, and head of clinical affairs there for women's health.

I'm also founder and CEO of the OBG Project. It's an e-learning company to improve patient care via disseminating guidelines and evidence-based medical information in women's health, genetics, and primary care, and those are my conflicts.

CLIAC CHAIR: Thank you very much. Moving on with the agenda, our next presentation is from Karen Dyer, and she's telling us about CMS updates.

Centers for Medicare & Medicaid Services (CMS) Update

CMS EX OFFICIO Dyer MT (ASCP), DLM

CMS EX OFFICIO: Good morning, everyone. What I thought I'd do today is it had been a while since we really had gone into some detail about what we do at CLIA Central Office. So I thought I'd go in a little bit deeper in some of the particular areas of the things we do, update you on some of the statistics, talk a little bit about our Listserv and our outreach program. There we go.

I always like to provide this slide, because it gives kind of a general overview of what our world is in CLIA and the laboratories. So we are now up to about 266,000 clinical laboratories, and these range in size from an ambulance all the way up to the big LabCorp, Quest, and university facilities. The number that really is kind of amazing to me is the 192,000 waived labs. They currently make up almost 75% of the laboratories that we have, and if you know about waived labs, those have no oversight from CLIA.

So I provided this for you so you can just kind of see how the growth has been since 1993-- basically, the early days of CLIA. And it's been kind of interesting to watch how those numbers have gone up and down. So CLIA kind of came about, if you're not familiar with the history, is back in 1988, we had a wild west as far as laboratory testing. Everybody's doing whatever they wanted.

And particularly, in the area of cytology, this is very dangerous. We had people setting up shop for cytology in their basements, in their houses, wherever; doing whatever number of slides they wanted to do, not caring whether they reported them out correctly or not; women were dying, and women were having unnecessary surgeries. Congress found that that was abhorrent, so CLIA was born based on some of these cytology issues.

So the CLIA law is in Section 353 of the Public Health Services Act, and the regulations are published under 42 CFR Part 493. We also had an update in 2003-- this was before I got there, but we updated quality control, we

updated the quality systems for non-waived testing, we did some personnel qualifications, and we did some consensus requirements for grading proficiency testing challenges.

So CLIA, in all its great and glory-- I'm very partial, sorry-- CLIA established uniform quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of a patient test results, regardless of where it's performed. And CLIA applies to all entities which conduct testing on human specimens for health purposes. The other thing to note is CLIA is entirely user fee funded. We get no money from Congress, and we get no money from CMS to perform the duties of this program. We did a fee increase-- I believe it went into effect last February-- was the first increase in fees for CLIA in over 25 years.

So some of the things we do at CLIA-- we approve all the accrediting organizations and all of the exempt states, and they are approved as deeming organizations for CLIA. The AOs and the ES must meet the minimum CLIA requirements and regulations, but they can become more stringent if they so desire, and I think in most cases, they are more stringent. So we had a somewhat haphazard process when we first started doing all of these, and we formalized it in 2012.

We revamped it, piloted with two of the AOs-- I believe it was CAP, and I think the state of Washington. I'm not quite sure if that's-- but I think CAP was one of them. And we updated the implemented process in March 2012 for everybody.

We have a scheduling process for all of the accrediting organizations that we adhere to that schedule. They only submit final materials to us. The AOs cannot make any changes into their standards while we have them under review. We send them a courtesy letter and a courtesy call, and we have that high-level schedule of what they need to provide to us.

The re-approval process for an organization takes approximately one year. Their packages include crosswalks of all their requirements to CLIA regulations, and our review team will actually go on site to the headquarters of the organization to audit records, such as their survey reports, complaints, personnel, PT monitoring, et cetera. We can approve them up to six years, and that notice gets published in the Federal Register when we have finished that re-approval.

We also approve 10 proficiency testing programs, and these programs are approved on an annual basis, as well. PT programs are required to have at least three events per year, consisting of a minimum of five challenges prevented for all the analytes listed in subpart I, and all specialties and subspecialties-- except for microbacteriology, which only requires two events per year-- and that list of those approved programs can be found on our website.

So a little bit basic CLIA here-- we base all our requirements on test complexity. So we have waived requirements and non-waived requirements, and under non-waived, we have moderate, which includes the provider-performed microscopy and high complexity testing. The more complex the test, the more stringent the requirements for that test.

We rely on the FDA to do our test categorization for us. We do talk with the FDA about things as they come in if they feel that they need to get our input, but the FDA actually determines the test categorization, and those requirements are found at 493.17 17 in the CLIA regs. So this is a list of the certificates that we have. Again, we have the certificate of waiver, which we affectionately call the COW certificate. We have PPMs, or provider performed microscopy, certificates of compliance, and certificates of accreditation.

We also have a certificate of registration, which we give to the COC or COCA labs, which allows them to set up their testing, start testing until we actually get in there, and ensure they're doing it properly and they get their

final CLIA certificate. When we go in to do an inspection, we need to have some data to look at, which is the purpose of having that registration certificate.

We also have a research exception, which is a very hot topic right now. For research laboratories that test human specimens but do not report patient-specific results for diagnosis, prevention, or treatment, those labs do not need to have a CLIA certificate. If a research lab reports out result to an individual, whether it has a name on it or not, they're giving it to an individual for that person's knowledge-- that test would fall under CLIA.

So a certificate of waiver-- obviously, only waived tests. They do not get routine surveys. We can only go into a waived lab if we have a complaint. They're required to follow manufacturer's instructions for performing a test. That's their only requirement. They have no personnel requirements, either.

PPMs-- provider performed microscopy-- those are KOH preps for yeast, for saline, for trichomonas, urine dipsticks-- those kinds of things that they can do with a provider, nurse midwife, nurse practitioner, or physician assistant. We can also go in and do surveys on these labs, but they're, again, usually complaint surveys that we would go in on.

Certificates of compliance perform all types of testing. They are subject to biannual surveys, complaint surveys, the full authority under the regulations that we have to survey them. And we can also do validation surveys and complaints surveys on accrediting organization labs as well. These labs can also do all types of testing, but if they're only performing waived or PPM testing, a laboratory cannot have a certificate of accreditation. They would need to have a PPM certificate to do just that type of testing.

Our inspection requirements apply to all certificate types. A laboratory must allow access for us to assess compliance with the requirements. The laboratory must also provide upon request all information required to determine compliance. CMS or our agents, such as the state, may reinspect if performed complaint surveys, and the failure to permit survey results in adverse action. Depending on the circumstances, we can suspend their ability to bill Medicare.

The COC process is what we call an outcome-oriented survey process, and our principal focus is the effect or the outcome of that laboratory's practices on patient test results and on patient care. So our surveyors review and assess the overall functioning of the lab, and evaluate the laboratory's ability to perform quality testing-- the accurate, reliable, and timely test results.

We put an emphasis on the laboratory's quality system, as well as the structures and processes throughout the entire testing process, that contribute to quality test results. So when our surveyor goes in, we select a cross-selection of information from all aspects of the laboratory's operation, and we have the ability to expand a survey if quality issues are found.

So I think I talked a little bit about the Listserv the last meeting, and we're kind of excited about this. We wanted a way to get information out to labs that we currently didn't have, so we've developed a Listserv, and this slide and the next one are the directions. If you have not signed up for it, I would recommend you do. We promise-- and I've made this promise before-- we will not spam you with information, but we plan to use this for updates on regs or new policies, things we think will be pertinent to the laboratories.

So these are the directions for signing up on this, and we currently have over 7,800 subscribers for this. And our first message is now in clearance, so we hope to have that out within the next two weeks or so. I hope it'll at least be filed for the end of the year, depending on how the clearance goes.

So the last thing I wanted to talk about and give you an update on is our outreach. This was a particular project of mine that I thought was desperately needed, and I know it kind of ties in with the workforce development. But I was very concerned about med tech schools closing, MLT schools closing. They're not being a workforce to come behind us, and I'm also concerned about the workforce that we have that does not seem to realize why regulations are in place, why we do what we do to ensure good testing in the laboratory and safety for our patients.

So my outreach goals-- and my team, I have to be really proud of my team that has taken this and run with it-- but we provide medical laboratory science students with a basic knowledge of CMS and CLIA. We demonstrate the link between compliance with the regulations and the production of high quality laboratory testing. We also want to promote clinical laboratory science as a vital and dynamic career for high school and post-secondary students.

So we started this in the summer of 2016, and our target was allied health students with two- or four-year laboratory science programs, and in 3 and 1/2 years, we've built a school client list from 80-- eight; 80, that would be great-- eight to 20, and have reached over 250 students. We provide website information and 50-minute presentation on CLIA, like a CLIA 101.

We have a collaboration with Healthcare Students of America. We've been to some of their large meetings, and we are continuing with the post-secondary growth for schools with the MLT programs. We try to keep things within a 2 and 1/2 hour drive of Baltimore, so a day trip for us. And given the growth of point of care testing, we are looking to expand into our local nursing schools in the Baltimore area as well, so we can get them a better understanding of this type of testing. We also are exploring options to do professional videos that we can also put on our website for laboratories to use.

So I provided the CLIA central office contact number and our Lab Excellence mailbox number that if you want to share the Lab Excellence mailbox, that's where we handle most of our emails now. So it comes in, it's a consistent staff, and we usually turn an email around within about two days to get an answer back to someone. So with that, thank you very much.

CLIAC CHAIR: Are there questions for Ms. Dyer?

CLIAC MEMBER: I'm really excited to see that you're thinking about creating web-based educational tools. Just anecdotally, we were having a conversation last night, especially related to point of care, point of service testing, that we do need to expand that education in a standardized manner to the other allied health services, such as nursing and pharmacy. So I think, from the conversation and conversations in Iowa, it is appreciated to have a standardized web-based educational site, not just for what CLIA is, but how the standards and expectations of testing for like waived test. Thank you.

CLIAC MEMBER: So I also would add to that comment, phlebotomists in our system are doing some waived testing, and they have their ASCP certification, they're very compliant-- sometimes more compliant than the higher-paid medical subspecialties because the answer to the laboratory, so that's another area, perhaps.

CLIAC MEMBER: Oh, OK. Thank you. I said I was looking at your CLIA outreach goals, and I'm particularly looking at "promote clinical laboratory science as a viable and vital and dynamic career for high school and post-secondary students," and also I was looking at your COPA, where it said "targeted allied health students with two- to four-year laboratory science programs," et cetera, et cetera.

I know the university where I am-- and I played a role in it-- we were looking at being able to add some allied professions, where students could obtain degrees in allied health, and we have not completely formulated that

yet. We were looking at some others, so my comment is this may be an opportunity for us to collaborate and see if we could work together to address some of these concerns. And I could be work strategically with key persons in that regard.

CMS EX OFFICIO: I think we've actually been to Bowie State.

CLIAC MEMBER: Great.

CMS EX OFFICIO: I think we have. So I'd have to double check, but I think Bowie is one of the ones we've been to.

CLIAC MEMBER: Thank you.

CLIAC MEMBER: So this is going to come up tomorrow, but since you mentioned the 10 CMS approved PT providers, the work group on non-standardized testing from our last time identified the fact that since only regulate analytes have their scores transmitted to CMS. But since 2016, CMS has imposed requirements on how PT samples for non-regulated tests are handled, both by the CMS-approved PT providers and by laboratories, which has really prohibited PT models of following distributive testing, and inhibited the ability to probe accuracy for these complex non-regulated tests. Is that something out of the last work group that CMS is considering? Or I know it'll be-- tomorrow, are you going to wrap up those comments, and then go figure out whether or how CMS might adapt to the need to do distributive PT testing in light of the rules since 2016 on treating them-- PT providers and labs-- imposing those requirements as if they're regulated analytes?

CMS EX OFFICIO: I can't really talk about all the PT rules-- you do that. But some of that has been discussed, but as far as what the outcome will be, I really can't say at this point in time.

ADVAMED LIAISON: Thank you. I was curious about the comments around research labs. I wonder if you could expand upon some of the concerns that CMS may have around research labs.

CMS EX OFFICIO: As far as what?

ADVAMED LIAISON: Well, you said it was a particularly hot topic at the moment.

CMS EX OFFICIO: Yeah, there is an act in Congress that's involving with the FDA that they want to look at how that whole process of laboratory developed tests works, and trying to get some of that back under CLIA. We don't think some of it belongs under CLIA.

ADVAMED LIAISON: So you're mainly talking about a lead laboratory developed tests as opposed to research--

CMS EX OFFICIO: No, that's just an example. It could be whatever. You know, our concern with research testing, again, is that depending on how you're resulting it-- if you're doing it in the aggregate, you get 50% are showing this or 70% or showing this-- we're OK. You know, you don't really need the CLIA certificate. But as soon as you start giving something to a patient, and that's where some of the confusion is now, we consider that giving it back to a patient, whether it's just an overall vague answer or not, is still giving them something to act on, and that we would consider that a patient-specific result.

ADVAMED LIAISON: Thank you.

CLIAC MEMBER: Yes, so actually, that's a great point about the research. I direct a large hospital-based point of care program, and we're always struggling to interpret when a research project or an IRB protocol-- when the clinical decision's being made, and we try to educate our colleagues that if you're using this to decide to enroll a patient in a study, that's a clinical decision. Does CMS or CDC have education materials? Because it seems to be a constant battle in academic institutions-- probably others-- whether you're directing a point of care or trying to educate researchers on when they crossed the line and this is now a clinical test, so education material would be great.

CMS EX OFFICIO: Yeah, CMS currently doesn't have anything for that. I don't know about CDC. Anything else?

CLIAC CHAIR: Nancy, did you want to?

CLIAC EXCUTIVE SECRETARY: Well, this doesn't really get at the research question, but it somewhat answers the earlier comments about the need for online education for personnel, whether it's laboratory personnel or a phlebotomist or a general person off the street doing waived testing, that CDC does have a number of resources for Ready Set Tests, both in booklet form as well as a free online training or offers a variety of types of continuing education credits. So in the meantime, before CMS develops anything, if you're in need of that, just a reminder to go back to those types of training materials.

CMS EX OFFICIO: And we get good responses from the Ready Set Test book, because we distribute that out to our labs, as well.

CLIAC CHAIR: Are there any further questions? Thank you very much, Karen.

CMS EX OFFICIO: OK, thank you.

CLIAC CHAIR: Our next speaker is Dr. Peter Tobin, and he will be giving us an FDA update. It is presentation number 3 on the website.

Food and Drug Administration (FDA) Update
Peter Tobin, PhD

FDA EX OFFICIO: Good morning, everyone, and thanks for the opportunity to provide an update on some of FDA's recent activities. In today's presentation, I'm going to start out with some updates about the recent Center for Devices and Radiological Health reorganization, and then go through some updates in the areas of precision medicine, biotin safety communication, and SHIELD.

So when I was here last year, I talked about that we were going through a reorganization to support a total product lifecycle approach to devices, and this reorganization is now completed. And the reorganization across the center combined offices that were involved in premarket as well as postmarket activities, such as compliance, surveillance, and biometrics, into one single super office called the Office of Product Evaluation and Quality, or OPEQ. OIR, the Office of In Vitro Diagnostics and Radiological Health that I'm in, is also now called OHT7, or Office of Health Technology 7, and it's one of seven health technology-specific offices within OPEQ, along with two programmatic oversight and support offices called ORP and OSEA. They're down at the bottom.

Now, within OIR, we've also had some new staffing changes at the front office. In general, our management division level has been pretty consistent over the last year, but there's a few people that I'd like to introduce to you that our new deputy and associate directors at the office level. Dr. Wendy Rubinstein is a clinical geneticist

and molecular geneticist who's advanced the care of patients and families with hereditary cancer syndromes during her 15 years directing academic clinical and research programs.

She comes to FDA from the American Society of Clinical Oncology, where she was Deputy Medical director of CancerLinQ, ASCO's real world evidence platform, to improve the quality of patient care. Dr. Rubinstein also previously served in the federal government as director of the NIH genetic testing registry, and chief of medical genetics and human variation at the National Center for Biotechnology Information.

And Dr. Sara Brenner is our new associate director for medical affairs. This role is previously called the chief medical officer for OAR. Dr. Brenner is a preventative medicine and public health physician. Before joining FDA, she was senior policy advisor in the White House office of Science and Technology Policy, and associate professor of nanobioscience at the Sydney Polytechnic Institute.

And these two leaders will help FDA to continue enabling precision medicine updates in this rapidly developing area. In recent years, FDA has been involved with 37 unique companion diagnostics, as well as more than 100 human nucleic acid tests being cleared or approved, and we've issued more than 24 guidances in this area since 2005. And FDA continues to work with a wide variety of stakeholders, including industry laboratorians, academia, and patient and professional groups to develop a flexible regulatory approach to next-generation sequencing-based IBDs, and to continue to rapidly support and evolve in this area.

Many of these aspects are really community efforts. Some of the main areas that we're working with stakeholders are the development of technical and analytical standards for NGS, as well as efforts to develop reference sample sets that can be used to support validation of NGS platforms. Another area where there has been development in the last year has been the FDA recognized databases.

So last year, I mentioned that we put out a guidance related to a process whereby publicly available hemic genetic databases can be recognized through a process that's similar to the recognition of standards. And on December 4th of last year, we had the first database that was recognized, ClinGen, and then now that it's recognized, it can be used as a source of valid scientific evidence to support clinical validity and premarket submissions.

And the specific scope of recognition is germline variance for hereditary disease, where there's a high likelihood that the disease or condition will materialize given a deleterious variant. And for more information, I would encourage you to see the decision summary, where there's a lot more details about the recognition process.

Another area that I'd like to talk a little bit about is the aspect of when bioinformatics software is a medical device. As some of you may know, 21st Century Cures modified the definition of a medical device in the area of clinical decision support software to specifically exclude certain clinical decision support software if it meets a certain four criteria. So this guidance that went out in September, the clinical decision support software guidance, is a draft guidance. And it's open for comment right now. So I'd encourage you all to take a look and comment on it.

And it describes in more detail those criteria, as well as FDA's interpretation of that wording, "cures," and also which types of bioinformatics software is considered to be a medical device based on this 21st Century Cures update, in which would follow within the exclusion under 21st Century Cures. And I've highlighted a few specific aspects of the draft guidance right now in that box.

And as I'll note again, this draft guidance is not for implementation yet. It's a draft guidance, so please comment, and we'll be trying to finalize it once we receive comments and work through those. Also, one thing that I wanted to bring to everyone's attention is yesterday, we updated our previous safety communication from

2017 related to biotin, in order to remind the public, including health care professionals, patients laboratorians, and developers, that biotin often found in dietary supplements can significantly interfere with certain lab tests and cause incorrect results that may go undetected.

And so since the 2017 safety communication, some lab test developers have been successful in mitigating the biogenic interference in their assays, but others have not yet addressed it. And we've continued to receive adverse event reports, in particular related to troponin results, where biotin interference caused falsely low results. Because of this, we've also launched a new web page, Biotin Interference with Troponin Lab Tests-- Assays Subject to Biotin Interference. And this web page includes a list of FDA-listed troponin IBDs that are subject to biotin interference, but have not yet addressed this risk.

So one thing I'd like to point out is that within this area, these types of troponin tests fall within the MMI product code. And many of these tests within that product code either are not subject to significant interference, or have already addressed the risks. So roughly, within that product code, approximately only about a third of those currently listed tests are listed on this website.

The other 2/3 are either not signicantly effected, or the test developers have already been able to successfully mitigate this issue. But the FDA wants to make the public and health care providers aware that biotin interference continues to be a potential issue in this area, and be transparent about the current status of which assays are subject to Biogen interference to help prevent adverse events.

So now I'm going to move on to a few updates related to SHIELD, and this kind of relates to some of our topics later in the day today. So HHS and FDA have provided funding to conduct implementation pilots of SHIELD lab data infrastructure in six health care institutions and three public health laboratories for a total of nine labs by September 2021. And these implementation pilots, which there's a schematic of on the screen here, each IVD manufacturer will send vetted descriptive coding for the test that they provide in the same structured format to each lab, so that the information can automatically integrate into the lab information system.

Once implemented, all that lab will have to do is validate the accuracy of the coding, as opposed to manually entering their best estimate of what descriptive coding for that lab test should be. So it'll not only help improve how orders and results are transferred within a health care institution, it will also help transfer lab test data to other institutions, such as CDC or registries.

Under the clinical Laboratory Standards Institute, the SHIELD public-private partnership, is currently developing a report called Auto 17, and how labs, manufacturers, and electronic health record vendors can navigate available lab data standards and guidelines to promote IVD semantic interoperability. The goal is to release the first draft for public comment within a year.

This next slide is essentially just a reference slide that describes some of those lab data standards that will be part of the implantation pilots and the Auto 17 document. And that's all the updates that I have for today, and I'm happy to take any questions.

CLIAC CHAIR: Thank you, Dr. Tobin. Are there questions?

CLIAC MEMBER: Oh, OK. I just have a question in reference to the part where the FDA wants to make the public and health care providers aware about biotin's interference with lab tests, et cetera-- that particular area. So could you expound on that? What has been done so far, in terms of working toward achieving that? Because troponin is a very important part of our clinical practice.

FDA EX OFFICIO: Right. Well, we initially started a safety communication in 2017 after we started to see adverse events in this area, and we've reached out to manufacturers in that area as well, to help work with them to mitigate interference within their tests, and help them to communicate about biotin interference to their customers and, ultimately, to the users of those tests.

And we're continuing to try to get the word out in this area. That's one of the reasons why we worked hard to try to get this out in time to be able to speak at a CLIAC, and get the word out to laboratorians, as well as health care providers. And we're continuing to work in this area related to this updated safety communication to really try to get the word out that this is a continuing issue. There's been work toward mitigating it, but it's not a solved problem yet, completely, so there's still more work to be done in this area.

CLIAC MEMBER: Thank you.

CLIAC MEMBER: Yeah, and a very related similar question. So a number of manufacturers obviously realize the importance of biotin interferences, are working to mitigate them, and then those modified reagents have to, of course, get back through FDA. And the FDA has rightly had scrutinized very closely analytical clinical claims related to troponin, so are you working with these manufacturers to try to find an expedited process as they have reformulated reagents to get them approved, so that they get out in the hands of the labs, like all of ours, probably, doing the testing?

FDA EX OFFICIO: Yeah, we definitely recognize the importance of this area, and we want to get those tests that have improved performance and mitigated interference out to the labs as quickly as possible. So we are trying to work with those developers to make that happen as quickly as possible. And also, I think having this listing there on the website will help laboratorians to be able to identify which tests have already been able to successfully mitigate these issues, and which ones are still in the process of doing so.

CLIAC MEMBER: Has the FDA looked into whether or not there's a possibility to kind of centralize all of this information, not specifically with biotin, but just with drugs that we know interfere with lab tests? That includes guidance for clinicians as to when is it OK? You know, at what point can you tell a patient that yeah, it's been several days versus several hours, versus when can you actually get this test and have an accurate reading?

FDA EX OFFICIO: I think that's a good idea. I don't know specifically about that aspect, but I can certainly bring that back. It seems like a good idea to try to have that information available.

CLIAC MEMBER: Yeah, I mean, I just know from personal experience that one of the first questions you get is, or that I could get, is well, my patient took this two days ago-- will it matter?

FDA EX OFFICIO: I mean, unfortunately, there's not a lot of data available, a lot of times, from scientific studies to support that, but it's certainly good information to have and try to distribute when possible.

CMS EX OFFICIO: I'd like to add a comment. The biotin thing is kind of really big, especially in our setting for point of care urine pregnancy testing, where we recognize there are invalid results because of the biotin interference, so that takes out a large population at a time when we are really stressing the importance of prenatal vitamin supplementation.

But aside from that, my question to you is there are a number of assays in development that are using the streptavidin biotin detection system, and it is the FDA, as you meet with the pre-submission groups for these startup companies. Has the biotin interference been part of the conversation, so that the manufacturers or the designers can understand this will be a variable they need to think about in their design process?

FDA EX OFFICIO: Yeah, so we have a biotin group that goes across and includes leadership from the front office, as well as representatives from the various functional divisions. And so there is definitely a coordinated effort to work with test developers as they come in for pre-submissions, as well as to reach out to them when there's products already in the market that there are potential issues related to biotin interference, and to try to develop an path forward that's going to be effective at trying to mitigate that issue.

And you know, it does take time, because it was such a core piece of many assays that it can be quite a significant redesign for certain assays in order to mitigate that effect. So the timeline may vary from a particular technology to another technology, in terms of being able to successfully mitigate it. But it's something that's important to us to get the word out, and to continue to try to move that forward as much as we can.

CLIAC CHAIR: Are there other questions? Thank you very much, Dr. Tobin. Well, we are on time, so we are up for our 15 minute break, and we're going to give you 13 minutes, so we're going to reconvene at 10:05 to stay on the schedule. Thank you very much.

❖ Presentations and Committee Discussion

Follow up on CLIAC Recommendations

Introduction to Topic
Nancy Anderson, MMSc, MT(ASCP)

CLIAC CHAIR: Thank you. We will now have updates on CLIAC recommendations. And Miss Nancy Anderson will provide an introduction followed by updates on the APHL Opiates Task Force-- Opioids Task Force-- and the next generation sequencing quality activities. The online presentations are numbers 4, 5, and 6. Time has been allotted in addition for discussion on future CLIAC topics before we break for lunch at noon. So we will start with Ms Anderson.

CLIAC EXECUTIVE SECRETARY: Thank you and good morning again. I am here to kind of kick off really the rest of the meeting, not only the next two update presentations that you'll be hearing. Because really, all of the topics that will be discussed today and tomorrow are things that have previously been discussed at CLIAC meetings and for which there are CLIAC recommendations already in place.

So we thought it would be good to kind of give you some follow up, let you know about the recommendations, and where we are with respect to implementation of them. And to start out-- let's see. Before I do any of that, I did want to just remind you all that we keep a table with all of the recommendations that have been made posted on the CLIAC website. They're currently under the tab that says Meeting. And then if you go all the way to the bottom of that tab, you'll see this table.

And you can look up every recommendation going back to 1992 and the status of those recommendations. Including some links to letters that have been sent to HHS and other relevant information. But since 1992, when CLIAC was first chartered, there have been 151 formal recommendations made. And we track these and include in our annual report to Congress that of these right now, 121 of them OR approximately 80% have been fully implemented or completed, and then the other 30 THAT are listed there have to some degree been partially implemented. So as you scroll down through this table and are interested, you can see the status of each individual recommendation.

I'll also just give you another reminder that the information you provided to these recommendations is considered advice to the government. And while the government isn't required to follow up on every single recommendation, they really do significantly influence the work we do. And we rely on these recommendations for helping guide us as we move ahead. There is also no deadline for implementing the recommendations. In fact, recently, I went back to some that were from 1993 and took a look at them. So we don't forget about them after they've been made.

So just a brief refresher on the last two meetings that we've had, the recommendations that were made, and what we'll be following up on today and tomorrow. Going back a year ago now, the meeting that was held at CDC at the other campus, the main topics that were at their meeting you see listed here. And the next slide kind of summarizes the number of recommendations that were made at that meeting. There were two recommendations on improving diagnosis and the role of the laboratory.

One of those related to including laboratory professionals in multidisciplinary diagnostic improvement programs, and the other one was some targeted recommendations for the federal inter-agency work group on improving diagnostic safety and quality. There was also a recommendation made at that meeting a year ago that a personnel workgroup be formed to address questions that CMS had posted with respect to specific personnel elements in the CLIA requirements. There was also a recommendation made about the laboratory role in the opioid crisis, and a blue ribbon panel was recommended to be formed by the government to address a number of questions that were part of the CLIAC recommendation.

And then last, there were two recommendations related to antibiotic resistance, one asking for required use of contemporary break points for these antibiotics, and then another recommendation made to update FDA guidance so that the timely integration of updated breakpoints would be prioritized. So today, you will hear updates that are somewhat related to these. The recommendation on the lab role in the opioid crisis will be up next an update from Dr. Ewa King from the Rhode Island Department of Health who also chairs the APHL Opioids Task Force. She will be giving a report. And some of the things in that report will address the questions and the recommendations that were made a year ago by CLIA.

Then going to last April meeting, I think everyone hopefully remembers that meeting, which was kind of-- had both a record number of workgroup reports provided from workgroups that had met since that November 2018 meeting. The CLIA personnel regulation workgroup, the nontraditional testing workflow model work group, and the next generation sequencing work group. We're going to have some follow ups on all of these at the meeting both this afternoon and tomorrow.

There were 23 recommendations made at that meeting. And that was also a tie for the number of recommendations made at any CLIAC meeting. It tied with PT recommendations that were made some years ago. And those PT recommendations were very influential in the proposed PT rule which was followed which was published earlier this year. So the 23 recommendations at the April meeting then were from each of the workgroup reports. And these recommendations focused on things that were suggested as potential changes to the regulations.

There were several related to guidelines or guidance that should be developed by both the government, as well as professional organizations. There were two recommendations for surveys or information gathering to take place. Then the recommendation related to the new workgroup which would pull together representatives and other experts from the previous three groups and form a new workgroup to look at emerging technology in the clinical laboratory and where the needs were for CLIA for additional guidance.

And this one, you'll hear about tomorrow. And then engagement with external partners. So go to the website if you want to see the detailed recommendations and where we are with each one of them. And with that, I'm

going to turn it over to Dr. King who will be presenting her APHL Opioid Task Force report. She is going to be presenting remotely. After she finishes, Dr. Fitzgerald will be back here at the podium and will give an update on activities that CDC is involved with, as well as CMS and FDA, related to next generation sequencing quality. This afternoon, then, we will have some reports related to the clinical laboratory workforce. And again, these go back to recommendations that were made by CLIAC in April of 2018 and earlier.

And also this afternoon, we'll have several presentations and discussions related to improving integration of lab information systems with electronic health records and interoperability. This has also been a topic that CLIAC has made several recommendations on. And then tomorrow will be a very special morning's presentations and discussion, something that we are doing for the first time at CLIAC and we are really excited about. You'll hear more about it from Dr. Salerno when he introduces the session tomorrow. But this will be in response to the three questions that were posed for public input and discussion related to current and emerging technologies and lab practices and the needs that are resulting from these changes. So with that, I will turn it over to Heather, who will help get Dr. King set up.

The Association of Public Health Laboratories Opioids Task Force
Ewa King, PhD

HEATHER STANG: Dr. King, are you on the line?

DR. EWA KING: Yes, I am. Can you hear me?

HEATHER STANG: We sure can.

DR. EWA KING: Excellent. Thank you. Good morning, everyone. I'm Dr. Ewa King. I'm the director of the Rhode Island State Health Laboratories and also the chair of the APHL Opioid Biosurveillance Task Force. And thank you for having me back to provide updates on developments on this topic since last year. And I apologize for not being able to attend in person.

So some of you have seen my presentation last year and some of the slides might look familiar as I'm looking to introduce you back to the world of opioids crisis. Next slide, please.

As you I'm sure are aware, the opioid crisis is continuing in the US. Many states, including Rhode Island, are still experiencing very high rates and numbers of overdoses, not only due to opioids but also due to other illegal drugs. We are increasingly seeing this as being a multi-substance epidemic.

Therefore the surveillance of this problem is continuing to be extremely important. And I've been spending a lot of time thinking about the laboratory's role in surveillance for the opioid overdoses, both fatal and nonfatal. Next slide, please.

This slide illustrates the potential sources of surveillance that have been going into the surveillance reports. They include a lot of different data streams. Prescribing data, drug use surveys, hospital emergency department data, death certificates for fatal overdoses.

However, we do see a lack of laboratory data being utilized to the extent that we feel would be optimal. So this was something that was noted last year and the year before and is changing, but potentially not quite to the extent we were hoping for it to be seen. Next slide, please.

We really do feel laboratories present an awful lot of opportunities that could be utilized more heavily. While on the non-fatal surveillance-- on the fatal surveillance, that's already firmly established, and death certificates are generally, although not always, based on laboratory determinations, we feel for nonfatal overdoses as well as neonatal abstinence syndrome, the use of laboratory data is not quite as extensive as it perhaps could be.

This slide illustrates some potential surveillance data that we're still working on, including the increased use of commercial drug testing data. And public health laboratory programs that are in development. Next slide, please.

One significant development since my last presentation in the fall of 2018 is that now we have a firm, solid case definition for non-fatal overdoses. It was finalized by the Council of State and Territorial Epidemiologists just this year, in the summer of this year, and provides state and local jurisdictions with very definitive guidelines on ascertaining cases and includes a combination of epidemiology and laboratory data to really make sure that opioid overdoses and drug overdoses in general are being looked at the same way across the nation.

So we feel that's a very significant development. Also, the neonatal abstinence syndrome case definition has been established and also includes a laboratory result as the basis for case definition. Next slide, please.

This slide is included here as a reminder of how traditionally, illegal drug testing or drugs of abuse testing has been conducted. That is very much an evolving area these days. It's not necessarily a license screening or immunoassay screening and then confirmatory testing by mass spectrometry. There are some new technologies being included.

However, hospital and emergency department testing is still very heavily dependent on immunoassays with sometimes lacking confirmatory testing. This is important to note because much of the case definition has to deal with the reality that not all drugs of abuse tests are being confirmed by mass spectrometry, which would be most desirable. Next slide, please.

I'm repeating a couple of slides from my presentation from last year. So this is current issues as of last year. However, the situation probably has not changed dramatically, although I will point to many areas where we hope we are making progress and hoping to improve the situation.

So the issues as they apply to surveillance in toxicology testing among different types of laboratories-- forensic laboratories, commercial, clinical laboratories, public health laboratories. It's still very much that the scope of testing or the list of analytes. It's not standardized among the laboratories.

So we can never be quite sure that when the laboratories are listing something has not been found whether they have been actually looking for the same type of drugs. Fentanyl testing in particular is something that has taken a long time to standardize. I think that has improved, but not quite as much as we would hope, and there is still room for improvement.

The differences in methodologies is something that continues to exist and probably will persist based on different resources. Inadequate capacity that exists, especially in the forensic arena, and the inadequate capability to test for novel analogs or designer opiods or fentanyl analogs is something that we all continue to struggle, though there has been some progress made. Next slide, please.

I have also listed last time the barriers to a standardized approach, which includes expensive, very expensive instrumentation that would be required for mass spectrometry-based confirmations. Also expensive calibration, internal standards, QC standards for isotope dilution. LCMSMS, which is something we consider the gold standard. And differing accreditation requirements for clinical versus forensic laboratories.

Regular oversight is very different between forensic and clinical labs. And again, the lack of standardization among those types of laboratories on methodology and defined list of target analytes.

Let's move on to the next slide. We're moving to introduce the APHL Opioids Biosurveillance Task Force. Just a quick reminder about APHL, which is a membership Association that works with state and local public health laboratories.

So we're looking to liaise with federal agencies such as CDC and CLIAC and represent our members. So the APHL opioid biosurveillance work is placed within the environmental health program, kind of highlighting the unique nature of this and the new nature of opioids in terms of the public health laboratory portfolio.

So I chair the task force, and the task force meets quarterly by teleconference. And we also have met in person once and will meet again early next year. Next slide, please.

So we're looking to let you know that we have been working very hard on addressing some of these barriers to utilizing laboratory data for biosurveillance of opioids and other drugs. We are definitely concentrating on opioids at the moment.

So we have what we call the opioids community of practice which is a platform, an internet-based platform to share ideas and experiences. There is bi-weekly teleconference call where we have presentations from subject matter experts. We discuss lab methodology project design for laboratory-based surveillance.

We are working on a model surveillance plan, which will be a document that will be publicly available we're hoping very soon. It's in draft version right now. And that is basically guidance for states that would like to improve and implement biosurveillance, meaning laboratory-based surveillance, especially for non-fatal overdoses and for neonatal abstinence syndrome. Next slide, please.

So the specific charge for the Opioid Biosurveillance Task Force is to design, again, a model opioid biosurveillance program for states to use to implement. It's meant to be a flexible rather than prescriptive guidance for states to, depending on the state to implement, depending on their resources and also the extent of the problem in their states.

We are also looking to develop technical and safety guidance for laboratories and define and develop the roles of public health laboratories in this area. Next slide, please.

The task force composition includes 16 individuals that were selected to represent various stakeholders in the area of opioid biosurveillance. So we have CDC representatives. We have toxicologists, clinical toxicologists.

We have public health laboratorians. We have representatives from forensic laboratories. Epidemiologists-- we have a representative from a private laboratory from Quest Diagnostics. And it is Dr. McClure who has given a presentation on opioid surveillance last year, if you recall last fall.

And we also have a representative from the Council of State legislatures to help us work through issues of authority to implement biosurveillance for opioids. We also have for our organizational liaisons, we have representatives from the CDC and the Council of State and Territorial epidemiologists. This is very much a joint project for laboratories and epidemiologists. Next slide, please.

So the question in very general that we are asking and we're looking to answer is how the public health laboratories-- because that's our membership, ADHL membership-- can contribute to the response to the opioid

epidemic. So we are looking for us to provide laboratory data for non-fatal overdoses, and more specifically, to concentrate on the novel sentinel analogs.

That is something that the CDC has I feel made great strides in by providing free of charge and to not just public health laboratories, but any qualified laboratory. Set off standards, instrumentation standards.

And those are called the TOMKits-- the Traceable Opioids Materials Kits. Those have been really very much a success. They have sold out at one time, and I do feel they will do a great-- they will be a great help in helping standardize the list of banned for novel sentinel analogs, as well as make them available to a wide variety of laboratories.

So in terms of biosurveillance, we're looking to help elucidate temporal and spatial trends in opioids use or drug use that does not result in a fatal overdose. So just as a reminder, we're really concentrating on the non-fatal overdoses of something that has been dramatically underserved in terms of laboratory data.

And we're looking to inform and we helping to inform and evaluate the efficacy of public health interventions, since that's something that also is being asked frequently. How do we know we have succeeded? So some interventions will and should manifest themselves in laboratory data. And that's something we will be monitoring.

So the public health laboratories in particular are looking to leverage the Laboratory Response Network, the chemical side of LRN. The infrastructure that we have put in place in the last several years, or a decade by now.

So we have specialized instrumentation that is meant for a response to public health emergencies, such as this one. We have the technical skills and expertise. We also very importantly have relationships with clinical providers-- hospitals and emergency departments and the poison control centers. Next slide, please.

Just a summary of what do we have accomplished to date. So just keep in mind that the biosurveillance task force has been convened earlier this year. Our first meeting took place in February of 2019. This is what we have accomplished so far.

So we have developed and disseminated our resources such as the DEA-- Drug Enforcement Administration-- registration that the laboratories would need to be able to introduce and implement opioids testing methods. That's not something the majority of public health laboratories had in place. So that was a new topic for many labs and they had to gear up and receive that registration.

Also, we have disseminated resources on the informed consent and human subjects review. Again, some public health laboratories are active in research, others not so much. And certainly, there will not necessarily be people applying directly for IRB reviews. So that's something we needed to summarize for those who were unable, for the states that are unable to use public health surveillance authority to collect specimens.

We also are working to put in place some informatics infrastructure. We have a data analytics workgroup. That is something that we recognize as being very important, since potentially we might be generating-- and there's already a lot of laboratory data generated.

We need to figure out how to structure the data, how to transmit the data sets, and how to store it and analyze. That's kind of a big ask.

The model surveillance plan I have mentioned already. And I will speak about it on the next slide. Safe handling of fentanyl. That is something that was a somewhat surprising concern but a very major one of many laboratorians who are not used to dealing with and handling drugs.

That's something we had to spend quite a few sessions of our community of practice on. And we also had the safe handling of fentanyl video now available for laboratories. So that's another product out there from the work group. Next slide, please.

So a little bit on this flagship document that we are working on, biosurveillance strategy on non-fatal opioids overdoses. So the guidance document that is in draft has been developed in collaboration with the task force and we have dedicated APHL staff working on it.

We are also-- so this is what is envisioned to be contained in existing draft version right now. So we discussed screening and confirmatory testing methodologies since it's fairly complicated these days and differently implemented in various laboratories.

We talk about the role of different toxicology laboratories, from clinical laboratories, forensic laboratories, and now public health laboratories involved in the surveillance undertakings.

We are talking about the specimen collection strategies, including the legal authority of public health departments to collect specimens and collect data on non-fatal overdoses. We will provide recommendations on results reporting and partnership building. And that would be with epidemiologists and clinicians, primarily. Next slide, please.

So once again, the safe handling of fentanyl. That's something that is a concern that actually is not just a laboratory concern. And perhaps a laboratory concern is of importance to us as laboratorians at APHL. However, that is something that transcends laboratories.

And there has been a lot of concerns among first responders and others who might come in contact with fentanyl and fentanyl analogs. So we have a video that really brings a lot of factual information as opposed to concerns, sometimes unfounded concerns, about the ability to handle fentanyl safely.

So we talk about the roots of exposure, of risk assessment, safe disposal of samples, and related topics. And we will have a more formalized safety guide, and we are expecting to have this completed by early next year. Next slide.

We have also spent a lot of time on reaching out to partners which is invaluable in coming up with a brand new surveillance program that a lot of people are involved in. We have been participating in a lot of national opioids related public health summits and meetings.

I have been to the summit that was organized this summer by the American Medical Association. The ESOOS, which is the Enhancer Surveillance for Opioids Overdoses for States partner meeting. That this is one of the CDC grants available for states for opioid surveillance.

So we have represented laboratories at that meeting, as well as a meeting by the National Center for Health Statistics opioids mortality data. Next slide, please.

We also have reached out early on to partner with our forensic toxicologists on the laboratory end. Especially, I have just come back recently from a workshop that we have put together and presented at the annual meeting of the Society Of Forensic Toxicologists-- SOFT.

So we have provided this for our workshop to really explain and educate our forensic toxicologists on what public health laboratories do and what the public health laboratory role is in the opioids surveillance, as opposed to what the forensic toxicologists do which is more on the fatal surveillance end and the death certificates.

So it was well-received and we had many questions. But I think that was a very important effort on our part next slide, please.

So this is the bulk of my presentation. I would like to just acknowledge that these slides and the presentation has been based on the efforts of the entire task force as well as APHL staff. So I'd like to have it mentioned here.

And also acknowledging that the CDC financial support has been provided to APHL to stand up this task force and to be able to conduct all of the activities that I have just described. Thank you very much, and I would be happy to answer questions if there are any.

[APPLAUSE]

CLIAC CHAIR: Thank you, Dr. King. This is Valerie Ng. Are there questions for Dr. King?

CLIAC MEMBER: Thank you so much. It was a great presentation, and obviously a lot going on. And I was, as you were presenting, I was thinking-- and I guess I didn't pick it up originally when I looked at these slides-- about the engagement of the National Center for Health Statistics, and particularly looking at their death data.

But while you were speaking, I looked up at the NCHS site on the National Ambulatory Medical Care Survey. And that's a little dangerous, because when you don't really know how to look at data you can draw some conclusions.

But it does look in their ER data that in fact the presentations for drug opioids and others actually exceeds that for people with cardiac disease. And so I'm wondering whether you've involved the people dealing with the death registry and perhaps the National Hospital Discharge Survey, whether in fact in the ambulatory people have been engaged as well, because I suspect they're going to have some data such as that which they've already published.

CLIAC CHAIR: Dr. King?

DR. EWA KING: Yes, thank you for this question. I'm sorry, this seems to be a little bit more echo. Thank you for this question. So we are, at least in Rhode Island if not the task force specifically, we have been working very closely with our hospitals and emergency department staff on really understanding the data from the non-fatal as well as the fatal end of the spectrum on opioids overdoses.

So we are in Rhode Island, just for context, we are in a somewhat unique situation where we have both forensic toxicology laboratories here, the medical examiner's office, as well as our opioid biosurveillance laboratory. So we're really looking at this from many different viewpoints and working very closely with those who provide and interpret data.

And I could not agree more with your statement that when one does not necessarily know what to look for in data, conclusions can be drawn that are clearly erroneous. So we very much are looking to have laboratories and laboratorians at the table not just as data providers but also data interpreters. Because we have seen this where we're feeding laboratory data, but they are not being understood properly and they may being misinterpreted.

CLIAC CHAIR: Dr. King, this is Valerie Ng. This is scary because [CLIAC MEMBER] and I, we're thinking the same thing. As a hospital lab, we frequently get toxicology screens for our ED patients with the real intent to determine if there is substance use happening prior to referral to psychiatric care.

Many of the opioid-positive reactive specimens that we receive are often not the cause of recreational use. They're often the cause of intentional medical administration to manage pain. If you are getting reports from hospital ERs, are they subsetting out those positive opioid results to only those who are using it recreationally instead of intentional medical administration?

DR. EWA KING: Those are very valid questions, and we recognize that this is a limitation. So I wouldn't say at this point that this part of the interpretation has been worked out necessarily. But it's very much understood that conclusions cannot be drawn based on lab data alone precisely because some of it is administration of pharmaceuticals at the hospital or another health care facility.

So that is something that remains to be figured out, I believe. Because we are in very early stages of biosurveillance, of the implementation of the biosurveillance, we are really concentrating on receiving data, and that's both screening data and confirmatory data from our laboratory. But we certainly understand and realize that this cannot be interpreted completely separate from the rest of medical records.

CLIAC CHAIR: Thank you. Are there other questions?

CLIAC MEMBER: Thank you for the presentation. In the course of building relationships with clinical laboratories, I wonder if you have or perhaps you have reached out to organizations such as AACC, CAP, ASCP and so on, which would be a way to-- they probably have people in those organizations that are working this issue or are interested in it. And it might be a way to build some relationships there with the community.

DR. EWA KING: Thank you for the suggestion. We have not explicitly reached out to these organizations, although I am aware and have seen some webinars and other documents produced by those organizations. We do again have Dr. McClure on our task force. But we do not have representatives from these organizations. But that's an excellent suggestion.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: Are there other questions for Dr. King? Thank you, Dr. King. Very helpful.

DR. EWA KING: Thank you.

Next Generation Sequencing Quality
Collette Fitzgerald, PhD

CLIAC CHAIR: Our next speaker will be our very own Dr. Collette Fitzgerald who will be providing an update on the next generation sequencing quality. And this will include some committee discussion.

CDC EX OFFICIO: So good morning again, everybody. Thank you for the opportunity to share some brief updates on next generation sequencing quality activities.

I'm going to share updates this morning firstly on activity CDC, CMS, and FDA have begun, following the CLIAC April 2019 NGS recommendations. And then also share some brief updates on the CDC APHL, the Association of Public Health Laboratories, next generation sequencing quality initiative.

So this next slide here is a refresher on CLIAC NGS activities to date. So a next generation sequencing session entitled Implementation of Next Generation Sequencing in Clinical and Public Health Laboratories was held at the Spring 2018 CLIAC meeting.

Dr. Ira Lubin, Rebecca Hutchins, and Dr. John Pfeifer described the challenges and gaps in applying the CLIA regulations to NGS-based testing from the public health and clinical laboratory perspectives.

The CLIAC committee made the recommendation to form an NGS work group. So a 22 member CLIAC NGS work group was formed in the fall of 2018. The work group was chaired by CLIAC committee member Dr. Jordan Laser. And their charge was to provide input to CLIAC for consideration in developing recommendations to CDC, CMS, and FDA for assuring the quality of next generation sequencing in the clinical laboratory setting.

So they held a face-to-face meeting in January of this year. And their report was presented to you at the CLIAC April meeting which then resulted in the eight NGS CLIAC recommendations.

So CDC, CMS, and FDA have restarted the tri-agency next generation sequencing group. This group consists of representatives from each of the agencies. This was on pause during the formation and tenure of the CLIAC NGS work group.

The tri-agency group will focus on the CLIAC recommendations from April 2019 and from this meeting and begin to strategize on each agency's role in addressing these recommendations. So the next series of eight slides highlight some of the activities to date on five of the eight CLIAC NGS recommendations.

So this slide here shows the first NGS recommendation. I'm putting the content of the entire recommendation into the record of CLIAC, but I'm not really expecting you all to read all of the content on each of the recommendations slides that I'm going to be showing.

So the first recommendation-- CLIAC recommended HHS thoroughly update the CLIA regulations to address issues related to new biomarker testing and other new technologies, including NGS.

To assist with addressing NGS recommendation 1, CLIAC is specifically soliciting public comments to three specific questions in tomorrow's public comment session on Emerging Technologies and the Clinical Laboratory.

Information provided via these public comments will be used by CLIAC to inform your deliberations and recommendations to HHS and to help focus a CLIAC workgroup that was part of the NGS recommendation 2 that is shown here to form a new CLIAC workgroup.

The three agencies are forming the next CLIAC work group and will be soliciting nominees for consideration. This workgroup will use information provided by the personnel, non-traditional workflow model, and NGS workgroups, and also feedback gathered from the public comment session and potential CLIAC recommendations from this meeting to identify potential areas in the CLIA regulations that could benefit from additional guidances, best practices, to address issues related to NGS, new biomarker testing, and other new emerging technologies.

As a requirement of all CLIAC workgroups, there must be a CLIAC member to serve as chair. We may also consider having an additional co-chair due to the potential size of this new workgroup and because this work group may be standing for a longer period of time.

In addition to the CLIAC members, the federal agencies will have ex officio representation. The remainder of the work group will include individuals with representation from clinical and anatomic pathology laboratories, public health laboratories, laboratory accreditation organizations, CLIA-exempt states, and industry.

We're encouraging submission of potential workgroup candidates to submit to CLIAC at cdc.gov. And we will assess each candidate and ensure the work group has subject matter expertise across the topic areas.

So the next two recommendations are related to NGS guidelines and standards. In recommendation number 3, CLIAC recommends that CMS, CDC, and FDA encourage professional societies and others to develop and/or update NGS guidelines. And in recommendation number 4, CLIAC recommends that CMS, CDC, and FDA create guidelines or best practices related to clinical and public health NGS.

In response to recommendations 3 and 4, this winter, CDC will be convening a forum of organizations involved in the development and publication of NGS guidance and standards. The CLIAC NGS work group report linked in the April 2019 CLIAC meeting summary included a list of recent publications and guidelines related to NGS.

Professional organizations that have written guidelines include those that are listed here on this slide. CDC will be reaching out to these organizations with an invitation to nominate individuals for this upcoming forum. Other organizations that would like to participate should contact us at CLIAC at cdc.gov.

The forum may include a series of conference calls or a face-to-face meeting and will provide an open discussion to gauge the current activities of each organization, not only for NGS, but other emerging technologies, and to determine where the three agencies can assist or lead the charge in fill in the gaps.

For recommendation number 6, CLIAC recommends expanding the CDC GET-RM, or the GEnetic Test Testing Reference Materials coordination program, with regard to scope and type.

So the goals of the GEnetic Testing Reference Materials coordination program, or GET-RM, is to coordinate a self-sustaining community process, to improve the availability of appropriate and characterized reference materials for quality control, proficiency testing, test development and validation, and research.

Based on CLIAC recommendation number 6, GET-RM has initiated a new reference material project for hereditary cancer. The feasibility of developing commutable NGS data sets for development and validation of NGS informatics pipelines is being explored with CAP, the College of American Pathologists, and AMP, the Association of Molecular Pathologists, at a meeting that's going on this week. An update on the GET-RM program will be provided at the April 2020 CLIAC meeting.

So I'm going to shift gears now just a little bit. And you might ask, well, what are we doing right now for NGS quality in the public health laboratory community? So I'm going to share a few brief updates here now on our public health laboratory community project called the NGS Quality Initiative.

This project is a collaborative effort between CDC, APHL, and state and local public health laboratories, and is funded by CDC's Office of Advanced Molecular Detection. So advanced molecular detection technologies such as NGS require novel processes for incorporating quality management practices.

We are actively partnering together to maximize our resources across the public health laboratory community to assure quality of NGS-based testing. The goal of this project is to develop an NGS-focused quality management system to address challenges public health laboratories encounter when they develop and implement NGS-based tests by providing deliverables of customizable, ready-to-implement guidance documents, SOPs, and

forms. We see this quality management system as the foundation on which other guidelines regulations and standards sit.

To support laboratories to build foundational quality and development and implementation of NGS-based tests, the QMS will be organized and prioritized using the 12 Quality System Essentials, or QSEs, within CLSI's quality framework. And you can see those 12 QSEs listed in the 12 circles on this slide.

Our plan is to work on four QSEs per year for the three years of the project where we'll be creating a QMS toolkit for CDC and public health laboratories based on iterative needs assessments to avoid duplication of efforts, increase efficiencies, and provide a platform for knowledge and information sharing. The four QSEs we focused on in year 1 were personnel, process management, equipment, and information management.

So we held an in-person meeting on May 8 of 2019. The purpose of this meeting was to bring together key stakeholders from CDC, APHL, and state public health laboratories to inform the deliverables and priorities for this project. At the meeting, participants got the chance to discuss their laboratory's current strengths, gaps, and needs associated with implementing a QMS and NGS workflows.

The pictures on the right-hand side depict the outputs from a group discussion that separated the wet and dry lab processes. The red stickers represented the gaps, yellow signifies items that were in progress, and green were the strengths. So items that were either complete or that the lab had under control.

This slide summarizes one of the group discussions on prioritization of the QSEs to address for year 1 of the project. QSEs on information management, process management, and assessments were identified as the top priorities for laboratories well on the way to implementing NGS-based testing.

The group also agreed that equipment and personnel would be included as QSEs to work on in year 1 because they are foundational for laboratories and many pre-existing documents and resources are available to share. In addition, an agreement was made to form a technical coordinating committee.

So the Joint Public Health Laboratory and CDC Technical Coordinating Committee, or TCC, includes eight CDC staff and six Public Health Laboratory members representing 14 different CDC and public health laboratories and consists of laboratory scientists, bioinformaticians, and quality managers.

They're providing recommendations on the priority levels for each QSE. They're providing existing QMS tools and documentation for review and possible adoption or adaption by the project. And they review and provide feedback on work products before they are released to the externally-facing website.

This slide summarizes their current activities. So laboratories have shared 127 documents from public health laboratories and CDC programs to date. TCC members have reviewed the existing 46 documents that were developed and published earlier this year by Rebecca Hutchins, Dr. Atis Muehlenbachs, and colleagues on behalf of the CDC NGS quality work group related to QSEs on personnel, equipment, and process management.

The TCC is also creating consensus documents for equipment and personnel QSEs. The TCC subgroups have also been formed to work on development of resources for information management and assessments and quality indicators. And information management QSE consultations have begun with STAPH-B, and this is the STAte Public Health laboratory Bioinformaticians workgroup.

So we use a traffic light rating system on this next slide here to show a very high level, a status update on the QSEs we've been working on in this first year. So we've met key requirements for personnel, equipment, and process management, though there's one remaining requirement outstanding for personnel.

There's still more work to be done. We need to develop additional documentation to meet the requirements for information management and the assessment QSEs as we move into year 2.

So an important goal for our project is to share all technical documents or products that are developed with the broader laboratory community. I'm very excited to be able to share that our NGS quality initiative project website has just gone live.

The first 48 technical documents related to personnel, equipment, and process management QSEs are all now up on the site and are freely available for other laboratories to download, customize, and use. I want to thank the project team, including James Bratton and members of the communication team for their assistance to make this happen. Those documents literally went up this morning.

As we move into year 2, we've got lots of ongoing activities. A subgroup of the project team has been working hard on developing a needs assessment to help better understand the current needs of CDC and public health laboratories and to provide information to support prioritization of activities as the project moves forward.

This will include a comprehensive assessment of the sequencing total test process. All questions in the needs assessment will be mapped-- are mapped to corresponding QSEs. And the audience for this needs assessment include all state public health laboratories, large local public health laboratories, and CDC laboratories.

And we're going to continue development of consensus, ready-to-implement documents. If you'd like more information on the project or if you've any questions, you can check out the new website or you can email us at ngsquality@cdc.gov.

I'll just finish by saying that collaboration and communication have really been key to the success of the project today. And I do want to thank co-PIs Dr. Atis Muehlenbachs and Christin Hanigan from the Association of Public Health Labs, as well as Lorelei Krasinski and Kristy Kubota from APHL.

The entire project team, the technical coordinating committee, and the subject matter experts across the public health labs and CDC programs who are participating to make this project happen. And I'll close with that and take any questions. Thank you.

[APPLAUSE]

CLIAC CHAIR: Thank you, Dr. Fitzgerald. I just want to comment, this is a remarkable and very impressive coordinating event with some of the leaders in the field of NGS to try to derive consensus standards. I'm very pleased at this action in just such a short period after the last CLIAC meeting. So thank you very much. Are the questions for Dr. Fitzgerald? OK. In Epic training, we were taught 7 seconds of silence to make sure the person unwilling to speak will speak. I've done the seven seconds.

Future CLIAC Topics

CLIAC CHAIR: So there are no questions at present. And we thank you again. Next on our agenda is a discussion around future CLIAC topics. And this is open to the committee to comment or suggest topics you would like to hear about at future meetings.

CLIAC MEMBER: I think I may have mentioned this before, but I think one of the biggest issues facing us as a community now is the valuation of social determinants of health. And the CDC has a whole group on this. Multiple other groups do. The major health plans are now focusing on this. And I think addressing what are

some of the key roles that the laboratory can play in addressing social determinants of health, whether it's directly in terms of offering feedback and analysis from data, or even using our laboratory systems, our order and reporting and our patient portals to gather the data and report it I think would be very important. So I'd be interested to know where CDC is and where we as a laboratory community can help.

CLIAC CHAIR: So this is the third time I've heard you bring this up in about six months.

CLIAC MEMBER: [INAUDIBLE]

CLIAC CHAIR: No, that's fine, that's fine. And I've just been trying to understand concretely what can the laboratory community provide. So I know on the front end, we collect SOGI data. But on the laboratory side, how does that translate to useful information where we can improve the health of these communities?

CLIAC MEMBER: Well, I'm hoping the discussion will lead to a better sort of profile of that. But there is--

CLIAC CHAIR: You're supposed to have the answer.

CLIAC MEMBER: No. I mean, I have some answers in terms of the kinds of that we can provide are better access to the laboratory, specimen collection, reporting linking patients to providers, and so on, I think are one strategy.

Another thing that I've thought about is we all-- I mean, not we all, but many of us, either through reference laboratories or large health systems, have patient portals where we report diagnostic information. In some ways, looking at gaps that patients have is a form of diagnostic information. It's a little bit nontraditional, but there are clearly validated instruments to determine gaps in care. What if we put those instruments into our lab systems in a way? The physician could order a SDH profile much as they would look at a liver profile, and then it would pop up in the patient portal and ask the patients the validated questions and report that information back on a laboratory.

It wouldn't be a laboratory service, but it would report it back with links to where one can go to identify or fill some of those gaps. That information has already been worked on in some areas. So I think that that's an opportunity where we could actually provide something where we haven't even thought about that. So I have some thoughts. But I think a discussion about more areas where we could make a difference would be important.

CLIAC CHAIR: I just want to comment because I've thought about this a lot trying to understand where we could go with this. And certainly on the social determinants-- things like food insecurity, housing, and all that-- that's collected at the point of patient intake. I do know on a very small, separate section, when trying to configure the LIS to report lab results, I know the reference range fields are not adequate to display both genders at the same time. So it's creating a lot of nightmare. If I don't know the gender coming in, am I reporting the correct reference range? And then a missing piece of it is whether or not folks are in the midst of hormonal treatments and how the correct reference range needs to be applied depending on where they are in that course.

CLIAC MEMBER: Yeah. I mean, I think there are clearly in delivering and providing information and so, and how do we do that. I think there's information, the insights that come from looking at laboratory data-- using laboratory information collectively with our clinical colleagues to better identify people who are at various risks would be important. But I think that, although it's a little bit nontraditional, I think the biggest opportunity we have is we touch most patients. And so one of the biggest problems with social determinants is not being able to identify who's at risk. Well, what if we leveraged our laboratory information infrastructure to provide a strategy

to get that information and provide it back to clinicians, much as we tell them what their lipid profile is, or what their basic metabolic panel is? Their SDH panel might be something that we would want to look at.

I know that also-- well, CDC has been involved in it, but HIMA, AHA, CDC, and others have now developed ICD-10 codes that they're promulgating for looking at these gaps. And so I think pulling this together and really figuring out how we can do it-- I don't have all the answers. If I had the answers, I probably would have been doing it already. I have some thoughts on it. But I really do think that it's an area where we could probably make more of a contribution as a laboratory community than we have already. And I think we should really have that discussion and figure out those ways.

CLIAC MEMBER: Yeah, I think that [CLIAC MEMBER] has some really good thoughts. I have had a little bit of a unique career in that I spent most of it in the clinical laboratory setting and then the rest-- a shorter amount, but a very significant amount-- in public health.

And one of things I-- and there was some crossover work-- but one of the things I've come to believe and why I asked the question of APHL is that I'm convinced that clinical medicine and public health never talk to each other. They don't even know they exist. And when I was CMO, I had lunch with a physician one time who was a very socially conscious physician. And he said, well, I want to know about my practice. I want to know about obesity rates, and all these other things about education. He said, we need to get that data.

I said, we have all that data. We can tell you practically by block what all that data is, but nobody is doing anything with it. And depending on the geographic area of your practice, you could learn an enormous amount of things about your patients. This is a wish list. I don't know what to do with it, but I think that trying to get public health and traditional medicine closer together and cross-fertilizing and working on these issues with non-traditional methods of care is a good thing to do. And if we could help with that, that would be a good thing, I think.

CLIAC MEMBER: So I think this might have gotten wrapped into the new technologies topic, but kind of pushed under the carpet because NGS and bioinformatics kind of took over that discussion.

But Ramy and I both discussed last meeting about digital pathology and artificial intelligence. It's coming out fast, whether we want to acknowledge it or not, I think there's a lot of trepidation about where does CLIA, CAP, other regulatory bodies stand on is it a test? Is it an augmentation tool? How is it being used?

I think people are very, very trepidatious about there being nothing that really addresses it. So I think it might be a good talking point. Radiology using it. AP is using it. CP is now getting in there. So I think it needs to get its own talking point.

CLIAC CHAIR: Sorry. Did someone want to comment on [CLIAC MEMBER] before we move on? OK.

CLIAC MEMBER: So a not related, separate idea for something CLIAC might consider. And I hadn't thought of it until Ms Dyer's presentation this morning. So we've talked so many times here about there's, what? Over 100,000 certificate of waiver labs. And they're not regulated by statutory limitations. We can't regulate them. But this idea of research-based testing, which at least a certificate of waiver, somebody has filled out a form and acknowledged yes, I am providing diagnostic testing.

I mentioned this issue of in both academic and nonacademic hospitals and health centers. Researchers are not aware when they are doing pure research, collecting data for information, versus clinical diagnostic testing. And I know that many of us, Dr. Hilborne and I when we had that subject came up kind of nodded that this is a big problem that researchers that are doing diagnostic testing don't even realize they're doing diagnostic testing.

Therefore are unregulated. There's no lab over them. And HHS is responsible for the protected human subjects regulations that oversee all these IRBs. So it seems like we should be able to work within CMS, HHS, to get some concrete education and guidance and examples out there somewhere where the research community can see them. Because I think we understand when it's a diagnostic test. But getting that information to the research community through IRBs and that branch of HSS has not worked at all and we still have a large risk from this research-based testing that's really clinical diagnostics but no one realizes it is.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Yes. My idea was going to be [CLIAC MEMBER] comment this morning was brilliant and we should run with it. It just affects so many major institutions. And also just living both sides, from the research side and the clinical lab side, and having actually been a vice chair on an IRB, it would be a wonderful thing if there was some guidance. And we just mentioned it before, nobody means ill. And that's the most important thing. Everybody is on the same page to do good. So it would be potentially an excellent project.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: So I wanted to bring up the issue of laboratory productivity consultants. They are for-profit entities that go from laboratory to laboratory with productivity ratios based on billable tests or cost per test or test per tech. They each have their own proprietary matrix. Having recently gone through several of these, the recommendations that come from these folks are not evidence-based. There's no control over their for-profit mechanisms. And they're driving decisions in laboratories who have to answer to CFOs.

Many of the recommendations were borderline-- not only is there no evidence, but some of them are borderline go against the CDC guidance. Go against standard of care practices that people have done to save time and money. And I think that this is going on in laboratories across the country. It's sort of a crisis because it's been going on without any oversight, without any transparency, and without any holding people to document evidence. If you are-- and no knowledge of the documented guidelines, at least in microbiology.

I mean, we had 80-some recommendations, one or two of which we accepted and some 75 we refuted with evidence, CDC guidelines, standard of care, CLSI documents, et cetera. And I just think it's dangerous because they go from lab to lab and say, well, your buddies down the road are cutting this, so you should cut this, too. Well, where's your evidence for that? Well, we can't tell you who these people are because this is proprietary. They're our customers. And since we have good manufacturing practices, we have good quality practices, we have good biobanking-- we have good practices for everything except for consulting. And I really think that it's damaging the laboratory community.

And it is the wild west. Everybody has their own proprietary recommendations to save a dollar. And they're telling you they're based on quality, and maybe some of them are. But my experience has not-- I've not met up with anybody who's given me any evidence yet. And many of my colleagues, by talking to me, I've given our pushback. Some people are just afraid or don't have the time to push back and gather that evidence or the infrastructure to do so. And I think labs are kind of like sheep to slaughter in a way. That's a bad image, but you know, they're just vulnerable. And I think that's an important thing we need to take a look at.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: So as we all have seen in tech and in our world, there's a new development for a new segment of self-serve which we all have been using for decades now as we get our own gas without any intervention, as we do our banking without any intervention from humans.

As we see what's happening with health care today, there is a huge part of our civilization that is used to doing things on their own. So I'm saying this is an agenda item that needs to be addressed now for several reasons.

There is a need to empower patients, as CMS and many of our leaders are sharing through the programs that are put in place to empower patients. If this group led the way on self-serve, there's a way to be able to teach patients how to do many of the preventative lab tests directly with labs within each state.

I know today, Arizona, you have the ability to request labs. There may be other states that have that now, too. But if we could focus on how can we empower patients to self-serve? What legislation or regulatory changes would need to take place in order for me to ask for a MRSA test? This comes up because of many patients have come to me and said, I am moving from day care to a nursing home for my job and I can't get a doctor that will test me to see if I'm colonized for MRSA or any other thing.

And this has gone on for 13 years. I've had people ask me the same question. And it is true. Doctors will not test for certain things. So it's time to start empowering the public so that they can be a better-- they can use their individuality to prevent health care harm and have the tools to be able to read labs. I can look at my labs now and it makes recommendations on there. And I'm not a genius. I can understand what that lab says. So I think it'd be great to start a segment that focuses on self-serve in laboratory diagnostics.

CLIAC MEMBER: I just want to go back to [CLIAC MEMBER]comment. Who is inviting these groups in? OK. Like, I think I know. But if you can tell us.

CLIAC MEMBER: It's the C-suite. It's the finance organizations. And sometimes with or without-- I mean, we're lucky that we have some say in which we choose and we can somehow vet them. But many places don't have any say. They're just imposed on the laboratory. I think it's probably tertiary care and up. But they have categories that go down even to community hospital. So it's driven by the CFOs and the financial folks. And PAMA I think has brought out a massive amount of this because laboratory revenues are going down, obviously.

And instead of looking at downstream savings or whatever, let's take the now $0.02 on the dollar that laboratory provides to care and ratchet it down even more instead of leveraging that $0.02 or $0.03 to look at downstream economic improvements and improvements in quality at the same time. It's easy to just put the screws on because laboratory is still considered a service. And the switch from service to value-based care-- laboratories have a lot to offer that nobody thinks that they can offer. But if they decimate the laboratories before that happens, really, the whole value-based care initiatives will be at risk, I think. But that's just me.

CLIAC MEMBER: And I'm going to maybe show my ignorance here, but I don't recall any professional organization yet address this specifically because it's not ringing a bell. So I'm just putting that out there. And again--

CLIAC MEMBER: Not that I'm aware of. And it is a very cryptic community. You can Google those companies, but there's no national transparent standards for consulting. There's no good consulting practices. There's no organization who has addressed that at all to my knowledge. But maybe there are others that I'm not aware of.

CLIAC CHAIR: I'll just say we've been through three cycles of it. And the consultants are paired with the group purchasing organizations. So when the GPOs come in to address how much you pay for towels or whatever, labs are thrown in that same bucket.

CLIAC MEMBER: Yeah. That was not my experience. But at the same time, we were going through another supply chain experience with two different groups. But it seems like this is just a two or three year cycle that happens to all big labs.

CLIAC MEMBER: One topic, if I can move on to a different topic, that seems ripe for discussion is diagnostic error. The ECRI reported recently that 47% of patient safety incidents in the outpatient setting were associate with diagnostic error, the majority of those being that the test result was never reviewed by the physician. And there's other reports. There was one out of Australia 15 years ago or so showing up to 72% of test results were not reviewed by physicians after in the outpatient setting, typically after release from the ED. And I'm wondering if that post-analytic loop might not be a fruitful effort for this group to look at how to tighten that review of test results when the patient is no longer at the hospital.

CLIAC CHAIR: Thank you. That's an excellent question. And with the improving adoption of electronic health records and now in-basket management-- because all those results drop in your in-basket-- I'm wondering if this is an evolving field and whether or not the EHRs would diminish some of that post-analytical error. It's a moving target. So it's a great comment.

CLIAC MEMBER: I'm just going to comment, it looks like Dr. Singh's going to touch on some of these things in her slides based on what she has in her content. Can I add my two? Oh, Andy, you go first.

ADVAMED LIAISON: Since we're talking about all three phases, I think it's been a long time since we've talked about the pre-analytical phase. And I think a lot of times when we're looking at tests that are drawn in-house and brought to the lab, we feel that those are well under control. But a lot of the tests coming from outside, outside the institution or outside the immediate building, I know sometimes we throw our hands up and go well, we look at them when they come in and we hope they're right.

But I think it would be an interesting conversation and interesting input from organizations about where the agencies may be able to provide guidance to laboratories about how to help get that under control. We know that there are requirements around sample tracking and monitoring. But what are some best practices in that area? Do we need to provide some guidance to the agencies as to how labs need help with this? And something along those lines.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: So I want to echo and support ADVAMED LIAISON in this, and specifically in the molecular collection world. I recently advised a group where I was contacted to help provide education to an outside group whose providers were collecting swabs and laying them on counters and yet having been trained in sterile techniques.

For some reason, the DNA piece-- so I think more than just the transport and the collection, it is the education about that proper awareness. And with all these molecular point-of-care tests, I mean, I want to sort of lose my lunch thinking about the possibilities of contamination in the way of setting. And that's not being addressed by any of the manufacturers. Our laboratory is addressing it with a standard practice and doing education for our providers. But I think there's a gap in knowledge there that he addressed.

CLIAC CHAIR: I'm curious. On [ADVAMED LIAISON] point, it sounds a lot like part of that non-traditional workflow model that we discussed. Samples collected somewhere, brought into a testing lab, moved off to other labs for different parts. Would the quality around that pre-analytical piece be something we would want to align with the nontraditional workflow model discussion?

ADVAMED LIAISON: That's interesting you say that because I would have not thought of it as being nontraditional since it's such a historic part of what labs have received for years from physician clinics or from clinics and physician practices. I think it could be. I'd be worried about even expanding that group's scope even more so. And it may be that this could be a contained, smaller focus on it for a future meeting.

CLIAC CHAIR: And [CLIAC MEMBER], your point is well-taken. I was just hoping, because I don't have a lens into that, that as the FDA looks at new products that are being developed that are molecular amplification, I'm very concerned about-- if these are point-of-care-- I'm very concerned about amplicons contaminating the environment and therefore rendering those results--

CLIAC MEMBER: Actually, template in this case. I mean, they're all closed systems. So unless you take a hammer to them, the amplicon should be contained. But this is really template contamination and sample collection that led to this conversation.

CLIAC CHAIR: I would like to bring up my two things I've brought up previously, but we haven't moved on it, and they're both blood bank related. And one of them is personnel requirements. I'd like to know if there is a role for specialists in blood banking in the CLIA regs as a technical supervisor. We did not discuss that. It was not part of the charge at the last time we looked at this. But we all recognize the tremendous value that they bring to this practice.

And the second thing is I've had these low-level conversations, but I think I'm going to bring it out in the open. Some of the CLIA categorizations of tests complexity date back to the origins of CLIA. And the one that hit my radar were the automated blood banking instruments for ABORH and antibody screens. And while they're classified in the FDA database as moderate-complexity, there's this little asterisk. And the little asterisk goes down to a footnote that says if used for transfusion, they are now categorized as high-complexity.

And that creates a little bit of confusion in the clinical lab because receiving samples for type and screen, it's not always obvious downstream that they will be used for transfusion. And if you're using personnel who are not qualified for high-complexity testing to do your type and screens, what are the liabilities you reach when that result is to be used for transfusion? But more importantly, is the rationale that was back in '92 for adding this additional safety layer asterisk, is that still relevant in today's world? I say this because there's some limited publications showing that automation tends to be safer than humans. And there is at least one recent article on the automated blood banking platforms that show they have lower error rates than humans. So I would like to bring that topic back up, in particular with devices classified at the origins of CLIA and whether or not they should be revisited and that categorization revisited. Thank you.

CLIAC MEMBER: It's been rich conversation this morning. I'd like to echo one of our newest members of the committee that talked about regarding self-care, but refocus it. We were talking the last time we were together about communication and communication directly to our consumers of health care. Tying in some health literacy, as we talked about, with social determinants of health.

And is there a way that we could get all the agencies together and make advisory comments about improving the communication of lab results and also the pre-analytic phase that we talked about earlier today from our colleagues from the FDA about labeling and product labeling and making sure that are our consumers know that they may be ingesting things that may impact their test results? Is there a way that we can communicate better digitally with our patients to let them know how the pre-analytic, analytic, and also post-analytic communicating the results, as we've talked about in the ambulatory setting. Can we make recommendations to improve communication with the new technologies that we have by staying in our lab, staying in our lane, which is lab resulting, lab ordering, and interpretation?

CLIAC CHAIR: Thank you. You know, I have to think that this EHR era is giving the lab incredible visibility as patients come in directly to pick up their lab results. And how do we leverage that power to include the recommendations? The interference? The dietary precautions? How do we start to own that space so that patients can be the best steward of their own care?

CLIAC MEMBER: And I think it's also important to acknowledge in the pre-analytic and post-analytic communication, our colleagues on the clinical side, particularly as we go into next generation sequencing and the molecular world, assistance with the test menu. What are the appropriate tests to order? And how do we simplify such that clinicians are making informed decisions as well as truly understand all of those results coming through? And I think it's also important to acknowledge that they need to understand, they've got a lot of things that they need to know about their area of practice. We need to make sure that we're providing enough information for them to know how this integrates into their practice and that they are also a stakeholder.

I'll just say I believe we have a presentation from Ila Singh around the TRUU project. And it will be eye-opening as to how our colleagues think they're ordering the correct tests and how we can help. How we can help.

CLIAC MEMBER: I wonder if there's just an opportunity to-- the pre-analytical, the self-serve, direct-to-consumer-- that whole direct-to-consumer is encroaching. It's state-to-state. It's different. What recommendations can we do? Does the patient have a right to screen themselves if they're having an operation and the hospital they're going to doesn't screen for surveillance? That's different from state to state.

And then how to ensure that it's not just a have and a have not. If you have the money to pay for direct-to-consumer, then you get better laboratory care. And if you don't, how will that play into direct-to-consumer? So I see a lot cross over between those three topics.

CLIAC CHAIR: Come on, you guys are quiet. You're usually more vocal than this. Additional thoughts.

CLIAC MEMBER: So my interest really is education, especially for, full disclosure, particularly to providers to keep them up to date using the latest mobile-friendly tools. But in our world, who is responsible-- like, this is education, truly. And is that-- again, just for my own edification-- is that a CLIAC role? The educational piece-- who does that fall under? I would like to know it's everybody's responsibility. But to share thoughts on how the agencies view that. Like, kudos on the biotin.

CLIAC CHAIR: Actually, for us, we are very limited in what we can do under the federal government as far as education opportunities. We do try to do education. We try to work and present things as best we can. But we do also rely on CDC because they have a little bit more freedom to do things that we do not. And they do a very good job of it with providing what they provide.

FDA EX OFFICIO: Yeah. So I think some of the area where we are involved with is in the documentation that goes along with the tests. So the package inserts, insert manuals for waived tests. The quick reference information. So there's certainly room for continued improvement in those kind of documents. And for some waived tests, we have documents that are aimed at the providers in addition to the operators. So I think there's still potential room for development in those areas of improved communication. It's a good topic to consider.

CMS EX OFFICIO: And like CDC did with the Ready, Set, Test! book because I know I participated in developing that along with several of my staff, along with CDC. So when we come up with ideas for those types of things, because they're really well-done and the booklets, they're very well-received. So we look forward to trying to do those kind of things. It's not that we don't want to do them. We want to be involved in doing those.

CLIAC DFO: Can I answer first? CDC has the advantage within the CLIA program of not being a compliance-enforcing organization. Both CMS and FDA have responsibility to enforce the regulations in a way that CDC does not. And so CDC, as I think Karen has implied, has more responsibility to the clinical laboratory community to provide education and support than the other two agencies because of that different role that we have.

And so within the CLIA program, CDC really is charged with engaging the clinical laboratory science and medicine community in a way that doesn't conflict with a compliance role that the other agencies might have. It's part of the reason I think that CDC is responsible for managing CLIAC. It's an example of our outreach to the community. And you will hear from our branch chief in our training and workforce development branch later today.

And you will see that the challenge we have at CDC is that the scope of need is tremendous. And our resources are relatively limited. As Karen indicated, the resources we have for the CLIA program across the three agencies is limited to laboratory fees. There is no congressional appropriations for this. And so we have a relatively small budget. And we'll review later today the kinds of activities that we're doing in this area that goes from everything from guidance like Ready, Set, Test! to e-learning courses, to the VR stuff that you see out in the lobby, to support to fellowships and other things.

But I think education is also something that we rely highly on our partners in the professional organizations to help us do. Not only help us understand what we should be doing, but to have them help us develop and circulate training materials and guidance materials. But this is something that we constantly need guidance from you all and from the public on. What are we doing well and what are we not addressing adequately so that we can adjust on the fly?

CLIAC MEMBER: So just a random topic put together from a couple of people's comments. We talked a little bit, I guess, about consumerism maybe here, and move to direct-to-consumer testing. And one thing I'm not sure it's within the CLIAC purview to suggest that maybe physicians and hospitals are graded quite a bit now on their quality. And that information is out there for the public to see. But this same level of information is not out there about laboratories particularly. And there are just dozens of dozens of newer entries, commercial entries into the fields, particularly genomic sequencing and next gen sequencing. Things like that.

And there's really no information out there for me as a customer trying to look at this information whether I'm going to send something out, or particularly for patients. And maybe I have a little bit more idea of how to find this information out. But certainly, patients would have no way of finding out this information. And so I wonder if that's within the CLIAC purview to perhaps look at that at some point, or a topic for discussion at some point.

CMS EX OFFICIO: I understand what you're saying. I know that CMS has Nursing Home Compare where they talk about the different nursing homes and their ratings and all like that. Is that somewhat what you're thinking of?

CLIAC MEMBER: Again-- right. There are, I guess, public and private ratings of different physicians and hospitals out there now. That data is out there. But I don't know of anything specific to laboratories that's similar. Certainly, there's probably information on complaints and surveys and things like that from within CMS. But I think a lot of that is not available to many of us. Or it's not definitely not publicly available to patients if they went to look for information. So that's kind of where I was going with that, with the comment.

CLIAC CHAIR: OK. I just wanted to-- that's what I thought you were.

CLIAC MEMBER: Right.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Along the lines of that discussion with medicare.gov, we can go online and look at grades and patient safety. That'd be a wonderful addition to be able to include the data from these lab reports.

CLIAC MEMBER: Thank you. I don't remember if we do, or at least, I don't think we do enough awareness-raising regarding the responsibility that we health care professionals have to participate collectively and inter-professionally in educating the consumers.

And when I look at this from an operational perspective, like from the hospital or other health care settings, when a patient has to take a particular test, frequently, all the patient knows is that your doctor or your health care provider has ordered this test. And many times the patient will say, well, what is that? Or whatever. And then they take them to the lab and sometimes the lab will say, oh, we only have to draw one tubes or two tubes, and it'll be a little poke. And they come back really illiterate in terms of-- except for the fact that they have had the experience of having the puncture.

And so when I reflect on this, yes, I agree. Education is critical. And I know we're all educators to some degree. And I'm wondering if it's-- you know, we see on TV all of these advertisements regarding medication. But I don't ever remember except seeing when there's an outbreak CDC advertise anything in reference to we all have a responsibility-- just a general PSA that we all have a responsibility to continue to educate you, not only on medication but on the lab tests that you're receiving. So ask your health care provider.

And because we're in Gen X and Gen Y, Q, whatever, we need to also consider using social media to get the word out. And so I would like to see us at least reflect on, would that be another avenue for us to be able to maybe raise awareness about the responsibility that we all have and then encourage us to participate? Because I know at my practice, sometimes you don't always explain as much as you need to. And you should, just like patient teaching is a foundation piece.

CLIAC MEMBER: I think that that's another one where partnering with AHRQ would be good, because frankly, that follow up and looking was part of their-- it's been on their patient safety agenda from the beginning. So there's already a group in HHS. So I think working together is good.

I think we need to have this discussion. It's going to happen. I'm just always anxious about patients getting information that they simply, as much as you'd like, they don't have the capacity to absorb. I have a friend I talked to last night who's going to another country where I happen to know the CEO of the best cancer center there. And he's going for a second opinion. And I told him I'd get him an opinion with the best people.

And he just said, oh, I made an appointment online. Right? He lacks the capacity to make the right judgment about what to do. I can't protect him from himself. But I think our notion that we will be able to put the information out there all the time, even though we should, to expect people to be able to make the right decisions is very risky. So I just say that because I had this experience last night.

CLIAC MEMBER: In response to that, I would just have to say each person is individual. And we are hearing loud and clear from the CDC and from CMS and from health care and understanding that we need to become a bigger part of our education and health care. There's no better time than now to start. And if we make the resources available, those people who are ready to go and want to do it themselves, they'll have certified, correct information, instead of just guessing and going to Google.

CLIAC MEMBER: So totally separate topic. But I had a question, and I'm not quite sure if this falls under the CLIAC purview but I can't figure out where it would fall if it's not with this committee or with this group. So

there are certain softwares that are available for Bayesian dosing recommendations, that use these Bayesian kinetic models, that are currently considered clinical decision support systems and therefore don't need to undergo any FDA medical device approval and so on and so forth.

But these dosing softwares-- for instance, the most popular one that's gained quite a bit of attention lately is using vancomycin for AUC dosing. And these softwares use a level, a patient's serum creatinine and a patient's vancomycin level. And it essentially puts it into this Bayesian modeling and shoots out a recommendation. But you really wouldn't actually be able to do that without that software. And whereas clinical decision support is something that you should-- the data's there. This is just kind of putting the pieces together. This software is actually something novel and new.

And I'm curious as to where do where do we draw the line to say that this software needs some quality assurance measures or something because we're essentially using it to make patient care decisions. And there's traditional ways to calculate these things, but those require multiple levels and this is just using a single level. So it truly is kind of using laboratory data to kind of make these projections. And sometimes, I just don't even know when to say that the model's been outdated. Or is the model still performing where it's supposed to be performing? Does that make sense?

FDA EX OFFICIO: So those are all really good questions. And I would definitely encourage you to take a look at the recently posted clinical decision support software guidance, because it does talk about some of the aspects that goes into whether a particular software is considered clinical decision support.

And whether it would be regulated as medical device or not, depending on several factors, including the risks related to what type of clinical use it's going to be used for as well as whether the health care provider can independently ascertain the results, or whether it's sort of a black box for the provider and they can't independently verify how the result came about. So I would definitely encourage you to take a look at that guidance and to comment on the guidance as well. It is a draft guidance right now so the comment period is still open. So it's an area that is under development. And we would really appreciate your comments about where the boundary should be, within the scope of-- we do have to work within the language of 21st Century Cures. But to the extent that we can interpret that, we're interested in feedback in that area.

CLIAC CHAIR: [CLIAC MEMBER], is your comment related to this topic? Because [CLIAC MEMBER], also wanted to make a comment. Then [CLIAC MEMBER],.

CLIAC MEMBER: I just wanted to comment to [CLIAC MEMBER]about, I'm not sure if the patients don't have the capacity or they don't have the information. They're vulnerable to-- just like getting your car fixed. And so I think the definition of what the laboratory is responsible for pre-analytic or information related to that-- yes, it does have to come down to an eighth grade language level. Yes, it does have to be interpreted in many languages. And there are some tests to your point that it may truly be so complicated that an M.D. or a PhD needs to have some interpretive value.

But I think the bulk of what we're talking about are things-- how to collect your urine specimen appropriately. What does it mean when you get a blood draw or collect a throat swab? And things that are kind of the more common things that we do ignore that maybe we shouldn't. And start there with the things we can describe and not let the perfect be the enemy of the good.

CLIAC MEMBER: I completely agree. So I want to make clear that I'm not saying that this is a bad idea. But-- I'm waving my hands like Bernie Sanders.

[LAUGHTER]

My only point is there are people-- this guy is not stupid. He has a master's degree. But he cannot make a logical decision. And we have people-- not everybody. Everybody around this table will because we're familiar with all of this. But there are a lot of people out there who cannot put together three items and come up with a logical conclusion. So it's not to say we shouldn't do it, because many people will benefit from it. And we should make it available. That's the way it's going. But I just want to reiterate, we shouldn't be so naive as to believe that this will be useful to everybody. That's all.

CLIAC CHAIR: [CLIAC MEMBER]. Final comment.

CLIAC MEMBER: So my question is related more along the lines of post-analytic. And when lab reports are sent out and posted, do black box warnings always get integrated into the results? Because I'm seeing fluoroquinolones still being prescribed for sinus infections. And so I'm wondering, how does that integrate with the FDA when you put on a black box warning? And how does it integrate with all labs? Are they getting the message? Because there's many doctors that don't know of the challenges of fluoroquinolones and the harm that they're causing.

CLIAC CHAIR: Wow. That's an excellent point. Integration of the harms of pharmaceuticals linked to the lab result. I don't think we've thought about that before. OK. [CLIAC MEMBER]. This is it because we got to go to lunch. And take our picture.

CLIAC MEMBER: I'm just going to remind us that we still need to remember the basics. Who will be providing the test? Who will be performing the test? And who will be training and teaching the people who are performing the test? We were reminded that we have the young people who are coming along. And the people who are dealing with, the succession planning have not really worked as well as we thought they were with the new test. Even just going and pushing a button, you still need to know how to interpret the results.

From a professional perspective as well, we will not be able to educate the public if we are not professional enough to be able to know how to communicate that information. So I think we still as a community need to remember to focus on the basics-- who will be performing the test and how they will be trained. Thank you.

CLIAC CHAIR: Thank you all. This has been a very rich conversation. We've enjoyed it. It is time for lunch for CLIAC members, including ex officio and our lovely [INAUDIBLE]. We are going to go adjourn to that staircase, get on there and take our picture, and then everyone else, please have lunch. And we will reconvene at 1:00. OK. Back to the staircase. Thank you.

Clinical Laboratory Workforce Updates

Health Resources & Services Administration (HRSA) Health Workforce Activities – Health Careers Opportunity Program
CAPT. Corey Palmer, MS, MPH

CAPT. COREY PALMER: I'd like to talk a little bit about the health career opportunity program, the National HCOP Academy. The purpose of the National HCOP Academy is to assist individuals from a economic or educationally disadvantaged background who are really trying to enter and graduate-- enter and graduate from an allied health or health professional program. You can advance to the next slide, please. Next slide, yes.

The goal of this program, it's really threefold. We are working to try to develop the necessary skills for the individuals to successfully compete for, enter, and graduate from these allied health and health professional

schools. We try to make sure we improve their retention, the matriculation, and the graduate rates of these individuals. And we do this through trying to develop and address these academic and social needs of these trainees.

And we also try to provide for an opportunity for these individuals to have community-based health professional training, and one of the things that we emphasize in our program really is in underserved and rural areas for this particular program. Next slide, please.

Some of the eligible entities for this program, we-- then we kind of categorize them in four different areas. The credited health professional schools which are listed here, some of them medical schools, public health, dentistry, and veterinary schools. Then we have the public and nonprofit schools, and these are mainly focused on the graduate schools that have a focus in behavior and mental health. And then we have some of the four the physician assistants, the PA schools that we focus on. And then the last one is for other public and private nonprofits, and some of what's going to be included in these are the community, the technical and tribal colleges that are eligible entities for our program. Next slide, please.

This program, the National HCOP Academy overview, they have nine different legislative required activities for these programs, they're listed before you. Then you have the recruitment component, and you have to facilitate-- when they need help, facilitate these individuals into entries into these health professional schools.And you have some components of counseling and mentoring. And the preliminary education and health resources, of course they help with some of their financial aid disseminating that information, and we try to provide them with primary care exposure. And each of them, of course, has to develop their own competitive applicant pool of individuals, and they do provide stipend, and scholarships are for individuals that are currently in health professional school. Next slide, please.

Just want to go over some other program requirements for our grantees that we require of them. The first requirement is that for the HCOP National, a bachelor's program, this is one of the required program that each of the grantee has to develop a program for. I will talk a little bit more about that in some slides later on. And then they have the component that we require that each of the individuals set aside a 0.5 full-time equivalent case management position, and this position will work on the academic and social support for these students that are from these disadvantaged background.

And then we have where they have to have another set aside 0.5 FTE for data management, and we want to really try to track the data for our students that are participating in our program, trying to track them from the beginning of the program into actually the practice and where they actually end up practicing in these underserved rural areas.

They also require to have a formalized partnership. This is a articulation agreement will-- that's within the university or community partners-- will allow these individuals to-- as they set aside the real pathways for the individuals that are working for individuals with-- that are in high school or undergraduate or in health professional school, kind of put them on a track where they have a way that working with these different entities, whether it may be a community college it's trying to work with, the undergraduate school, or undergraduate trying to work with health professionals school or with high school-- just have these agreements in place so they are better able to facilitate that process.

And then also the last opponent is, they each have to develop some activities that will support these individuals to completing their degree program and exposing them to employment that are in a primary care rural and underserved medically served areas. And this is a partner of the community-based training that I was representing earlier. Next slide, please. Next slide. Thank you.

Another aspect of the program requirement is that we have what we call structured program, and we also have unstructured program. Well the structured part of the program is this is what I referring to. The structured part is really a formalized enhancement program that has a specific limb with specific design curriculum. And set aside activities that are designated for the particular students that are participating in the program.

And the unstructured activity are the ones that are standalone single activities, like maybe a recruitment fair or activities that happen as one time. But particular in this program, we require them have structured program that will include-- they have to have a stipend component of the program. And they also have to develop their curriculum, which in the curriculum must have some of these activities that will help with preliminary education such as standardized testing preparation, study skills, and enrich some of the science ability for some of these students as well. They have to also have health research and training on current and emerging issue. And it's kind of touch base with a lot of the ones that are in the field, these clinical laboratory areas that would touch on those areas. And then they also had that specialized training component for their program which will give individuals exposure in the primary care and community-based setting, also rural and underserved areas. Next slide, please.

There are several different structured programs that we'll go over that's a part of the program that we've considered structured programs-- qualify. We, of course, have the mandatory program is required, the HCOP National Ambassador Program. This program is really a longitudinal and integrated curriculum-based program that's designed to assist students from these disadvantaged population. They had to have about 25 students of a cohort of a student in this program, the National Ambassador Program. Then we have the HCOP Summer Program. This is a program that has a designated educational level that provides six hours of structured learning activities. They have to have six hours learning per day for a minimum of six weeks during the summertime, and the cohort of students have to be 25 at there as a minimum.

And then we have the HCOP Saturday Academy Program. This one has to have a curriculum set aside activities, too. This one has to have a minimum of 25 and provide six hours of structured learning per day for a minimum of 20 weeks. And the HCOP Pre-Matriculation Program is also a curriculum-based program. This one has a minimum of 10 students per educational level that provides six hours of structured activities per day for a minimum of four weeks for that program.

And the HCOP Post-Baccalaureate Program, this is a comprehensive program that has to have a minimum of five students, and it's the health professionals-- in the health professional school or allied health professional school. And these students have to be-- have an undergraduate degree of science-- focused and conditional acceptance into a health professional school as well to participate in that aspect.

And then the last part of it is a HCOP adult non-traditional students, and this can include veterans as well. We actually tried to reach out and recruit veteran individuals as well for this program. It has a minimum of 10 students that could provide some educational opportunities for adults that are interested in pursuing a bachelor's degree. And it's curriculum-based, too, as well, and it provides some academic and social support services to help these working adults and parents for this program. Next slide, please.

This is the required program, the HCOP National Bachelors Program. Just want to give a little bit more information about the required program that all of our grantees must have. Now this program must have a formalized application process that defines eligibility criteria for this program. They also have to have a minimum of 25 students for each year, and helping these individuals from disadvantaged backgrounds matriculate to completion and graduating from these health professional or even certificate programs.

The program goal is really to help lead these individuals in matriculating into the applicants or the partnership organization as they form these articulation agreements that they have in the beginning. Helping these

individuals matriculate to whether it's a two-year or four-year college or university, whether they're going into health or allied health professional schools, or just into employment in a primary care setting. The bachelors program also have to make sure that they have their curriculum aside that will help prepare these students to meet their mission requirements of some of these schools so they can set up that educational pipeline trajectory for these students.

And the last component is curriculum should have some type of integrated education activity, such as a research project that focuses on clinical areas, such as opioids, mental health, and behavioral health, and also some of the emerging health issues that may occur as well. Next slide.

The target population for the National HCOP Academy, each of the grantees are required to choose at least three of the target population that you see up here. They either have to choose a rising high school student as a junior or senior, an undergrad freshman or sophomore, or undergraduate students or adult nontraditional students or students that are already in a health professional degree program. They have to choose at least three of these various target population and show that they are helping them matriculate through the pipeline or to the educational trajectory. Next slide, please.

Here's just a snapshot of the HCOP Academy. As a project period for this grant, it started in September 1 of 2018 and goes to August 31 of 2023. And in 2019, the funding was around about $13.3 million, and per grantee, we were funding up to $645,000 per grantee. We have 21 grantees, and they are located in at least nine of the HHS regional-- federal regional areas, and it's located in 15 states, and including the District of Columbia. Next slide, please. Here's just some of the program characteristics of the program. As you can see that we train for the HCOP, we train about 5,000 students in academic year 2017 to 2018. And of the awardees, they had 157 structured and unstructured programs doing that time, and 200-- 2,868 of these individuals actually complete the program training.

As you see there, the HCOP, the [INAUDIBLE] program, we no longer have this program, but we still have data from the academic year 2017-2018. It was a component that we did where we focused mainly on the paraprofessional individuals and we trained mainly on individuals in that certificate program or community college and technical college individuals. And this was kind of like the last year of the data from that program, and we had a total of 683 students that participated in 11 different programs. So we were able to have 332 of them that graduated and earned certificates for that program. Next slide, please. About current grantees, just want to go into some programs that have really a particular focus that are really research-related activities. Our program with the Emory University include some of the health research training component. They have a urban health initiative leadership component where they have students work on a health research summer project throughout the summer that they have to complete, and it's either with the undergraduate students or the post-bac students that work on this program through the year.

And then we have Icahn School of Medicine at Mount Sinai. They have a biomedical research component to their program, and this really focuses on trying to-- on the science enrichment and impact preparation and medical school application and community-based primary care exposure for these individuals. And the biomedical research gives them opportunity to boost their medical school readiness and facilitate their interest into that medical school. Next slide, please. And then we have a few of the current grantees that are of a community college or technical college, and one is at a university. So the Columbia State Community College, they focus on recruiting the medical laboratory technician technology half. That's their main focus. Then we have George Washington has a medical laboratory science focused in their program, and then Mount Wachusett Community College has a medical laboratory technician focus as well. So those are the three colleges that kind of focus on the medical laboratory component of our current grantees. Next slide, please.

That completes my presentation. So I'm not sure if we take questions now or we take questions and doing the public comment.

CLIAC CHAIR: Thank you, Captain Palmer. I think we have time to entertain some questions.

CLIAC MEMBER: Captain Palmer how many trainees do you have in those three laboratory programs right now? And do you know the breakdown between technologists and technicians?

CAPT. COREY PALMER: We don't have that-- those totals yet because those numbers were in the annual performance report, and that data is still being looked at, given to us. But we don't know the exact numbers. So we we're at the first year of their first complete year, and we submit that data at the end of July and August. So we haven't analyzed the data yet, but we should have the data that's coming up readily available probably-- it takes them awhile, so we probably won't have it until around March/April when the data will be available, unfortunately, but we don't have the breakdown yet.

CLIAC CHAIR: Thank you, Captain Palmer. Your voice was breaking up a little bit. We heard only single syllables, but we gather you don't have that information yet, but thank you.

CAPT. COREY PALMER: Oh yeah. So basically I was-- so basically I was saying that we don't quite have the data all the way down. We just-- they just completed a full year of the program and they are submitting the data towards the end of July or early August, [INAUDIBLE] our [INAUDIBLE] to process the data. We won't have it available until April or March.

CLIAC CHAIR: Thank you, Captain Palmer. We are not laughing at you, we are still having audio difficulties. But while we're solving those, [CLIAC MEMBER] would like to ask a question.

CLIAC MEMBER: I hesitate to ask a question because of the technical difficulties, but maybe an answer could come later if we can't understand. My question-- a number of trainees is impressive to me. I'm wondering if the Captain has any data on how many individuals they feel would be qualified to participate, but they have to turn away for lack of funding for the program.

CAPT. COREY PALMER: We don't have-- of course this grant is highly competitive. We've had-- I think in the last cycle of grantees, I think we had around about-- was it about 70 or 60 the applications?

MS. TAMMY MAYO-BLAKE: No, we had-- for the grantees, we had 120 applications.

CAPT. COREY PALMER: So we had 120 applications, and we only could fund about 21 grantees. And so as you can imagine, it's highly competitive and it's a very important program that people value in the university and communities.

MS. TAMMY MAYO-BLAKE: At the universities, the programming that they offer really includes a lot of students. So it encompasses a lot of students, so they really try not to turn students away. So as long as the students qualify as educationally or economically disadvantaged, they try to find a way to have them benefit from some of the programming and from the curriculum.

CAPT. COREY PALMER: And another piece is what we tried to do understanding we have limited funding, and we try to make sure that we distribute the funding throughout the US. As you can see, that it's represented in nine different federal regions out of the 10, so we try to make sure geographically that we try to spread so we can touch as many populations as possible.

CLIAC CHAIR: OK, thank you.

CLIAC MEMBER: Thank you. Thank you, Captain Palmer, for this excellent information. I'm excited about what I've heard. As I shared with Dr. Dreyer this morning when she touched upon this, that there's the possibility that my university where I am would be very interested in this, because a couple of years ago, we looked at adding an allied health career option. And so I've written articulation agreement as the past interim chair of the department, so this is something that I'm familiar with being able to do and certainly as our provost.

And so the other question that I have is, the funds-- I heard you mention that it's granted that this is-- funds are granted. Is this part of the workforce development or Title VIII funded? Or is it another pool of money? I noticed in the PowerPoints that we have, it says, what, PHS Act? And so if you could expound on that a little bit and answer the question if as part of Title VIII or whatever-- Title VII or workforce development, because I know there was a great deal of funds that were in that pot to be able to increase health education workers in other career options.

CAPT. COREY PALMER: Certainly. Thank you for your question. It's part of the Public Health Act-- VII. It's Title VII. And we fall-- for the Health Resource and Service Administration, we fall under the Bureau of Health Workforce. So that's around building the health workforce trying to-- this is one of the pathway programs, the diversity programs that we have here that is designed to help health professionals with the skills starting at a young age and trying to get their career interests into the health professional field. And so that's kind of where we fall in the health workforce area for strengthening their workforce and putting them in areas that are medically underserved areas.

CLIAC MEMBER: So what kind of-- if I may follow up, please. What kind of time frame do you have to take this to the next level? I heard you mention that you had already had some recipients of the funds and that you fell short with the number that you could accommodate. So what is your strategy going forward and are you actively interested in putting this into high gear? Or maybe you already are, I don't know.

CAPT. COREY PALMER: Currently we're still under the same-- this grant-- project period for the grant is from of course September 2018 until August of 2023. And I think for-- during this current time period, this is probably like the year funding that we have for this program. And so what we try to do, we try to work with other programs to try to leverage resources to try to maximize whatever we can do with these programs, whether it's collaborating with Department of Education, collaborating with other workforce programs to try to-- and also working with this committee to see how we can work to leverage each other's resources and try to build workforces in whatever way that we can.

CLIAC MEMBER: Thank you, because I will be taking this information back next week to my university. Thank you.

CAPT. COREY PALMER: Oh, you're welcome.

CLIAC MEMBER: Thank you for this very timely topic. It's one that we were discussing at lunch, as a matter of fact, because it's of concern to all of us in the laboratory profession. My question surrounds phlebotomy, and as mentioned earlier, many of us are only hiring certified phlebotomists, and that we're using them for more and more complex activities. And I know at least in my area of the country which is fairly rural, we have as much if not more issues finding qualified phlebotomists than we do the medical technologists and the more highly skilled laboratorians.

So I'm wondering-- it seems like it might fit within your initiative for folks that are looking for a career that may or may not be wanting to go on to a baccalaureate curriculum. Have you looked at phlebotomist training

programs particularly in rural areas and something-- workforce development of that particular strata of the laboratory profession?

CAPT. COREY PALMER: We have-- what we try to do with this grant is-- and even kind of touching bases with the data that I shared about the paraprofessional skills one where we-- we're trying to build within the community a need where we can get individuals that may not be interested in getting a bachelor's degree or a health professional degree, get those individuals that are interested in certificate program or two-year degree and meet the community needs there. And so we try to incorporate different aspects of what the community needs or what the workforce need is trying to projection.

So we try to look at data that's whether it's the label-specific, we have our own internal data system that we look and try to project the need for the various areas-- what's the growing need? For instance, when we came up with this current project period for this node as a funding opportunity, we saw that there was a growing need for the allied health professions, so we kind of put more of a focus on allied health for focus, and also tried to make sure there are some matriculation agreements and for individuals that are nontraditional work component adults that are trying to get jobs that are right out of high school and right out of military that may not want to go in a particular field.

And so we try to work with the different entities, and if they're able to provide the data, we can, of course, do our data needs on the different areas as well where there's a shortage of individuals. And so we try to work as much as possible to try to meet those needs, and we also try to let our grantees to kind of work within their community to kind of guide us on what their focus areas may be for their community, whether it's rural or underserved areas that they may have.

CLIAC CHAIR: Thank you, Captain Palmer. I see no more hands up, so we thank you for your presentation. And we're going to move on to our next one, which is Senia Wilkins presenting on CDC's Division of Lab Systems-- updates on the laboratory workforce activities. Ms. Wilkins?

CAPT. COREY PALMER: You're welcome.

CDC Division of Laboratory System Updates on Laboratory Workforce Activities

Yescenia Wilkins, MPH

MS. YESCENIA WILKINS: Good afternoon, everyone. I'm Senia Wilkins as you just heard, the chief for training in lab-- I don't even know the name of my branch now-- Training and Workforce Development branch in the Division of Laboratory Systems. And I'll be giving a couple updates on some exciting activities that we've undergone this year, and also that we are very much looking forward to this next year.

And so as you heard from Collette earlier, our goal is to strengthen the laboratory workforce through a variety of strategies. And in terms of our training specifically, we have a growing inventory of free training resources including e-learning courses, web-based resources and tools, and print materials for laboratory staff.

Topics vary across pathogen-specific diagnostics, preparedness, laboratory safety, and laboratory informatics, microbiology, and other topics in addition to those as well. In fiscal year 2019, we created and maintained 40 e-learning courses, we held 19 live webinars, and we supported 148 in-person workshops and seminars for CDC staff and/or external laboratory audiences as well.

Now our list of courses changes pretty often. So for the most recent list of our current course offerings and other resources can be accessed at cdc.gov/labtraining. Learners can also take our courses on CDC Train. CDC Train

is our learning management system. Anyone from anywhere can create an account completely free and access all courses and trainings that are available on CDC Train.

For additional specificity, learners can join our laboratory training group within CDC Train. Members of this group are the first to be notified of new courses that DLS releases. And I'm very proud to say that this is the most popular group on CDC Train with over 32,000 members. However, we definitely want to see some more growth in that number in the next couple of years.

I also want to provide an update on our Workforce Assessment for Laboratory Communities project, also known as the WALC. In past meetings, we shared a general update of this project, but to recap, this is a three-year project. In year 1, we-- the purpose of the overall project is to enable the development of collaborative strategies and initiatives to address laboratory workforce development challenges and needs. And in year 1, we focused on identifying what are those challenges and needs and uncover any gaps in the current workforce development data. We did that through a literature review which is currently being updated since it's-- we're now entering year 3.

We also conducted interviews across-- with CDC partners to better understand the laboratory training and workforce development activities that were occurring across CDC programs so that we can better coordinate and collaborate with each other on those activities. Year 2 was primarily collecting primary data collection around to address some of those needs that were identified in year 1.

So our research question for a year 2 was heavily influenced by the data collection mechanisms that are available to us, and as a result, we focused on issues around training and professional development of the current workforce to help us potentially further tailor our DLS portfolio of training and resources. This was especially important to us because we are focusing on increasing our reach to better-- and better reaching in general the clinical laboratory professionals as well as public health laboratory professionals.

So we centered on three main evaluation questions that related to current use and perceived effectiveness of our programs and resources, current and prospective gaps of those resources and programs, and facilitators and barriers for accessing those programs and resources. We held focus groups with high-level leadership and through one-- we held focus groups with-- and one-on-one interviews with high-level laboratory leadership as well as bench-level staff, and we really were able to gain some really good feedback across a variety of topics related to our resources and programs.

In the end, we had 87 participants, 46 from the public health laboratories, and 41 from the clinical laboratories. This is a fairly-- which is fairly-- a fairly large sample size for this type of qualitative study. Now to not get too much into the weeds, but provide some examples of some prominent themes that came from the data, quality data analysis, and are categorized here by the three evaluation questions that I just referenced.

To provide some highlights, participants expressed a desire for courses targeting different levels of proficiency, they expressed preferences for course length and learning modalities. Under current and prospective gaps, there was a distinction between leadership management and soft skills related to communication or negotiation. From other cross-cutting topics that related more to laboratory systems-- so laboratory safety, quality, informatics.

Under facilitators and barriers, nothing too surprising, but it still pains me a bit is that there is still limited awareness of offerings of our resources and programs. So in other words, a lot of participants still aren't aware that CDC offers these free courses. Many of them also offer continuing education credits for learners.

So we have now kicked off the third and final year of this project where we will begin work around developing collaborative strategies with our partners. We hope that the strategy-- well, we anticipate that the strategy will

be tackled differently by each of the various partners depending on priorities of our partner organizations. However, we hope to continue to work together to develop an overall collaborative strategy, and DLS specifically, we hope to develop of subsequent implementation plan to, again, ultimately further tailor our portfolio of training resources, which will lead to new courses, new programs, new resources, and hopefully newer and better ways of reaching our target audiences.

So in that same spirit of better reaching our target audience, we've hopefully by now have experienced the virtual reality course that is out in the lobby or you've heard about it-- we've mentioned it a couple of times today. This course we're especially proud of because we have built the first ever CDC laboratory training course that abides by instructional design and adult learning principles, so this is a huge accomplishment for us.

We developed a complementary module to an existing e-learning course around biological safety cabinets, and the complementary module really allowed us to explore-- we love our e-learning courses, they're convenient, they're widely accessible to all types of audiences. However, they're limited to knowledge-based learning objectives. And so VR really excited us because it gave us the possibility or the potential to veer into more skill-based knowledge objectives, and so that was what we were really trying to explore here.

So we said that we created this complementary module to our existing e-learning course, and the current module focuses on setting up a biological safety cabinet.

So we were, again, interested in VR technology for a variety of reasons, but mainly because we-- again, it creates an immersive training environment with the ability to evaluate laboratory skills. It also creates a safe and controlled training environment for topics that are otherwise high risk, hazardous, expensive. And it's also scalable and deployable to anyone online who has VR equipment, which primarily consists of a headset and sensors.

We piloted this course with internal CDC staff this year and got very good feedback-- that data is currently being analyzed. We hope this year to pilot this course with public health laboratories and some clinical laboratories to get an understanding of how feasible is it for us to take this type of course and put it in the hands of our target audiences on the ground, which is really what we want to do here. These pictures here are just images captured from our course. They really don't do it justice. If you haven't taken a look at the demo out in the lobby I encourage you to do. It's really quite an impressive project.

We also hope in this next year to complete our biosafety cabinet course training package. So we have an e-learning course that I mentioned, we now have this complementary VR module around setup of the BSC, and we'd like to create another module to complete that where learners actually have the opportunity to work inside of the BSC and respond to some emergency situations. So we're excited about that as well.

We're also looking into developing a second course. We're still deciding looking at data from needs assessments to decide what's the best topic there, but we're leaning towards Personal Protective Equipment, PPE, but we're-- again, the technology is still evolving as we're exploring it, and so we're trying to stay current with that as well as respond to the needs that we're hearing from our target audiences.

And last but not least, we are also-- also to help expand our reach, we are looking at exploring how can we syndicate our current courses that are available on CDC Train on other learning management systems? So in other words, we want to look at how can we share our courses with partners that gives partners the ability to reflect these courses on their own systems while also allows us to maintain version control and consistent data pools?

So this is very exciting. Hopefully next year when I present, I will be able to let you know that this is a service that we now offer and it is a reality, and I do believe we're on the cusp of making that happen.

So again, very excited for this next year. We are looking forward to continuing to collaborate with all of our partners, with members of our target audience to continue to support and strengthen the laboratory workforce. And in order to do this, we of course need all of you as well. And so here, we've drafted some questions to help guide the committee discussion that will happen later during the meeting. And so I'll go ahead and just recap what these are.

So one question is, how can the clinical laboratory community take advantage of the HERSA Health Careers Opportunity Program to address workforce shortages? What are effective ways to increase awareness of freely-available CDC laboratory training resources among the clinical laboratory community? What major goals or areas of focus should be part of a collaborative strategy for public health and clinical laboratory workforce development? And how should federal agencies and partners work together to achieve those goals?

So again, those will be addressed during the committee discussion. Any questions for me?

CLIAC CHAIR: Thank you very much Ms. Wilkins.

[APPLAUSE]

Questions? Yes, go ahead.

CLIAC MEMBER: So both a question and maybe a prompt to question 3 of the discussion. So across allied health training, the shortage of clinical rotations is a major barrier to programs. Groups like the Association of Schools of Allied Health Professionals, others have written white papers about lack of clinical rotations and the potential value of virtual reality simulation, alternate ways to do allied health education.

The accrediting bodies like NAACLS and others are the sort of barrier to doing this, and so this is sort of a-- you've got this beautiful virtual reality core set up, one way to work together be to study outcomes and demonstrate outcomes for accrediting bodies and others that the value of a virtual course versus an actual live-- in this case, setting up a safety hood, live course versus the virtual course demonstrating outcomes help to bridge that barrier to show that virtual reality simulation are alternatives in terms of competency-based education to live clinical rotations.

MS. YESCENIA WILKINS: Yes, absolutely. And we see a lot of VR training already happening in the medical field in some ways. I haven't seen as much courses in this way where we're evaluating learning outcomes like you said. And so we're excited-- we're testing that out a little bit with this current course with a follow-up survey, but it's very subjective, right? Like three months out we're going to ask, did you apply what you learned in this course?

But we continue-- so we would love to work with you, because we continue to explore and brainstorm how can we do this in a more objective way? How can we really learn and prove that that VR training is as powerful or even more powerful than other training alternatives dependent on the topic, of course.

ADVAMED LIAISON: With regard to your second question of effective ways to increase awareness of your materials, I have to say, I was impressed with a couple of the brochures or leaflets in the lobby today because I have often questioned or wondered what else is available? So I would think that a couple effective ways would be one, through accrediting organizations who are going in and talking to labs almost every day, and could that

become part of their discussion or a leave-behind, something that references CDC Train or some of the other sites.

And then also manufacturers. Many manufacturers have learning management systems to house their own courses for labs to learn how to properly use equipment or products that they provide, and there could also be links potentially to your materials as well. Many of us do not-- many of the manufacturers don't want to recreate materials that are already well done by organizations such as CDC.

MS. YESCENIA WILKINS: Those are great ideas, thank you.

CLIAC CHAIR: Thank you, Ms. Wilkins. You stunned the audience with that awesome presentation. Thank you. I believe we do have one public comment, Dr. Chiriboga, if you are ready. Thank you.

Public Comments

DR. LUIS CHIRIBOGA: Can everybody hear me? Yeah. OK. I want to thank the group for allowing us to speak today. And my name is Dr. Luis Chiriboga, and I've worked in a CLIA-certified laboratory for over 10 years. Currently the director of a translational histopathology laboratory. I'm here to comment on the CLIA 88 laboratory personnel requirements on behalf of the National Society for Histotechnology to address the continuing workforce issues.

We would like to thank CLIAC and the Laboratory Personnel Requirements Group for its recommendation to include histotechnology as a specialty in the 2019 meeting. The specific recommendation was that recognition of histotechnologists as laboratory personnel should proceed because histopathology is a specialty under CLIA. Histotechnologists perform services that are closely tied to patient diagnosis and prognosis, therefore histotechnology should be added as a personnel category similar to cytotechnologists and be trained with courses that are required for certifications similar to cytotechnologists.

Upon review, the meeting notes-- the recommendation was not specifically included in the April 2019 summary report, but was a topic of committee discussion. Unfortunately it was rolled into other recommendations, and we fear it may be overlooked for future consideration. So NSH would greatly appreciate an update on the status of the discussions because of the following concerns.

In terms of the workforce shortage, I can speak directly from experience. My current institution has 18 vacancies in the anatomic pathology department. My laboratory specifically is short-staffed and it's extremely difficult to find trained individuals who are willing to accept low salaries and the high cost of living in a metropolitan area. The lack of trained individuals has an even greater impact on my research because of the complexity of the work that's taking place in there.

Recent data suggests that retirement rates in our anatomic pathology will approach 13% over the next five years, and vacancy rates will continue to rise above the current 8%. The continued shortage of qualified personnel will only intensify the vacancy issue, because staff are already overworked, and this is just increasing their susceptibility to burnout in the future.

While laboratory automation has been touted as a solution to the workforce shortage, instruments only perform as well as their operator. The operator must have the knowledge and expertise to oversee instrument operation. In order to do so, the individual must have the necessary education and training to manage all aspects of an assay as well as to be able to diagnose and interpret issues when they arise.

Furthermore, new technology does not imply automation or new automation. In anatomic pathology, FISH, SISH, IHC, multiplexing, and other imaging and image analysis modalities are all methods that have not been fully adopted by the pathology community, yet the technology has been in place for a number of years. In fact, anatomic pathology is moving towards even more advanced modalities-- molecular tissue analysis, mixed multiplexing, digital slide profiling, and artificial intelligence.

With a limited and untrained workforce, current staff will spend more and more time training, exhausting already limited personnel resources. We suggest that the criteria used for categorizing tests should be modified to be more relevant to evolving technology and the future role of laboratory personnel. In reality, there is already confusion about test complexity among histology professionals, because science technology and medicine have involved beyond the current model. In fact, we have examples that even CLIA inspectors are not sure under what category tests fall within the laboratory. We strongly recommend that CLIAC we consider the CLIA complexity model to consider including histology as a moderate and high complexity testing.

To fill this role, we need to start preparing the histology workforce of tomorrow for today. Minimum education requirements with relevant training and experience must be in place in order to build on a strong educational foundation. Personnel must be trained to be competent for the testing they perform. This is even more important as new and emerging technology which does not fall into the traditional workflow models begins to enter a laboratory workspace.

Many lab supervisors have indicated that more testing is done with less staff through automation, but turnaround time is affected by the need to train staff on how to use these instruments, leading many supervisors to actively seek certified technologists who are already well-educated and well-trained and are able to expand their responsibilities, however, there are none available.

Increased automation is increasing the need to have this well-educated staff skilled in critical thinking as is evidenced from the most recent ASCP vacancy survey. To this end, we recommend adding personnel requirements for histotechnicians and histotechnologists. We strongly support the expansion of accredited educational programs to promote all the laboratory sciences. In addition, we should seek to leverage the current non-traditional student pool. Those with previous or other science degrees that meet CLIA criteria by cultivating pathways into professional laboratory scientists. In order to make these more attractive, personal requirements should graduate as roles and responsibilities increase.

We support the AACP certification structure and education requirement as a mechanism for laboratory personnel to demonstrate competency and proficiency. NSH is a nonprofit member organization comprised of over 3,000 members which supports histotechnicians and histotechnologists worldwide through education, collaboration, and innovation.

NSH is a leading provider of histotechnology education designed to demonstrate continuing competency in an increasingly complex laboratory testing environment. Our members look forward to CLIAC's response to these issues and continued discussion in order to advance the histotechnology profession and provide the highest quality care to our patients that we serve. Thank you very much.

Committee Discussion

CLIAC CHAIR: Thank you, Dr. Chiriboga. That ends our presentations for this session, and now this is open for a committee discussion. And if we could put back Ms. Wilkins' slide outlining the four questions for our committee deliberation please. You can speak about anything related to the workforce. You don't have to feel obligated to address only these four points. OK, who wants to go first?

CLIAC MEMBER: So I certainly can add my support to the request for histotechnologists-- obviously a critical role in laboratory sciences and laboratory services. Certainly in Kaiser Permanente in northern California, we always have about 10% vacancy if not more. Exceptionally difficult to hire, so adding them to-- especially under CLIA makes sense and I fully support that.

CLIAC MEMBER: So I touched on this in the question, but the third bullet, the goals for workforce development, I think there's a lot of unknown questions about what skills, what clinical rotation competencies can be replaced by simulation and virtual reality. I haven't got a chance to put on the headset, but it looks amazing.

Setting up a biosafety cabinet, could you teach someone to streak a plate by VR as well as you could in a lab? I know there are MLS programs that have tried to use a lot of simulation VR, and it's unclear the outcomes and how good the techs are, and there are a lot of unanswered questions, and that would be just a fertile area to work together as the virtual reality are being developed by CDC to try to understand to what extent--

And I'll ask, but I guess you could look at cytotech, histotech, any allied health training program, clinical rotations can be replaced by VR and simulation and have the same competency-based outcomes, because I think that's the barrier to hospitals starting programs as-- well, one of the barriers certainly, and one of the major ones identified by ASAP and other health professional groups is-- science professional training groups is the availability of clinical rotations.

CLIAC MEMBER: And I think to add on to that, there's fewer and fewer programs for the didactic portion of training at the baccalaureate level as well as the other levels that we've discussed today, particularly in rural areas where those programs pretty much don't-- at least in our area do not exist any longer. And so online programs perhaps supplemented by virtual reality or whatever opportunities there are online to start building some of that knowledge, but I think we need to-- I would suggest that we also think about what happens when there aren't programs nearby for individuals to access.

CLIAC MEMBER: One of the things that I've heard in relation to the lack of training sites is there's no real financial incentive for people to provide that part of the training program. So I just wonder if part of the HCOP program couldn't be to financially compensate those people who are willing to train somehow. I mean, I certainly don't have any idea how that works, but I know that many institutions do not have the flexibility anymore to train students. The PAMA regulations, the other things that we've talked about trying to squeeze more out of what we're doing, training just isn't a priority anymore because they're not getting compensated for it. Just a thought.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: So I wonder if anybody's thought about leveraging the-- I mean, this is specific to microbiology, but that's just sort of one example of the total lab automation digital libraries for training microbiologists. One of the most complicated things to do is train somebody to read a plate, and they still have to do it in the virtual world to some degree for some of the organisms, even if they have UV or chromogenic components to them.

So if some of the hospitals in the industry and the government got together to build kind of like your GeT-RM program, but a digital library of unknown-- of unknowns, of actual-- and you see lots of images of pure cultures, but seeing images of mixed cultures and picking out the relevant colonies could be very much aided and abetted by this TLA technology and maybe some vendor support for this or some hospital support for this.

I don't know how they could fit it in, but that could certainly be linked to the HCOP in terms of providing computers doing the virtual picking of colonies. It would actually even help our medical schools understand-- they're cutting microbiology programs for residents, and that makes our pre- and post-analytical training of physicians all the harder. And some labs are training them on virtual unknowns and things like that, some medical schools. So it's just something that I kind of think about that model.

CLIAC MEMBER: So I think this VR technology is awesome, and as a gamer nerd myself who's used the Oculus Quest on multiple occasions for date nights, I can tell you, those are not cheap systems. And we struggle to get high bats into our first year medical labs for micro so that students could do more exactly, [CLIAC MEMBER] I know exactly what you're saying. Here is a throat culture that you get on yourself and it's a mess. So then we show them virtual images from our digital collections, we're doing a lot of slide imaging and digital microbiology.

And just getting those high bats was barely feasible. To think that we could get 20 Oculus Quests set up with the computers capable of running them with good operational efficiency, I don't think that technology is feasible right now, but I think it's cool that this is getting developed on it, but there needs to be some kind of foresight about how we're going to leverage an affordable system if we're going to use that as a training option, because they are very expensive. And if you don't have the all-in-one system that they have now that are a little more basic, you have to have a pretty powerful computer driving each one. So I think that poses the problem for most medical schools and MLS programs because that's a huge capital investment.

CLIAC MEMBER: Thank you. Just as a-- one of the major goals, I think, are-- a focus for workforce development could be is in my area, we-- in many people's area, we have a severe shortage. But we were approached by a local institution who is renowned for putting out-- or awarding degrees in biological sciences, but they're having trouble sometimes placing these people in graduate programs, whether they be pharmacy or med school or dental or whatever.

And many of these-- many of these graduates are looking around for a job opportunity. And so we've begun partnering with them on possibly developing our own technologist, medical technologist program. And there may be other opportunities, new opportunities in areas where traditional academic centers have closed their programs. There may be other opportunities now in other health care-- or other academic scenarios where they may want to reopen programs.

So we've talked a lot about how programs have closed, but there may be other opportunities, new opportunities for us to open programs. And I certainly understand that hospitals now have certain cost constraints on training technologists, but our health system is really motivated to hire every one of these technologists we may train, and large health systems may be natural partners for some of these programs because they certainly have a need and we have the ability to put trainees in multiple different environments-- we don't have to put them all in just one place, we can distribute them amongst multiple different hospitals.

So maybe as hospital consolidation has happened, there are new opportunities to partner with either current or possibly newer training programs. So I'm not sure who owns part of that, but I know locally we are owning part of that because it's part of our own internal workforce development strategy. Besides partnering with local programs for MLT, we've determined we really need to build more MTs also besides just partnering for the MLT program.

So I think these are possibilities maybe in other areas to look at also, and I'm not sure how this group or-- could push-- help push some of that forward. But I just feel like maybe there are possibilities for opportunities for new training programs, particularly new opportunities for partnering with larger health systems now.

CLIAC CHAIR: [CLIAC MEMBER], but first an editorial comment. So through my various rounds of consultants, we've lost one of our two training slots. But certainly in our local area, we've developed the ROI for the C-suite to show it's like a one-year payback. It's unbelievable. You don't get that kind of superb ROI. So perhaps that's another tool that could be shared with your organizations, right?

CLIAC MEMBER: So where I was privileged to practice for many years, we're doing what you said. It's a relatively large health system in Omaha, not the largest-- Methodist. It's now been for a number of years an independent school. The Methodist system actually has a college that trains people in the health sciences and nursing as well as a-- so we are able to offer our own degrees, it's accredited. There's six to eight students a year. The medical technologists actually teach them, they get enormous amounts of clinical experience, we love doing it. It's wonderful to have the kids.

And guess what? When you're done, you can hire a number of medical technologists who already have operated every instrument in your laboratory. And it's worked really well. The other-- and the only thing I'd say is that I think one of the biggest impediments I've anecdotally found about people, including a young woman I was talking to not a couple of months ago who wants to get-- work in microbiology, never heard of medical laboratory science. So I said, I'm going to take you to the hospital, I want you to meet our director because this is you. She didn't even know it was a profession.

CLIAC MEMBER: Probably just echoing some of the comments that were made. I think we do have to think about our education and our professional laboratory medicine in a whole different way than what we've subscribed to before with that traditional clinical rotation. The example of health systems creating their own colleges, we have that in Iowa. And I think a lot of the answer is a local or state-level reactions, because we know what we need so.

So Allen College, they grew their college from laboratory professional shortage. Now they have nursing, RTPT, and they hire their own people. But we're also seeing the resurgence of programs. Kirkwood Community College in Cedar Rapids, Iowa just opened their programs two years ago, their second class just started. They have a-- they want to accept up to 24 students, the second class had 22.

The thing that this program is doing, though, is assuring that once the program is started, they're now working with all of the high schools for the career academies, which I think most states have something like that, where we're making sure in that junior and senior year in high school, they know there's a profession for laboratory medicine, and then they can also start taking their core courses so by the time they graduate from high school, they only had that one year of clinicals, so they end up with their associates.

Then on that backend, we're making sure we have a 2 Plus 2 program, which many of you have or are familiar with, and that's through a resurgence of the clinical laboratory scientists program at the University of Iowa. So I think we really have to think much differently how we create and develop our professionals.

The other thing with clinical rotations, when we first started the MLT program at Kirkwood, that was a big conversation. Everyone was saying, oh, we won't have enough rotation sites. We have more than enough rotation sites. Part of it is because we're willing to have the students go one place for one type of education, microbiology. The public health laboratory supplies that. Another place is really good in toxicology and chemistry, that's where they rotate, because we know we don't want to overburden our clinical and public health laboratories with too many students.

But the other option we're looking into is how can we have incentives for these laboratories to be clinical sites? So when the laboratory can't afford a micro scan or some high tech equipment that they know they need to have in place, we offered this suggestion of, we will place that instrument into your laboratory as long as you take x

number of students, and they just get wide-eyed and happy. So I think that's the one thing with workforce. I truly am passionate about a trained laboratory professional, and I think we can do it as long as we're willing to try different things.

CLIAC CHAIR: Thank you, [CLIAC MEMBER]. Can we do a cross-national thing where I can get a MALDI TOF and the inputs-- I'm just teasing.

CLIAC MEMBER: No, I think the other piece from the standpoint of our laboratory professionals that I found is when we have a training program, it raises the performance of our own staff because they have to stay on top of things, and actually it's a really good system. So there's a-- that never gets measured, but it's really important. And you can see, when we reinstituted programs, you talk to people, they're much more on top of their game.

CLIAC MEMBER: And I just want to say, that's really important in states that do not have individual licensure for their laboratorians. Because we don't in Iowa, but we know that doing education and staying on top of things is how our laboratorians stay current.

CLIAC MEMBER: So I'll move to the last question, because something just occurred to me based upon my experience in the DOD. The DOD trains-- I don't even know what the current numbers are, 265 MLTs a year through the military training program. And that's a huge pool of people that will someday leave the military and join the workforce. And I know that they have struggled to provide clinical training programs in San Antonio, because the school is all consolidated there now. So again, just another potential pool that we could partner with.

CLIAC CHAIR: Thank you. [CLIAC MEMBER], were you-- military training--

CLIAC MEMBER: Well I'm excited to make a comment on that comment. The other thing that we are working on is we do have a large VA hospital in the Iowa City area, and the director of that laboratory is also the national director for the VA labs. And we're working with them to develop another program so that we can take those people that we know we're trained in the military to make sure that they can do an abbreviated clinical activity and make sure they have the courses so they can come out and we can hire them and they will be qualified under any sort of CLIA requirements. And we're hoping to make that into a national program.

CLIAC CHAIR: Just want to jump in, there's a minor lull right here. These questions are here because we are being asked, do we have concrete recommendations? And so we've talked about a lot of great ideas. Does anybody want to put any of those in a formal motion for recommendations for our agency partners to help?

CLIAC MEMBER: I guess I'll make one with the first. Is there-- I mean, it's-- the HCOP seems like a wonderful program. Has that-- who does that mailing go out to? Is it the laboratory manager? Is it-- how is that made aware of all of the people? I mean, I looked up, I have a couple in my area, but didn't know about them until this presentation. So where do we direct laboratories or can we make a recommendation that the information goes to the laboratory and not the family practice or not-- that the lab-related things come to somebody within the-- by the CLIA certification or I don't know what mailing list you use right now, but is there one that could be updated?

CLIAC CHAIR: So I hear the motion would be to encourage or to request distribution of HCOP programs to clinical laboratories.

CLIAC MEMBER: The ones that are related to the laboratory, at least.

CLIAC CHAIR: Right. And just piggybacking on [ADVAMED LIAISON] comment earlier, the one thing that comes to every laboratory is your license renewal, right? So maybe an informational brochure could be with HCOP, could be the availability of CDC laboratory training resources, right? All of these things that we're seeing, how do we know? You can get it to us and we had to pay our dues, you know?

CLIAC MEMBER: This is [CLIAC MEMBER] on the phone, can you hear me OK?

CLIAC CHAIR: I can hear you, Steve. Did you want to say something?

CLIAC MEMBER: Yes, please. So this isn't really ready for a recommendation, but maybe it's to throw out as an idea along with-- and I hear we're getting some feedback, did that fix it?

CLIAC CHAIR: We can hear you fine.

CLIAC MEMBER: OK.

CLIAC DFO: So if everyone can turn off their microphones, it'll help minimize feedback online.

CLIAC MEMBER: I just wonder whether or not we could ask our either HHS or CDC partners whether there are some public service announcement opportunities to put something out there on TV and radio talking about the opportunity and the need for people in the medical technology field. It would be great if we were able to see an announcement from CDC or HHS and sponsored by one of the public service partners saying, here's something that everybody should know about and it's a real opportunity for parents to get their children involved, et cetera.

CLIAC CHAIR: That's a great idea. So [CLIAC MEMBER], since you stealthed in we need you to introduce yourself, and please, tell us your conflicts of interest. And I personally want to know, when did you start listening in?

CLIAC MEMBER: So actually I came in twice just before noon, and then again as you started the afternoon session.

CLIAC CHAIR: So tell us about yourself and your context please.

STEVE HINRICHS: Yes. Well first of all, it's great to hear everybody, and it's certainly a different experience listening on the phone versus being there in person, because obviously I can't see any people's hands go up or the lights go on, et cetera, but I recognize all the voices and it's great to hear everybody again.

My name is Steve Hinrichs, I'm a pathologist at the University of Nebraska Medical Center. I'm the chair of the department, and we're engaged in basic research training and clinical service. And my areas of interest are in the molecular virology and acute infectious diseases and emerging infectious diseases. I've been a member of CLIAC for a number of years. And then I do not have any conflicts of interest, thank you.

CLIAC CHIAR: Thank you, Steve. OK, so back to point number 1, I've heard a number of comments that the overriding goal is to publicize at the level of the individual clinical laboratories, the availability of these opportunities. And I've heard public service announcements. I tried to recommend out with the mailing with the licensure agreement, but [CMS EX OFFICIO] says that's probably not doable.

CMS EX OFFICIO: Yeah, the government has this little thing called burden. That for anything that we send out, we have to have an evaluation of the burden on the consumer and on the public. So it would really be very nice if we could just tuck that in the envelope and send it out, but we can't do that without an analysis of that burden. And you might not think that it is a big burden, but when you actually start doing the calculations and the hours and everything, it does become an issue.

CLIAC CHAIR: So thank you.

CLIAC MEMBER: Burden on the recipient? Or how--

CMS EX OFFICIO: It would a burden on the consumer or anybody that would fill that form out or take it and read it or whatever they would do.

CLIAC MEMBER: So-- because it just sounds like-- if we took a quick flash poll here, it sounds like people would love that burden to know that there is some help. So what does that mean? It's a possibility if it goes through process or it's just not-- that's a non-starter. I'm just trying to--

CMS EX OFFICIO: Right now I'd say it's probably a non-starter, really, because to go-- we're trying to reduce burden on people with the federal government. That's what our overall goal right now is. So to start adding things for them to do. And like I said, it doesn't seem like it's a lot to shoot a piece of paper in there, but it does become when you start calculating it all out, and we do have to calculate out all of that things that go along with it-- like you would do for regular regulation.

CLIAC MEMBER: OK. No, that's fair, I just want to know if it's worth going down that path at all or you're suggesting--

CMS EX OFFICIO: For that particular path I'd say is a no-go.

CLIAC MEMBER: OK.

CMS EX OFFICIO: OK? There's public service and things like that, I mean, that is a potential-- I mean, I don't know what we have, the LISTSERV now that we're starting? I mean, we could do something there. I mean, CDC has opportunities as well. So I think we could look at it from that advantage, but it's just not easy to shoving something in an envelope and mailing it out from the federal government.

CLIAC MEMBER: Sure we get that, except for my taxes.

CMS EX OFFICIO: Well, there are some things that are easy to do.

CLIAC MEMBER: Yeah. I can't tell--

CMS EX OFFICIO: --is a big burden, yeah, I have to-- I unfortunately don't work for the IRS, OK?

CLIAC MEMBER: Is Ren there? Would he know whether or not there are some companies, other donors, et cetera who would be willing to engage on a public service announcement regarding laboratory training?

CLIAC DFO: Yeah. I don't want to speak for [CMS EX OFFICIO], but I think, [CMS EX OFFICIO], you were speaking specifically about linking these communications with clear licensure?

CMS EX OFFICI]: Right--

CLIAC DFO: Yeah.

CMS EX OFFICIO: --licensure and everything.

CLIAC DFO: Right. So I think-- I think we at CDC can look more broadly into how we can communicate better with the clinical laboratory community about some of these resources. And so-- does that answer your question, [CLIAC MEMBER]?

CLIAC MEMBER: Of course.

CLIAC MEMBER: Yeah. I mean, I think there's resources that we sort-- we have as well. I think that AOs could reach out and they have their mailing lists. I'd also engage the board of certification in terms of individuals that-- individual laboratory professionals to be spokespeople as well. I know also at the last ASCP meeting, they brought in a bunch of high school people to learn about laboratory professions, and that may be another place to start to promulgate that. And if you bring that the AI stuff in, let me tell you, those people will eat it up.

CLIAC MEMBER: So [CMS EX OFFICIO] since state inspectors are inspecting labs all the time, is that a potential venue or is that not proper?

CLIAC CHAIR: Yeah, these are all excellent ideas, and I'm going to propose that we take a step back about proposing specific solutions and instead make this very broad recommendation, that the goal is we want the individual laboratories to be made aware of it and let our friends figure out the best strategies to do that.

So the motion reads, CLIAC recommends CDC/HHS create a strategy to communicate broadly to the community the resources available through the HCOP program in an effort to comprehensively reach a larger audience. That's the motion, is there a second? [CLIAC MEMBER], seconded. OK. Discussion.

CLIAC MEMBER: So to add on, many of us are talking about high school, and junior high and elementary is the new high school. I mean, I think if we're waiting to capture people at the high school level, many of them already have their chosen colleges and things like that. So I think perhaps making the recommendation go down to a level at which we wouldn't normally think, because kids are more savvy. We had a [INAUDIBLE] program at the University of Arizona where we reached out to kindergarten through Elderhostel, and many of those kindergartners are in graduate school for microbiology right now.

And so I think to capture them before we think we should in our generation might be something to think about, and how to reach that through elementary and junior high level training, because we've lost them-- by the time they're in high school, they have their decision made.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: So I was just going to say, I added in some of the words as we were talking, but I think to [CLIAC MEMBER] point, I think we've discussed this at previous CLIACs about junior high students, high school students, they see physicians, they see nurses, they don't see us, and that's why we're an intangible to them. They don't know we exist because we don't exist.

So, I mean, I remember at my son's kindergarten, I brought a bunch of worms and ethanol and showed them different tapeworms and roundworms that my laboratory identified, and his classmates in fifth grade still talk about it. So it's just a matter of catching that interest and attention, and we get the handprint on the auger before and after handwashing, those kids remember this stuff. So I was the weird dad.

But I think that the point's being made is that you can't just do it once, you've got to stay relevant, because the doctors and nurses and dentists are the ones that are constantly in their personal life. They see it, they want to emulate it, it's a noble profession. Our profession is noble, they just don't see us.

CLIAC CHAIR: OK.

CLIAC MEMBER: So there's an organization called Wear a Scrub, Get a Career, and they worked in Pennsylvania to help with-- and they target junior high. And I've got an incredible video that I can show of what they're doing. They're really targeting at-risk kids, and I think that's definitely right. They're early age, but I'd be happy to share this and we could see if they could adopt-- they've added infection preventionist, and in honor of my son Niall, we're trying to get them to add an environmental cleaning expert. And we could also see if we can at some point have them come in and do a presentation and add any kind of specific lab and science to that.

CLIAC MEMBER: Yeah. My comments are directed more towards the second and third-- or excuse me, the third and fourth questions that are being asked in this area. And we, like some of you folks over here, have also seen in our portion of the country, there's a whole lot of biology graduates out there. They had 10-- all of whom want to be a physician's assistant for which there were 10 slots and 400 applicants. And so there's a whole lot of biology folks that no longer have an avenue towards a paid profession. Some of them come to work as phlebotomists, in fact, because they don't have that.

So I'm interested in the three of you on the left and one of you on the right that have developed local programs. Developing that kind of didactic program, to go back to my previous comment, is a lot of resource for an individual community hospital. Is there some way that some of these learnings that you have developed might be translated into a developed product that could come from CDC or some other entity?

And my other one-- one of my questions, too, is this a NAACLS-approved program at your local-- so you've actually have gone the whole route? OK. And yeah, and so again, is there a way to leverage that, then, to a national online program so that each hospital isn't having to develop their own curriculum and their own material? That might be a way for the collaborative strategy, because we also see that biology majors with no career path as our low-hanging fruit.

CLIAC CHAIR: Thank you. [CLIAC MEMBER], before you go on, I do want to comment, we do have an open motion on the floor and we're trying to close out this motion before we move on. It's OK, we're going to continue on that. And along that line, [CLIAC DFO] wanted to help us understand some tools at our fingertips.

CLIAC DFO: So this is primarily for the three new members, but a reminder for existing members. We have a SharePoint site that all of you can use simultaneously. I'm guessing that [CLIAC MEMBER] has been the one who actually created the language that's in red, am I correct? This is you, right? So [CLIAC MEMBER] took the initiative, which we're really grateful for. Because this is the meat and potatoes of CLIAC, right? This is how you develop recommendations and put those officially into the record, but we rely on members to actually draft these recommendations.

And so I appreciate [CLIAC MEMBER] taking the initiative. I hope others will also use their own devices to log into this SharePoint site. If you have trouble, you don't know how to do that, please talk to Heather, but you actually can edit this document together, so I just want to make sure everyone knew that. Thank you.

CLIAC CHAIR: OK.

CLIAC MEMBER: Sure. So going back to what [CLIAC MEMBER] said, I remember one year during the Laboratory Professionals Week, which takes different forms depending upon where you are, but we brought in hundreds third-graders to do different stations in the lab to make them aware of laboratory medicine. I wish I could have tracked how many of them are now laboratorians today, who knows? But back in elementary school.

And I think sometimes during Laboratory Professionals Week, we don't always focus on that part of what that we could mean, is educating other people on what we do even down to the elementary school level, but again, the marketing programs that the various organizations put on, that could just be a focus as well.

CLIAC CHAIR: So we started this conversation talking about how do we make the individual clinical laboratories aware of HCOP, and we've migrated away to-- over to saying, how do we attract potential students as early as kindergarten? The motion right now is addressed at reaching the clinical laboratories. Do we want to modify this motion?

CLIAC MEMBER: I think we should probably, based on how this question is stated, is address workforce shortages, something we should decide if we want to interpret that as the existing laboratory community as a target as well as the younger community that is eventually coming into the workforce. I mean, I guess do we want to discuss it-- do we want to be that broad? Or do we want to just kind of keep our target manageable to what we can actively reach through CLIA, maybe?

CLIAC MEMBER: So like, I'm looking at those two bullets. It's the same bullet. Whether you're letting the community know about training resources or the program we heard about today, like it's-- just to be efficient, right? If you have a LISTSERV you need one LISTSERV to put out two messages.

So the third bullet a little different, but just to make the point, it's-- so-- and again, like you said, these-- we can speak of other things aside from the bullets. So I think what we're hearing is aside from-- communication always has two sides. So you're trying to be a matchmaker between the laboratory community and people who might be interested in that as a career. So that requires a different communication pathway, but it looks to me like those two bullets are similar.

CLIAC CHAIR: So I see this. The first bullet really specifically asks, how do we take advantage of the HRSA HCOP program. The second bullet is really broader, how do we increase awareness? So if we wanted to close out the first bullet, I would recommend that it be a very tight statement, that what I'm hearing is the clinical laboratories, as the bullet has phrased, how do we take advantage? And we're saying the way we take advantage is we need to know, and the recommendation is how-- what is the best way to let us know? How do you reach down to the individual laboratory?

So I would recommend-- and I can't type and talk at the same time, so I'm sorry. I would just recommend this be rephrased-- CLIAC recommends that CDC/HHS create a strategy to communicate broadly to the clinical laboratory community the HCOP resources available, period Yes, with a period after resource-- after resources. I would lop off the second part of the sentence.

And while we're doing this, [CLIAC MEMBER]?

CLIAC MEMBER: Yeah, I'd just like to speak to the motion for a point of clarity. Related to what Captain Palmer said, because this is a follow-up in reference to that, it was not only just the clinical laboratory community, he talked about the fact that they had reached out-- or at least he had a whole list of persons that would be available. So my question is, do we want to say that we only communicate broadly to the clinical

laboratory community? Because they only got 21 people as I remember, and they could have received at least 25. So my point is, do we want to communicate broadly to the clinical laboratory community and others the HCOP program resources currently available?

CLIAC CHAIR: Yeah. I would question whether or not we need to be more specific about and others I did hear there were 120 applicants of which they could only accept 21, so it sounds they're already oversubscribed. But in front of us, we appear-- many of us appear to be completely unaware of this program at all. And I would-- my position is we would just take a first step and saying, how do we know about it? And once we know about it, how do we grow it?

CLIAC MEMBER: OK. I'm comfortable with that, thank you.

CLIAC CHAIR: Is there further discussion? I ask because there are three more bullet points and we are supposed to break in about 12 minutes. So I'm going to call the motion.

CDC EX OFFICIO: Just to spell it out, would you just add in the HRSA health workforce? Because it's in the broader--

CLIAC CHAIR: So before HCOP, [CLIAC MEMBER] if we could insert HRSA? Yeah. OK. So I'm going to call the vote. All in favor, raise your hand or say aye, Steve.

CLIAC MEMBERS: Aye.

CLIAC CHAIR: Any opposed? Any abstentions? That looked like the majority. I didn't take a headcount. OK, thank you. So that motion passes, thank you. The second bullet is, what are effective ways to increase awareness of freely-available CDC laboratory training resources among the clinical laboratory community? Do we even want to make a recommendation, a motion to the agencies on this? I was really intrigued by the 22,000 subscribers to-- Ms. Wilkins talked about to one of your training sites.

CLIAC DFO: Yeah, that training workgroup.

CLIAC CHAIR: Yeah. Whoa. That's an immediate way to help increase awareness, although they are aware. So this is open for-- I'm sorry, is-- we don't have a motion yet, so this is open for discussion. Andy.

ADVAMED LIAISON: While 22,000 is impressive, if you think about the number of labs, it's less than one in seven. One person in seven labs. So it still is-- while it's a start, it's a long way to go. So to further what I said earlier, being a liaison, I can't vote or-- but my-- I would suggest that you make a recommendation to encourage outreach to AOs, professional societies-- what was the other thing we heard? Certification or boards and manufacturers to promulgate this information and encourage them to do the same as well. Many of these organizations have newsletters, and these are-- if they're scripted, and things like press releases, they can certainly go out, just cut and paste into a society's newsletter.

CLIAC CHAIR: So is the motion that we request our agency partners to collaborate with accrediting organizations, manufacturers, and-- there was a third one.

ADVAMED LIAISON: Professional societies.

CLIAC CHAIR: Professional societies to-- and boards?

ADVAMED LIAISON: Certification boards or-- I can't make a motion, though.

CLIAC MEMBER: Is there an organization that primarily serves the needs of MLS directors and MLS programs?

ADVAMED LIAISON: I don't know.

CLIAC CHAIR: I don't know. I'd look at the folks who've been on ASCP or CAP or-- it would be NAACLS, is that what Lee is saying? But-- yeah, but should we be that specific in this recommendation? Should it be a broad global-- Jennifer?

CLIAC MEMBER: Yes, perhaps the recommendation that these resources be provided to organizations educating medical professionals to build their curriculum and to build the portions of their training products. So NAACLS would certainly be one partner. Universities might be another partner. But I think it's really educational organizations that would be best placed to utilize some of this information along with the accrediting organizations, perhaps.

CLIAC MEMBER: There's also patient safety movements that are building new curriculum for domestic and international partners. One is called the Patient Safety Movement Foundation, and they are building out new curriculum. Those might be excellent places to include this kind of curriculum.

CLIAC MEMBER: Well, and I feel the need to add, don't forget your educational coordinators, and your state public health laboratories, and even your CLIA surveyors who-- even though it's called a surveyor-- survey, is technically an educational process for our laboratorians.

Yeah. That's exactly good, yeah.

CLIAC CHAIR: So [CLIAC MEMBER], if I could impose on you to help me describe this-- oh thank you, [CLIAC DFO] can do this.

CLIAC MEMBER: I just-- I can't make the recommendation.

CLIAC CHAIR: Right.

CLIAC MEMBER: I can type [INAUDIBLE]

CLIAC CHAIR: OK. I will try to dictate.

CLIAC MEMBER: I can type, I'm just not sure what the recommendation is from what I've heard, sorry.

CLIAC CHAIR: OK, so CLIAC recommends that our agency partners work collaboratively with accrediting organizations.

CLIAC MEMBER: Whoa, I don't type that fast, sorry.

CLIAC CHAIR: See, that's why I wish I could type when I could think.

CLIAC MEMBER: OK, keep going, I'll change the typos later.

CLIAC CHAIR: Collaborate with accrediting organizations, comma, manufacturers, comma, and other professional societies or organizations engaged in education, comma, to increase the awareness of freely-available CDC laboratory training resources.

CLIAC MEMBER: And I think if we want to try to have some specificity and thinking about the groups, you have accrediting organizations, those are generally organizations that accredit labs. Professional or-- professional societies are kind of general, we have a lot of them in AACC and ASCP and lots of others. You have higher education accrediting bodies. That would be your NAACLS and those accrediting bodies that accredit higher education programs. And then you have certification bodies-- so the bodies that certify individuals, ASCP, American Board of Pathology, ABCC.

So I guess the general categories of accrediting organizations, professional societies, higher education accrediting bodies, I guess, or organizations, and then certification bodies. So that might give some specificity of who we're talking about anyway.

CLIAC DFO: While [CLIAC MEMBER] typing, if accessing the SharePoint site is difficult or awkward for you, another option is to type words to-- and email them directly to Heather and she can put your words into this document for you if you like.

CLIAC MEMBER: So I always get nervous when there's like a long list of things, because it has the effect of-- so if we do include all of those, which are all great, maybe a collaborate with-- like some language not limited to-- including the following, but not limited to or something like that, because it's-- it's excellent because of its specificity, but--

CLIAC CHAIR: Yeah, I agree. And [CLIAC MEMBER], just-- I'm just too used to using MModal and Siri, which is why I don't type anymore. But I would then modify the motion, CLIA recommends that our agency partners collaborate with relevant organizations, parenthesis, e.g., for example, accrediting organizations manufacturers professional societies, blah, blah, blah, blah. And then you end the parentheses before to increase awareness. So this is a probably not grammatically correct and unwieldy motion. Is there a second? OK, [CLIAC MEMBER] seconds. Is there further discussion? Do we think this is motherhood and apple pie? I do.

CLIAC DFO: Yeah. I mean, if you don't think it's necessary to make the recommendation, you don't have to.

CLIAC CHAIR: So we don't have to make a recommendation. If we don't make a recommendation, I'm not convinced things will happen.

CLIAC MEMBER: So this brings me back to my point a few minutes ago. Do we have a good pipeline for letting us know about what's going on, right? Like, that's really-- whether it's-- like whatever the program is, an easy, non-burdensome, efficient way to communicate, right? Like is that-- just-- I'm just getting to what the issue at hand perhaps truly is. Amazing stuff, and we're hearing about it because we're privileged to be sitting here today.

CLIAC CHAIR: And I think what you're hearing from some of the committee members that the communication can be improved because we are unaware of this. I do want to include in that parenthetical phrase, we should have patient safety advocacy groups, to make sure we include that. Is there a further discussion? I would like to call the vote. All in favor, raise your hand, or say aye.

CLIAC MEMBERS: Aye.

CLIAC CHAIR: Any abstentions? Thank you. That motion passes. We're onto the third bullet. One major-- and this is for Jennifer, you get to lead it off. What major goals or areas the focus should be part of a collaborative strategy for public health and clinical laboratory workforce development?

CLIAC MEMBER: Well, it's a big ask. The recommendation is to develop a standardized curriculum to be used for on-site workforce training at the baccalaureate level.

CLIAC MEMBER: It's probably long overdue. Standardization.

CLIAC CHAIR: CLIAC recommends CDC or the agencies?

CLIAC MEMBER: I think it'd be CDC, we're talking about workforce development. Correct me if I'm wrong on that.

CLIAC CHAIR: OK. And develop standardized curriculum. Finish, finish the--

CLIAC MEMBER: To be-- to be employed at individual organizations wishing to locally develop workforce talent at the baccalaureate level. And I'm doing this off the top my head, so please wordsmith me. Well, sort of what we heard from the folks here, that their training biology prepared students, graduates that they're bringing them in and training them in medical-- to be medical technologists in the workplace.

But they're having to each develop their own training program, so were there to be a standardized training program for post-baccalaureate workers to become medical technologists, I think that would-- that could be easily employed is kind of what we're-- is what I'm trying to say.

CLIAC CHAIR: [CLIAC MEMBER] has furrowed brow, but [CLIAC MEMBER] has her hand up. So [CLIAC MEMBER], you go first.

CLIAC MEMBER: OK, sorry. So please-- I'm not a full-time educator, so please correct me if I'm wrong, but NAACLS has requirements for post-baccalaureate categoricals that many of the universities like the University of North Dakota and Cincinnati and other places use for just those kinds of people, and they already have requirements for laboratory site training for microbiology, for hematology, for chemistry, for blood bank which they call immunoserology or something like that.

So I'm not sure that CDC would have to recreate the wheel, but rather maybe help support the distribution of that to appropriate academic institutions that have biology majors or laboratorians that could-- laboratories that could take students. I mean, I think the big tent there is to take what we have and leverage it at the national level, is that correct?

CLIAC MEMBER: Quite a bit. With the hands-on-- and I have had an online program responsibility in another position, so you're right, NAACLS gives you some pretty specific requirements. I guess what I'm thinking is some of the materials that-- each program then still has develop their lecture materials, their own quizzes, their own tests.

So there's some of the specific-- the actual educational materials end up still needing to be developed, some of which might well be served by some of these already developed programs that Ms. Wilkins presented to us that might suffice for the lectures or are might help train those who are providing the lectures in delivering those I guess is where I'm trying to go. And I suspect each of you have had to develop some level of those at your institutions, am I correct?

CLIAC MEMBER: But then does that-- does that-- I mean, these universities are trying to recruit students, they've taken the time to develop these broad products according to NAACLS. I guess that's where I'm struggling with this, is then if that's out there in the national sphere, which it isn't for MLS or any other group, I see the role of the agencies more as trying to promote all the available options. A web listing, a search engine that where people could find this information, where people at hospitals could reach out to each other and freely share, but not necessarily put a non-compete clause, because you're kind of taking away the university's ability to launch.

And I'm just kind of playing devil's advocate here a little bit. I think it's a worthwhile effort. I don't know that prescribing it in this fast-paced changing world is the way to go rather than being an information warehouse for anybody from fourth grade on to try to find these programs and talk to people and allow the programs to talk to each other and share resources.

So I don't want to squelch this, but I'm worried about the competitive-- universities are a competitive organization, too, so I guess that's where I struggle with this concept.

CLIAC CHAIR: Both of you [INAUDIBLE] a lot of activity down there.

CLIAC MEMBER: Yeah. Information warehouse, I'm glad you put that up, because I think what we're really talking about is a repository of tools and resources, because I agree that depending on what the institution is and where you are and-- like the community college I worked with, you have certain courses that will qualify but they won't have the same names or anything like that.

When we developed the MLT program, I talked to NAACLS, they gave me names of different community colleges in the nation that they thought had really good programs. That's who I contacted. I made a repository of their entire programs, and that's how we developed it. So having a repository where entities could go into those systems, look up how to create, what they need to have, where you need to go, and then maybe taking it a step further and saying, and here are your course development things, and then perhaps something after that I think would be very helpful.

Because, like you're saying, number one, it's very unique in every situation. But number two, the people that you're relying on to develop these programs may not have that educational development background needed to assure they have a program that meets all requirements and standards, and this could be very helpful.

CLIAC CHAIR: So I wanted to just quickly wordsmith this. CLIA recommends that CDC create-- so delete helps support the-- create. Delete, delete, delete, delete, delete. Create the resources for organizations. The-- sorry, just remembering. The resources for organizations to use in their own educational programs for post-baccalaureate clinical laboratory professional training.

CLIAC MEMBER: So does it have to be limited to post-baccalaureates?

CLIAC CHAIR: This is what I heard, is this-- some people reality checking me.

CLIAC MEMBER: Yeah, I would just sort of agree. I know Mayo Clinic, we have our own blended curriculum, UND has a very good one. I think these are existing out there, so I don't know that the lack of curriculum is the issue. I think that there's a lot of proprietary information and institutions have their own take on how to train. We've tried to distribute, find the markets for our curriculum for several programs, MLS, histotech, and others, and haven't found takers because the universities and programs all have their own way.

So I don't know that a standard curriculum or even content will be that effective. Actually, just I couldn't connect, so I sent an alternative recommendation for number 3 around this idea of piloting research on competency-based outcomes for VR and simulation-based clinical training.

CLIAC CHAIR: Did you want to modify the motion?

CLIAC MEMBER: I think we can discuss this motion and see if we want to modify and edit it or-- and approve, and then I sent one that we could consider separately. I think it's kind of crude, maybe, and hopefully we can get it in the SharePoint cause I couldn't connect and maybe consider it separately.

CLIAC CHAIR: So [CLIAC MEMBER] just sent the motion over to [CLIAC DFO] who will post it shortly, but I believe it is a variant and different. Yes, that is different. So we still have this other motion in red. It is break time, and we have a new [CLIAC MEMBER] motion and we have a fourth bullet, and I would like to try to close these out before break.

Yeah, so I recommend we delete the highlighted distribution of standardized blah, blah, blah, and I want to ask the committee on recommendation number 3-- does this capture the intent, and is this something we still want to recommend?

CLIAC MEMBER: Yes, I'd like to speak in favor of number 3. It captures the intent of what I was mentioning earlier in that, again, partnering with a local institution who had to dust off an old NAACLS-approved program, and they have that, but it's in partnership with them, not in competition with them, but we had to create an educational-- or hire an educator within our own institution, and I think this would be invaluable-- if they had this resource available to them for the-- for the piece that we're responsible for, the training in the hospital, this would be a valuable-- very valuable resource for that person, because this is a new program for her. So yes.

CLIAC MEMBER: And just one more thing about-- I think somewhere in one of those, I mean, the pilot research is a great recommendation, but also shouldn't CDC be partnering with existing medical labs sites, training vehicles like NAACLS, or even high school, junior high, sort of actual educators? And maybe they have their own team that I don't know about, but I think some kind of partnership with the active educator community would be important.

CLIAC CHAIR: Mm-hmm.

CLIAC MEMBER: I would like to speak to the aspect of a standardized curriculum. I know there are some pros and cons. However, I am not sure what we have up there when we say professional organizations create their own resources, that we will have it measurable, and that we can implement or encourage some type of quality.

I would like to see us go back to what was there before, or consider it, that CLIAC recommends that CDC facilitate the utilization of a standardized curriculum. And how we could get to that would be we could call together the stakeholders so that it is acceptable. When we come up with that, we wouldn't do it just ourselves, we would get input from the stakeholders. And then we could utilize that. Otherwise, I am not so sure how quantitatively and even qualitatively we will be able to measure it, OK? And have the quality that we're talking about we consistently need. And if we don't go this way, we need to have something that there would be minimum requirements. Thank you.

CLIAC CHAIR: So [CLIAC MEMBER], I'm going to ask you to state that again. CLIA recommends that CDC facilitate--

CLIAC MEMBER: The utilization of a standard curriculum to be employed and-- go with the other language-- at the dah, dah, dah, is the first one that was there. I just modified the-- you got the first one? To be employed-- pick up on that.

CLIAC MEMBER: Well there's three people writing right now, so I don't-- I think [CLIAC DFO] is writing.

CLIAC MEMBER: Oh, you are? OK.

CLIAC DFO: I'm sorry, go ahead. Utilization of a standard curriculum, is that what you said?

CLIAC MEMBER: Yeah. To be employed. What was that language? It was--

CLIAC CHAIR: To use--

CLIAC MEMBER: --that organizations--

CLIAC CHAIR: To use in their own educational programs.

CLIAC MEMBER: Right.

CLIAC CHAIR: For post-baccalaureate.

CLIAC MEMBER: I didn't write that part down, I just wrote the-- so the first part would be CLIAC recommends that CDC facilitate the utilization not just distribution, because distribution mean I give it to you, but it doesn't mean you utilize it. The utilization of a standard curriculum to be employed, and finish it--

CLIAC CHAIR: Wordsmith that for there-- to swap--

CLIAC MEMBER: So the only thing I would say about that is we already have NAACLS. NAACLS has a standardized curriculum, it has the hours that you have to complete in each subject, it collects data from every accredited program on graduation rates, certification rates, et cetera. I don't think that's our role here, and I don't think it's our responsibility, because NAACLS does that for our profession already.

CLIAC CHAIR: So what prohibits us from just using NAACLS-prepared materials for use in our own laboratory? Why do we even need this motion?

CLIAC MEMBER: NAACLS doesn't, to my knowledge, like provide you with-- who was it that was saying like, how did-- how to train somebody to read a plate in microbiology? But they will tell you that it needs to be done. And they'll tell you how many hours of training you need in microbiology and how many-- how much time you spend in the lab in your clinical training program. But I don't think CDC should be in the business of creating standardized curriculum, because I don't think that's their role, and I don't think that's CLIAC's role either.

CLIAC MEMBER: And I agree. NAACLS tells us what needs to be included. Where I was trying to go with this earlier is just at the community hospital level, with so many programs closing and there's areas of the country without any programs, that you have students with biology degrees, and again, several of you discussed train those in your own facilities, how do we help a facility do their own training program for somebody with a baccalaureate degree? So we know what needs to be in there, but we don't necessarily have the resources to

develop those particular programs and the training materials themselves. So I like the repository idea of trying to reach out--

CLIAC MEMBER: I'm the one who sent Heather those major goals, and the bottom ones said create an online library of clinical laboratory educational resources, and that's what I meant by that, is I don't know if the CDC does it, CMS does it, somebody does it, but they create a virtual library of the things that people can use to help train their students so that we don't have to recreate the wheel everywhere it needs to be done.

CLIAC CHAIR: Thank you.

CLIAC EXECUTIVE SECRETARY: My comment was actually similar to what [CLIAC MEMBER] said. I think what I'm hearing you say is that there are curriculum out there, and that what's needed is the coursework that supports that. And so that-- and that's something that is the type of thing that's our training branch does here. So if that-- and it's close to what you had on that bullet up there. If that's what you mean, maybe tweak it to state that.

CLIAC CHAIR: OK.

CLIAC MEMBER: So I like this wording in terms of-- I guess this is recommendation 3 still, but facilitate the utilization of standardized curriculum wording I think is-- makes more sense to give a parallel example to the pathology residency. The PRODS group has produced standard curriculum for the trigs for molecular testing and peer informatics. And these are standardized curriculum, the PowerPoint slides, instructions, how to give the lectures, but yet programs don't implement them because there are barriers that people haven't figured out-- even if you create the curriculum, there are barriers to getting it used.

So I like this wording of our recommendation being that we facilitate the utilization of existing curriculum, because I think there are barriers-- people haven't figured out what they are-- to taking this curriculum, whether it's a MLS or pathology residency or whatever it is, and getting it used, and I guess our main focus should be on MLS, cytotech, and histotech.

CLIAC CHAIR: I'm hearing still enough conversation around this that I don't think we're settled. I also feel we've not yet addressed the final bullet, and we've not even discussed the issue of outcomes research on VR training. And we are past our break time. So I would recommend we take a break, we reconvene at 3:15, and those of you passionate about this motion we're trying to create, congregate up here and we'll try to wordsmith it. OK. Thank you. We will reconvene at 3:15.

Improving Integration of Laboratory Informatics Systems with Electronic Health Records

Introduction to Topic
Jasmine Chaitram, MPH

CLIAC CHAIR: Because we have speakers lined up for the afternoon session and out of respect for their time, we are going to continue the conversation of the previous session at the end of this session time permitting and/or hold till tomorrow. So to move on, the topic of this afternoon is improving integration of laboratory information systems with electronic health records. Ms. Jasmine Chaitram will provide an introduction, followed by three presentations.

Ms. Talisha Searcy will present on the current state of interoperability. As an update to the agenda in place of Dr. Singh, Dr. Julia Wong will present on standardizing lab test names, the true lab initiative. And we will finish with Dr. William McKenzie on CDC's Digital Bridge activities. These are online presentations number 9, 10, 11, and 12.

Is there anyone in the audience who would like to address the committee during the public comment portion of this topic? There are no hands that are raised. After reading public comments, CLIAC will have time for questions and general discussion on this topic. So moving forward, introduction to topic, Ms. Jasmine Chaitram. I still can't pronounce--

MS. JASMINE CHAITRAM: That's fine. That works. Good afternoon. Before we get into the presentations for today, I was going to briefly review some recent recommendations around interoperability. Nancy Anderson mentioned this morning that there have been a lot of recommendations from CLIAC around interoperability. I think the most recent ones were in April 2018. And the first one was-- sorry.

For FDA and CMS to create and implement guidelines for in vitro diagnostic device and laboratory information management system manufacturers, which would describe specifications for interoperability. And the rest is there. I'm not going to read the whole thing.

And the update on this is that since April 2018, the Clinical Laboratory Standards Institute published CSI auto 16, next-generation in vitro diagnostic instrument interface first edition. And this is a standards based document that is based on laboratory analytic workflow or the law profile, which helps the laboratory or the in vitro diagnostic manufacturer improve interoperability, reduce connectivity, installation cost and time, and improve integrity of patient data. And this document can be found on the Office of the National Coordinator for Health Information Technology ONC website. Also was mentioned actually this morning by Mr. Peter Tobin is the CLSI auto 17, semantic interoperability for in vitro diagnostic systems, which is in development, and this will provide information on how the standards developed by different groups fit together to make laboratories more interoperable and as Mr. Tobin mentioned is under development and is anticipated to be finished in about a year.

The second recommendation was for CDC to consult with ONC to identify the appropriate agency to develop a report on the current state of interoperability, and that report would include a lot of items. All those bullets are listed here below. And you can see that there's quite a bit of information being requested. So after discussion, both CDC and ONC agreed that the information requested in the second recommendation is not readily available to adequately address all the questions that are being asked. And it could be costly to collect this information.

And there was also concern that if we decided to do some kind of query of laboratories or institutions that we might not get a good response rate, so we still wouldn't have good data. Fortunately, ONC collects data that could help determine the status of interoperability, and we're going to hear that in the first presentation today. And following the presentations, the ask, is for CLIAC to consider these two questions in your discussions. How can HHS encourage laboratory adoption and use of voluntary standards, guidelines, and tools, for example, a guideline for naming laboratory tests, a tool to harmonize launch codes, standard implementation guides for test ordering and resulting.

And the second is, what should CDC or HHS do to reduce the use of varied local codes to facilitate more efficient interoperability and improve the value of laboratory medicine data to patient care and public health? And these are the presentations and the speakers, which you already heard I'm not going to repeat that. And I think you heard about the change for the second presentation. We'll be having a different presenter presenting remotely.

The State of Interoperability of Clinical Laboratories
Talisha Searcy

MS. TALISHA SEARCY: Good afternoon, everyone. First, I'm just going to check to make sure that I know what I'm doing, and that is arrow. Awesome, I could do that. So as was mentioned, my name is Talisha Searcy. I am the branch chief for the data analysis branch at ONC, and I'm here to talk a little bit about some of the results that we have in terms of the current state of interoperability.

So the CLIAC was not alone in asking ONC to report out on the current state of interoperability. Congress also asked for ONC to work within the department to identify measures to assess widespread interoperability under the Medicare Access and CHIP Reauthorization Act of 2015 as we leveling call MACRA. So today, I'm going to talk a little bit about the current state of interoperability using the measures that we were developed to fulfill the requirements under MACRA.

Also talk a little bit about how hospitals, physicians, and individuals access laboratory data and then just kind of close out a little bit with the barriers that we're seeing in the data and perhaps some of the roles that laboratories can play in addressing some of these challenges. So what you see here is the conceptual framework behind how ONC has been measuring interoperability. What we care about is the care continuum. So we are focused on trying to measure the extent to which hospitals, physicians, behavioral health, long-term care, as well as individuals have access to the information that they need available the point of care.

And one of the mechanisms in which we are assessing whether or not that information is coming to you is through the movement of electronic health data. And we've identified four domains of interoperability. One is, can you send information electronically outside of your own organization? And we include a standardized format.

So we're looking at the movement of summary care records for hospitals. We also measure the extent to which hospitals and office-based physicians report that they can receive information from outside of their organization, the extent to which they can query or find information, as well as their ability to use or integrate that data within their HR for the purpose of leveraging the data and making use of it for clinical decision reasons. Now, our idea is that if you're able to do these four things, then you should ultimately have, as the health care provider, the information that you need available at the point of care.

And if you're a consumer and you're able to access that information, you should be able to have a more complete medical record. So we shouldn't see gaps in your health information, because if everyone else is doing what they're supposed to do, which is moving that data in a seamless way, then you, as an individual, when you look at your online medical record, you should see a full record there. And then ultimately what we want is through that data movement, that sending, receiving, finding, integrating, you will have information you need available. And then as a result, you will use that information.

As a clinician, you use it to make decisions for your patients as an individual. You may make decisions for your own health, as well as the health care of your family or loved ones. So what you see here is our latest data on hospitals rates of interoperability. So ONC works with a number of different partners for the purpose of fielding surveys.

This particular survey, we work with the American Hospital Association to produce an annual survey called the HA Health IT Supplement. It is a census survey of hospital CIOs. And it includes a lot of questions around, not just interoperability, but also methods of exchange, as well as barriers to interoperability.

And what we're showing here is that, although, we see that there was an increase in the number of hospitals that are reporting that they can send, receive, find, and integrate, the numbers still aren't as high as some might believe. So 88% of hospitals in 2017 reported that they can send information outside of their organization. 74% reported that they can receive information from entities outside of their own. About 61%, and that was a significant increase over 2016, reported that they can query for information outside of their organization.

Now, one thing that I will note that has been a significant increase in 2017 is the percent of hospitals that report that they able to integrate data. So we are now showing about 53% of hospitals are reporting that they can integrate information from outside of their organization. As a result, we currently see about 41% of hospitals report that they can do all four of these things. Now, I should say that there are disparities that exist in those numbers. Small, rural, and critical access hospitals are behind that national average.

So now let's talk about what's happening in the office-based physician space. Their progress is not as robust as that of hospitals. We work with the National Center for Health Statistics to field the National Electronic Health Record Survey of office space physicians. And as you can see, our 2017 results show that only about 36% of office-based physicians reported that they're able to send information outside of their organization. And that was not a statistically significant change from 2015.

38% reported that they were able to receive information. Again, that's not different from 2015. However, we are seeing a significant increase in the number of physicians that are reporting, that they're able to query for information. And this is going to be increasingly important specifically for ONC as we're working on the Trust Exchange Framework and Common Agreement or TEFCA designed to try to encourage increased use of health information exchange organizations and the like. So we were very happy to see at least the query aspect of things have increased. However, integrate still remains low. Only about 28% of office-based physicians reported that they're able to integrate data. And as a result, only one in 10 physicians in 2017 reported that they were able to do all four of these things.

Now, some may ask, well, what evidence does having the ability to do all four of these things show? What we're seeing in the hospital space, as well as the physician space, is that those providers that report that they're able to do all four things are eight times more likely to report that they have the information that they need available at the point of care.

So now, I'm going to switch to the individuals and consumers. And then we'll kind of go back and dive a little bit deeper into the integrate numbers as it relates specifically to exchange of laboratory results. So we work with the National Cancer Institute on questions included in the health information national trends survey that they field. And we were able to ask questions related to access and use of online medical records. And what we found, it's about 51% of individuals reported that they're able to access or they were offered access to their online medical record from either a provider or an insurer. However, only about half of those that had access actually use that record.

So you had about half of the folks that actually were offered access, but only half of that actually were able to enter into the portal. But one thing that's important is what individuals reported that they were able to view once they were in the portal. So 3/4 of individuals who access their online medical record within the past year reported that it included laboratory tests results, current lists of medications, and summary of their office visits.

So as you can see here, about 51% reported that they had access to their clinical notes. Only 55% reported that they had access to immunization or vaccination history, but 92% reported that they had access to laboratory test results. So you may ask yourself, well, if everyone has these lab results, that means they should have all of the information that they need. However, when we asked whether or not you experienced any gaps in your

information, one in three individuals reported that when they went to a provider within the last year, they experience one or more gaps in information exchange.

So 70% reported that they had to redo a test or procedure because the earlier results were not available. About 14% reported that they had to wait for results longer than they thought were reasonable. And about 19% reported that they had to bring a test result to an appointment, because it was not available. So at least one in three reported that they had to do at least one of those things.

So if we know that the lab results are available in the portals as the patients are reporting, however, we are still seeing gaps in information. It makes you want to look further into what are the actual capabilities that health care providers and insurers have to view order and access those lab results and to what extent are they able to kind of move those lab results around if needed. So what we found, it's about 79% of office-based physicians in 2015 reported that they could view labs. 62% reported that they could send lab orders. And about 51% reported that they can graph lab results. And then for hospitals--

PHONE LINE: This meeting will soon be disconnected, unless there is at least one authenticated user present. To join as an authenticated user from the phone, you must provide a valid extension and pin.

MS. TALISHA SEARCY: I'm going to get out of the way just to make sure there is nothing else. All right, I'll keep going in the interest of time. And so far hospitals, what we found was that 96% reported that they had the capability to view lab results, but only 89% reported that they were able to order lab tests.

Now, one last thing that I do want to highlight is the differences for office-based physicians specifically as it relates to their ability to send, receive, find, and integrate lab results. So when we looked at the types of data that physicians reported that they were able to move, what you'll see is only about 28% in 2017 reported that they were able to send lab results. So they have the capability, but they're not able to do it.

And this kind of relates to some of the barriers. What we've heard-- and we'll talk about that in the next slide-- is there may be some technical barriers to exchange, which people who will follow me will be able to report a little bit more about some of those barriers, where your system may tell you you have the capability to do something, but when you're trying to do something in practice it, may not happen as seamless as you would think. About 40% reported that they were able to receive lab results in 2017. And the query capability was statistically significant in terms of this increase with about 48% of physicians reporting that they're able to query for lab results in 2017.

So in terms of some of the barriers that ONC has seen, not just as it relates to office-based physicians, but hospitals as well, is that there's still technical barriers that exist to interoperability, lack of standards, development, data quality, patient matching, provider directory, matching, limits the ability of folks to be able to move data. So again, you may possess a certified technology that technically has the capability to move data, but because of things like standards and the ability of your system to speak to a system that is not your own, it may be challenging for you to move data. There's also financial barriers that exist. And this relates to the cost of developing, implementing, and optimizing the use of health IT.

Again, your small rural critical access hospitals are less likely to be interoperable than their counterparts. The same is true for solo practitioners and how they compare to those providers that are part of larger group practices. And so there are also a number of exchange partners, for example, that never received any financial incentives to adopt electronic health records.

So your behavioral health providers, your long-term care providers, they were not necessarily included in the Meaningful Use Program. And as a result, they lag behind. So if you have hospitals or physicians who need to

exchange results with anyone along that care continuum that don't possess the technology, then they're not able to move the data in a way that would be seamless.

Lastly, there are trust barriers, legal, and business incentives to keep data from moving. So we're talking about infill blocking. We've been measuring the extent to which hospitals, for example, report that they share patients with another facility and yet, they don't electronically share information.

The inability to exchange across vendor remains one of the major barriers to exchange reported by hospitals. And there's a lot that ONC is doing to try to address some of these challenges and specifically, as it may relate to movement of lab test orders and results. One, with the 21st Century Cures Act, there's a lot of efforts underway to work on the USCDI or the US Core Data for Interoperability, which takes a common clinical data set and expands it a little bit. And it includes things like in a clinical notes category that would include lab report narratives.

We still have laboratory tests and value results that are part of the USCDI, but what the USCDI does is kind of provide the foundation of the clinical data elements that need to be moved. And it would be relevant for the other aspects of our rule, which would relate to APIs. 21st Century Cures requires health IT developers to attest to having APIs. And so what we're doing in our rule is really trying to provide that foundation of these are the data elements that you really need to make sure you make available to folks. There's also a lot of efforts underway related to our health IT advisory committee. And there's a standards task force, specifically focusing on some of the challenges related to data standardization, specifically as it relates to lab results as well.

Lastly, 21st Century Cures requires ONC to work in partnership with OIG to define what info blocking is not. And it also puts civil monetary penalties on those entities that may be found by OIG as engaging in information blocking practices. So there's a lot of things that are currently in 21st Century Cures that really aren't designed to try to tackle a number of the barriers that we're currently seeing in the data.

So with that, I'm going to say thank you and happy to answer any questions that you all might have about the data that I've presented here or other data sources that we may have available. Definitely want to encourage folks to take a look at the health IT dashboard. That is where my team post a lot of public use files, data sets, data visualizations, and the like.

CLIAC CHAIR: Thank you, Ms. Searcy.

[APPLAUSE]

Are there questions?

CLIAC MEMBER: Could you tell us the laboratory data this exchanged? Is it all laboratory data? Is it a certain subset of laboratory data that you ask about? Certain tests? And is there a time frame that the data has to be provided by? Because, like, I know some institutions make laboratory results available immediately, some hold it for three days, five days, seven days, whatever. Do you gather data on that?

MS. TALISHA SEARCY: We do not. So we don't specifically ask about nuanced aspects of the lab data that's exchanged, or the time frames in terms of, like, the number of days that they-- like, their practices for moving those data. We basically ask about whether or not they often, sometimes, never move those data. So it's a little-- it's more high-level than the specific data elements. I will say that ONC back in 2012, we did do a survey of lab, clinical labs directly, and had a little bit of information there. But those results are dated. It's back in 2012. We had some reports there.

CLIAC MEMBER: So when somebody reports that they're sharing lab data, they could be sharing just a glucose and that, they could answer yes.

MS. TALISHA SEARCY: And they could answer yes.

CLIAC MEMBER: OK.

CLIAC MEMBER: Thank you very much. It was a great presentation. I have a question. And I may-- I'm not the most informed about semantic interoperability, but I've often wondered, as someone who's been asked to incorporate data from different sources in our Epic EMR, are there discussions you're aware of-- just because we can display data together doesn't mean we always should, meaning there are some tests that probably-- although they may have the same units, then the same methodology, but they're very different, they're different vendors, different antibodies, and they probably shouldn't be compared together in the same way. Are there discussions about that, because that's something I don't really hear much about, if that makes sense.

MS. TALISHA SEARCY: Yeah, I mean, so I'm not the-- nor am I the semantics guru. I actually defer to the folks on the standards team that actually know this stuff in and out. There has been some efforts underway to really try to first, identify priority use cases for standards development. And then from there, try to work towards addressing some of these semantics issues that you've mentioned. I know that the High-tech Standards Task Force has really been trying to explore more on aspects of LOINC and others, and terminology, and things like that that might help to make a more seamless process in terms of, what are the expectations for data exchange, and what data elements should you expect if you're using LOINC, and how can they sync up? But again, I don't know, in conversations I've had with staff, how much progress has been made.

I think that the folks that will proceed me will provide, perhaps a lot more clarification on what may be possible. But from an ONC perspective, we certify the vendors, and we may require the use of a standard. And we may even suggest standards that could be used. And we may offer best practices in terms of some of those things, but we don't go as far to specifically regulate the nuanced way in which everything needs to be coded such that it's moved, if that makes sense at all.

So it requires a broader community to think through some commonalities in terms of terminology, ways to bring different stakeholder groups like the EHRA, and bringing those developers and everyone together to reach an agreement that they can then all incorporate into their systems to allow for a more seamless exchange, if that makes sense.

CLIAC MEMBER: I would just like to comment. This particular topic, I think, speaks to what, [CLIAC MEMBER], you spoke about with the social determinants of health, and how laboratory can be involved in the sense that a lot of times we need a lot of information with laboratory tests and things like that related to demographic information that either the local EMR can't do, or the public health departments can't pull out from those medical EMRs. And then we have the issues of databases that our public health departments use that are not linked to the medical community. And so it's a volunteer thing where they get the information put into the public health databases, and then we don't have the right information.

So I think what you have presented really strongly points to the issue of if we want to do primary prevention or primordial prevention and look at those SDOHs, the social determinants of health, this is a very important topic that we need to address and take care of.

MS. TALISHA SEARCY: I would just add that we've also seen in the data, particularly in exploring meaningful use attestation data, that public health entities, or public health agencies' ability to receive data electronically is problematic. There are a large number of providers that claimed an exclusion to aspects of

syndromic surveillance reporting, public health reporting immunization, because their public health agency couldn't-- they couldn't accept it. So I know that working with the department on Healthy People 2030 goals, many of the responses that we received from ASHTO and other public health stakeholder groups was, how can we try to better incorporate the needs of the public health community in setting requirements for interoperability for them, and trying to think through ways in which to make sure that they have the technology that they need to be able to bring in that information and move information in a seamless way.

CLIAC CHAIR: Thank you. I'm going to call an end to this discussion. Thank you, Ms. Searcy.

MS. TALISHA SEARCY: Thank you.

Standardizing Lab Test Names: The TRUU-Lab Initiative
Ila Singh, MD, PhD
Julia Wang

CLIAC CHAIR: Our next speaker-- we are grateful to Ms. Wang, who is substituting for Dr. Ila Singh to present Standardizing Lab Test Names, the TRUU-Lab Initiative. Ms. Wang, I note there are 66 slides in your presentation. And you have 20 minutes. Thank you.

MS. JULIA WANG: Hi. OK, is audio working properly?

CLIAC CHAIR: Yes.

MS. JULIA WANG: Hello?

CLIAC CHAIR: We can hear you. Thank you.

MS. JULIA WANG: OK, great. Thank you. All right, yes, I am aware that there are a lot of slides. So I have planned to skip a number of them. So today, I'm presenting Standardizing Lab Test Names, The TRUU-Lab Initiative in the place of Dr. Singh, who had a family emergency, so. Next slide.

The objective of this talk is to recognize that names of lab tests lead to considerable confusion on ordering and serious patient safety concerns. The second objective is to recognize that many lab test utilization management or stewardship programs use lab test name change as a major tool. And third, to analyze and participate in a process to create lab test names that are easy to understand, use, and make widely available. Next slide.

Out of all of the malpractice claims, one out of eight actually are related to lab test ordering and interpretation. So out of those, 55% are due to failure to order the right test, 37% due to misinterpretation of the results, and 13% to failure to retrieve or receive a result. Next slide.

And these tests are very common. These inappropriate test orders are very common. Out of all of the lab tests performed in the US, 10% to 30% are either unnecessary or incorrectly ordered. A big number of genetic tests are inappropriate. And of those, 5% of tests are frank medical errors, really.

And if you click Next, this is put into perspective where there's 13 billion tests performed in the US every single year. And next slide. So not only is it very widespread, it also costs every hospital up to-- or an average hospital $1.7 million a year when these tests are ordered. Next. And next. And next slide.

So a survey that asked primary care physicians about uncertainty reported that 15% of these physicians are uncertain about which tests to order. And 8% are uncertain about interpreting the results. From conversations with these physicians, however, it seems like this could be an underestimate of the number of tests that people are uncertain about ordering or interpreting. Next slide.

So there are a couple of reasons why it could be at this state. The number of lab tests has increased to more than 4,000 different ones in the recent years. And laboratory medicine teaching hours in medical school have often reduced to zero. And most recently, there has been a review by Elissa Passiment, where they reviewed how and why test names are confusing. Next slide.

So here, I'm going to start going through a few scenarios of why lab test names are confusing and why. So one example that is pretty commonly brought up is vitamin D, where there are two major choices. And I'll delve into that a little bit more later.

So how do clinicians usually compensate for this level of uncertainty? First, they typically order more tests. And also they use the H and L approach, which means that they will ignore most lab test results that come back normal, but then focus on the ones where it's abnormal with high or low indications. And so is this really a solution? A psychology study indicated that more data usually brings people more confidence in their decisions, but not necessarily increase the accuracy, and thus create a lot of extra costs and maybe difficulty interpretation later on.

Next, I want to go through the first scenario, where test names are well known, but the lack of standardization and clarity leads to these uncertainties. So the first example is hemoglobin A1C. As you can see, there are six quite commonly used names. And if you click, you can see that these names are starting with a different letter, which makes it very difficult to search through a list of lab test names or however your EMR system is allowing you to select a lab test of choice. Next.

And in the next example, there are some standardizations, for example for BMP. Because there are CPT codes for these panels, their components are standardized and defined. However, on the next slide, there are no standardizations for things like liver function panel, respiratory virus panel. And these will really vary by hospital, vary by manufacturer.

And if you click again, the hope is that there will be a technical fix for this, where EMR systems are becoming more flexible. The ideal is if someone hovers over a panel, the list of actual contents of the panel can be displayed.

In scenario 2, some test names are difficult to interpret. I'm going back to the vitamin D problem here. So there's two major forms of vitamin D in the body. First is 25 hydroxy-vitamin D. This is a screening tool. And clearly, here we define as the correct test, because it should be ordered more often. And the second one is 1,25 dihydroxy-vitamin D, which here we define as the incorrect test. It is not used for screening.

So three hospitals faced with the problem of people ordering the wrong vitamin D tests about 30% of the time. And each of these hospitals has come up with their own solution. The first hospital, their strategy was to call the ordering clinician whenever they were ordering the wrong test.

And as you can see, during the time period of when this intervention was in place, there was a significant decrease in the ordering of the wrong test. But as soon as the intervention was terminated, you can see that this is not sustained. And this approach is really not sustainable in the long run.

In the second hospital, their strategy was to change the lab test names in their order system. So the first one, they would say, it's a deficiency screening. And the second one would be labeled as a bone/renal disorders test. However, this actually resulted in an unexpected result, where there were more people ordering the wrong test.

And the reason why is the people from renal actually thought that was the correct test for them for all of their patients. So that gave a really unexpected or the reverse result that they wanted. And they went to a second solution, which was to simply hide the second option and have them call the lab when they have to order.

So the third hospital had yet another solution. And their strategy is to provide clarification to the test names without really changing the test names themselves. So here a note for deficiency screening or not for deficiency screening is shown. And the results on the next slide is-- so here the graph is showing the ratio between deficiency screening and not for deficiency screening-- the wrong test.

So as you can see, before intervention, the ratio of the correct versus the wrong test is 6 [? to 5. ?] However, after the name clarification, you can see a steady increase in the ratio and the final ratio of 30 of between the correct test and the wrong test. So in the next-- so as you can see, even what we think are very simple interventions can give us unexpected results. And there are multiple ways to solve these issues.

I want to give one more example, testosterone, where you can see, there are five different choices standardly provided to people. And the first one, the testosterone free dialysis and total LC/MS/MS is ordered 40% of the time. And this is the gold standard, which most people should be ordering. However, you can see that 34%, 22% of the time, something else-- the physicians are ordering something else.

And when we asked the physicians why they're ordering the other ones, they actually said that because my patients are not on dialysis. So I didn't order the gold standard. And as you can see, these lab test names are descriptive for the lab. But it doesn't really help the physicians decide which ones to order. In addition to the drastic cost difference, as you can see, the first one is-- the third test is 12 times the cost of the first one, even though the first one is the gold standard. So next.

In scenario 3, they're clinically superior and cheaper tests that simply have really poorly recognized names. A really good example is the APC resistance test and the factor V Leiden test. So as we know, APCR can pick up 10 times more cases than just ordering the factor V Leiden testing. However, people are ordering the factor V Leiden testing a lot more than the APCR simply because it's more recognized.

And as you can see, the cost is actually much higher as well. APCR is $5. And factor V Leiden is $60. And one possible solution that has been proposed is to have APCR as a reflexive testing for factor V Leiden, which could solve the problem. But what do we do when there are a lot of different examples like this?

In the next slide, here are a bunch of different-- can you-- if you just click through, there are different-- many, many examples. I think I'll just talk about one or two here. Looking at the third one, for example, HSV 1/2-- we heard people ask us, you know, when do you order HSV half? And for the next one, eGFR versus EGFR. Some people have-- we later realized that the EMRs converted all the names to uppercase. So it's impossible to distinguish between the two.

And also the last on the bullet point-- free PSA. Some community health clinics have mistakenly ordered a lot of the free PSA thinking that it was free of cost versus PSA. So all of these names are really not designed for optimal understanding and utilization. Next slide. And the next slide. So genetic testing is a really good example, too, where Rett syndrome, with the cause in the MECP2 gene, and the RET gene, which is the cause of multiple endocrine neoplasia type 2. These confusions are also quite common. Next slide.

So let's take a little bit step back to see why we ended up here. So how lab test names are usually chosen is without consulting with pathologists or clinical scientists, no style guide, and without consulting the ordering clinicians either. So usually when the EMR is being set up, whoever was in charge would simply put in whatever was the default. And so they could be imported from things like the vendor's name of the test. It could be named by the analyte, the reagents. So all of these things could end up in those lab test names, without regard for utilization.

So how do we fix this? Currently, there are some approaches where individual hospitals and labs have stewardship committees that will go through each problem and propose a solution and test them. However, this process can take several months for each test. And if you imagine every single hospital doing the same process for every single problem, you can see that it has significant cost in terms of time and effort and everything involved.

So our question is, can this be done on a bigger level? Can this be done systematically and nationally? Previous attempts, of course, have happened, so for example, the ONC Tiger Team. Australia and Canada have also had their individual efforts in coming up with some type of naming guidelines.

And of course, I have to mention LOINC, which is-- I want to make a point here in the next slide that we've had multiple conversations with LOINC. And our understanding is that the purpose of LOINC is for [? machine ?] understandability and interoperability. And it was not designed for the display and the ordering system and for physicians to understand which one is the best one to order and for those type of purposes. So while LOINC has been widely used, we believe that the display name is still an outstanding issue here.

In the next slide, you can see that erythrocyte sedimentation rate has six different LOINC codes. And actually, a clinical informaticist from UCLA recently presented at Baylor. And he reported that about 40% of their lab tests have incorrect LOINC code and mapping because the initial mapping was not done by a pathologist or a laboratory scientist. So there's still a lot to be done there for sure.

So in the next slide, why do we think that we need to start another test naming initiative? So first, to reiterate, we need names that are for standardizing, for easy to understand, not simply for machine readability. And I think-- we think that the timing is correct right now, because many hospitals are increasingly-- have this awareness when they have stewardship committees. And they are going through this process that's very slow and can be done once instead of at every single hospital.

Another couple of examples of why we think it's a good timing is we are truly trying to harness the power of big data. And without a good standardized display name, how would people be able to analyze these data across the board? For example, A1C or glycosylated hemoglobin. And I think EMRs, right now, are more and more willing to accommodate for this type of user friendliness. And we are hoping to work with them on this.

So I want to go through what our effort is all about. So TRUU-Lab stands for Test Renaming for Understanding and Utilization. We have a website. On the next page, you can see that's a screenshot of the web-- the home page, truu-lab.org. You will find the mission statement, the scope of our efforts, our goals, and a list of our members.

And if you click through the next two slides and next slide-- so this is a list of the current TRUU-Lab members. We have pretty good representation from a lot of the pathologists, professional organizations. We have representation from the CDC and FDA. We have a number of pathologists. And we have PLUGS, Nudge Unit, and terminology groups that have participated in our monthly meetings. Next.

We also have a good number of international partners from UK, Norway, and Australia, who are sharing with us their experiences, their failures and successes in doing this similar type of work in their respective countries. And we actually hope to standardize and use the kind of resources that they've already developed.

So given that we have a good number of representation, we are still lacking two groups of people. One is clinical professional organizations, so internal medicine, pediatrics, OB-GYN. These people who are on the frontlines ordering these tests every day-- we would need their opinion on which lab tests are truly understandable. And of course instrumentation makers, who will determine the contents of the testing and if they're willing to standardize with all of this effort.

So I want to go through the goals and also how we are achieving these goals. So the three goals are to first, generate a consensus guideline for test naming. The second is to generate consensus names for existing lab tests. And third, to promote the adoption and implementation of consensus lab test names and guidelines.

So I'm going to skip the next slide to the next slide.

CLIAC CHAIR: Ms. Wang, with full respect, you are at slide 47. And you're at 20 minutes. And you do have 66 slides. I was hoping you can perhaps wrap this up in a minute or two. Thank you.

MS. JULIA WANG: Yeah, of course. So we have-- we've done-- we're doing this work in different committees. So first, we've done this-- identified the difficult names that people reported. And second, we've gathered all of these guidelines from the people we've worked with.

And we are learning from these existing guidelines and will attempt to really go through and see which part of those guidelines work and come up with a guideline that we will try to implement. And our idea for implementation, or testing first, is to have some kind of simulated EMR environment, where clinicians can go through and use the proposed new lab test names and see if that truly will change the ordering pattern.

And if you just scroll all the way to the last slide-- I'd just like to mention that there's a number of ways that you can participate in TRUU-Lab. Oh, and that's not the last slide. So if you just go on our website, there's a number of ways where you can contact us. And there are many ways to participate. Thank you.

CLIAC CHAIR: Thank you, Ms. Wang. There is a final slide in her presentation that has a QR code, if you would like to participate. And the slides she was unable to discuss in depth have a number of contact folks who are leads in the different projects if you'd like to help. I'm going to ask if there are a few questions. We are running late. Susan.

CLIAC MEMBER: So the funding for this-- so I saw the sponsor us. Funding is coming from where? And just before you answer, I know the LOINC was set up for data sharing. But you made the point that was extraordinarily important. Data sharing and good clinical care is all based on simplicity and uniformity. So I think everybody is rowing the same direction.

So and one more comment-- I am an OB-GYN. And yes-- that slide-- we were the number one offenders by far because of the factor V Leiden. But I just want to make clear, the factor V Leiden-- that is an educational gap in the women's health community about using factor V Leiden, just ordering it inappropriately. We're still having issues with MTHFR and factor V so that might be an overlap as to ordering it at all, and not just that the name was the wrong name. So again, back to the funding.

MS. JULIA WANG: Right, so we actually do not have funding for this project. Everyone is donating their time, including Dr. Ila Singh and myself.

CLIAC MEMBER: Ms. Wang, can I ask a question? Are you recommending or do you only use terms which are English terms? Or are you considering having other languages incorporated into the process?

MS. JULIA WANG: We're really focusing on English. We recognize that this problem is throughout the world. So we are primarily working with UK and Australia right now. But we haven't really gone beyond that.

CDC's Digital Bridge Activities: The Importance of Curation of Standard Codes for Laboratory Test Orders and Results
William R. Mac Kenzie, MD

CLIAC CHAIR: Thank you, Ms. Wang. Very much appreciate you stepping in. Our final presentation is Dr. William Mac Kenzie, who will speak on the CDC's Digital Bridge Activities, The Importance of Curation of Standard Codes for Laboratory Test Orders and Results. Dr. Mac Kenzie.

DR. WILLIAM MAC KENZIE: Good afternoon. I'm really glad to be here. It's been three years since I've been here last, and it's a pleasure. It's only about the 47th interoperability presentation that CLIAC has seen in the last 10 years.

So I'm glad to-- so the last presentation was given from a health care perspective and how interoperability provides an important issue that has to be addressed to care for patients effectively. And now I'm going to switch and look at the public health side of how public health surveillance is greatly impacted by laboratory codes and how they're used or not used effectively.

So for those of you in the audience, most of you know that public health surveillance is the ongoing systematic collection and analysis and interpretation of data, closely integrated with the timely dissemination of that data to those responsible for preventing and controlling disease. The important pieces there-- it's systematic. And it needs to be timely. And it needs to go to the right people. And a lot of that is not happening with laboratory codes today.

So what I'm going to tell you about is a multi-partner effort that includes health care, the developers of electronic health records, and public health to create something called electronic case reporting. And electronic case reporting is the automated generation and transmission of a case report to health care without the clinician required to do anything-- no burden to the clinician-- so public health can review the information and act.

So you know that approximately 70% of the medical record is laboratory. And approximately 70% to 80% of all notifiable conditions require a laboratory result for reporting. So for electronic case reporting, we really need the laboratory engaged. This is what the technical framework for electronic case reporting is. A patient sees a health care provider, up on the left hand side of the screen. And information is entered into the electronic health record. And that information, if it includes a diagnostic code or an ICD-10 code, a test order such as for measles-- we'd want to know that about that right away-- a LOINC code, or a test result, a SNOMED code, then if there's an appropriate match, then there's an automatic generation of a case report which includes information that I'll show you on the next slide.

That report would go to an intermediate platform, which is the AIMS-- the APHL Information Messaging Service-- right now, on which a software sits that tells us whether a case is reportable in the jurisdiction from which that patient is from. Now, why do we need that? Why isn't it just reportable everywhere? Well, we run a federated system. And each state has slightly different reporting criteria. So we want to make sure that the states get the right information.

If it is reportable, it will be sent to the public health jurisdiction in question and acted upon. And that information eventually gets to CDC. What we're hoping, and what we're working on, is then a reportability response goes back to the provider-- it could be just the corporate provider or the individual provider-- saying that the information was reportable and who it was reported to, and potentially have some useful contextual information about how to treat the patient or what's going on in the community.

So this is the type of information that gets transmitted. And it includes information that is on the electronic health record and is required to be on the electronic health record through meaningful use. On the left, there is information about the provider. On the right upper corner, there is information about the patient, including their identity, how to contact them, where they're located, demographic information, and risk factors such as pregnancy. Then there's information that we currently don't get, which is clinical information, notes, symptoms, laboratories, diagnoses, medications, outcomes-- things we desperately need and currently don't get.

So we've been working on this. But I want you to understand that it requires a code to be present to be reportable. Now, for ICT-10 codes, it's pretty clear, because everyone-- there's a clear standard. For LOINC codes, as we saw in the last presentation, there is a lot of additional codes. Now, we put the right codes together. And LOINC is required in meaningful use. So we just put a number of codes down. But what if someone starts a new code? This happens more frequently than we want. LOINC is not adequately curated. So that's a problem.

And for a laboratory test result, we usually think about SNOMED codes. Well, do all laboratories use SNOMED codes? No, they don't. And even those who have SNOMED codes don't always send them to health care. So how is health care going to get this information? SNOMED codes are not required in meaningful use.

So you can see that electronic case reporting, which would be an important step forward for public health, is a problem because the laboratory isn't giving us the information we need. Now, there are a lot of reasons for that. I'm not pointing fingers and blaming. I'm just trying to figure out how we're going to solve this.

So let's talk about the Tower of Babel for laboratory codes. Laboratory codes are often local. They are one-off solutions. They're solutions to try and get the information right for the providers in that system. But what that leads to is national disarray, because that's not a code that you can easily send to someone else. So what we have to do is this extensive mapping and translation of the codes for sharing and interoperability. And that requires that someone figure out what the right code is. And we've already heard how often that code is incorrect.

And there is a proliferation of LOINC codes. And I'll show you that going forward. So many labs have adopted SNOMED-CT. And that's wonderful. But it's inconsistently sent to health care. And there's a reason for this. I mean, laboratories aren't paid for putting in SNOMED codes. There was no incentive program for laboratories. I get the problem. But that wasn't thought of. And that still remains an issue.

Now, Quest actually uses SNOMED code for electronic laboratory reporting. But they don't send that code to health care, so that health care doesn't have it in their system to actually kind of trigger a report through electronic case reporting. So you can see the problems. We have a lack of standards. We have inconsistent use of codes. And we have a lot of codes that haven't been deprecated.

So the last speaker already spoke about this briefly. But LOINC codes weren't thought of very-- they did a wonderful job in helping us get to machine readable information that could be shared. But they were based on sequential. When you came in, you got the next code. So there is no characteristic that a LOINC code tells you anything about the test or what it does or who made it or what the units of measure are.

It has this penultimate dash. And once it's released it's never removed. OK, so that's a problem. This is what the anatomy of a LOINC code-- this is what a LOINC code in the background means. So the numbers mean something. But there's nothing that-- you look at the number. It doesn't tell you anything. You can see-- and the last speaker spoke to this-- that since 2010 to 2016, we went from around 8,000 LOINC codes to over 50,000 LOINC codes that are laboratory only. That's a problem. It just keeps growing and doesn't really get standardized.

So we thought, OK, what would be the potential solutions for this? Well, we could try to make-- obviously, we want to make codes semantically interoperable. We could map-- we could encourage local codes to be mapped regularly to LOINC codes and SNOMED codes and then sent to health care. So the lab-- that would be on the laboratory to do that. That's a lot of work. And we know it.

But how are we going to get to the place where we have interoperable ways of sharing information? We could formulate national laboratory code standards for tests that are performed. One way of doing that is just try and curate LOINC and get it to be more manageable. Or we could take the nuclear option, which you can devise a hierarchical system that can be parsed and analyzed and actually useful in other ways. But that's a lot of work.

We could explore incentives for LOINC and SNOMED codes to be sent out to health care and used by laboratories. We could have the manufacturer package insert or recommendations in the package that has the standardized codes for to simplify adoption. All these things seem like the right thing to do. But they're timely. It takes time. They're expensive. And they're not really easy.

So I was coming here to tell you just that. And then I started to talk to my FDA colleagues, who have been working for the last three to four years on something called SHIELD with a multi-stakeholder public-private partnership. SHIELD stands for the Systematic Harmonization Interoperability Enhancement for Laboratory Data.

Mike Waters of FDA has been working on this. And I understand that Peter presented this briefly this morning. And the purpose is to accelerate diagnostic data digitalization and standardization and harmonization. And the method is done by consensus adoption and development with industry, with laboratories, and with public health and FDA at the table. And the goal is to enable health care data to be interoperable.

Now this is the SHIELD architecture. I don't know. [FDA EX OFFICIO], was this shown this morning?

DR. WILLIAM MAC KENZIE: OK, this slide's a little bit complex. And I'm going to spend some time on it. And what you need to know is on the left-hand of the slide, this is what the manufacturers are being asked to do. And several, including Abbott and Biomérieux and Roche, have already done.

They have taken their in vitro devices and decided what the LOINC code is, what the SNOMED code is and the UCUM codes are and put them together and said, OK, this is what this is for this device. And they went further to create a LIVD code. Now, what can be done now for newer devices-- obviously, older devices won't do this-- but you can actually just send out that information to the device. And that device can receive it.

And then, from then on, using a software called LAW-- which I'm trying to remember what that-- so it's the Laboratory Analytics Workflow. And what that does is, in a plug and play way, makes it so all those codes-- LOINC, SNOMED, and LIVD-- can be sent to the laboratory information system and utilized. That solves a lot of our problem. That's a great thing.

So the labs, though, have to download the information and then utilize the data in their LIS system. That's work. But it's a lot less work than all the things I suggested before. And then that data should be sent on to health care

and all the rest of us who need it. So what it is, it's a requirement to-- not a requirement, but a voluntary act-- to try and make laboratory codes useful for health care and public health to improve health. And the laboratory is at the center of this. And the developers of in vitro devices are essential in this process.

So this is just another way of saying the same thing. Vendors, on the left side, send their standards to their analyzers in your laboratories. And that gets, in an automatic way, put into the LIMS system, and then can be sent out to providers for use. I'm not going to talk about that. So I'll end here.

What are the considerations for CLIAC? So what additional information does CLIAC want about SHIELD? One thing I didn't mention is there are pilots that began last week with health care and with public health laboratories. There are three public health laboratories that started.

What kind of follow up do you want about these SHIELD pilots? If the pilots are successful, what kind of ways can you incentivize laboratories? Help us think about how to incentivize laboratories to do this uptake of SHIELD at a low cost. And finally, in relationship to the last presentation, let's do this systematically. Let's not separate out the actual name of the test that's readable and useful for the clinician from the laboratory code. Let's have them all go together, so that you just send things forward and don't have to make up things as you go along. Anyway, so I'm going to stop there and take questions and let you guys talk. Thank you.

[APPLAUSE]

CLIAC CHAIR: Thank you, Dr. Mac Kenzie. Are there questions?

CLIAC MEMBER: So I really-- I don't have answers. You already asked the question. And regarding both the TRUU-Lab and SHIELD, I think the incentive for reference laboratories to invest time, energy, resources into test naming, reporting, ordering, reporting, interoperability is clear and obvious.

I know we're both reference lab and health system. And I mean, in our health system, people spend an inordinate amount of time developing enterprise ordering and reporting conventions. And I don't recall in the many years of that conversation that external facing questions ever came up, because there was just no incentive for a health system.

So I think that's what I'm struggling with or what the million dollar question in my mind is. For both TRUU-Lab and SHIELD or all of these efforts, what's the incentive for health systems to reach out to each other and to come together around common naming conventions across health systems as opposed to the obvious incentives to standardize within health systems?

DR. WILLIAM MAC KENZIE: So I think it's a great question. And part of the question I would have back to you is, how many tests need to be redone because of the way the system sits now? And how many inappropriate diagnoses or decisions are made based on inappropriate use of the laboratory test and the interpretation of that test? I think those are not easily answered questions. But we're in the business of caring for people, both as individuals and populations. And I think--

CLIAC MEMBER: And some of the answer, again, I don't have an answer. But if you look at our health system, we don't have as many patients-- I mean we-- that was the incentive to standardize within-- Mayo enterprise. And we have patients come into Mayo enterprise and go out. But it's not as fluid as you'd think. And I would think one of the obstacles to doing this is a consolidation of health systems regionally across the country even though people are mobile, the focus isn't on people coming in and out of the health system, because health systems are focusing on consolidating. I want all the patients in this region of the country to be in our health system. And so the thinking isn't across health systems right now.

DR. WILLIAM MAC KENZIE: Right, I think that's correct.

CLIAC MEMBER: I think that's a good point, because we've all struggled even as we integrate within our health systems. And we've merged with another hospital, and we've had to address this. I mean, I think that this could make a lot of those mergers and integrations following mergers, whether it's a hospital or a reference lab or whatever, a lot easier. I mean, I would love to see what's learned from the pilots. And then-- and actually, I would hope that we'd have some folks participating in that to be able to provide the real world kind of feedback.

I just also want to point out you kind of implied that ICD coding is actually more standardized. We did a little study about that. And we sent four charts to 20 places and not one of them coded it at exactly the same as another one. So while there were certainly common themes--

DR. WILLIAM MAC KENZIE: Right.

CLIAC MEMBER: --the sense that that coding is reliable is a little bit questionable.

DR. WILLIAM MAC KENZIE: All right, thank you for that comment. I appreciate it.

CLIAC MEMBER: Thank you very much. This was very informative, so I appreciate it. One point that I'll mention is that I think there is some incentive for health systems that I see, particularly my own places, that as we have more capitated patients or patients that may have labs done outside of our system because they're capitated, and we want that data, there's incentives for us to capture data from Quest or LabCorp or other foreign systems.

And so the way I struggle with that, though, is because I still don't understand the way the data the results are harmonized, meaning I still don't-- I mentioned this earlier. I still don't know how those should be displayed in the EMR from a comparability standpoint. I very much struggle with that piece. But I do think there is some incentive that way to share data. So I think there are some reasons out there. So--

DR. WILLIAM MAC KENZIE: Thank you.

CLIAC MEMBER: So it looks good. Coming from a background of system modernization, I look at that design. And I see this as software that needs to integrate. And we all know when we're trying to switch over from Windows--

DR. WILLIAM MAC KENZIE: Yes.

CLIAC MEMBER: --to Windows 10, to-- it's never really that easy.

DR. WILLIAM MAC KENZIE: Yes.

CLIAC MEMBER: So I guess it does-- there are so many different systems that a piece of software doesn't always work. So the whole kind of-- we need a whole new layer of consulting people to get together with all of the different laboratories to see what percentage really are going to be green, yellow, or red. They're going to go. They're maybe going to go. Or they're not going to go at all. So I think that's probably what everybody needs to see.

DR. WILLIAM MAC KENZIE: I think you're absolutely right. And the fact that they're just starting the pilots on this is important to recognize. And I think for those of you who are interested to think about your system, Mike Waters at FDA is someone who's been heavily engaged in this and wants to try and make it work.

And as you said, usually these kinds of efforts take time and a lot of work to try and figure out all the issues and work out the bugs, so-- but you've got to start. I mean, we've-- it's been a long time that we've faced this problem. And everybody suffers for it. Thank you.

CLIAC MEMBER: Yeah, my one comment was the LOINC codes are sequential. But they are also searchable by category. The concept of giving us all another layer of codes-- ICD-10, SNOMED, LOINC, and now these new codes-- I guess just seems a lot more confusing to me as a user, someone who's mapped 15,000 LOINC codes for microbiology organisms. So is LOINC going-- is the intent that LOINC will go away? I guess I refer to the FDA colleagues. Or will it be LOINC plus, like, LOINC on steroids with the new codes? How does that work?

FDA EX OFFICIO: So my understanding is, for the pilots, LOINC is one of the data standards that's being used. And the intention is to try to provide sort of vetted and harmonized use of LOINC codes through unambiguous coding manuals type approaches to help harmonize the use of those codes along with the other standards that serve different purposes of describing different aspects of the data.

So I mean, it's-- of course, all this is a work in progress. But I think that they're trying to use the available standards that are out there right now in the most efficient way that they can. But of course, there's always room for improvement among data standards.

DR. WILLIAM MAC KENZIE: I would say, it's all-- we're in a period of change that will continue for the next 50 years. And it's just going to continue to change. But you start with the standards you have. And then you adopt and adapt with time.

But the thing is, if the provider of the in vitro test is the one who's in control of what that information is, and it gets standardized as it's sent out to the health care providers, then that curates things as you go along. And it doesn't require the laboratory to look up the code. And I think that's a helpful step.

CLIAC MEMBER: Bill, this is [CLIAC MEMBER]. If we can have the vendors and the manufacturers generate those codes and put them-- and push them to their instruments, which is what I understood, that would be huge progress. And then, did I hear from [FDA EX OFFICIO] that the FDA now would be willing to support an EMO code that's acceptable from which the vendors would draw into the future?

FDA EX OFFICIO: Can you just repeat the last part of that question? I didn't quite catch it.

CLIAC MEMBER: Yes, so will CDC-- excuse me. Will the FDA support, financially support, let's say, the amalgamated compendium of acceptable LOINC and SNOMED codes going into the future that vendors would draw from?

FDA EX OFFICIO: So I don't know exact-- I don't know that I can say they will necessarily have the ability to provide funding. But I know that Mike Waters and others have been working on applying for grants. And there has been grant funding for certain projects through HHS and other organizations. But I think that there's general effort. And it's not just from FDA.

I mean, there's a lot of other people involved in the SHIELD effort. So I think it's important. And it isn't just an FDA effort. There's lots of CDC folks involved. There's lots of industry folks involved across a lot of different stakeholder groups, patient groups as well.

So I think it's a really broad group of folks that are working through SHIELD. So it's a public-private partnership. And CLSI is involved as well with some of the standards that are coming out. So it's really been about stakeholders coming together from a lot of different groups to try to solve these problems in incremental ways that we can keep moving forward.

I think everybody that's involved understands that some of the standards aren't perfect. But it is a way to try to move forward with what we have and then to keep improving as it goes along. So I think, in general, it's a voluntary process. But it has continued to pick up momentum. And support from CLIAC has been very helpful with that process as well.

CLIAC MEMBER: I just raised that as an issue with Bill giving the presentation that the support of that code compendium is key to continued success. So that has to be supported by some agency or combination of agencies.

CLIAC MEMBER: I just had one quick question slash comment. So when we look at the list of all of the participating sites for SHIELD and TRUU-Lab and so on and so forth, the common denominator continues to be the EMR. And the EMR tends to be-- in addition to the manufacturers, they also tend to need some sort of incentive or some sort of ask. And maybe not so thankfully or thankfully, there are a very limited number of EMRs in the US that are available. So is there work being done with them specifically to incentivize standardization?

DR. WILLIAM MAC KENZIE: So it's a great question. As we have worked with Cerner, Epic, Allscripts in the kind of electronic case reporting space, one of the interesting things is when we wanted them to use-- get their SNOMED codes, they said, well, we don't really have a lot of SNOMED codes. And [? they-- ?] from the laboratory. And [? they ?] said, well, you know, we have them for electronic laboratory reporting, [? and ?] said, well, no one sends them to us.

I mean, this is really just the issue is getting the kind of the standards as to what gets sent. And it-- because oftentimes, those-- Quest has them. It just doesn't send them, because that hasn't been asked for. So it's really just about creating the right standards and systems by which people can utilize the system effectively. Yes, go ahead.

CLIAC MEMBER: I guess my follow up comment to that is that seems to be a very common answer. And there seems to-- there's not always a lot of transparency about what kinds of things you could be sending that you're not, and how to get there and how to build that out. And whether or not you have the-- sometimes you buy the Cadillac of the EMR. But you don't actually have the resources to build it out. But you didn't even know that, because you don't know what you don't know.

So I think that there needs to be some sort of just a, hey, well, maybe you should ask for it up front, because it could be useful for X and Y later down the line.

DR. WILLIAM MAC KENZIE: I think you're absolutely right. And I think it was surprising to Epic that they could actually get some value out of it, so--

CLIAC CHAIR: Thank you, Dr. Mac Kenzie. We'll relieve you of addressing all of these questions to CLIAC. So for the CLIAC Committee, it is-- we have 17 minutes before 5:00 when the session is supposed to end. And

these four questions are in front of us. We'd love to hear your opinions, and in particular, whether or not we need to make any recommendations.

Committee Discussion

CLIAC MEMBER: So for the first bullet, what additional information would we want to know about SHIELD? Just based on what is known today, what kind of budgetary numbers are you looking at for the software and the professional services to integrate?

CLIAC CHAIR: Yeah, I just-- I'm sorry. Just want to clarify a little bit of my confusion. This is Dr. Mac Kenzie's final slide. But there's a larger slide that we are being asked to respond to. So you had an excellent response to that.

CLIAC MEMBER: OK.

CLIAC CHAIR: But these are the two questions that we are asked as a committee to respond to and whether or not we want to make any recommendations.

CLIAC MEMBER: Well, you're welcome to--

CLIAC MEMBER: How can agencies encourage laboratory adoption and use of voluntary standards

CLIAC MEMBER: Well, one thought after the first one-- did I interrupt you?

CLIAC MEMBER: Is if I was in a laboratory, I would say, how can this help me? What can this help me with? Can it actually help me with IT, with difficulties, with technical issues, with time spent, with programming, et cetera, et cetera, et cetera. Maybe it can.

CLIAC CHAIR: So you're saying you want an incentive.

CLIAC MEMBER: I mean, I just want to know, what is it going to mean? Budgetary, for sure. But if-- some of the things that my limited understanding of IT would suggest is this might actually be quite helpful in some ways.

CLIAC MEMBER: So my comment is, I guess, the ultimate incentivizer would be that CDC uses its public health and FDA regulatory to issue a strong suggestion slash mandate. I believe that the labs are very-- attempt to be compliant with recommendations that come from CDC and others in many cases. Now, everyone will say, where do we get the money to do this?

But in the greater good of the value-based health care and treating our patients, if we don't do this, what is the alternative? I think-- and simply sort of recognizing that or putting out the information in a way-- so I would recommend that they-- I mean, that they just say, you're using this SHIELD that's been developed. And give people time to comply, just like they do with any other compliance issue. And put out information to the value of that to value-based care and patient care. Anybody who works in a laboratory will know all the diagnostic errors and inaccuracies. And I mean, I think this is not a should we, but why haven't we done this before?

CLIAC CHAIR: And [CLIAC MEMBER], I think the comments you made earlier are very applicable to this since we're talking about incentives and what it would take. So if I could ask you just to repeat your comment from earlier.

CLIAC MEMBER: A little bit different thought as it relates to incentives-- I would think if I was you and they're asking what you need to feel comfortable, you need, like, the Navy SEALs team that knows this inside and out. You can't call into a customer service number and just get anybody. This needs to be a national, strategic strike to do this. You've got to have a core team, dedicated to doing just this.

And then once people commit, then there needs to be a hero award-- this group did it in so much time. And now it's working-- and PR behind it. So to give them confidence that they've got the experts. And then to show the results in awarding them and giving them recognition and showing all their happy customers, or patients.

CLIAC MEMBER: The integration with the TRUU-Lab initiative-- it would be really nice to have more information on what that even means. And with the SHIELD program, if there isn't a vendor who's working on that particular lab test, does that mean that other tests won't be in the SHIELD system? You know what I'm saying? It's voluntary. So and there are some tests that don't have large companies behind them. That's also fascinating. Roche is already all in, or just for certain specific tests? So just I guess the broad question would be, via SHIELD, does this really encompass all testing? Or just initiative from industry?

FDA EX OFFICIO: Yeah, so initially it doesn't encompass all testing. I mean, it is a pilot that's being implemented that's somewhat limited. But I mean, the intention is to try to continue to expand it and bring in people. At the moment, it is a voluntary effort from a number of different groups working together. But that's sort of where we're starting at right now. So I think some of these questions-- it will-- I think we have to sort of see how the pilots go a little bit. But certainly, I would agree with a lot of the end goals of what we're trying to ultimately achieve. But it still is in some of the early phases at the moment in terms of seeing how this works together.

And adding on each of these elements are certainly important. And I think the idea of how to integrate the TRUU-Lab is a certainly important point. I don't know that that's been-- to what extent that's been figured out yet. I think it's still in the early phases.

CLIAC MEMBER: We also have to think about LDTs and what type of recommendations we give to institutions who are creating them.

CLIAC MEMBER: So I think that if we're asking laboratories to adopt voluntary standards, guidelines, and/or tools, my gut reaction is, well, we're already doing something. And ours is better than yours. Or why do we need to do what you're doing? So do we have an inventory of that?

And is it worth recommending to HHS that they ask labs to essentially report on what are their local guidelines for naming laboratory tests, or what is their local tool to harmonize codes, and so on and so forth. And hey, if you don't have that, there is this available. And then at a minimum, you're able to describe what practices look like and what the variability is. And at least you'll have some evidence and literature to point to when you're trying to make the financial case for what the impact of this could be on patient care.

CLIAC MEMBER: I think what you just said, [CLIAC MEMBER]-- unfortunately, we've been talking on various other topics about CFOs and financial pressures, et cetera. And to me, that first question-- unless we incentivize it, either by giving a bonus if you do it or penalizing if you don't-- I think there's just too many large institutions that are not going to do anything, because it does involve an investment of time and resources to do whatever it is. And then to the second one, what should CDC or HHS do to reduce the use of varied local codes? I think it was in one of the slides about the SHIELD presentation, where I think it should start with the vendors. Why should I, as an end user, try to figure out what LOINC code should go with a glucose that comes off my analyzer? I think the vendors should do that.

And if most of our laboratory results are produced by instrumentation that could, at the vendor level, produce the LOINC code that's needed and be sent across with the test result, I think that solves a tremendous amount of problems for us as end users trying to figure out what LOINC codes to use.

CLIAC MEMBER: It's an incentive, too.

CLIAC MEMBER: And an incentive to the vendors to do that.

CLIAC MEMBER: And everybody.

CLIAC MEMBER: So a softer version of that would be that CLIAC recommends the communication of the-- you said you had six pilot data sites in the SHIELD. Do you happen to know if any of them have improvements in patient safety, reductions in cost? I mean, that could be a first step to communicate, to get more people to volunteer prior to a mandate of some kind.

But if we would recommend that that be communicated back to financial officers, if indeed those things exist-- improvements in care, costs, value-- then they would come to us and say, here's the money to do it. Hospital one, two, three, four, five, six saved this many millions of dollars doing this, in stewardship and needless tests and lawsuits or whatever. So I would focus-- I would make the recommendation to do that in a systematic way with those groups. Just a few wins related to money might be an intermediate step to the incentives, which you have to find funding for.

CLIAC MEMBER: I think you mentioned it in your presentation. But when did these actually start the pilots?

FDA EX OFFICIO: Yes

CLIAC MEMBER: OK, because I saw my institution on here. And I was like, wait, what? But--

FDA EX OFFICIO: Some of them haven't started yet. I think it's only some of the pilots have started

CLIAC MEMBER: OK, and since these are pilots, you've obviously-- or I'm assuming that the outcomes have been delineated. Do the outcomes that you're measuring-- do they include things like that? I mean, do they include outcomes like tests saved? Do they-- are they going to tell the story that you were just mentioning?

FDA EX OFFICIO: That was great.

CLIAC CHAIR: I think, Dr. Mac Kenzie, one of your slides asks, what does CLIAC want to know more about SHIELD? And I think we want to know the follow up.

CLIAC CHAIR: I'm hearing this. Yeah.

DR. WILLIAM MAC KENZIE: You really want that follow up. And you need to see if it works.

CLIAC CHAIR: And I just want to comment, I think a lot of our attention is focused on automated testing. But as we know, anytime we do something so foundational, all of those manual tests-- microbiology, point of care, blood banking, genetic testing-- all that comes into play. And they're still even further behind in their standardization, let alone LOINC codes. So while we can whack off maybe 70%, we got a thorny bucket of the remaining 30%. Bonnie.

CLIAC MEMBER: So as a laboratorian, and I think for all of us who are here at this meeting, when we see this, it's sort of like common sense, kind of a, duh, why aren't we doing it? But then the cynical person and the public health person arrives in my mind. And I guess, every meeting I say this. So it must be the time now. Follow the money.

In this situ-- where we are now in this nation, when we talk about health care and the issues of the cost of care in our nation compared to where we are compared to other nations, as far as the healthiness of our nation, our congressmen, the people who control the money, are the ones who are most interested in knowing, will we save money by doing this? Will we reduce the cost of health care? Will we reduce the number of errors?

And the folks who are in big systems and big hospitals-- there's going to be a definite cost to do this. And what will be the incentive for them to do it? And we have to have that data that's going to say what will be the impact on the whole. And it has to be financial, because that's where the decisions are made. OK, I'm done.

CLIAC MEMBER: I just had one thought to throw out for consideration. I know I heard in one of the presentations about the hospitals and all having stewardship committees. And when they were developing-- this is in reference to question 2, how to reduce the use of various codes. To ensure with all of these committees-- I think there were maybe five or six and doing various things-- that maybe we need to make sure that these pertinent entities are not reinventing the wheel and that they're doing some sort of cross walking of what is there.

I think I saw a survey to say, what do you have the most difficulty with? That's a good approach, but maybe the start should have been some sort of cross walking to what is already there and existing. What do we call this test? What do we call-- what are the examples of what we're calling this test? And look and do a crosswalk. And then from there, you start.

And that be your-- that's your beginning as to how you go about trying to reduce those numbers of different names for the same tests. Does that make sense? So that's something that just keeps resonating in my head. I don't-- I mean, because there are a lot of things that are being done. And you might get different answers, but it might not solve the problem. Thank you.

CLIAC MEMBER: I think I'm hearing that we don't have enough data to answer these two questions on the slide. And at least, that's what I think I'm hearing. But I would share that I believe, at least in my institution, that it's not just convincing the laboratorians. But we need to bring the IT folks in, sooner rather than later, because they could present a real barrier.

And I think about the sensitivity to security and just the difficulties I've had bringing in new software, with the discussions and some of the new laboratory instrumentation that we still can't get bi-directional interfaces established, because of the concerns about security. I think the sooner some of those conversations can occur between the vendors, the IT folks, and some of the non-laboratorians, for to get them on board and to reassure them that this is not how people are going to get HIPAA information, would be helpful as well. And I don't know if that's part of the SHIELD project. But I would highly recommend that security concerns be addressed upfront, because they're going to happen-- yeah, the security concerns about the HIPAA information.

CLIAC CHAIR: So it is 5 o'clock. Is it fair to say-- thank you, [CLIAC MEMBER], for crystallizing-- what I'm sensing is that this committee feels, perhaps, it's too premature to answer the questions posed to us and that our only-- I'm sorry. I would propose our only recommendation is that we would like a follow up on the pilot, and with special consideration for what was the impact on outcomes and what's the financial cost.

CLIAC MEMBER: One final thought-- and I won't make a recommendation or anything. But I mean, we've basically said, the problem with the TRUU-Lab and the idea that health systems will all get together is that incentives around value-based care improving utilization outcomes are only realized within the health system. There's a societal benefit to between health systems. But nobody's paying for that.

But with SHIELD, you're talking about reporting from health systems to public health labs, the state health labs. And there is a cost to doing that. So an obvious way to demonstrate the value of that is to show that using a standardized terminology decreases the cost for health systems to report, because large health systems do more reporting.

And so that would seem to me to be an obvious outcome of this pilot is if you show that there is a budget number that can be reduced to gain a cost savings through use of standardized tools for state reporting, now you've got at least some incentive to work towards the SHIELD project, the reporting from health systems to public health labs.

CLIAC CHAIR: Thank you. With [CLIAC MEMBER] final comment, I would like to adjourn this afternoon's meeting. I don't think we should do a formal recommendation.

Some logistics-- if you need a shuttle between the hotel and the CDC, please arrange with the front desk. Or if you're calling a Lyft or an Uber, you have to stand outside the building.

And then finally, the CLIAC dinner tonight will be at Cafe Lily. It is scheduled for 6 o'clock. If you want to walk, it's about three blocks from the hotel. And if we can meet in the hotel lobby perhaps at 5:40, 5:45, we can walk as a group. Thank you.

November 7, 2019

Call to Order/Roll Call

CLIAC CHAIR: Good morning.

CLIAC MEMBERS: Good morning.

CLIAC CHAIR: Thank you. This is day 2, and just some housekeeping things. Want to remind you about our quorum. Members are again reminded it is important to remain in attendance for today's full meeting to ensure a quorum until all matters before the committee are addressed and the meeting is adjourned.

One housekeeping issue is a number of us need to leave this meeting quickly and either get to the airport or back to the hotel. We have two cars available, one from Cindy and one from Sharon. And I'm not sure where you're planning to go, but if you need a ride somewhere, ask these two if you can jam on, and do that during the break, perhaps. OK, thank you. Do you want to-- I'm sorry.

OK. It's-- I'm going to do the roll call, and if you could just say here so we can move through this. Birthale Archie.

BIRTHALE ARCHIE: Present.

VALERIE NG: Marc Couturier.

MARC ROGER COUTURIER: Present.

VALERIE NG: Keith Davis.

KEITH DAVIS: Here.

VALERIE NG: Susan Gross, not yet. Lee Hillborne.

LEE H. HILBORNE: Here.

VALERIE NG: Steve Hinrichs, are you there?

HEATHER STANG: Not today.

VALERIE NG: Not today, thank you. Brad Karon.

BRAD S. KARON: Here.

VALERIE NG: Tom Lorey.

THOMAS S. LOREY: Here.

VALERIE NG: Sharon Massingale.

SHARON P. MASSINGALE: Here.

VALERIE NG: Lavinia Middleton.

LAVINIA P. MIDDLETON: Here.

VALERIE NG: Carole Moss.

CAROLE MOSS: Here.

VALERIE NG: Valerie Ng, here. Katherine Perez.

KATHERINE K. PEREZ: Here.

VALERIE NG: Jennifer Rhamy.

JENNIFER RHAMY: Rhamy here.

VALERIE NG: Bonnie Rubin.

BONNIE D. RUBIN: Here.

VALERIE NG: Greg Sossaman.

GREGORY N. SOSSAMAN: Here.

VALERIE NG: Cindy Wilkerson.

CYNTHIA E. WILKERSON: Here.

VALERIE NG: Tom Williams.

THOMAS WILLIAMS: Here.

VALERIE NG: Donna Wolk.

DONNA M. WOLK: Here.

VALERIE NG: Andy Quintenz.

ANDY QUINTENZ: Here.

VALERIE NG: Ren Salerno.

REYNOLDS SALERNO: Here.

VALERIE NG: Collette Leaumont.

COLLETE FITZGERALD LEAUMONT: Here.

VALERIE NG: Karen Dyer.

KAREN DYER: Here.

VALERIE NG: Peter Tobin.

PETER TOBIN: Here.

VALERIE NG: Nancy Anderson.

NANCY ANDERSON: Here.

VALERIE NG: Thank you. Roll call's done. Ren?

CLIAC DFO: OK, this morning session will be a public comment session followed by a discussion by the committee. There will be a morning break, and the meeting will end promptly at noon. As [CLIAC CHAIR] mentioned, if you need taxi transportation after the meeting, please visit the CDC concierge at the security desk.

Just a reminder, again, that this meeting is being webcast, so people are watching us. And it is being audio taped, and so people are listening and will be transcribing our words for posterity and for the public. The audio tape-- the audio tape is being provided to prepare an accurate summary of the proceedings, so we like to remind you to please speak into the microphone at all times. And if you're interested in information about the webcast, please visit the CLIAC website. Please restrict our sidebar conversations to outside of the meeting room, and we ask that you please silence your cell phones.

CLIAC CHAIR: Copies of all-- copies of all public comments are posted on the CLIAC website. There are 20 posted. Eight will be presented orally today. Is there anyone who is not on the agenda for public comments who would like to provide one? Seeing no hands, we will then restrict to those who are already on the agenda.

The public comment time allotted today is no more than 10 minutes for each presenter. We would ask that the presenters be prepared to take the microphone when the previous speaker has finished their presentation.

Our first presentation today, it's public comment PC1, it's from Microbiologics.

CLIAC DFO: Do you want me to introduce this?

CLIAC CHAIR: Oh I'm sorry, I'm sorry. I'm sorry, I jumped.

CLIAC DFO: So I promise this won't take very long, but we thought it was important for the record to introduce this session. CLIAC has long focused on the fact that advanced technology and emerging technologies are constantly being introduced into the clinical laboratory environment, and as a result, laboratory processes and systems are constantly evolving and changing. And we depend-- we in the government depend on CLIAC to help us understand how those changes affect the overall regulatory environment.

And these concerns have been particularly pressing for CLIAC recently. And yesterday, multiple references were made to the three separate groups-- CLIAC groups that were held between the meeting in November 2018 and April 2019-- the reports out from each of these workgroups in April 2019.

And based on those reports and the CLIAC discussion in April, a decision was made to do something rather unusual for CLIAC, and that is to dedicate an entire CLIAC session to receiving comments from the public about the role of emerging technologies in the clinical laboratory space. And the government developed these three questions that were posted publicly in the Federal Register earlier this year in August in preparation for today's session. And for the record, I'll read these questions out loud that were presented in the Federal Register earlier this year and are the basis for the comments that we will be receiving this morning.

Are bioinformaticists needed in clinical and public health laboratories? If so, what are the current roles, responsibilities, and competencies of bioinformaticists in these settings? What areas exist in CLIA where specific requirements or guidance might be needed to ensure the accuracy and reliability of new and emerging laboratory technologies and non-traditional testing workflow models, including next-generation sequencing, biomarker testing, metagenomics, and others? What data are available that could assist in answering how CLIA may need to be revised over guidance may be needed to ensure the accuracy and reliability of emerging technologies?

Following these public comments that CLIAC will receive this morning, we would like to ask CLIAC to consider at least these three questions. Based on the public comments, do you have specific recommendations in response to the three questions posed for comment? How might the public comments inform the focus, direction, and priorities of the CLIAC workgroup that will be convened in the near future? What specific actions should CDC, CMS, and FDA consider taking in response to these public comments?

CLIAC CHAIR: Thank you, Dr. Salerno. Our first speaker is Dr. Brian Beck from Microbiologics.

DR. BRIAN BECK: Good morning. Thank you for this opportunity to discuss areas where CLIA requirements or guidance may assist in ensuring the accuracy and reliability of new and emerging laboratory technologies. I am Brian beck, vice president of research and development for Microbiologics. Microbiologics produces a uniquely qualified array of highly-accredited biological reference materials. We specialize in offering

microorganism preparations and molecular standards for use in clinical, food, water, cosmetic, and pharmaceutical laboratories. Based in St. Cloud, Minnesota, Microbiologics has a strong global network providing biological reference materials to more than 140 countries.

There are two specific issues to raise with you today. First, let me address the use of external quality control materials. According to the CLIA Interpretive Guidelines, laboratories must establish unassayed or verified assayed the criteria for acceptability for all control materials. In 2017, the Food and Drug Administration issued an order on the classification of assay control material for clinical microbiology.

As molecular kits and standards become even more prevalent in the clinical laboratory, the understanding, use, and availability of these assay quality control materials become even more important. It is equally important to understand the uses and limitations of these controls. Some controls are labeled for research use only, and these are not suitable for clinical use.

While there is standing regulation on this matter, there appears to be a continuation of marketing of research use only-labeled products for use as quality control and of clinical assays. Interpretive guidance and education may assist in clarifying for laboratories what is or what is not represented as an effective control for in vitro diagnostic products.

We all know that in the clinical molecular field, laboratories must have confidence in the assayed materials they use to perform-- in the materials they use in such that they perform with accuracy and precision. Secondly, strengthening the understanding of how the laboratory-- of how laboratory testing might change under the rubric of personalized or precision medicine would be helpful.

Our society is on the cusp of a new era and providing customized and individualized medical treatments to patients. Laboratories will continue to play a significant role in testing for biomarkers of disease. Accurate laboratory data will be of the essence. Standards in molecular controls must be a requirement in a personalized medicine environment. New technologies and instrumentation will require controls and may very well challenge their composition and design.

There is a risk in assuming that molecular testing or customized testing is somehow more robust in its performance, and as such, external controls may not need to be as comprehensive. The opportunity for error may actually be masked due to the apparent simplicity of some of these tests and the opportunity to use nine-laboratorians to perform them. Yet the very complexity of these tests makes them vulnerable to changing conditions.

Enzymes, nucleic acids, molecular arrays, probes and, so on may all be altered over time in underchanging settings, such as shipping and storage. Material and processes are still susceptible to stresses and mishandling by staff. From syndromic testing for infectious disease, to highly complex next-generation sequencing assays or precision diagnostics for cancer, a consistent policy for controls is needed. This will require some adaptation for customization. We know that molecular technologies can now detect essentially an infinite number of diagnostic markers. Future policies should consider what is an appropriate representation and number of targets in a complex control.

The use of in-house isolates and patient samples often do not perform consistently, yet assay performance must be confirmed for traceability and consistency purposes. We urge the CLIA panel to consider these issues as well.

In many ways, the laboratory community is raising the bar already. Some laboratories are following ISO 15189 accreditation to assess personnel qualifications, competence, quality assurance, and the full analytical lifecycle.

Laboratories and manufacturers are already insisting on FDA 510(k) approval of assayed materials. Additional guidance on the use of controls with emerging laboratory technologies will be helpful.

I'd be glad to answer your questions. Thank you for your time.

CLIAC CHAIR: Thank you Dr. Beck. Glen.

MR. GLEN FINE: Good morning. I'm Glen Fine, CEO of the Clinical Laboratory Standards Institute. For over 50 years, the Clinical and Laboratory Standards Institute, CLSI, has been the only globally-accredited standards development organization exclusively focused in the field of laboratory medicine. Its 200-plus standards are developed using an inclusive consensus-based process that balances the interests of government, health care professions, and industry constituencies. CLSI members include almost 2,000 organizations and individuals from 60 countries over 60 countries, including 20 more than 20 government agencies around the world.

CLSI creates and revises the standards that drive quality tests results, enhances patient care delivery, and improve public health around the world. CLSI recognizes molecular diagnostics as one of the most rapidly-developing laboratory disciplines. We specifically identified the need for harmonized global guidance for Next Generation Sequencing, NGS, and is currently revising our guideline MM09, human genetic and genomic testing using traditional and high throughput nucleic acid sequencing methods.

This guidance is especially critical and timely as NGS enters additional clinical practice and areas-- and new approaches are applied to areas in which NGS testing is already used. CLSI's approach to document development always strives to include representatives from all key stakeholders and interested parties.

In addition to providing necessary guidelines for industry and laboratories to implement current best practices and facilitate standardization of NGS test development and validation procedures, the MM09 guideline will also include basic guidance for managing the bioinformatics aspects of next generation testing.

The creation of bioinformatics pipelines for sequencing is rapidly expanding, as we heard yesterday. CLSI recognizes that although limited guidance is available for pipeline validation, it is insufficient for creating and versioning pipelines and managing data. CLSI is launching a separate new guideline, MM25, sequencing bioinformatics for human genetics in oncology to fill this need and expand on the information provided in MM09.

Another area that would benefit from specific requirements or guidance is semantic interoperability. Semantic interoperability for in vitro diagnostic systems is a worldwide topic of interest, and recent initiatives across the globe have highlighted the need for interoperable IVD test results to support the development of big data repositories for recommending-- recommended acquire-- requiring the harmonized use of semantic standards that describe and transmit laboratory data, e.g., LOINC, as we heard yesterday, SNOMED, LAW, and LIVD. Sorry, Val, a lot of acronyms. She said no acronyms, but can't help it.

The digital format for publication of LOINC to vendor test results. In recent years, particularly since the 21st Century Cures Act was enacted, the importance of quality and real world evidence has been increasingly recognized. The harmonized and consistent application of informatics standards to describe and transmit diagnostic information is the key to enabling quality and health data and ensuring its utility in downstream applications.

Semantic interoperability enables real-time epidemiology across geographic regions which is vital to combat major threats to public health, most notably antimicrobial resistance. Structured, high quality, and

electronically-transmittable health care data are critical to safeguarding the integrity of real-world evidence used to support regulatory and clinical decisions and meaningful use reporting and supplemental activities.

Semantic interoperability is also the key to effecting-- effectively using and analyzing big data in the pursuit of innovative health care solutions. Most laboratories strongly favor the enhancements of semantic interoperability, however, it can be difficult, as we heard yesterday, for them to keep up with a range of applicable standards.

To encourage these efforts, CLSI is collaborating with informatics experts to create a suite of documents that one, describe how currently available standards fit together to support semantic interoperability; two, clarify best practices for promoting the benefits of implementing semantic interoperability; and three, outline issues to consider related to semantic interoperability when procuring IVD instruments and software systems.

This guidance will help laboratories understand the capabilities they need to consider when procuring IVD instruments and software systems. It'll also describe what laboratories, manufacturers, and vendors need to consider with respect to interoperability another recent initiatives aimed at improving the integration of laboratory information systems with the electronic health record.

CLSI applauds the efforts of the CLIAC committee in addressing this advanced-looking and forward-looking set of issues, and we stand ready using our mature consensus process to assist wherever we can. Thank you.

CLIAC CHAIR: Thank you. The next comment, PC3 from Dr. Laura Lane, is a written comment only. I'm not going to read it to you, so hopefully you will have reviewed it. The following one is PC4, for the first of two written comments. Two public comments from the American Board of Bioanalysts. PC4 is Dr. Birnbaum, and it is a written presentation only. PC5 is from Dr. Tammie Schalue. Thank you.

DR. TAMMIE SCHALUE: Hello. My name is Tammie Schalue, and I want to thank the committee for allowing me to speak here today. I'm here today representing the American Board of Bioanalysis. I am a certified ABB high complexity director, and I direct embryology laboratories where we do andrology testing, endocrine testing, as well as other reproductive testing for our patients.

And I also apologize, I think my granddaughter gave me her cold, so my voice is coming in and out today. I last spoke in front of this group some 20 years ago in 1998, where interestingly enough, we were discussing the emerging technologies of molecular and genetic testing in reproductive laboratories.

At that meeting in 1998, the committee overwhelmingly voted to recommend that CMS exercise its authority and recognize that reproductive labs be covered by CLIA. However, fast forward to today, and very little has changed in the way these labs are regulated. I do recognize agencies, accrediting agencies such as CAP and Joint Commission have developed reproductive programs and checklists specific for our field.

And the CLIA-- in the FDA requirements for donors-- excuse me-- provide some protection for recipients. The Fertility Clinic Success rate and certification act also were designed to provide protections for these laboratories. However, each of these falls short in assuring through regulation patient quality care and safety. The accrediting agencies have excellent program, but there's no regulatory mandate that say that these laboratories participate. The fertility clinic success rate was intended to be adopted by each state. However, since its inception in 1992, no state has Done so.

And while the FDA HTCP rules do cover donor safety and recipient safety, it exempts reproductive facilities from the majority of the good tissue practices assuring quality patient care. AAB feels that CLIA would provide

the regulatory compliance that patients expect and deserve. We feel like CLIA is the correct fit for reproductive laboratories for the reasons detailed in the written comments supplied to this committee.

I'd like to take just a couple of moments to highlight a few of our comments and the written comments that relate specifically to our laboratories and explain a bit about what we do. In reproductive laboratory, at each stage of the process personnel perform test that are reported to positions that are used to use and diagnose assess the infertile individual and ultimately treat them in current and subsequent reproductive cycles.

When a woman comes in for an oocyte retrieval, the follicles are aspirated, and the aspirate transferred to the laboratory where a reproductive biologist isolates microscopically and grades the oocytes. If there are no oversights or if the oversight number is low, this can be used to diagnose a low responder.

This as well as other information gained from analysis of the is reported to the physician and may be used in subsequent cycles to alter the stimulation protocol call, or in extreme cases, to recommend oocyte donation. Each oocyte retrieved is then analyzed by the laboratory staff to determine morphology and maturity, and determine any abnormalities in the oocyte cohort.

Success of this oversight cycle-- of the ART cycle from these old sites little is then to provide information to the physician for further treatment of the patient in this and subsequent cycles.

Normal oocytes are then fertilized either conventionally or by ICSI which is the injection of a single sperm into the ooplasma of the oocyte. The selection of the sperm for the ICSI process, either ejaculated, ependymal, or testicular in origin, requires skill in assessing sperm quality as well as skill in the placement injection into the oocyte.

After insemination, the fertilized oocyte is assessed, and with conventional insemination, binding and penetration of the sperm into the oocyte is one factor the laboratorian will document. Failure of sperm to bind or to penetrate the oocytes may be used by the position to diagnose male factor infertility.

In addition, the laboratorian will microscopically evaluate the oocyte for abnormal fertilization, such as polyspermy and other fertilization abnormalities. Microscopic analysis of the resulting embryos will continue over the next four to five days. Morphological development of the oocyte will be documented at several times points for cleavage number, shape and size of the cleavages, timing and formation of the blastocele, and the size, cell number, and morphology of the inner cell mass. All of these are critical.

All of these parameters will be used to morphologically grade the embryo to determine which embryos to transfer to the uterus. In addition, this information is used by the physician to assess issues such as egg factor in fertility, and to make determinations regarding future cycles and/or the use of donor oocytes.

The diagnostic assessment of our oocytes and embryos requires as much-- if not more-- expertise and training than the assessment of sperm and the handling of blood in blood banks, both of which are covered by CLIA. Excuse me. ABB strongly believes the failure to include ART laboratories under the purview of CLIA, CLIA provides patients-- places patients at risk, and is in direct contradiction to the mandates of the CLIA statue.

The urge CLIAC to recommend once again that CMS exercise its authority to recognize that ART laboratories fall within the regulatory preview of CLIA. Thank you very much.

CLIAC CHAIR: Thank you, Dr. Schalue. The next comment, PC6, is from Quest. It is a written submission only. The following one is PC7 from the Association of Public Health Laboratories, and Dr. Tonia Parrott will be presenting.

DR. TONIA PARROTT: Good morning. I'm Dr. Tonia Parrott from the Georgia Public Health Laboratory. I'm representing the Association of Public Health Laboratories as a member of the Infectious Disease Committee. The Association of Public Health Laboratories appreciates the opportunity to advise the Clinical Laboratory Improvement Advisory Committee workgroup on how new technologies, workflows, and bioinformaticists are changing the current and future practices of laboratory science. Updates to CLIA in these areas will offer clarification and consistency where it is currently lacking.

Our members routinely work at the leading edge of innovative developments in laboratory practice, and thus have valuable perspective on how emerging technologies benefit public health. APHL encourages CLIAC to provide recommendations to CMS allowing for regulatory language that has broad yet flexible, allowing CLIA to adjust to emerging technologies promptly while ensuring quality and preventing delays in diagnostic and surveillance activities.

Question 1-- are bioinformaticists needed in clinical and public health laboratories, and if so, what are their current roles, responsibilities, and competencies? bioinformaticists this play a vital role in public health laboratories, as they are critical to modern day disease detection and surveillance. In a rapidly-changing field, bioinformaticists are responsible for identifying and building appropriate programs and analytical pipelines helping to interpret results, identifying outbreaks, conducting disease surveillance, and implementing quality metrics.

They are important for successful collaboration with information technology staff, helping build greater computing capacity, and ensuring data security, migration, and integrity. bioinformaticists are necessary for any public health laboratory utilizing next generation sequencing in areas such as human genetics, molecular subtyping surveillance, molecular microbial testing, or other technologies that generate large data sets.

The particular skill set required may be different across laboratories. For some public health applications that provide data to a national program, bioinformatics can sometimes be handled by off-- off-site by a reference entity. However, for programs working locally, including foodborne outbreaks surveillance, newborn screening, or region-specific disease outbreak detection, a dedicated bioinformaticist this may be needed within the public health laboratory. Laboratories may sometimes find it more efficient to utilize staff-sharing arrangements to equip them with necessary tools and skills to meet bioinformaticists' needs.

The competency guidelines for public health laboratory professionals, CDC, and the Association of Public Health Laboratories developed in 2015 address basic competencies for progressing in a career as a bioinformaticist. A CLIAC recommendation for an expert group to update these competency guidelines, including consideration for biology and public health expertise, would improve the characterization of the skill sets required for bioinformaticists. Vis

Question number 2-- what areas exist in CLIA where specific requirements or guidance might be needed to ensure the accuracy and reliability of new and emerging technologies? A few suggestions for where recommendations are needed are outlined below, however, APHL concurs with the April CLIAC meeting report that a thorough review of the CLIA regulations is needed to define all areas where updates related to these fields are necessary.

New technologies such as NGS could have separate specialties. However, if placing new guidance in existing specialties would allow more expeditious release, this may be preferable. Guidance is recommended for qualifications for high complexity testing personnel and bioinformaticist commensurate to the complexity and responsibility of the work. Laboratory leadership provisions should also be reviewed to account for knowledge in these areas.

Our member laboratories have and need a spectrum of expertise and bioinformatics, from qualified users to leaders in the field. Given the breadth of the field, bioinformaticists is currently have an array of backgrounds. Some have strictly computer science backgrounds with hands-on biological science training in the laboratory. Others have degrees in microbiology or molecular biology with thesis projects and/or training utilizing bioinformatics. In some instances, laboratory personnel are trained to perform basic analyses, however they cannot perform the full scope of bioinformatics work.

In other situations, a deeper understanding of the biology is required than can be ascertained by training a computer scientist on the job. Education and experience requirements need to account for the scope of work and diversity of backgrounds and training. Emerging technologies often cannot follow the same validation strategies used in traditional testing and require a dynamic framework for validation as these technologies evolve.

For example, a method-based validation is likely more appropriate than validating each of the genes on a disease-specific screening panel. NGS requires independent validation for the wet lab, bioinformatics, and reporting, therefore, recommendations for handling validation of distinct yet linked portions of a protocol that may even be performed in separate laboratories are needed.

In-house.-developed bioinformatics pipelines need rigorous validation, both with flexibility in interpreting results, since previous standards may be less sensitive and specific. Guidance would also need to address how best to validate pipelines and analysis tools previously validated by an outside entity. For example, tools and services provided through the bionumeric software and the calculation engine used by PulseNet contain analysis parameters that cannot be altered by the laboratory that generated the sequences.

QA and QC guidance will need to be carefully considered for emerging technologies. The use of traditional positive and negative controls are not always applicable in NGS workflows, as numerous other measures, including in silico methods, can be used to assess quality and acceptability of the data generated.

Non-targeted analysis through high resolution mass spectrometry, that for example, quickly identifies things such as designer opioids and cannabinoids in clinical specimens, also does not lend itself to traditional approaches. Bioinformatics does not fit clearly into the QC requirements under the current CLIA guidelines. Guidance related to documenting development of bioinformatics pipelines, version control, and database usage is needed.

The amount of data generated by NGS is unlike any other biological test to date. Data management, including storage mechanism and location, duration of storage, curation, and sharing is a substantial challenge. The database and pipeline used can vary the output, so guidance in how to implement and maintain version control is essential. Guidance addressing storage of raw versus processed data is also needed. Guidance should reflect the different needs of microbial and human data also allowing for extension to other or mixed methods where data may contain sequences of both human and microbial origin.

And biomonitoring programs and other public health surveillance programs where biomarkers of exposure are measured in clinical samples, the applicability of results to patients health conditions may be unclear. Clinics CLIAC should consider providing a recommendation for guidance on whether these tests should require an ordering provider, reasonable reference ranges, and the Public Health Laboratoy's responsibility to provide context in patient education.

Question 3, what data are available that could assist in answering how CLIA may need to be revised? To successfully gather and learn from available data, CLIA will need to continue to collaborate with partners, subject matter experts, and laboratories using new emerging technologies in a multi-stage process to develop a

consistent guidance. There are some data on use and challenges with emerging technologies, including the need for data standards-- for example, next generation sequencing in public health laboratories 2014 survey results.

Since updates of this level to CLIA would reasonably be expected to take years, it is suggested that CMS consider the release of interpretive guidelines for laboratories to serve as a reference when seeking clarification on how existing regulations apply to new emerging technologies. These guidelines could serve as a reference for both laboratories inspectors to ensure consistency across CLIA in a shorter timescale.

CLIAC CHAIR: Dr. Parrott, with--

DR. TONIA PARROTT: Thank you.

CLIAC CHAIR: --all due respect-- thank you.

DR. TONIA PARROTT: Thank you.

CLIAC CHAIR: Thank you. The next public comments, PC8 is from Lucia Berte, it's written. PC9 from Lawrence Kaplan is written. PC10 from ARUP, Dr. Erica Andersen. I will give you a two-minute Warning if you're getting near the end, and then I'll yank. Thank you.

DR. ERICA ANDERSEN: I think I can do this in under five minutes. Good morning, my name is Erica Andersen, and I am the Section Chief of Cytogenetics at ARUP Laboratories. We are an academic national reference laboratory located in Salt Lake City, Utah, and I'm here today to talk to you about a topic that is likely going to be unique to this session, but that does relate to the modernization of the laboratory workforce. And I'm here to share with you our experiences with CLIA certification of home office sites, and to highlight the real-life challenges that laboratories like ours face in using a remote workforce to fill staff shortages.

So five years ago, we began to hire full-time remote site genetic directors and technologists. These individuals perform analysis and interpretation on computers physically located at AAUP using a secure virtual private network or VPN to access cytogenetic images and data. No patient samples or data are sent to, received at, or stored in these home office locations.

We implemented this model alongside local and regional CLIA office consultation and with the understanding that this work would be covered under our central laboratory CLIA certificate lab quality programs. Since then, we have successfully integrated the work of four medical directors and nine certified cytogenetic technologists across 10 different states at our laboratory.

Last year, CAP sent notice to AAUP requiring us to obtain separate CLIA certifications for these individuals, citing a requirement that specimens must be referred to CLIA-certified laboratories for testing. Thus, these home offices are being viewed as testing sites. In our experience and as I hope to illustrate, requiring CLIA certification for this type of remote work impedes rather than improves our ability to provide high quality patient care. First, timelines and requirements vary widely and are either undisclosed or unknown within individual states. Current timelines for obtaining CLIA certificates range from a few months to over a year, and restart when employees move to new locations, which has happened to us with a few of our employees.

In addition, some states do not allow new hires to perform testing until the entire application is approved. Recently we made it-- we waited four months to get a medical director who we hired on clinical service waiting for her inspection to be completed and all of her paperwork to go through.

Second, CLIA certificate sponsors are required for remote technologists and quite quickly reached the limit of five CLIA certificates per lab director, which are in no way equivalent to institutional CLIA certificates. Sponsor qualifications also vary. In one extreme example, we applied for three different directors to serve as sponsors in the same state over a six-month period. Two directors were required to submit extensive educational history, a letter of recommendation, were fingerprinted, and were required to travel to the state for a quarterly board review. A third director took on sponsorship in that very same state without any such requirements.

While this clearly was an improvement, it also demonstrates the variability that we have encountered. The inspections themselves have ranged from two to five hours and vary greatly in content. Inspectors often seem unfamiliar with the home office certification process, and so the burden to educate them falls upon us.

To date, we have received no deficiencies of recommendations and no significant insights, process changes, or improvements have resulted from these inspections. The value provided to laboratories is unclear.

Finally, implementation and maintenance of these certifications creates a heavy administrative burden. In our laboratory, which employs close to 70 certified technologists, and where multiple individuals routinely analyze each case, we must now track and add appropriate home addresses for each remote employee to patient reports they work on, which creates a process both error-prone and impeding to workflows.

Moreover, this requirement creates unnecessary privacy risks to these individuals. Proficiency testing must also be performed separately for each CLIA certificate holder. Our remote employees are now no longer able to participate in CAP challenges and ARUP has had to implement separate recurring PT assessments for each individual.

We urge the committee to further define what constitutes a remote testing site and to provide guidance on the requirements associated with home office locations such as ours Additionally, we provide the following recommendations. First, with proper security and risk mitigation measures, allow for remote home office locations to be administered under a single CLIA certificate. Second, if the requirement for separate CLIA certificates for home office locations is retained, we recommend to improve this process by A, eliminating the home office inspection requirement; B, removing the five CLIA certificate maximum for these types of sites, and C, removing the requirement that home office addresses be listed on clinical laboratory reports. I thank you all for your time and consideration.

CLIAC CHAIR: Thank you Dr. Andersen. PC11 is from API the American Proficiency Institute, and is a written comment. PC12 is from A2LA, and Ms. Kessa Jules will be presenting. Thank you.

MS. KESSA JULES: Hello. My name is Kess Jules. I represent the American Association for Laboratory Accreditation and oversee our clinical laboratory accreditation program. The American Association for Laboratory Accreditation has offered accreditation for over 40 years. It currently holds deemed status for the Centers of Medicare and Medicaid Services and recognition from the International Laboratory Accreditation Corporation to provide clinical laboratory accreditation.

A2LA is the only accreditation body in the world to achieve and maintain both of these formal recognitions. This means a different approach to accreditation services. It means an adherence to international quality management standards, or for clinical laboratory, ISO 15189.

This brings important distinctions to how laboratory oversight is conducted from the bench level to top management. Take for example how laboratory deficiencies are addressed what ISO 15189. Under this standard, laboratory deficiencies are not categorized as major or minor. All deficiencies, by definition, are

considered cases of nonconformity. This means they do not meet the given standard or requirements for accreditation.

Under 15189, it is not unreasonable to expect that all deficiencies will be addressed with root cause investigations and lead to corrective actions. A2LA-accredited laboratories are required to resolve deficiencies by providing records of their root cause analyses, corrective actions, and objective evidence providing that the deficiency-- I'm sorry-- proving that the deficiencies have been resolved. A plan of corrective action is not accepted. And this process instills a culture of continuous improvement and preventative action.

Because of this approach, A2LA reports show where the number of deficiencies actually decline as the laboratories undergo renewal assessments. As CLIA considers how clear may address the accuracy and reliability of emerging technologies, a focus on ISO principles for corrective action and root cause analyses that promote continuous improvements would be beneficial. ISO 15189 would provide support for the clinical laboratory and bring improvements to patient laboratory data.

A second topic to raise relates to the quality of biobanking. Some CLIA laboratories rely on biobanking materials. Emerging technologies such as genomics, proteomics, and the use of biomarkers rely on high quality biospecimens. Another standard, ISO 20387, includes requirements for acquisition, collection, preparation, preservation, testing, and distribution of these materials. While not a direct CLIA responsibility, promoting accreditation of biobanks will help to assure quality materials are provided to clinical laboratories, thereby improving patient outcomes.

A quote attributed to Dr. Carolyn Compton, former director of the Office of Biorepositories and Biospecimen Research at the National Cancer Institute, the quality of data derived from biospecimens can never be higher than the quality of analytes from which data are derived. It only encourages CLIAC to recommend ISO 20387 for the accreditation of biobanks. Thank you for this opportunity to raise these issues today.

CLIAC CHAIR: Thank you, Ms. Jules. The next public comment is PC13 from the CDC. Dr. Atis Muehlenbachs will present. I mutilated it, I'm sorry.

DR. ATIS MUEHLENBACHS: Hello, good morning. I'm Atis Muehlenbachs, I'm the CLIA laboratory director at the Atlanta Campus Infectious Disease Laboratories here at the CDC. These comments are on behalf of the Infectious Disease Laboratories Centers for Disease Control and Prevention. The impact of data-intensive laboratory technologies on the workflow, data management, and workforce requirements of clinical and public health laboratories cannot be understated. Guidance and clarification are needed to perform genomic and metagenomic sequencing, and other data-oriented test systems that will be needed for routine microbiology.

So for the first question, are bioinformaticists needed? Yes. Are they needed in every public health and clinical laboratory? Probably not, so long as these laboratories have access to bioinformatics expertise as needed and can adequately implement and validate standardized bioinformatic analysis tools that are provided as ready to use or turnkey products that can provide end-to-end automated analysis at the push of a button.

However, there are very few standardized commercially-available sequencing based in vitro diagnostic assays on the market that could be performed without a bioinformaticist, and of those, most are slated for a specific and narrow clinical indications that are not applicable to dynamic public health responses.

At this time, infectious disease diagnostics have not been a development priority for most of these platforms, and as such, most infectious disease diagnostic applications will be laboratory-developed tests regulated by CLIA. Standardized tools may partially reduce the bioinformatics need for individual laboratories, and these include tools within centralized systems such as CDC's PulseNet or MicrobeNet that are being set up to perform

automated bioinformatics. This lack of standardization that drives the need for bioinformatics expertise. Without standardized assays and without bioinformatics expertise, laboratories will be unable to incorporate routine sequencing into diagnostic lab-developed test-based workflows.

So for current roles of bioinformatcians, guidance is needed for CLIA personnel regulations. And there are two major roles of bioinformatcians in regard to CLIA. First, there are bioinformatcians that are involved in the development, evaluation and implementation, and upkeep of standardized bioinformatics tools and pipelines that can be integrated into a test system that's operated by a classically-trained CLIA testing personnel. And these bioinformatcians could be based in diagnostics development companies or centralized laboratories.

Second, there are bioinformatcians that are involved in the direct handling and evaluation of patient specimen-derived data within the lab-developed test system. And this may include the cleaning up of sequence reads, assembly and analysis of genomes, determining whether quality control criteria are met, running programs as needed, as well as troubleshooting. And these bioinformatcians would be needed in laboratories that rely on non-standardized lab-developed tests, and these activities overlap with CLIA testing personnel roles.

Responsibilities,. Bioinformatic analysis within a non-standardized LDT system needs to take into account, for example, data and workflow management, including file hashes and signatures and version control, establishing the performance characteristics of bioinformatic methods, reference databases and determining their associated dependencies, process logging and audit, integrated quality control and quality assurance, appropriate standards and controls for all phases of sequencing in bioinformatic analysis, new information security requirements, integration of data into existing laboratory and clinical information systems, and then consultation with laboratory personnel and clinicians.

Competencies. Competencies would include basic knowledge of the biological underpinnings of disease, basic understanding of test design strategy, specialized knowledge and experience in using and developing analysis pipelines for various sequencing platforms, expertise in sequence analysis software, ability to manage the results of outputs, carry out statistical analysis of validation data, data presentation and visualization, they'd collect and monitor performance metrics, maintaining quality standards and quality control, and adequate knowledge of computational and IT infrastructure, including networks and storage systems. So please also refer to the CDC and APHL 2015 MMWR document on competency guidelines for public health laboratory professionals that includes a part about bioinformatcians as well.

OK, so for the second question, what areas exist in CLIA where guidance might be needed? So please refer to the earlier presentation to CLIAC April 2018 for prioritized challenges from a public health laboratory perspective. For personnel, it is difficult to qualify bioinformatcians as CLIA testing and supervisory personnel. Current CLIA personal qualification requirements do not address the bioinformatics skills required for newer sequencing-based testing methods.

Further, at present time, individuals who have bioinformatics expertise and competency may not meet the traditional CLIA chemical, biological, or physical science or medical technology degrees, or have sufficient chemistry or biology course hours.

CLIAC CHAIR: Dr. Muehlenbachs, you have two minutes.

DR. ATIS MUEHLENBACHS: Two minutes? OK. [LAUGHS] OK. So please refer to the written comments in addition to our comments on CLIA applicability, on database practices. Database practices are important. Next generation sequencing and other emerging technologies are database-oriented, database-dependent. And laboratories must validate the database, should also establish a periodicity to confirm the accuracy of the database, whether the database is internal or external, static or dynamic.

Guidance for controls is needed. Guidance for specimen and data identification integrity is needed, particularly as data crosses certificates, including association of a patient identifiers and traceability to the files themselves. Guidance on validation is needed. And please refer to the written comments regarding guidance for data retention and reporting.

What data are available to assist CLIAC in developing guidance? Please refer to the written comments for examples of databases, including CDC MicrobeNet and FDA-ARGOS that can be looked at for examples of good database practices. For controls, our CDC laboratories are willing to share individual laboratory control data for individualized quality control plans. And last, these external resources looking at validation data across laboratories that are in the written comments in addition to an example of a glitch that affected results reporting based on computer operating systems that I think is a valuable insight to how precarious some of our systems are. So thank you for your time and for these comments.

CLIAC CHAIR: Thank you, Dr. Muehlenbachs. PC14 is from AACC. It is a written comment. PC16 from Wyoming Public Health Laboratory, written. PC17, Association for Molecular Pathology, written comments. PC18 from the College of American Pathologists, Dr. George Birdsong.

DR. GEORGE BIRDSONG: Can everyone hear me? I'm kind of a long way from the microphone. Good morning, I'm George Birdsong and I'm a board-certified pathologist and director of anatomic pathology here at Grady Hospital here in Atlanta, and a professor at Emory University School of Medicine right down the street here.

I'm here today on behalf of the College of American Pathologists. We thank you for the opportunity to provide comments to CLIAC on emerging technologies-- excuse me-- and the clinical laboratory, because of its important role in assuring the accuracy and reliability of clinical laboratory testing.

As the world's largest organization of board-certified pathologists and a leading provider of laboratory accreditation and proficiency-- proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

With the rapid changes in technology and integration of the health care delivery system, clinical laboratories are no longer just standalone sites, but are an integral part of health systems. Such systems include at least one hospital and one group of physicians providing comprehensive care that connect with one another in the hospital through common ownership or joint management. Moreover, these health care systems are using advances in technology to perform clinical laboratory testing in a myriad of settings that are closer to the patients.

The Clinical Laboratory Improvement Amendments of 1988 provides an adequate baseline to ensure the accuracy and reliability of clinical laboratory results, but we recognize that specific updates to CLIA are needed to address and accommodate the changes in practice and technology. I will focus my remarks on areas where CLIA can be enhanced to assure the accuracy and reliability of these emerging technologies.

We have also submitted a written statement to the record that includes additional data for your reference. The CAP is dedicated to assuring accuracy and reliability of next generation sequencing-based testing in clinical laboratory settings by offering accreditation and proficiency testing. Since publishing our first NGS-specific checklist for the laboratory accreditation in 2012, we have continuously worked to improve and update the checklists to reflect advances in NGS technology and the ever-growing diversity of clinical applications to which NGS is being applied. The CAP continually revises the NGS checklist to add recommended metrics and quality control parameters for this dynamic field, including the standalone bioinformatics facilities.

It is important that a proprietary or complex algorithm, . including bioinformatics used in the generation of a test result, has oversight since it is an analytical component of high complexity influencing the clinical laboratory testing results. As such, CLIA certification should be required of any organization performing portions of the testing process, including application of proprietary or complex algorithmic interpretations of a clinical laboratory test that generates an individual result, whether or not that organization receives or processes physical specimens.

In ensuring the accuracy and reliability of NGS testing, personnel requirements for bioinformaticists are needed for clinical and public health laboratories since these roles need specialized expertise. bioinformaticists are responsible for analysis of exome and genome scale data sets as well as being able to align multiple algorithms and perform variant calling and annotations.

They also need expertise in interfacing software with the existing laboratory information systems. Therefore, bioinformaticists should be designated as testing personnel within the CLIA regulations.

To develop these personnel requirements for bioinformaticists, health informaticist qualifications can be leveraged as minimal requirements. Health informatics professionals use a methodical application of information technology and computer science and health care with the goal of improving patient care by increasing the effectiveness of treatment and the efficiency of its delivery. Health informaticists work with other health care professionals to design, develop, and assess ways to collect, share, standardize, and integrate health data with-- and the information systems used to manage it. Given these similarities in functions, CLIAC should consider incorporating similar requirements into CLIA for bioinformaticists.

Since the inception of CLIA, new and emerging laboratory technologies and nontraditional testing workflow models, including next generation sequencing, biomarker testing, metagenomics, and point-of-care testing have exploded in clinical laboratory testing. These dynamic technologies range across several specialties and subspecialties while evolving quickly through continued rapid advancement. As such, CLIA specialties in subspecialties should not be expanded since each application within a specialty and subspecialty would have notable differences that require additional specificity which is not feasible in a regulatory process.

The CAP accreditation program continuously works to improve and update the checklists to advance-- to reflect advances in NGS technology and the ever-growing diversity of clinical applications to which NGS is being applied. Since 2012, the CAP has revised the NGS checklist items six times to add recommended metrics in quality control parameters for this dynamic field.

Regardless of where any of the test components are performed, laboratories should observe good laboratory practices throughout the total testing process. Instead of developing regulatory requirements for new emerging technologies and non-traditional workflow models, the focus should be on recognizing bioinformatics, including standalone facilities, as subject to CLIA, adding personnel requirements for bioinformaticists, and revamping the PT requirements to test the total testing process.

This includes all aspects of clinical laboratory testing performed in a distributed testing model, such as a non-traditional workflow model. For example, bioinformatics and cloud-based software computing. Also, an important quality metric in determining clinical laboratory testing accuracy and reliability is to perform PT. Laboratories should perform PT by observing the same good laboratory practices they do for patient samples, including moving samples and/or data among multiple sites to complete all aspects of testing.

CLIAC CHAIR: Dr. Birdsong, you have two minutes, thank you.

DR. GEORGE BIRDSONG: Doing so should-- should not constitute intent to commit proficiency testing referral. The CAP PT program allows laboratories to evaluate their performance regularly and improve the accuracy of the patient results they provide. In 2015, the CAP launched PT for an NGS in which laboratories can test up to 200 variants in a method-based challenge using either gene panels, exome, and/or whole genome sequencing.

The initial NGS PT program designed to assess the ability of laboratories to determine germline variance was followed by NGS PT for the detection of somatic variance and other NGS clinical testing applications. The program can test the wet and dry bench components of NGS testing. Under the current regulatory paradigm, clinical laboratories are unable to test their total system if a portion of the tests are performed in a non-traditional workflow model. This makes it difficult to assess the complete process and an implementation of a potentially good quality indicator.

Laboratories are increasingly added exome sequencing tests to their test catalogs. Between January of '16 and March 2018, the number of the number of sequencing genetic testing units in the market grew from 72 to 125, a 74% increase. During the 12 months ending March 1, 2018, a total of 801 new test panels entered the market. These testing products are entering the market at a rate of 15 per week.

CLIAC CHAIR: Dr. Birdsong, 10 minutes, thank you. There are two additional written comments that were submitted yesterday, PC19 and PC20. Both from ASCP and the latter specifically from the ASCP Board of Certification. That concludes all of the public comment. I want to thank the speakers for travel and donating your time to help educate and inform committee panel members.

The questions. Based on what we've learned today, the agencies are seeking our comment and input on these questions. So I'll just read them. Do you have any specific recommendations in response to the three questions? How might-- we need the three questions. There we go.

Number 1, are bioinformaticists needed in clinical and public health laboratories? If so, what are the current roles, responsibilities, and competencies of bioinformaticists in these settings? Number 2, what areas existing CLIA or specific requirements or guidance might be needed to ensure accuracy and reliability of new and emerging lab technologies and non-traditional testing workflow models, including in NGS biomarkers, metagenomics, and others? And the third, what data are available that could assist in answering how CLIA may need to be revised or where guidance may be needed to ensure the accuracy and reliability of emerging technologies?

I'm going to open the floor to conversation. Do we have specific recommendations is what we are being asked. How do the public comments inform the focus, direction, and the priorities of the workgroup that will be convened in the near future? And then what specific actions should the agencies consider taking in response to the public comments?

So if we could move back to the previous slide, I think the first question was relatively more encapsulated. It is 9:40. We will be taking a break, and we will be ending this meeting at noon, so I want to be mindful of time. Lee has his hand up.

CLIAC CHAIR: So I think that based on the public comments and sort of implied by this, that with respect to the importance of people with expertise in bioinformatics, I think that that's an important area to be-- that needs to be explicitly articulated along with the competencies. I think the other piece we heard is that those individuals fit in two places. One is with respect to test development as it's being developed, and the second is as it's involved in direct patient care in terms of analysis and reporting.

And I think that CLIAC needs to consider, but it seems to me that the role of CLIAC really would be in the latter, not the former, much the same as CLIAC doesn't regulate what manufacturers are doing specifically to get the approval of the personnel in the development phase. There obviously are standards and FDA approval and the data and so on, but I think that identifying the distinction between the development and the actually direct patient care provision is important, and there probably is-- we heard in the personnel group-- we need to make sure we understand where does that process of patient care actually begin?

CLIAC CHIAR: For the record, I would like to note that Susan Gross has appeared.

SUSAN J. GROSS: I'm definitely here.

CLIAC CHAIR: Go ahead.

CLIAC MEMBER: So the CDC, that was-- it shows up in so many of the comments, and the bioinformatics piece really is divided up into two. Your comment about where patient care begins-- so where does our responsibility begin? But those that are maintaining the pipelines, they-- it does impact, I believe, on patient care and what's going on in the lab. They just kind of bifurcate to a certain extent, but they're really intimately involved with that patient data.

And I know FDA, like other centers, are looking at how to make those definitions, because it looks like they're-- we're using one name for two different roles. So I just want to put that up for discussion also, that just defining that. My own thought is that they both really are critical to the lab. It's not just the technical computer scientists, they're called bioinformaticians for a reason. So I'd like to make sure we discuss that as well.

And I think it might fold into the next bullet-- so I don't want to mess this one up because it's a little-- it's nice and tight, but this idea of working remotely. A lot of this work can be done either remotely or in the cloud. So I'm not sure if we want to keep that discussion distinct, so we can keep bullet 1 nice and a little tidier. Thank you.

CLIAC CHAIR: Thank you.

CLIAC MEMBER: Just following with her comment. I think the definition need to be more fine-tuned, too, so that adequate recommendations could be made, and I think a few of the CDC and APHL reference foundation with the publication for the competencies that might can be a starting point that could help define the roles and responsibilities as well as some of the other comments, and I think that's the beginning. We need to start there.

CLIAC MEMBER: Thank you. The-- I thought the comments from the representative from ARUP around cytogenetics and the working-- work at home were very much-- were very good and-- there were some very concrete recommendations in there, which I thought we should-- I'm not as familiar with the regulations around at-home test-- at-home workflow, but that seems to fit directly into what we talked before about nontraditional testing workflow models.

And their issues with the cytogenetics I think could-- seem to be very much in line also with the comments from ASCP around digital pathology. They seem to be almost exactly mirroring each other. So that seems like that would be a ground-- fertile ground for us to have discussions around and possibly look at some of those very concrete recommendations that the ARUP representative mentioned since they have obviously had some extensive experience in that area. This seems like those would be good starting points for conversation for us.

CLIAC MEMBER: It seems to me that the 20 comments that we have fall in line with the three working groups that we had, whether it was the personnel group or the non-traditional workflow or NGS. Would it be

appropriate that those groups look at the recommendations that were under their purview, if you will, and maybe those groups come up with recommendations? I think discussing 20 different widely-varied topics and coming up with recommendations this morning might be difficult for us, whereas those workgroups who have already talked through those processes for a couple-- couple of days each might be better suited to do that.

CLIAC DFO: So just a process comment. Workgroups cannot provide recommendations. Workgroups can take a thorough in-depth look at a particular topic on behalf of CLIAC and may present a report to CLIAC, but only CLIAC may make formal recommendations.

CLIAC CHAIR: So I don't know who's typing.

CLIAC MEMBER: Yeah. So I was going to comment that I think out of this discussions, there were two themes that seem like they should be fertile ground to move forward. One is this idea that home inspections or these inspections of home offices for cytogeneticists and others don't add a lot of value and need to be simpler. And the second is I think around that second one, that we need a definition for bioinformaticists as a high complexity lab personnel and a high complexity lab, and we need to figure out what education and experience requirements should-- are needed to function as a bioinformaticist in a clinical diagnostic lab.

CLIAC MEMBER: Man, I think one of the things that's still is needing to get some fleshing out is, if you are connected to a virtual network, are you not sitting in your office at your institution? And this seems to be a technological misunderstanding that people making legislation don't understand the IT technology behind. That you're in your home, so that's your office, you need a CLIA license, it's ridiculous in my professional opinion.

When the-- like I'm connected to my computer right now in Salt Lake City. I'm not working in Atlanta. I'm not working right now, I'm just-- as an example, I'm showing you that I'm connected through CDC to my office in Salt Lake City. Why on earth would I have a CLIA license to be here? Or when I'm in a hotel at a national meeting and I'm doing review, why-- the whole concept is, if you sit back and look at it, doesn't make any sense given the technology we have.

So I think before we get too far into defining whether we need licenses, we need to make inspections more streamlined, do we even need this? If an institution can prove that the data security is in place and the virtual connections to the host network at the institution are sound, it seems like we're applying an old standard to a very new technology, and I think that's going to be a vast error in our thinking. So I think we need to look a bit earlier in the discussion than just how to make the inspections better. Should this even be getting to this point?

CLIAC MEMBER: [CMS EX OFFICIO] with this fall under the reducing burden? Would this fall under the reducing burden that you spoke about? Undue burden? I totally agree, because I'm pretty sure all of us that have lived through this or even considered what we just heard in that presentation, this could be something that could be dealt with. And that's why he's asking how we have to start with the bullets, because it does have to do with workflow. That's-- it absolutely is within the purview of today's meeting, so I'm just wondering if--

CMS EX OFFICIO: It would only involve burden if we made changes to what we currently had in the regs regarding cytology.

CLIAC MEMBER: So I was thinking reducing the burden of the-- I'm just trying to understand that better what you mentioned yesterday, because it's such an important concept. The burden of having to regulate in this fashion people who are working remotely with today's technologies. Does that fall under the scope of the burden or the burden issue when we're talking about putting things in the mailers?

CMS EX OFFICIO: I think it's talking about burden-- when I'm talking burden like we did the other day, it was actually implementing a certain-- in the very beginning that what it's going to do. This process is already in place where we do require them to have the CLIA certificate. And we have a regulation says they have to have the name and location of where the testing is being performed.

So if that person is sitting in their living room at home, that's where they're doing that test, that's where they're reading it, that is why their name-- and I agree. We've talked about that being an issue. We've talked about having surveyors go to people's homes. So it's not something that we haven't thought about and discussed. I mean, I can tell you that we are concerned about that as well.

But we also want to make sure that that person doing that testing in their living room or in the airport or wherever-- I have a problem doing stuff in the airport-- sorry, I do. Because that's not a secure location no matter what you have in my opinion.

Well-- but there are people that do testing in airports, they do them in hotel rooms, they do them in cafes. There's a problem there. Because you don't know what's going on in the world nowadays with all that kind of stuff and how people can see that. But I get the concern about that.

But anyway, our concern is making sure that that person, wherever they're doing that testing, is qualified, and that by having that certificate, kind of indicates that yes, they have the responsibility, they know what they're doing, they're going to be OK.

CLIAC MEMBER: So that is exactly the point. That's what we should be looking at. What security requirements are required to do that? So actually, nobody should be anywhere near a electronic health record or anything like this without a very strict VPN and firewalls.

CMS EX OFFICIO: Exactly.

CLIAC MEMBER: So rather than-- like we're not regulating perhaps the right thing in 20 almost 20, and that would be something that could be of real value, is to assess what are the regulatory issues regarding security rather than what we currently have, which we-- it really is a burden and it impacts patient care, it takes months to get people on board who sometimes aren't actually going to wait four or five months until you get them on board.

CMS EX OFFICIO: I guess it is an area that we've been struggling with, too. To provide the right amount of oversight and also respecting the person that's working in their home, but also making sure that that patient is protected. So it is a fine balance, and it's not something that we haven't thought about and discussed.

CLIAC CHAIR: In the nontraditional workforce model workgroup meeting, one of the recommendations-- I'm sorry-- one of the models that was presented, that if you're doing the spoken hub model of laboratory testing where everything is centralized through a single location with VPN access and all the security and all that, that there was a strong feeling there should not be the requirement for disparate licenses. I can't seem to find the recommendation table to know if it made it as a recommendation, but we certainly did debate that. OK.

CLIAC MEMBER: I think [CMS EX OFFICIO], if you think back to when the requirement for the name and address of the testing laboratory to be on a report, it was way before you could do work from home. So, I mean, I think using that-- I'm trying to figure out how to say this, but you're saying that you're trying to protect patients, whatever, and if you set up a VPN, you can do that from home, you can do it from a hotel room. So I think using that as a reason for why it's required, I don't think that's an adequate one. I mean--

CMS EX OFFICIO: That's the regulation right now.

CLIAC MEMBER: Yeah. But the regulation was before-- yeah, but it was before you had the ability to VPN from home to your desktop to look at lab reports and help finalize a report, certify a report, put your opinion on it, et cetera. And I agree, it's ludicrous, in [CLIAC MEMBER] words, to require that now, because I could be sitting on an airplane with my VPN connection doing laboratory result review.

CLIAC MEMBER: Well, so I think that-- I agree. And so I sent Heather-- and actually, I updated the proposed recommendation that was there that's sort of consistent with I think what the nontraditional group came up with as well as others, is that basically-- I changed it to say, CLIA recommends that when individuals are performing patient care through interpretation and reporting of patient results, so I wanted to distinguish that from analysis, right? Using a virtual private network be considered to be performing those services at the primary performance site where a CLIA certificate already exists and adequate security measures are in place.

CMS EX OFFICIO: I just want to respond back just in general. A lot of what we've talked about here today are things we are discussing, we are aware of. Part of the reason we did the workgroups was to get recommendations and we're working to resolve a lot of that issue. We're dealing with 30-year-old regs that have not kept pace with technology. And unfortunately, we're dealing with things that cannot be changed at a moment's notice. So you need to bear with us a little bit on some of this because we are aware and we are trying to address a lot of these issues.

CLIAC MEMBER: No, I agree with [CLIAC MEMBER] recommendation. I'm just going to say, do you want to use the technical term VPN or just use a more descriptive in general terms such as secure since it might be something different in three years?

CLIAC MEMBER: Yeah. I think that's general. All right. I realize that the reason I'm so schizophrenic is as others, I actually have two computers here, which means I'm now at three places at the same time.

CLIAC CHAIR: OK.

CLIAC MEMBER: So an answer to what [CMS EX OFFICIO] was saying, other industries are suffering the same challenge. Consider the music industry and the change of the way music is delivered. I can share with all of you that last year in 2018, the Music Modernization Act was signed after about 15 to 20 years of musicians and music-makers fighting to change. And I would propose that that might be the strategy. It was signed pretty much bipartisan, and this would be something that would be completely doable.

So perhaps we consider doing a CLIA Modernization Act where we begin today in formulating the topics that we've just heard from the public and identifying specific areas that we begin to formulate under a modernization act that I understand has to do with regulations. But that sounds like it's time to do that with the technology that's available.

CMS EX OFFICIO: There are already efforts for that.

CLIAC MEMBER: Great.

CLIAC CHAIR: I do want to comment that the recommendation from the April 10-11, 2019 meeting on the nontraditional testing workforce model, it is recommendation number 2. Any site that performs an activity that involves such data-- big parentheses-- shall be considered a laboratory if that site is not an extension of an existing CLIA-certified laboratory. So it's already a recommendation, and the current status is that CMS and CDC are collaborating to determine the path forward. So I would like to say this is a major concern, we're

hearing it from everywhere, but it's already being addressed. I would like to take that off the table, it's generating a lot of discussion.

CLIAC MEMBER: And that was actually only my question for [CMS EX OFFICIO], was should we bring up these recommendations to make sure we're not being redundant?

CLIAC CHAIR: Yes. So thank you. We should. All of you can help me, we are being redundant in this situation. So thank you.

CLIAC MEMBER: Yes, thank you. So clinical laboratories obviously are made up of the people that run the laboratories and are involved in the interrogation of tissue and sending the results, and with emerging technologies and certainly informatics, the ability for CMS to interpret is critical.

But I do think there is one element, and that is the personnel, and being able to recognize the various personnel and define or defer to those various expert bodies and accrediting boards for the qualifications and then adding the responsibilities or what have you is critical. It helps in recruitment, and certainly in the organization that I work for at Kaiser Permanente, having a license and having your field especially recognized I think is critical.

So it seems like given the shortage of laboratory professionals being able to address those adding the personnel that were perhaps overlooked previously, but then sort of emerged more recently and then ongoing those ones that we haven't yet foreseen.

CLIAC CHAIR: OK. So I want to comment. There were a couple proposed recommendations on the screen, but what I'm hearing, these are-- some of these recommendations contained more than one issue and they overlap. I'm hearing very strongly, we didn't give Dr. Luis Chiriboga appropriate attention yesterday, but I've heard both last night and it's showing up today that there is some sense we should include his histotechnicians and histotechnologists as a new personnel category, and perhaps we should merge that under new personnel recommendations. Histotechnician, histotechnologists, and secondly, bioinformaticists.

And I'm struggling with the assisted reproduction technology laboratories, whether or not those individuals would require a separate category over and above what a clinical lab scientist requirements would cover. OK, [CLIAC MEMBER], you had your hand up.

CLIAC MEMBER: Well, didn't we—[CLIAC MEMBER] have that as a recommendation-- as part of our information that came out of our workgroup? And I thought we did recommend adding histotechs already.

CLIAC CHAIR: But it was poor committee time management yesterday that we never made it a formal recommendation.

CLIAC MEMBER: No, I mean I think we did it last spring.

CLIAC MEMBER: Well, the issue was that that wasn't a specific question that was to the workgroup. So there were additional items at the end and that was an additional item at the end.

CLIAC MEMBER: So I guess I'd ask the question of the accredited CMS in CLIA that if the reproductive scientists or the histotechnologists are sort of already covered under the two and four-year that-- and if there's still that much question and discussion about it, perhaps a simple update that they're included in the four-year scientist in the two-year-- I mean, I think we just have to maybe recommend clarification, because it sounds like it's-- those things are recovered, but because they're not specifically called out, people don't realize that they are or are afraid to act accordingly because they're specifically not mentioned.

CLIAC MEMBER: Yeah, I agree with adding bioinformaticist, histotech, histotechnician. I'm not sure I understand the gap with the fertility labs. I think the fertility lab staff who work there either do activities that are not covered under CLIA, such as the embryology, or they do clinical lab testing, body fluid chemical testing that's already well-defined in CLIA. So I'm just not entirely sure I see a gap for fertility labs, or maybe am I missing something.

CLIAC MEMBER: So I guess my question would be not so much as are they associated with testing, but they're in some way similar to a blood bank where you're doing the pre-testing for something that's going to be placed into somebody, and that's kind of where I see the overlap or maybe they have to be lumped in with that kind of product-- not to confuse a person with a product, but that actively giving a component to somebody that will be used by their body in some way, shape, or form. That's kind of how I took the comments.

CLIAC MEMBER: Yeah, having had at least some contact with an ART lab where I work, the testing is relatively complicated and unique. And my own-- it's a gestalt thing, right? My own gestalt is it probably is related to patient care in my opinion. My mic doesn't like me, it turned itself off. But if we are going to classify the personnel, does that deal with the issue of the laboratory being identified under CLIA? Which I think was the request of the presenter. And I could have some other questions, but let's talk about that.

CLIAC MEMBER: I think that's an interesting point about-- that you're manufacturing a biologic that's going to be implanted, which makes me think of the tissue regulations which fall under another branch of the FDA. And I wonder if we need to consult those-- the tissue guidance and the tissue regulations much like blood bank where-- part of blood banking is FDA-regulated and part of blood banking is CLIA-regulated, and we typically live happily under that gray area where they intersect, and I would suggest that we perhaps step back and also look at the tissue regs and consider what's covered under those.

CLIAC MEMBER: And that was my-- embryology just doesn't fall under CLIA, So it's not-- it's not that it's not important, that it's well-done and well-regulated, it's just that embryology discipline doesn't fall under CLIA, and the lab testing done in these environments I think is usually pretty clearly defined as a body fluid or chemical test or is fitting under CLIA now.

CLIAC EXECUTIVE SECRETARY: In case it's helpful and any of you who do have access to the CLIAC recommendation table, if you would like to see the recommendation that was made in 1998-- granted, there have been many years passed since then, but when this issue was brought up to CLIAC in the past, the recommendation is on the table-- the recommendation table. I don't know how you can access that. I'm going to read it.

The recommendation that came from CLIAC at that time said, require the embryo laboratory procedures determined to be testing be under the purview of CLIA. And the status that has been there for quite some time now said CMS has determined that it will not cover embryo laboratory procedures. Some are strictly product evaluation, which isn't covered by CLIA; others both clinical and in the scope of the practice of medicine and therefore not in CLIA. So just in case that's helpful.

CLIAC MEMBER: I would suggest that they probably fall under FDA regulations and they're-- and well I know that they do. As a matter of fact as reproductive materials, they would fall under the same regulations as stem cell products and other cellular products. So it's a very valid concern, and I'm glad that it was brought to the attention of this group, but I think perhaps we could consult with our colleagues at FDA for some clarification of what they control, because I think there are regulations that perhaps need to be enhanced, but there's a regulatory body that specifically oversees tissues.

CLIAC MEMBER: Yeah, and I think that that's correct. And I have in the past been a surveyor for the Institute for Medical Quality which surveys ambulatory practices, and some of the ART facilities have been surveyed, there was one a couple of years ago I did in San Francisco that the problem was not-- because the lab group in the lab folks at-- in California don't regulate that facility, but that the big problem was that they were doing endocrinology type testing, which is CLIA-regulated, and they didn't appreciate-- appreciated that they needed to have a laboratory director who qualified as a laboratory director and actually do what was needed for the clinical laboratory type testing they did.

FDA EX OFFICIO: Yeah, so unfortunately I'm from [INAUDIBLE], so I don't have the detailed understanding of the CBER regulation, but I can certainly bring these concerns back to colleagues at CBER, try to get some more information in that area.

CLIAC CHAIR: Thank you. So we have a number of ideas swirling around, and before I let you talk, I do want to let folks know in the April meeting, CLIAC did have a recommendation that came out of the NGS workgroup, and we recommended the creation of a new workgroup with the charge of advising on how CLIA might specifically be updated, integrated, and reflecting the reports by personnel, nontraditional workflow models, and the NGS workgroups.

So that's what we are being asked to do today. What specifically-- we're going to create this new workgroup, what do we want them to address, what do they want them to come out with? What I'm hearing very loudly is we want them to address remote access and lab testing. We want to hear about what is the definition and the training requirements and the competency requirements for bioinformaticists. We want to hear for reproductive laboratories and histotechnicians and histotechnologists. Do they need a separate category under CLIA or do the existing high complexity regulations capture that?

And then what I'm hearing today is for the licensure and accreditation of reproductive laboratories in general, are we going to draw a line between CLIA-regulated activities and tissue oversight, which is historically a CBER-mediated thing. Did I miss anything?

CLIAC MEMBER: And the communication of lab results, including the critical-- oh, the panic, the alert all of our consumers, which include our patients.

CLIAC MEMBER: And I do want to support the recommendation that we not be too specific about how the information is conveyed between the home office to the-- in making the interpretation. And I may be taking a little bit of a gray instance, but I'm thinking of 15 years ago when I had oversight of an HLA lab, and in the middle of the night when we needed to decide whether we could transplant or not, we made a PDF from the flow cytometer, we faxed it across many states-- actually to Atlanta-- where the laboratory director of the histocompatibility laboratory would look at it, would make a decision on whether or not we could cross-match, did that interpretation, and it was reported out granted from the laboratory that did the flow cytometry testing.

But the point I'm making is that I think there's decisions and interpretations that have been made for many years at home, and that tech-- that it's becoming more prevalent with the new technologies, but I just urge us not to be too specific about exactly how that information is being communicated one way or the other. Faxes work just fine 15 years ago.

CLIAC CHAIR: Thank you. I am going to propose we take a 10-minute break while this gels in our heads. I see five recommendation-- proposed recommendations, and I might be wordsmithing it because I think we can condense it down. So we will convene at 10:20 thank you.

NOTE: CONTINUATION OF DAY 1 WORKFORCE DISCUSSION

CLIAC CHAIR: We have rather a tight window, and we have a lot more conversation I think will happen. But in the interest of flipping back to yesterday, and first completing the open motion that we never fully resolved, which was on workforce. And we were wordsmithing the issue around HRSA HCOP program and how to disseminate that knowledge. We will be bringing up the motion worded as we left it. And I'm hoping we can put that one to bed before we come back to what we're talking about today.

So we were discussing proposed recommendation number three. And where we last left it was CLIAC recommends that CDC create an online library of clinical laboratory educational resources for use by organizations for their own post-baccalaureate training of clinical laboratory professionals. The discussion around this was fairly wide-ranging, all the way through NAACLS standardized curriculum, with finally resolving on the intent that what we want to do is on-the-job training taking advantage of didactic material generated elsewhere for us to customize in our own laboratories to provide on-the-job laboratory training. Is there discussion on this motion? I'm sorry. The motion is open, yes. So is there further discussion?

CLIAC MEMBER: Yeah, I will speak in favor of the motion.

CLIAC CHAIR: OK, I'm going to give you seven seconds. There being no further comment, I'm going to call for the vote. All in favor, say aye. Any opposed? Any abstentions? Motion carries. For proposed recommendation number four, if I can just squeak that in, we were very interested in the virtual reality training, and we want to understand how that type of training can be used to produce competency-based outcomes in the real world setting. In other words, can you take something you're seeing in your mind, in your brain, and does that translate to musculoskeletal competency? How you use a microscope, how you streak a plate? We would like to know that relationship.

CLIAC MEMBER: Because it's already, it sounds like it is already being piloted, is there data for us to currently see on the virtual reality she just released?

CLIAC DFO: So the course is being piloted, but what we are not currently doing is to evaluate it from a competency-based outcome perspective, to compare the value of virtual reality training to in-person training. So that that's not in our scope at the moment.

CLIAC MEMBER: Yeah, I was a proponent for this. And that was the intention, because CDC has created these great virtual reality training courses and put them out there and related to number three, there's a shortage of programs and clinical science particularly. This is addressing a shortage of clinical science that we would like to pilot the outcome studies to show that doing a virtual course on cleaning a hood that exists or streaking a plate, or other virtual courses produce the same competency, the skills are the same from a live, clinical site lab training, compared to virtual reality.

CLIAC MEMBER: I agree. And I think that as it gets better, that will happen. And for frankly, all of us who don't live in Atlanta, when we get on the plane to go home, it is very likely that the pilot may have been certified entirely based on a simulator. And so the simulator is good enough now to do that. So I think what we're saying is, getting to the same point as other industries have done.

CLIAC CHAIR: I realize we have not proposed this as an official motion. Is there a motion to approve this? Is there a second? OK, further discussion.

CLIAC MEMBER: My comment is more of a semantic one, in the sense that instead of just saying simulation-based training can be, should say is and can be, because there are many virtual training systems out there.

Labster is one that's commonly used in Europe, and a lot of universities and colleges have adopted that. So I think our study needs to say what is being used, and how it can be used.

CLIAC MEMBER: So just to bring it back to simulation clinical sphere, which has been amazing, we sometimes do simulations for just rare events. So shoulder dystocia is rare. You will only probably ever be trained on a simulation, till you have to deal with one yourself. Just to, I don't know how to make sure this is addressed. But I would assume that you can do the simulation, you can learn skills, but you still have to do real world-- this is one of the ways of exposing and getting extra training. But you would still need to do a certain amount of hands-on. I think there is not a replacement.

CLIAC CHAIR: I think that's what we're asking for the assessment to be. Could this replace hands-on?

CLIAC MEMBER: Yeah and I think that's the question. And I know that it wasn't MLS program in the region. And it was mainly simulation-based labs and not lab labs. I know our program is blended learning, but all physical labs, you're streaking plates. I think what we want to know is, how far can you go? How much can you do simulation, virtual reality, what requires a checkoff now that you come to the lab and actually set up a hood or streak a plate? Does the final exam have to be live? I think that's one of the questions we need to find out, is how far can simulation go, because that's going to alleviate a lot of stress on clinical site placement for MLS out of Texas [INAUDIBLE] and others.

CLIAC MEMBER: Well, OK, from simulation background to not have real hands-on live, we don't do that in clinical medicine. So just--

CLIAC MEMBER: I just have a question in reference to the pilot research. My question is, are there no Cochrane database systematic reviews done already? Do we know that? I'm trying to see, do we really need to do the pilot? I would just ask, what's out there that may be able to launch us forward and be able to use that data to be proactive? And that I don't know. Does anyone--

CLIAC MEMBER: I don't know the answer to that, but my comment was the same in that we shouldn't restrict them to pilot research. Perhaps research or assessment of existing. To your point, I don't know that they have one, but I know there's products out there that might be able to be assessed.

CLIAC CHAIR: So perhaps we should change the word research to ongoing assessment. Further discussion. I'm going to call the vote. All in favor? Any opposed? Any abstentions? Thank you. Motion passed.

NOTE: CONTINUATION OF DAY 2 EMERGING TECHNOLOGIES DISCUSSION

CLIAC CHAIR: I want to say the other workforce issues that were brought up, we did not have adequate time to discuss. And in light of what we're going to talk about now, which is today's session, I would like to flip back to our conversation before the break. So if we could bring up the proposed recommendations that came through and then, I added my two poorly worded ones at the bottom. Right. So I think it's a different file.

So, to just reorient us, I saw many of the intertwined issues in each of the recommendations one through five. And I tried to consolidate at the bottom and focus it on what we would like the new workgroup to address. The workgroup that we have asked to be formed. There's three issues that were brought up this morning that sounded loud and clear. And once again, I want to remind everyone, the issue about remote access and separate CLIA licensure is already a recommendation under discussion between the agencies. So we do not need to repeat that recommendation. That leaves us with two. And if we could blow up the two, because I'm blind, so I can't quite read it, at the bottom. Heather, we could make that bigger. Yeah, good.

CLIAC CHAIR: I thought it was just me. So I just I just want to frame the two rewordings as I did as number one, do the existing CLIA requirements for moderate or high complexity testing personnel. Encompass activities performed by histotechnologists, histotechnicians, bioinformaticists, and assisted reproductive laboratory testing personnel. So that rephrasing was addressing, do we need to create new and separate categories, or do our existing definitions umbrella them, and we can put them into the respective categories?

And then the second thing I wrote down was, should laboratory testing performed in assisted reproductive laboratories be regulated by CLIA and the embryology? And I don't have the right word, but the stuff that results in embryology and transplant and all that be regulated by CBER. So open for discussion, either anything on the top five or if you're happy with my two in the bottom comments about that. Jennifer?

CLIAC MEMBER: Two comments. On the first one, would this also be an opportunity for the discussions that you asked yesterday about for example, moderate complexity instrumentation being run for high complexity, or do you consider that a separate issue?

CLIAC CHAIR: Yeah, to me that's a separate issue. To me, that's a CLIA categorization, which is unique from personnel or licensure.

CLIAC MEMBER: OK. And then on the second point, I guess my question is, should laboratory testing be regulated? Isn't it currently?

CLIAC CHAIR: It is, but I think what the workgroup has to define is given the menu of tests in reproductive laboratory, what is conventional laboratory testing? What is that stuff in the middle that I am ignorant about? Oocyte morphology, penetration, all of that stuff. And then where does it cross over into tissue? And then where is the boundary, or a soft boundary be drawn for who regulates what parts of it?

CLIAC MEMBER: I guess I'm still a little confused, because there are regulations currently. So I guess I'm not clear if we're asking for those regulatory bodies to be changed, or are you asking for clarification on how those are being regulated?

CLIAC CHAIR: As a single person, I am asking for clarification. Because hearing from Dr. Schalue, it sounds like it's not clear out there either. So if we can be more clear about the activities in an ART, who does what, then I think we can help all this.

CLIAC MEMBER: But then I guess as an add on on that, one of the things that CBER does not do is define personnel qualifications other than the doctoral level. And so perhaps a recommendation could be that CBER look at personnel qualifications associated with tissue in general, and their tissue regulations outside of the doctoral level, because I think that's also what I was hearing a request for.

CLIAC CHAIR: Yes, that's an excellent point. And that has a relationship. It'll be interesting how to tease out where the practice of medicine is versus things scientifically. OK, Lee and then Bonnie and then Sharon. Oh. OK, I'm sorry. Did you have your hand up?

CLIAC MEMBER: Just for my own knowledge, who oversees biobanks or when you freeze oocytes-- who is responsible ultimately for regulating that?

FDA EX OFFICIO: Yeah, so I don't have a complete answer on that. My guess is if there was a part of the FDA involved, there would be CBER, but I'm not sure to what extent they are. I think it will be good to have, you invite someone from CBER to address some of these issues, that has the right knowledge. And we were talking

earlier that it's probably helpful to have someone from CBER at these meetings in general, because these issues do come up.

CLIAC MEMBER: Yeah, so that's where I was going with that. If we do this, because it's so messy, and it looks like it touches so many different areas, the most important thing will be that you really get the stakeholders and people involved. Thank you.

CLIAC MEMBER: Thank you. I wanted to ask a point of clarification in the workgroup charge, as you're asking the question about existing personnel standards and definitions, how do we address the fact that CLIA may not even have that particular discipline in the role, such as histopathology?

CLIAC CHAIR: So that is the hidden subtext of this motion, because if the existing requirements do not apply, or in their entirety, then the recommendation to CLIAC could be, or the report back to CLIA could be a request that we form new categories under personnel.

I do want to say, we can never predict what technology will be in five years. And as we narrowly define personnel requirements, we have to be mindful that we might be locking ourselves into immutable type of things that will be hard to undo. So I tend to be a broad-based definition fan instead of narrow. Sharon and then Tom.

CLIAC MEMBER: OK. I don't know how this will all fit in, but I think a couple of questions have come up that what I would like to say is that, while we are determining requirements or the regulations, and if it is decided that some of these things are not apart. And since we need clarity now and we don't want to lock ourselves in, would it be appropriate then, [CMS EX OFFICIO], that in the interpretive guidelines, that they be extended.

CMS EX OFFICIO: That's something we can look at. We have to be really careful when we put things in guidelines that we have regulations to back it up. So if we're talking about something that is not currently mentioned in the regs, we have to be really careful if we include that.

CLIAC MEMBER: OK. Now just point of clarification, I don't know that this fully answers [CLIAC MEMBER] questions. But the CAP has checklist items and in surveys biorepositories, they recently updated that. So I'm not aware that other organizations are involved in it, but I don't know if that's correct.

CLIAC CHAIR: Taking advantage of a pause, I do want to assure the public that there was a discussion around semantic interoperability that's not showing up in any of these motions. I do want you to appreciate that recommendation from CLIAC was made at our April 2019 meeting, and the recommendation was CLIAC recommends HHS support the incorporation of standards for interoperability and data usage in clinical genetic and genomic testing in NGS across laboratory subspecialties. And a letter was sent by CLIAC from July 9 to the Secretary of HHS, that included this recommendation. So that issue is live and in motion. So again, that's not why it's here, even though we heard about it in-depth this morning.

CLIAC EXECUTIVE SECRETARY: So I have a question, and it has to do with recommendation for, and what was in the recommendation in the April meeting. The recommendation, and I'm interpreting them as two different things. And maybe it's just me. So the recommendation that was made in April says any site that performs an activity that involves data and then gives some clarification shall be considered a laboratory if that site is not an extension of an existing CLIA certified lab. My recollection of the discussion back then was that this came about when discussing bioinformatics facilities that were totally separate. What I'm seeing now in patient four, or in recommendation for talks about people connecting to an already existing CLIA certified lab through VPN, and that should not be considered a separate laboratory. So I'm seeing recommendation for as

different from what was recommended back in April. And if that's just me, then fine. But if it is, then maybe recommendation for should be considered.

CLIAC MEMBER: Yeah, I remember, in that meeting, Ramy and I were talking about if an AI algorithm is housed in offsite storage facilities such as Amazon Cloud, is Amazon Cloud going to have a CLIA license? Of course not. And we talked about the same thing with the bioinformatics. If the pipeline is housed at an external site, and the data flows through it and back in, without the-- so I completely agree that that was the discussion. It was not to this point.

CLIAC CHAIR: So then I'm hearing that the proposed recommendation number four is separate and unique, and we should consider that as a separate motion today?

CLIAC MEMBER: I think so. I also think to [CLIAC EXECUTIVE SECRETARY] point, the issue of the home address of the testing personnel is a really big concern that I think we should try to make sure is somehow spelled out as a concern. That does cause in some cases, it may seem minor. But I can tell you from my perspective of dealing with patients with delusional parasitosis, those patients can get dangerous. If my home address was on there, I would not feel comfortable. So I do think we need to make sure that's a spelled-out recommendation, that that requirement get reconsidered. Because that is--

CLIAC MEMBER: We have discussed it.

CLIAC MEMBER: But is it written? Discussion is different than having something-- if something is written, then we're good.

CLIAC MEMBER: Couldn't you just add that to the end of the proposed recommendation five, and eliminate the need for home addresses on laboratory reports? As simple as that?

CLIAC MEMBER: OK, I apologize, because now I'm confused. And I absolutely agree that has to be very specific and very clear. This has come up before. There are some things we discuss that are urgent, and I think everybody feels this is something that is very good it's under discussion, but I think the tenor of the discussion here is, it's an urgent issue that needs to be fixed because it's an issue for patient care.

But so now, just to do like a talkback, So we've got cloud, the cloud-based. Are we going to be looking at regulating or overseeing the cloud? That's one issue. Four and five are starting to look very similar. Five is just saying, how you do four. The VPN's showing up twice. Are they really separate?

CLIAC CHAIR: So my recommendation is four and five are interrelated. And if somebody can mash them together and wordsmith them into a single motion. And I think [CLIAC MEMBER] feels most strongly about it.

CLIAC MEMBER: And the cloud recommendation, that was part of the recommendation that we heard earlier, right? So we can let that go for now. Is that correct?

CLIAC CHAIR: Yes, because it's in play.

CLIAC MEMBER: Thank you, right.

CLIAC CHAIR: So [CLIAC MEMBER], if we can have you crunch together four and five, they seem to be related and presented as a separate motion. And while he's thinking about that, what do you as a committee think about the new workgroup charge motions?

[INTERPOSING VOICES]

CLIAC CHAIR: What do you feel about the proposed motions for the charge to the new workgroup? At the bottom, Lee. Do the existing clear requirements, that thing. We have to tell this workgroup what we want them to do.

FDA EX OFFICIO: So we just suggest a little bit of wordsmithing, maybe for the second bullet, that maybe we'd leave it more along the lines of whether that type of testing should be regulated by CLIA. I think we certainly want to hear from CBER as to what they already are regulating. But I would recommend that the focus be on what should be regulated under CLIA.

CLIAC CHAIR: Yeah, so perhaps instead of the word should, it should be replaced with what scope of laboratory testing? Tell us what the menu is, and then we can figure out how it's regulated.

ADVAMED LIAISON: With regards to the first bullet, there was a written public comment from the American Board of Bioanalysts. I can't speak this morning. And they had called attention to the fact that last year at the November meeting, there was discussion around the doctorate of clinical lab sciences, and that that there was discussion in the workgroup about it, it wasn't carried forward into recommendations. So I might suggest that that issue be added to the first bullet, and since you're looking at personnel.

CMS EX OFFICIO: I'm going to pose a question to all of you. You're saying you want us to regulate the cloud, correct? Is that what you're saying you want us to do?

CLIAC MEMBER: No, it's just that it came--

CMS EX OFFICIO: OK, because trying to regulate the cloud is a problem, OK? And that's what I was getting the impression of. OK, thank you. You make me feel so much better.

[LAUGHTER]

CLIAC CHAIR: To [ADVAMED LIAISON] comment, would the DCLS be a separate point, which is should the CLIA regs define the requirements for laboratory director qualified through the DCLS pathway?

CLIAC MEMBER: That's much more eloquent.

CMS EX OFFICIO: Not eloquent, just shorter. [LAUGHS]

CLIAC CHAIR: There's been a lull in talk, and I would like to suggest we start working through these motions. So I'm back at the workgroup charge, and the first proposal to the existing CLIA requirements for moderate blah, blah, blah. And is there a motion to approve that? Sorry.

CLIAC EXECUTIVE SECRETARY: So I pulled up the recommendations from the last meeting that did give some kind of a draft overarching charge to the workgroup. And I'm wondering if what you've got listed here as questions would be good questions to consider asking the workgroup under that charge. The recommendation made in April was CLIAC recommends creation of a new CLIAC work group with a charge of advising on how CLIA might specifically be updated, integrating and reflecting the reports of the personnel regulations, non-traditional workflow models, and NGS workgroup presented to CLIAC. And ideally, incorporating members from each of these groups for continuity.

So I see that more as the actual charge, but these questions might be then specific things that are asked of the workgroup under that charge.

CLIAC CHAIR: Excellent point, thank you. So if that's the case, if these are the questions that we would like the workgroup to address, we don't need motions? Or we don't need to propose recommendations? Is that correct? OK. So then that leaves, so that first bullet is irrelevant. It will be a question to the workgroup. The question around the DCLS qualifies laboratory director will be addressed in that work group with that overarching charge, and we don't need a separate motion. Is that correct?

CLIAC EXECUTIVE SECRETARY: Yeah, I think any guidance that CLIAC can give us on the questions, all-encompassing throughout what the workgroup might need to address and what should be priority questions, that's what would be really helpful.

CLIAC CHAIR: OK. So now they are not charges, they are questions for the new workgroup. And I do think the third-- so we have the histotechs, bioinformaticists, and ART. And then we have the scope of lab testing. And did we include third bullet to consider laboratory director qualification for those with a CL DCLS? However I said. Lavinia.

CLIAC MEMBER: Should we also include competencies?

CLIAC CHAIR: Yes.

CLIAC MEMBER: Since we're looking at assisted reproductive laboratories, although it wasn't brought up today, there are other tissue activities that if we're going to look at one type of tissue, should we or could we broaden this to look at other types of tissue management, and see what might or might not apply to CLIA, or do we want to stay very specific and left at ART? Just a suggestion that there might be other opportunities out there for tissue management.

CLIAC CHAIR: So what I heard earlier is that since we're a CLIA-focused committee, we should probably ask for more definition around the CLIA activities. And then related, but perhaps in a different fashion, converse with CBER and understand their role in tissue. Not just the embryology, but all the other tissue activities. Perhaps that's the way forward.

So Heather, if you can bring up that third bullet because it's not showing at the bottom of the screen.

HEATHER STANG: Up?

CLIAC CHAIR: No, down, down. Are there any other priority questions from today's public comment session? Regarding these specific questions we want the workgroup to address. So knowing that these are not formal recommendations, so we don't need to vote on them. Is that correct? OK. So these will stay on in the minutes. And then Marc was furiously trying to create a new motion. Is it up top or on the bottom? Or is it the bottom? It's up top. He says it's up top.

CLIAC MEMBER: Up top.

CLIAC CHAIR: Yeah, above that section.

CLIAC MEMBER: I don't know if I'm in control. Am I?

CLIAC CHAIR: I don't know who's in control. [LAUGHS]

CLIAC MEMBER: We're done with the workforce bullets, we're moving on. Moving on.

CLIAC CHAIR: It was four and five combined, that is [CLIAC MEMBER] revision. CLIAC recommends--

CLIAC MEMBER: Please help.

CLIAC CHAIR: CLIAC recommends CMS define when laboratory professionals are providing patient care by use of digital remote access with standardized security and risk mitigation place. These services would be considered as having been performed at and under the purview of the primary CLIA licensure site.

Is there a motion to approve? So moved, is there a second? OK. It's open for discussion. [CLIAC MEMBER], you were first. No? OK.

CLIAC MEMBER: Quick request.

CLIAC CHAIR: Oh, you got that look on your face. Yes, Katherine.

CLIAC MEMBER: Does this need to specify laboratory professionals, or is it just defines when clinicians are providing? I'm not sure I'm asking.

CLIAC CHAIR: I'm sorry, we were talking on the side, not paying attention. Could you please rephrase your question?

CLIAC MEMBER: My question is, if you're not a laboratory professional, but you're looking at laboratory results at home, your pulmonologist, does that need to be differentiated? Or does this need to be specifically related to laboratory professionals?

CLIAC MEMBER: That's a good point. Should we specify generating results, rather than someone reviewing results? So we're stipulating that either the laboratory professional is involved in generating a result through the remote activities? Do we want to specify that?

CLIAC CHAIR: Perhaps, because maybe what Katherine is getting at. It's like the pulmonologist goes in and looks at a PFT and then renders an interpretation, which is different than a result.

CLIAC MEMBER: Yeah, I think that's an important distinction, because that lab result didn't change because the pulmonologist. Reaction was a result of the result. But that would have happened whether it was generated in lab or out of the lab.

CLIAC CHAIR: Is doing that practice in medicine.

CLIAC MEMBER: That's why when I originally crafted, I guess it was four at the time, that basically I said, providing care through interpretation and reporting. That's the professional component piece, the language that's used conventionally in CPT, for example. So I thought just to be consistent. We're not talking about doing wet work in your kitchen, other than cleaning your dishes. So I think it's the interpretation of porting of data that put in the laboratory. So that's why I use that language, because that's familiar to the practice of medicine already.

CLIAC CHAIR: But I do want to comment that in the proposed recommendations, CMS should be replaced with CLIA. OK.

CLIAC MEMBER: To this point, would that preclude a hospital hiring data scientists who are allowed to have remote access just for the dry pipeline? And does this overlap, do both need to be mentioned? They wouldn't be generating interpretation. And to the same digital laboratory microbiology automation, there are microbiologists in Europe working from home, selecting colonies that are picked and reported at the core lab by mass spectrometry. So that sort of preinterpretation piece is not covered.

CLIAC MEMBER: So I think maybe in response to [CLIAC MEMBER] comment, I think what we're saying is we're looking at people who could be perhaps, possibly categorized as testing personnel in some kind of capacity. So in the future, we had stated at the last meeting, or in the conversation this meeting, that bioinformaticians could be acting, when they are acting and as testing personnel and in the process, then this would also relate to that activity, I think, is how I interpreted it.

CLIAC CHAIR: So I'm-- do you want--

CLIAC DFO: Not sure if we should be editing this recommendation or not.

CLIAC MEMBER: Now I'm confused, [CLIAC MEMBER]. So how would it work, though? So if someone takes a picture of a plate, and texts it to me, there's no HIPAA there, it's just a plate with colonies. And they say, hey Marc, should I work up these or not? And I say yes, have I really provided patient care? I don't think so. That's not documented, right? They're going to pick the colonies and go. So I don't know where the line gets drawn on that. They do that all the time off the cuff on rounds, and it's often not documented.

CLIAC MEMBER: Yeah, I'm just saying if they're going to look at it, there's underpinning technology that would allow for much, much more than that. Technologists working from a home computer doing microbiology plate reads, digital scientists doing what dry pipeline, there may be other work at home activities that relate to a patient result, whether or not a doctor or scientist has reviewed it. And then they would go through the normal checking process required. So I don't know if we want to put that piece off to another meeting in time, but it's overlapping, and it's related.

CLIAC EXECUTIVE SECRETARY: So my suggestion might be since we're talking about CLIA, replacing something like providing patient care with performing testing is defined by CLIA.

CLIAC MEMBER: So I would agree with [CLIAC MEMBER], I like the worryingly agents providing patient care through interpretation and reporting and test results. Somebody could be gating flow cytometry remotely, so that flow has been done. But they're changing both the report, the numbers that we reported, and the interpretations that are genetics, going to the pathologist, could mean reviewing raw data that's been done somewhere, but changing the report and making the interpretation. But we don't have the flow cytometry or the Illumina in the kitchen sink. What they're doing is providing patient care through interpretation reporting. So I think that those words make sense to me, and they seem to be standard kind of words for the actions that we're talking about.

CLIAC CHAIR: So I have flipped right back to [CLIAC MEMBER] original wording, proposed recommendation number four, because it's very clear. When lab professionals are providing patient care through interpretation, reporting of patient results, and then I would replace using a virtual private network with something like by accessing data remotely. So we don't have to say how they do it.

CLIAC MEMBER: Made those changes in four five.

CLIAC CHAIR: Yeah, four and five got way crazy. Access remotely, and then strike using a virtual private network. And then would be considered performing those services at the primary performance site. I don't know whether or not we need to include, you tell me, issues of security, risk mitigation, in the recommendation. Is that a fair thing to assume, when you say access remotely that that automatically includes secure and risk mitigation? OK, while you think about that.

CLIAC MEMBER: I'm sorry. I think we need to add the word selection, because that-- selection, interpretation, and reporting. Because we're reliant on our colleagues to select the right either field, or data, or tissue culture, for interpretation and reporting.

CLIAC CHAIR: We talked about-- I'm trying to understand the difference between what we're recommending and the April recommendation, because that seemed to be more directly related to cloud-based bioinformatics, whereas this recommendation is more all-encompassing, or more heavily focused towards digital images. Can someone help me understand the difference?

CLIAC MEMBER: So what it sounds like to me, the difference is, versus the cloud, this is really about the lab personnel, is the sense I'm getting for this. Like the actual bodies who are just conducting their work remotely. And I do like the idea, I don't know if we can regulate the security, but we could say that who are working in a secure environment remotely. So it's understood-- the kitchen, right? If we put in that phrasing, it'll be very clear that it's not our responsibility. It's always going to be responsibly of the lab or the center. We can't go in and assess your computer requirements, right? That's--Exactly. So if we just put it that way, I think it adds a little color and is a little more specific to what we're dealing with. This strikes me as being very personnel focused.

CLIAC CHAIR: Focuses, yeah.

CLIAC MEMBER: So I think that the recommendation from last April and this one exist together very well. The previous conversation was around a site that was not an extension. This, I think, is where the implication, this is clearly an extension of our already existing CLIA site. So that, to me, was the big differentiation. Here, I don't know if we need to say that, but that's clearly the implication here. One's an extension, one is, if it's not, then it should be considered a testing or laboratory site.

CLIAC CHAIR: Thank you. Cleared up my confusion. So I think we are working on proposed recommendation number four. You've all hit a lull in your excitement. Is there further conversation on this?

CLIAC MEMBER: Are we going to try to do the four and five combined and wordsmith that? Or now are we going to consider four and five separately?

VALERIE NG: So four and five existed initially, then we combined them together in that four and five, but I have flipped back thinking four should be the wording. So I guess we should have a discussion. Do we need separate ones? We eliminate everything. We just vote on four. What do you all think? [CLIAC MEMBER] busy doing his work on his other computer.

CLIAC MEMBER: OK, a lack of clarity for me on number four where, let's see, it said should be considered. If someone could clarify, let me just see where I am. Access in a secure environment, they should be considered as performing those services at the primary performance site when this CLIA certificate already exists. So they may or may not be. Is that right? At the site? Because when you say consider, or considered, there is no requirement. Or even if you say expected, there is no definitive. And so I just want clarity on that to know that that does not say that they are performative at the primary performance site. It just said that, you know, they should be considered. So what is your-- What do we want? Do we want to assure that they are performative where there is a CLIA certificate? If so, what we have there doesn't say it. OK.

CLIAC MEMBER: So we would need to say is required.

[INTERPOSING VOICES]

CLIAC MEMBER: My recommendation would be to change should to shall.

CLIAC MEMBER: OK, that's OK. Yes.

CLIAC MEMBER: And then when needs to be changed to where. Where the last performance site where the CLIA certificate already exists, not when.

CLIAC CHAIR: Where. So bottom sentence, when becomes where. Yeah. So do we agree 4 is the one we're going to vote on and 5 and 4/5 are no longer under discussion? Cindy. It's already been moved. The motion is open. So [CLIAC MEMBER], I'm waiting for, you guys have a lot of comments.

Hearing no. Hey, you guys want to share? We're getting ready to vote. You guys OK with this?

CLIAC CHAIR: 4 is what we're voting on. Everything else is dead. Yes.

CLIAC MEMBER: OK. Madam Chair?

CLIAC CHAIR: Yes

CLIAC MEMBER: Yes. We were just trying to clarify, does it say what we wanted. I still had a problem with considered. If is considered as left there, does it still have the ambiguity? Shall be considered. I'm asking for other input. Or am I the only one seeing the ambiguity of consider or considered?

CLIAC CHAIR: So I think that we want to be absolutely clear. That phrase should say they are performing those services at the primary performance site and the CLIA certificate of the primary performance site covers those activities.

CLIAC MEMBER: I'm comfortable with that, absolutely.

CLIAC CHAIR: They are performing those services at, and the CLIA certificate of the primary performance site covers those activities.

CLIAC MEMBER: So Madam Chair I'm ready for an a call for the vote.

CLIAC CHAIR: And the CLIA certificate covering the primary performance site covers those activities. So past site, and then covers those activities, period. Then delete the rest.

CLIAC MEMBER: Not to continue discussion, but that's a little contradictory if you read it at face value. I think shall be considered, the word shall--

CLIAC CHAIR: --is good.

CLIAC MEMBER: Shall fixes everything. If it says shall, it means that's a must in clear legalese.

CLIAC MEMBER: May I follow up, Madam Chair?

CLIAC MEMBER: Sure.

CLIAC MEMBER: When it says, though, the word considered takes that away . In my opinion, it has it in an ambiguous. It shall be considered so I've considered it. But I'm at my house rather than at yours. I've already considered it. So that's where I was trying to clarify. I'm good with it if I'm the only one who sees the ambiguity.

CLIAC MEMBER: Well, perhaps [CMS EX OFFICIO] can comment. I think shall be considered is--

CLIAC MEMBER: I like shall.

CLIAC MEMBER: Yeah. That's a very specific term.

CLIAC CHAIR: [ADVAMED LIAISON] would like to make a comment before we turn it to [CMS EX OFFICIO]. I want to hear what [ADVAMED LIAISON] wants to say.

ADVAMED LIAISON: I feel like we're trying to wordsmith regs. And what we're really doing is making recommendations of which the entire transcript and the conversations are all taken into account as we've learned from previous times.

CLIAC DFO: So if I could add, CLIAC cannot write regulations. All CLIAC can do is make a recommendation to the government for the government to consider changing what the government currently does. So this is not a regulation writing activity and cannot be.

CLIAC CHAIR Trust me. You don't want to be involved in that. It gets really complicated. What you're saying here, the way I'm reading this now, is-- which one? Was it 4? You're actually saying they are doing it at the actual site when they are not, in fact, at the actual lab site. So you need to bring in that it shall be considered. What you're saying is we're considering this home the same thing as the lab. So you have the word it in that way.

CLIAC MEMBER: Change considered to deemed and I think we're good. Shall be deemed.

[INTERPOSING VOICES]

CLIAC CHAIR: I got the intent really good. OK. This is going to blow you all out because we're wordsmithing. CLIAC recommends separate clear licensure is not required for laboratory professionals providing patient care, blah, blah, blah. By accessing data remotely-- you don't like that? OK. I'll leave it. [INAUDIBLE]

CLIAC MEMBER: So the last dangler is flipped around, I think. Services at the primary performance site that houses the CLIA certificate, or something like that, because it seems backwards or blurry.

CLIAC CHAIR: Site.

CLIAC MEMBER: Yes. Oops. Madame Chair?

CLIAC MEMBER: I'm going to speak in favor of the motion as it has been modified. So I think that motion, if you're ready to attain a motion.

CLIAC CHAIR: We already have a motion. We already have a second. The motion is active. We got to settle on the wording then we can vote. We're close.

CLIAC MEMBER: My only concern is that we're not making a recommendation. We're making a pontification. So we need to state that we recommend someone is going to do-- is going to consider or assign this. Right now we're not saying that. We need to either assign CMS or CLIA like I wrote in the 4/5. But we need to clarify the word. OK. So I think we got. We need to just recommend that CMS considers or, because otherwise we're just kind of saying, this is what we think. It should be, we're not really asking someone to do it.

CLIAC CHAIR: You're all smiling. But does this make sense? Are we ready to vote? All in favor? Any opposed? Any abstentions? This motion passes. 5 and 4/5 combined are deleted. And I want to, I think, 1 through 3, we covered through the workgroup charge. So that is our--

CLIAC DFO: 1 through 3 are going away?

CLIAC CHAIR: They're going away. So that is the single recommendation out of the public comment with the other issues being addressed through direct specific questions to the work group.

CLIAC MEMBER: Are you able to show recommendations 1, 2, and 3 again? We don't really have access to the SharePoint. So it's just to review them or look at them again.

CLIAC CHAIR: We are lurching up there. Is there any conversation around these proposals 1 through 3? Anything we might have missed, and whether or not we need a separate recommendation or to include new specific charges questions to the work group? Your seven seconds have gone by. This is not a shy group. But that's a lot of text. Hearing none, I propose we strike these three. Do I need to make a motion to do that? Or can we just by show of hands? Who agrees, yes we should strike the three? Who's opposed? Who abstains? We did not have unanimous. What about you guys? You didn't raise your hands.

I'm going to call the vote again. Who agrees we should strike all three? Majority. So 1 through 3 are gone. So this is what we've agreed upon in this session. Is there further discussion, comments? I feel like a lighthouse. Cindy.

CLIAC MEMBER: So for the new work group, are we going to solicit volunteers like we did last time at this meeting for the work group to start? Or is that going to be done later via email? Or how are we going to do that?

CLIAC CHAIR: OK. So they're whispering here. But it sounds like we are happy to look for volunteers, right? Is that the question? Who wants to be on this work group, raise your hand.

CLIAC DFO: This, because we've had a-- we haven't been looking at the charge or the priority question. I'm wondering if we should, at least for a couple of minutes since we do have a little bit of time, just re-look at the work group charge and the specific priority questions that you've already developed and ensure that we've captured what you want the new work group to do. And then, yes, we would be grateful for volunteers to participate on this work group going forward.

And of course, as every work group of a FACA, we must have at least two members of CLIAC on the work group. One of those two members should be identified as the chair of that work group. We have the ability, if we wish or if you wish, to have co-chairs of that work group. So to the extent that we can address any and all of those issues, that's great. We don't have to finalize that today. But if we have the time, it'd be great if we could. Thank you.

CLIAC MEMBER: Maybe I'm missing something. This seems like a really broad topic for a work group compared to previous groups we've convened. Is there a concern that this is not going to be efficient to try to shift this broadly?

CLIAC DFO: I think that's a valid concern. And so I would think the committee should consider exactly what you want this work group to do, understanding the charge that you came up with for the work group in April, as well as an agreement in April that the original charge was exactly as you just said, very broad. And so the reason that we collectively decided to have to post public questions for public comment and to have a session dedicated to receiving those public comments was to help focus, ideally, the work of this new work group.

That said, those of you who served on the recent three work groups, those were fairly focused and had limited tenure, one or two meetings only. A new work group could be viewed to be convened over multiple meetings over more than one, between two CLIAC meetings. In other words, we don't have to complete the work of this work group, unless you want, between now and April. We could envision or you could envision a broader mandate and a longer term to address the issues. But it's really up to you. I think for those of us on the government side who'll be responsible for putting the work group together, the mechanics, and helping direct the work group, we'd be grateful for your guidance.

CLIAC MEMBER: So there seemed to be a-- to [CLIAC DFO] comments, there may be a larger mission here if we believe that there's an opportune time for more of a CLIA modernization or rework more broadly of CLIA. Then that, I think, is a workgroup that's established that is more of an ongoing work in progress that's going to take place over a prolonged period versus-- these are much more specific questions to advise on some revamp of specific areas within CLIA.

I had thought we had had a pretty good discussion or some tenor at the last meeting was more leaning towards a more broader approach to modernizing or changing the CLIA framework-- was a-- I think a good intent or-- and had a feeling that that was the intent of the group. So maybe that may be something we should talk about now. Is that really more of-- we're talking about or is it more just incorporating these and adjustments or rework to the current CLIA regulations, if that makes sense?

CLIAC MEMBER: Yeah. I think I probably don't need to add any more. But my sense was that these three workgroups were going to do the legwork, provide the input, and then, in fact, the next workgroup really had a much broader scope, probably would be taking-- they would integrate the information, but would be taking the discussion over a series of iterations and to the-- back to the CLIA act. Maybe some of them would come off, more would be added. And so once I saw this more of a continuing workgroup as opposed to the others, which had very discreet charges. That was my recollection.

CLIAC MEMBER: Yeah. And I-- just to add to that, what [CLIAC MEMBER] mentioned. I would agree that this is a huge subject. So we could go into a black hole. But if we have a workgroup with the intention of it's a longer term-- there might be things like personnel recommendations around personnel requirements for bioinformaticists, histotechnologists, histotechnicians that might come out earlier and then some bigger questions around how does the whole distributive testing model and drawing what informatics fit into CLIA.

That's obviously going to take longer period of times. But if we're intentionally setting up a group that's going to meet longer and may have people come on and off as topics and interests change, then that would seem reasonable as a way to start some of this. And hopefully, some of the lower hanging fruit, some of the personnel issues that we've talked about this meeting, are going to be easier to address and will come out as recommendations or discussed as recommendations at CLIAC meetings in the near future.

CLIAC MEMBER: I don't recall, but is it possible that the workgroup should have been workgroups and that the three categories were intended to be-- either a workgroup was intended to assign those three others? But it seems like putting those three topics together would not be the best way to get anything accomplished or have people volunteer for something that's that broad and the long-term commitment. I would recommend that we-- if we're going to do this that we get a workgroup that would help flesh out the questions for the other three workgroups. But that's just my suggestion.

CLIAC MEMBER: So I'm thinking a little bit differently. April 2019 actually holds together. Anybody doing NextGen will recognize that right away. Those are all the pieces of NextGen that we're struggling with. These additional questions, which are-- I voted-- I'd like-- well, I support all of them. They're all good. But that's the confusion. They diverge from the top workgroup, which is actually pretty tight.

And my worry also is Brad made the point that people can come on and off the group. But that can get a little messy also. I can see the people on the April 2019. You want broad, of course, opinion. You're going to have a lot of NextGen people on that thing as opposed to, for me as an OB/GYN for reproductive labs-- that's a different-- we've got embryology technology. It's different. And then the new biomarker testing and other new technologies fits a little bit better with 2019. But that's-- that sounds more AI. Are those-- if you input lab into an AI algorithm, do you actually-- now what? You've actually used lab information to treat patients.

So I'm not sure-- I guess I'm-- and long-winded way of saying-- I'm not sure these four bullets fit neatly on the top workgroup [INAUDIBLE] was-- does that make sense. The top workgroup is cohesive.

CLIAC MEMBER: Yeah. I think that's where the mismatch is, too. The top does relate to NGS. And maybe under that umbrella, they belong together as one workgroup. But the questions and the-- assigned to that workgroup would be different if that was framed for NGS, for sure.

CLIAC MEMBER: So based on the public comments and my recollection of our discussion and my recollection of our discussion in April, I feel like the workgroup charge was really not-- it was really looking at the bioinformatics and at personnel and the structure around that because we would need to address the personnel regulations, non-traditional workflow, and NSG. So is it-- could we consider just making the charge of that workgroup to flesh out what the bioinformatics, personnel, and qualifications look like across the spectrum of CLIA and then put these other questions into a separate work group or I take care of them not maybe now, but separately because it just-- there's not a lot of continuity between that?

And you really want to have a right-- the right qualifications for a bioinformatics personnel. You're going to need a lot of different people at the table. And those people may have nothing to do with histotechnologists or assisted reproductive lab testing personnel. Those are just really different SPEAKER matter experts. And I think that we're in a unique place where this is a whole new job description for the bioinformatics world. And I think we owe it to that to really bring in as many people with diverse bioinformatics or informatics backgrounds to weigh in.

CLIAC CHAIR: So I think the discomfort we are all feeling is that the broad charge to the workgroup is so all-encompassing. And it recognizes the work of the three previous workgroups, while artificially divided into three areas, really is an integrated whole. And part of that integrated whole discomfort might result in, instead of trying to fit square pegs into round holes, we might instead say it's time to modernize and rethink CLIA in its entirety.

So I think that's where we were in April. But as part of that, we asked the public to come forward and say, what do you think about this? What are your pain points today? And what's in the red, the specific question, is what we're hearing from the public about how CLIA doesn't work for them today. So we're trying to juggle what we

want tomorrow versus what is needed today. And how many workgroup, plural, do we need? Do we want to continue to artificially divide them knowing that decisions in one section will impact decisions on the other or do you want to single workgroup to tackle this with the entirety of CLIA in mind? Bonnie?

CLIAC MEMBER: Well, I-- at least to me, we're talking about a short-term versus long-term solutions, the short-term being trying to address those issues right now that are raising obstacles for how we provide quality laboratory testing in the United States, which I think-- excuse me-- a lot of these questions here and a workgroup could in a combined way-- I don't like the analogy. But what we have to be doing right now is putting Band-Aids on issues that exist right now.

My recommendation or thought is you have a second workgroup, which goes to [CLIAC MEMBER] recommend or thought about a long-term group-- that they're the ones who start having the conversation of the process and how do we go about, quote, "modernizing" or working on the solution of how to make CLIA to be something that can exist for the future. This will be long-term. It will involve a lot of different people. And it brought to me one of the first things that we'll have to address-- is the process for how to do this. So my thought is let's have some somebody who's helping us take care of things in the short term. But we have to direct another group to really have that long-term revamp focus.

CLIAC MEMBER: If we go by the public comments-- I don't know if anybody else. --but the sense of urgency was clearly the ARUP. This is a fire that needs to be resolved. That might be an urgent work group that should start working on these issues with whoever needs to address them, because this is happening now.

CLIAC CHAIR: So I do believe we made a recommendation that flat out stated, help us deal with this now. So I agree with you. It's an issue that is beyond hot. And I think we as a group have weighed in and say, do this now. These issues we have and read here are the remaining issues we heard from the public today. And that's short-term. We got to find a way to manage those.

And the question is, would we want separate groups working on the immediate short-term and an overarching long-term work group to talk about what CLIA should look like in the future? And what is the risk of those diverting and not integrating?

CLIAC MEMBER: So to get focused, it would probably be better to have separate groups for each topic, just so there is a focus with skill sets.

CLIAC CHAIR: And our CDC colleagues have said we are not limited to a single work group. But we did propose a single work group at our April meeting.

CLIAC DFO: I think the other thing just to keep in mind-- and I'm sorry to introduce resource limitations. There's a limitation in terms of how many work groups we can maintain simultaneously. Last year was the very first time that we'd ever had more than one work group working at a time. And it was a heavy lift for the government. But we did do three. But I think I want to dispel the idea that we could have five or six work groups going on at once. I don't think that's something the government can handle.

CLIAC CHAIR: OK.

CLIAC MEMBER: Can we start with the one combined work group that we envisioned? And if they come back and say we couldn't do it all, then we take a different path next time or whatever.

CLIAC CHAIR: Certainly.

CLIAC DFO: Two is fine, especially if one is short-term.

CLIAC CHAIR: So [CLIAC DFO] was saying two is fine if one of them is short-term, like a single meeting to address these very specific questions.

CLIAC MEMBER: Yes, that was going to be my recommendation since the group memory sort of refocused the April 2019 on NGS. That group needs very specific and very rare credentials to address those questions. But if you focus it just on NGS, and those three topics related to NGS, that seems like that's one group.

All the second fit in with a different set of skills that that could theoretically address all those other ones. But we would have to propose creation of that second and perhaps just as urgent work group. But that bottom one could probably happen pretty quickly and without too much consideration. That would be another recommendation to address the public comment with the read work group questions.

CLIAC MEMBER: Just a personal observation, I think maybe it comports with what Donna was saying. I think many of those things up there, in my laboratory background, I might be able to contribute to. When you get to NGS, forget it. I don't know anything about NGS. So to me, that kind of stands out in its own world as really something unique.

CLIAC MEMBER: Yes, so the black bullet and biomarker testing in new technologies, the last read bullet folds very nicely. You're now talking new technologies, next gen bioinformatics, AI, is kind of one real-- it's a skill set. And I think that fits nicely. We have resource issues, right? So I'm hearing we can't- having three or four work groups could be incredibly efficient, but is not a reality.

So just again, to educate me, this issue of people coming on and off the work groups is OK, right? That is all right that we could bring-- because that's going to be a problem. That's the issue. If you start folding in repro technologies, the requirements for histotechnologists, that is-- like what you're saying, that's a different skill set for people to really work with that.

If we could have a way of bringing in-- when it's time to discuss reproductive laboratories and you can actually bring in people with experience in embryology, then having one work group is a doable-- if the core group really deals with the dark, the top-- April 2019, get that taken care of because that was really the charge, new technologies. And then if we could look at the red dots, the red bullets by bringing in experts-- the histotechnologists show up for bullet one. Repro shows up for bullet two. That could work, but I don't know if that's OK.

CLIAC MEMBER: To move the agenda, I would recommend that we divide the new work group charge up into two groups. And I would also recommend for your consideration that once the two groups complete their work, the two groups would get together to make sure there's continuity, that there are no conflicts, so that the overall charge will be consistent. Because what I'm hearing is, is that if we break up that-- there was a concern about one part supported the other. And there may not be congruency. And I'm saying, let's go with two groups. And then after we complete our work in a PERT chart or a time chart, that the two groups get together to see if there is congruency.

CLIAC MEMBER: I'll defer.

CLIAC MEMBER: So I would actually say that I think these questions are fairly specific. In a work group could focus on this. And we could just use one work group to not dilute the resources we have. But I wonder-- and this is really more of a question to the group. If we talked about a second work group that has had a larger longer term mission of modernization, there are obviously a number of interested constituents in that. Is their

ability to outsource some of this by bringing in other interested groups to help out with the federal members and the work group members from CLIAC, again, and knowing it would be a longer term work effort and work product to help bring in those interested groups to look at.

I think what we're saying is, there's always going to be new technology coming in, new personnel standards, new things. We have to figure out a new framework for incorporating new things. We can't just keep reacting with work groups to change things as it is now. So we need to come up with a different framework. But that's going to take a while. And I think there needs to be a separate group that works on that that's not wholly dependent on our governmental colleagues to do that work. I'm wondering has that been done before? And do we have the ability to do that within the framework set up by a CLIAC?

CMS EX OFFICIO: Just a general comment. We talk about changing things for labs. When we change anything in the CLIA world, we have to consider every single type of lab that we have. So when you're talking about changing frameworks, you've got to make sure that whatever framework you're changing is going to adapt to that doctor's office lab, that ambulance, that big laboratory that's got the university attached to it, and all these huge-- lab conquest. I'll use names, ARUP.

So it's a big deal. And you're right, it is going to take a very long time to do. But when we consider changes, we have to take all that into consideration. So it's really great to bring in these people and say, hey, we need to do it here. But we have to look and say, well, if you do it here, what goes on in these other areas? So it's not just as simple as say, oh, we're going to just do all these little changes. You have to look at the whole picture. So you need to keep that in mind when we're doing these groups.

CLIAC MEMBER: And just to respond to that just very quickly. That was my kind of comment about perhaps bringing in the constituents into the process, so we know their concerns and-- the stakeholders.

CLIAC DFO: In terms of mechanics of work groups, the advantage of a worker, of course, is that it does not have to be limited to members of the committee. It has to be led by one or two members of the committee. Committee members be maybe a part of a work group. But the work group is designed to do exactly what Greg just said. It's to do identify experts outside the committee, outside the government who could contribute to the work of the work group.

However, the work group falls within the overall scope of the Federal Advisory Committee Act. And what we have to do administratively at some point in time is define the scope of the work group and the membership of the work group. And that becomes a reportable activity for CLIAC. What a single individual work group can't do is constantly change membership. I think that would mean we would have to establish a new work group. And I hate to be administrative and bureaucratic about it, but that's the way it's set up.

That said, I think that you could have this sort of long-term high level work group established. And at some point in time, the work group could decide that a new work group needs to be established to address these other issues that the work group identified. And that could be a recommendation back to CLIAC to say, hey, we've reached the extent of our abilities as a work group. But we would want CLIAC to consider whether another work group should be established for blah, blah, blah, blah.

CLIAC MEMBER: So perhaps with that long-term work group, the first thing would be just to establish what is the priority list and a roadmap. And that might take a little time. But in working with the folks on CLIA right now, many of them probably already know what needs to be fixed first, even though it's really hard to do. But perhaps just establishing a work group with a roadmap to begin would be a good place to start.

CLIAC MEMBER: I'm sorry. As we're talking about this, and sort of referring to what [CLIAC MEMBER] said, with other-- with other activities that I have done with CDC in public health, where in order to assure there's continuity in our long-term groups, we have had outside consultants like Robert Woods Johnson or Eagleston help us. Is that a possibility for this particular long-term work group, to have--

CLIAC DFO: I think that you're either on the work group, or you're not on the work group. There could be successive work groups that had members who were on each of those successive work groups. But I don't believe we're in a position to hire a consultant to manage successive work groups. I think that sort of would go against the FACA.

CLIAC MEMBER: I sense that there is a desire for a lot of dynamism in what is done here. I think that all of us-- and Karen can correct me. Mostly my experiences at state is, if you're embedded in a regulatory framework, it's not dynamic. Change takes time, and it's methodical, and it doesn't turn on a dime. So I think that we probably need to consider those constraints.

CLIAC MEMBER: So I'll go back to what I said before. If we have to establish a work group with a charge already defined-- we kind of have that with these questions here. And as we have those discussions, if we branch out into other topics similar to what we did with [CLIAC MEMBER] work group on personnel regulations, we can say, OK, here is what we have discussed with the charge that you gave us. Here are some other topics that we feel CLIAC should address. And that's what we could start with. Just my thoughts.

CLIAC CHAIR: So I'm a reductionist by nature. And I'm actually favoring [CLIAC MEMBERS] approach, that this overarching single work group with this integration charge is what will be convened. And because what brought this to our attention is basically new technology and trying to understand how a 31-year-old framework can adapt to the new technology, today will be no different than 20 years from now. So is the existing framework evergreen? If it's not evergreen, are there incremental changes? Or is it so greener pastures, or is it blue sky?

And I think those deliberations can be focused. When we look at the things that came from the public today, those were issues that were new technology at that time that were never adequately addressed. And as we look at each of those issues, we should be thinking about does existing framework today accommodate what the public has asked us to look at? Will it accommodate future similar requests for technologies we don't even know?

CLIAC MEMBER: Yes, I'm sorry. I agree with that approach. But to Susan's point, perhaps we need to call out NGS and the red bullets, because that was the original focus. And that's not now called out, but it was addressed in the comments so that we could have all those topics covered.

CLIAC CHAIR: So the NGS work group had what, nine recommendations from the April meeting? So there's already some of them in play. And the biggest thing that came out today was the whole bioinformatics thing. Where do they fit in with their qualifications competency? And I think that's something we really need to tackle.

CLIAC MEMBER: But I don't agree that it's just NGS because our group talked about histotechs and that has nothing to do with NGS. So I don't think NGS should be in the red bullets, because it is more than just NGS.

CLIAC CHAIR: Keep in mind, the technologies of tomorrow are unknown to us today. And if we talking about modernizing CLIA to understand those are high impact changes we would be proposing, because the impact will be felt by many, not just the groups we're thinking about.

So there was a lot of discussion. Can I summarize what I think I heard, and then you guys can shoot me down? And I'm going to put my reductionist bias on this. We have a single work group charged at integrating these three reports. But the first immediate task is to address the specific issues that came forward in the public today as an entryway into understanding how CLIA can work for us in the future. And if not, how to think about how it might be modified.

There are heads nodding, yes. So I think we got the single work group. I think we got the things we need to address. We got the [CLIAC MEMBER] thumbs up. And it's not a motion, so we don't have to--

CLIAC MEMBER: I'm not quite sure if that's a--

CLIAC CHAIR: He's doing this thing too. I don't know what that is.

CLIAC MEMBER: I'm not sure if it's a thumbs up or not.

CLIAC CHAIR: So if that is agreement, if there's no further discussion--

CLIAC DFO: Did I capture that-- we can bring back up what we were just looking at. I just added that bullet there. Is that--

CLIAC CHAIR: Yes. The bullet is first immediate task is to address the issues brought forward to CLIA from the public comments below in red.

CLIAC DFO: And are we comfortable with the bullets in red for now?

CLIAC MEMBER: Do we need to add the bioinformatics? Maybe not the NGS, but the biomarker, bioinformatics, and other new technologies just because of all we heard today.

CLIAC CHAIR: Yes. Well, biomarkers is twice.

CLIAC DFO: Oh, I think Heather and I are competing, maybe.

CLIAC CHAIR: You say, address issues related to new technologies, comma, including biomarkers and bioinformatics. I need to bring my laptop--

CLIAC DFO: That's what it says, right?

CLIAC CHAIR: Well, you have it twice. You have, address issues related to new biomarking tech. Delete biomarker testing and other new.

CLIAC DFO: Sorry, it's been a long few days.

CLIAC CHAIR: He's got us talking in both ears..

CLIAC MEMBER: And keeping with the theme in communicating these results, based on emerging a new technology.

CLIAC CHAIR: So address issues related to new emerging technologies, including biomarkers and bioinformatics and communication of such.

CLIAC MEMBER: There was one public comment that was written-- number eight. That had some rewording and edits. And I was curious about whether or not that's something that this committee can even do since it's the actual wording of the regulation. And if so, maybe that can also be included in this list, is to just review it to see what we can implement.

CLIAC CHAIR: So the value of group learning-- when I read Lucia Berte's comment, which is PC8, I thought it was more directed at the understanding of the accrediting organizations and the inspectors who were interpreting CLIA strictly, and not recognizing that procedures safety in lab general can apply to microbiology without recapitulating that entire procedure in microbiology. But you guys correct me. I personally thought that was really just an issue to work out with the accrediting organizations. Didn't require a change in CLIA. Didn't require a recommendation. But I often misinterpret things, so you guys got to keep me.

CLIAC MEMBER: Yes, I agree when I read that. To me, it was more changing CLSI, changing CAP or joint commission requirements for what needs to be in those types of documents.

CLIAC CHAIR: To me, it wasn't even changing the requirements. It's changing the inspector's understanding of how to accomplish those requirements. Is there any other comment in this public comment session? Cause we could actually adjourn on time. We could adjourn on time. There being no comment in seven seconds, I move this meeting be adjourned. Thank you very much. Safe travels.