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

Meeting Transcript

April 10-11, 2019

Baltimore, Maryland

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

April 10, 2019

❖ Call to Order and Committee Member Introductions

CLIAC CHAIR: Well everybody, I'll ask committee members to take your seats as we prepare to begin the meeting. Do we have quorum? I think we have quorum.

CLIAC DFO: Good morning, and welcome to CLIAC. I'd like to take this opportunity to thank our hosts at CMS. This is a great opportunity. It's the first time in CLIAC's history that we have held this meeting at CMS. So it's a great opportunity for us. We begin with introductions and conflicts of interest. And we'd like for each CLIAC member, beginning with Campbell, to introduce themselves, provide just their affiliation, as well as their indication of any conflicts of interest. And we'll go around the table. So we'll take care of introductions and conflicts of interest at the same time.

CLIAC MEMBER: I'm Sheldon Campbell from Yale School of Medicine and VA Connecticut Healthcare. I'm on College of American Pathologists Checklists Committee, the Lab Practices Committee of the American Society for Microbiology, and no other conflicts of interest.

CLIAC MEMBER: I'm Marc Couturier from University of Utah, ARUP Laboratories. I am also on the Clinical Laboratory Practices Committee through the American Society for Microbiology. I have a financial conflict of interest with BioFire Diagnostics, for which my spouse draws a household income. And I have a conflict of interest for research reagents with Apacor Limited, Meridian Biosciences, and DSORG.

CLIAC MEMBER: Good Morning. I'm Lee Hilborne. I am a Medical Director at Quest Diagnostics. That's probably my major conflict of interest. I'm also a professor and Medical Director at UCLA Healthcare. I am on the CAP Accreditation Education Committee, and am on the Commission on Public Policy for ASCP, and then past president of ASCP. I also work for Rand, but they're nonprofit.

CLIAC MEMBER Morning. Steve Hinrichs. I'm Chair and Professor of the Department of Pathology at University of Nebraska Medical Center. We are heavily engaged in both research and education, but I have no other financial conflicts.

CLIAC MEMBER: I'm Brad Karon. I'm at the Mayo Clinic in Rochester, Minnesota. Clinical pathologist. I am a member of the College of American Pathologists Council on Accreditation. And I have financial conflicts of interest-- I serve on advisory boards for Roche Diagnostics and Radiometer America.

CLIAC MEMBER: Good morning. Tom Lorey. I'm the Regional Medical Director of Northern California region of Kaiser Permanente. I have no conflicts, financial or otherwise.

CLIAC MEMBER: Good morning. My name is Sharon Massingale and I'm the Laboratory Director for the State of Alabama Bureau of Clinical Laboratories. I'm a member of ABB, where I serve as a representative to the public health interest group. And I'm also part of APHL where I'm a member of the workforce development group. And my laboratory received funds for two cooperative agreements from the CDC.

CLIAC MEMBER: Good morning. I'm Lavinia Middleton. I'm a surgical pathologist by training at MD Anderson Cancer Center. I am the Vice Chair for Quality Operations in the Division of Path and Lab Medicine. And I'm also the Deputy CMO for Medical Affairs. I sit on the AAMC Diagnostic Accuracy Committee. And I have no financial conflicts.

CLIAC MEMBER: Hello. I'm Helen Mills from Victor 12 in the VA of Orlando, Florida. I have no conflicts at this time.

CLIAC MEMBER: Good morning. I'm Valerie Ng. I'm Professor Emeritus of the Department of Laboratory Medicine at the University of California, San Francisco. And I'm currently Chair of the Department of Lab Medicine and Pathology at Alameda Health System in Alameda County, Oakland, California. I'm a member of the Health Laboratory Workforce Initiative Advisory Group for the California Hospital Association. I am a reviewer for the College of American Pathologists Point of Care Checklist. I am a reviewer for the Gordon and Betty Moore Inventors Fellows submissions this year. And I'm the Editorial Lead for Lab Medicine for Doody's Books Reviews. Thank you.

CLIAC MEMBER: Good morning. My name is Katherine Perez. I'm the Infectious Diseases Pharmacist in Houston Methodist Hospital System. I direct the antimicrobial [INAUDIBLE].

CLIAC MEMBER: Good morning. I'm Bonnie Rubin, and I'm currently an Adjunct Professor at University of Iowa [INAUDIBLE] college. And my only conflict of interest is that I'm on the Board [INAUDIBLE].

CLIAC MEMBER: Good morning. Greg Sossaman. I'm a clinical biologist at Oshner Health System in New Orleans. I have no financial conflicts. I have held several volunteer positions through ASCE.

CLIAC MEMBER: Hello. My name is Cindy Wilkerson. I'm the Director of the Laboratory Medicine Department at the Sloan Kettering Cancer Center in New York City, and I have no conflicts.

CLIAC MEMBER: Good morning. I'm Donna Wolk. I'm the Division Director and Laboratory Medicine at Geisinger Health, and an adjunct professor at Wilkes University. I have grant-funded financial conflicts with Roche, GenMark, Upjohn, CEPHIA, DiaSorin, BioFire, and I hold advisory positions with Streck and Safeguard. I also have a CBC-funded pandemic flu grant through ABT, and I'm the editor for "The Clinical Microbiology" newsletter from Elsevier.

ADVAMED LIAISON: Good morning. I'm Andy Quintenz, and I am a liaison to the CLIAC, and from Biroad Laboratories. I'm also the chair of the ISO technical committee for the US executive committee for TC-212, which is clinical lab testing. And members of the AACC corporate advisory board and CLSI consensus council.

CLIAC EXECUTIVE SECRETARY: Good morning. I'm Nancy Anderson from the Division of Laboratory Systems at CDC. I'm the Executive Secretary for CLIAC and I have no conflicts.

CDC EX OFFICIO: Good morning, everyone. I'm CDC EX OFFICIO Fitzgerald. I'm in the Division of Laboratory Systems at CDC. I'm the CDC Ex Officio for CLIAC. I have no conflicts of interest.

CLIAC DFO: Good morning. I'm Ren Salerno from CDC's Division of Laboratory Systems, and I'm the designated Federal Official for CLIAC. No conflicts.

CMS EX OFFICIO: And I'm CMS EX OFFICIO Dyer. I'm the Director of Division of Clinical Laboratory Improvement here at CMS, and I have no conflicts.

FDA EX OFFICIO: Good morning. I'm Peter Tobin from the Office of In Vitro Diagnostics and Radiological Health at FDA, and I have no conflicts of interest.

CLIAC CHAIR: And we have-- I believe we have Dr. Williams on the phone. Thomas Williams, are you on the phone? Susan Gross, are you on the phone? Is anybody on the phone? Do we have anybody on the phone?

CLIAC MEMBER: I'm Susan Gross. I am the Medical Director of the Reproductive Genetic Laboratory at Sema4. And I'm also a professor at the Genomics Department at Icahn School of Medicine, Mount Sinai. My other conflicts to say today, I am a consultant at [INAUDIBLE], which is an artificial intelligence software company for genomic medicine for interpretation and complication variance. And I'm also the President of the OBG project, which is a peer to peer educational online site.

CLIAC CHAIR: Thank you, Dr. Gross. Do we have Dr. Laser on the phone? Well, that brings us to me. I'm Ramy Arnaout. I'm the Medical Director of Clinical Microbiology at Beth Israel Deaconess Medical Center and Harvard Medical School up in Boston. I consult for Lexent Bio, a cell-free DNA diagnostics company, and Embold Health, a health care analytics company. I also sit on the informatics and personalized medicine committees for CAP, for the College for American Pathologists. And with that, I think we will get started

So about public comments. So during the period for committee discussion, participation is limited to CLIAC members. However, public comment periods are scheduled for both meeting days. Public comments will be limited to a total time of five minutes per individual or group. And we've got a pretty dense couple of days, so we do appreciate it for public commenters keeping to that.

If anyone in the audience wishes to address the committee, the public comment portion of the meeting is the proper forum to do so. Those who are planning to provide a public comment must fill out a speaker information form located at the registration desk. And again, please do restrict your oral comments to five minutes.

Can I get a show of hands for any public comments today? OK. Somebody help me count. I count three. OK, fantastic. Thank you very much. And could you, three of you, please indicate which topics your comments will relate to. Just yell it out.

AUDIENCE: Proficiency testing.

CLIAC CHAIR: Moving across the room, who's the second hand?

AUDIENCE: [INAUDIBLE].

CLIAC CHAIR: Which one?

AUDIENCE: Sorry.

CLIAC CHAIR: No worries. Take your time.

AUDIENCE: [INAUDIBLE].

CLIAC CHAIR: Personnel? Personnel. OK. Thanks. And the third one?

AUDIENCE: Personnel qualifications.

CLIAC CHAIR: Thanks all three of you. All right. Copies of all our PowerPoint presentations and other meeting materials are posted on the CLIAC website. It's www.cdc.com/cliac. Everybody should be able to get into our guest wireless here. If you have any trouble, turn to your neighbors who can help you out. At the start of each presentation, I will do my best to remember to announce a presentation number to assist you in locating the correct electronic file. They're all listed right there on the website. There'll be a blue number next to the presentation on the agenda, and then that number's what I will read out. Ren?

CLIAC DFO: This meeting is being webcast. We welcome those who are viewing the meeting today remotely. Links for accessing the webcast are provided on the CLIAC website, for those of you who would like to access the webcast. The meeting is also recorded to assist in preparing an accurate written summary of the proceedings. So we ask that CLIAC members, when they're speaking, to please use the Microphone So as always, we will have a morning and afternoon break. Drinks can be purchased downstairs at the cafeteria. But my understanding is that those of us who are not CMS employees need to be escorted by a CMS employee down to the cafeteria area. So look for your colleagues from CMS if you'd like a refreshment during a break. And the same will be true at lunch. We will go to the CMS cafeteria downstairs, but we will all-- those of us who are not CMS employees will require escort to the cafeteria as well.

CLIAC CHAIR: All right. Well, we'll start today as we usually do with updates from CDC, CMS, and FDA. These are presentations numbered one, two and three. And after that, we will have a report by Dr. Sheldon Campbell, the current CLIAC liaison to the CDC Office of Infectious Diseases Board of Scientific Counselors, and that will be presentation number four. These presentations have been shortened to include just the highlights to allow time for workgroup discussions. I feel like there will be especially a lot to discuss. We usually have pretty lively discussions here, but today looks like it's going to take the cake. And as a reminder to our speakers, please try to avoid the use of acronyms. There is an acronym reference provided on the website with the presentations, but help us out. And we've received a couple public comments on the proficiency testing proposed rule from the American Proficiency Institute available on the website. And I believe, although correct me, I believe that is in addition to the comment that we have from the audience member, but that might be the same. Oh, that is that comment. All right, so it is that comment. Well, without further ado, I'll turn it over to Dr. CDC EX OFFICIO Fitzgerald who will give us our CDC update.

❖ Agency Updates and Committee Discussion

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

CDC EX OFFICIO: Thank you, Ramy.

Good morning, everyone. Thank you for the opportunity to share some updates from our work in the Division of Laboratory Systems and the Center for Surveillance Epidemiology and Laboratory Services at CDC. In the Division of Laboratory Services Systems, our vision is exemplary laboratory science and practice, drive clinical care and public health. Our mission is to improve public health surveillance and practice, as well as patient outcomes by advancing clinical lab quality and science, data and bio repository science, and workforce competency.

Our mission and work focuses on supporting the 260,000 CLIA-certified laboratories in the United States in four priority goal 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 these four goal areas.

Starting with quality laboratory science, CMS and CDC issued a proposed proficiency testing rule in the Federal registry on February 4th 2019. This rule proposes to revise the PT regulations under CLIA related to required analytes, and microbiology sub-specialties and their associated criteria for acceptable performance. You'll be hearing more details on this proposed rule likely from CMS EX OFFICIO Dyer in the next presentation.

The comment period was just extended earlier this week and will now end on June 4, 2019. Following previous discussions and recommendations from CLIAC, three workgroups were formed and have met since our last CLIAC meeting in November, 2018. The non-traditional workflow model workgroup meeting took place at CMS on December 6, 2018.

The next generation sequencing workgroup meeting took place on January 16 and 17, 2019 at CDC. The personal regulations workgroup meeting took place on February 26 and 27, 2019 at CDC. The charges for each of the workgroups are shown here on this slide. This is the first time that more than one CLIAC workgroup has been convened between CLIAC meetings, and there wasn't one or two, but three of them.

It was a huge amount of work during a holiday season and we'd like to express our sincere gratitude and appreciation to all workgroup members who participated, including the CLIAC members who participated and/or led the workgroups, as well as colleagues from CDC, CMS and FDA who coordinated the workgroups and made them happen. We look forward to hearing report-outs and discussions from each of these workgroups over the next two days.

Moving now to a new project we have begun in DLS called the Diagnostic Error Scoping Review Project. During the November 2018 CLIAC meeting, there was an excellent session on the role of the laboratory in improving diagnoses, with presentations from Dr. Reynolds Salerno, Dr. Michael Laposata, and Dr. Gordon Schiff, where they describe the current issues surrounding diagnostic errors and the laboratory's contribution to diagnostic decision-making.

They describe that an estimated 40,000 to 80,000 deaths occur annually from preventable diagnostic errors. 14 billion laboratory tests are ordered annually, and laboratory tests inform the majority of diagnoses. So the laboratory clearly has a role in improving diagnoses. So we, in the Division of Laboratory Systems, are now engaged in developing a structured literature review, known as a scoping review, to summarize and report clinical laboratory practices, challenges, and opportunities that support accurate and timely diagnoses, reduce diagnostic errors, promote multidisciplinary collaborations to improve health care quality and patient safety.

Our scoping review question is, what does the literature tell us about laboratory involved opportunities in the total testing process to improve diagnostic quality and safety in support of health quality and patient safety?

Ultimately, the scoping review is expected to inform a framework for us, in the Division of Laboratory Systems, and others to prioritize laboratory quality improvement initiatives, directed to measurably improving health care quality and patient safety. This project is a work in progress, and the estimated completion date for the project is early summer 2019. So we'll be sharing more updates on this project at a later meeting.

Moving now to safe and prepared laboratories. CDC's 16th International Symposium on biosafety will be held in Atlanta in the winter of 2020. This will be the first time our division is responsible for leading and coordinating the meeting in partnership with the Eagleson 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, showcasing the needs of the biosafety community at large, with specific focus on the clinical and diagnostic laboratory

community. The overall theme of the 2020 meeting is risk assessment. We look forward to sharing more details on this meeting at a later date, as the agenda develops.

The tri-agency task force for emergency diagnostics was established in 2017 to improve the deployment and implementation of emergency use authorized assays, or diagnostic tests. This partnership of CDC, CMS, and FDA was made official through the signing of a charter in February 2019, followed by a press release from FDA. The task force recently met in March 2019, and is continuing to work on specific specimen acceptance and rejection criteria for laboratories using e-way assays so that they can remain in compliance with CLIA, and the authorization for the emergency test.

The task force is also working to improve the process for coordination and communication, for commercially developed emergency tests used by public health and clinical laboratories. Equally important is the development of materials to educate clinicians on how to utilize an emergency test for diagnosing a patient, and the importance of the laboratory adhering to the instructions for use of these emergency tests.

Moving now to accessible and usable laboratory data. Our division is collaborating with the National Center for Injury Prevention and Control, and the Division of Health Informatics and Surveillance at CDC to explore the utility of opioid-related testing data for large commercial laboratories who provide referral testing services. DLS is exploring the extent to which commercial data can be useful for assessing the incident of non-fatal opioid intoxication, and the possibility for understanding patterns of drug abuse, especially co-abuse of opioids with other drugs.

In January 2019, the Council of State and Territorial Epidemiologists or CSTE released a position statement to help states to identify non-fatal overdose cases. DLS participated, along with many other partners and stakeholders, in the development of this document. As more states implement opioid testing DLS is collaborating with the Association of Public Health Laboratories, or APHLs, Bios Surveillance Task Force to create a data repository of their results. CDC and the states would be able to use the data repository to observe trends within a given state, and nationally. And this data can be used to inform future response efforts.

Moving now, lastly, to highly competent laboratory workforce. DLS develops and disseminates a growing inventory of free training resources, including online courses, web-based resources, and tools, and print materials for laboratory staff. We have a national and global audience. This slide summarizes our current portfolio. All web-based resources are freely available on CDC TRAIN. In FY '18, DLS supported 132 in-person workshops or seminars, delivered 16 live webinars, and created 24 e-learning courses.

The website here, shown here in blue, provides access to all the currently active trainings and notifications of upcoming hands-on workshops. You are welcome to join the laboratory training group in CDC TRAIN, which will allow you to get alerted to new course offerings. So in 2017, we decided to take a more strategic approach to our training and workforce development activities, designed to better understand the real needs of the laboratory community, which had primarily focused on public health laboratories, but was now newly expanding to the clinical laboratory workforce as well.

This led to our Workforce Assessment of Laboratory Communities, or WALC project. These last two slides summarize at a high level the current status of this project. So the purpose of this three-year project is to enable the development of collaborative strategies and initiatives that address laboratory workforce development challenges and needs. In year one, we started with a literature review and stakeholder interviews at CDC.

Now in year two, our focus is primary data collection across the clinical and public health laboratory communities via focus groups and interviews. In year three, we will collaborate with partners to develop cross-cutting strategies to address, prioritize challenges and needs.

For our year two data collection, we decided to focus on issues around training and professional development of the current workforce to help craft our Division of Laboratory Systems' portfolio of resources. Our year two research question is, how can DLS support training and other professional development opportunities to make them more accessible, more effective, and tailored to the needs of the public health and clinical laboratory professionals?

The WALC project is, however, not designed to address all workforce challenges or needs. DLS will continue to engage with other partners on additional areas of interest, such as challenges in recruitment into the profession and retention. And we look forward to sharing more details on this project at a future meeting. And that's the end of my presentation. Thank you.

CLIAC CHAIR: Thank you, Dr. Fitzgerald. Any brief discussion or questions for Dr. Fitzgerald? Yes?

CLIAC MEMBER: Just a comment. It was very interesting to hear, the first time for me, the Diagnostic Error Scoping Project. Clearly, there's been work that's supported by CDC. Already, the Institute of Medicine's report a couple of years ago, et cetera. I think that's an area where a lot of us are very passionate. Is the intent to build on that and really go beyond it?

CDC EX OFFICIO: Yeah. Yeah. So right now, the initial strategy was to we gather over 400 abstracts in the initial review, and as part of the criteria for the project. That was sort of narrowed down to, I think, around 133, 135 abstracts. The next phase will be to crosswalk that against the IOM and other reports as appropriate. So that's a work in progress right now.

CLIAC MEMBER: OK, great.

CDC EX OFFICIO: So we look forward to working with others as that develops.

CLIAC CHAIR: Was there another question?

CLIAC MEMBER: No. On the timeline for the emergency use authorization, what is the timeline right now for completion for that?

CDC EX OFFICIO: So for which piece?

CLIAC MEMBER: [INAUDIBLE] from now, from the Friday [INAUDIBLE].

CDC EX OFFICIO: So the group is ongoing. The charter is now signed. For the specific activities in there, I don't have the specific dates on completion of those three activities that I described, but we can get back to you with specific dates on that.

CLIAC CHAIR: Thanks. And if I could remind the committee members, the radius of the microphone is pretty small, so do try to lean in so that it can be captured for purposes of transcription and recording, and for those listening along on the webcast.

All right. Thanks, again, Dr. Fitzgerald. We'll now hear from Miss CMS EX OFFICIO Dyer. This is presentation number two, and this is a CMS update.

Centers for Medicare & Medicaid Services (CMS) Update
CMS EX OFFICIO Dyer MT (ASCP), DLM

CMS EX OFFICIO: While we're waiting, I want to welcome you all to CMS as well. I hope you enjoy your stay with us for the next couple of days. So in the interest of time, I have a lot of information, I'm going to kind of go through it rather quickly. Some of the information is a response to some of the things I presented at the last meeting that I was asked to follow-up on.

I want to give you kind of a high level overview of some areas we're working on. And I also provided-- I'm not going to talk about it-- but I was asked to provide some information on opioid projects and things that CMS was doing. And I actually added about eight or nine slides at the very end that were provided by Dr. Shari Ling. She is not going to be here today as far as I know, but if you have any questions about any of that information, you can send them to me, and I will get them to her and get some answers back to you. OK?

So card stats, we're now up to close to 263,000, 264,000 clinical laboratories. We still see increases in the number of waived, and we see some slight fluctuations in compliance and accredited. As more and more tests get waived, some of these labs are going to COC or COA labs. Most likely the COC.

So again, distribution of the accrediting organization labs. We also included this. We had a question about, how do they self-select, or what are people selected when they apply for CLIA?

So as you can see, are most of our physicians offices, skilled nursing, home health, hospitals, pharmacies, and then there's that other category where they weren't quite sure so they're kind of lumped together.

Now, one of the things I was asked at the last meeting when we were talking about condition level deficiencies top 10, and someone had asked, or a couple of people had asked-- I don't remember who-- what rolled up into that lab director condition level being out?

So two of my staff-- I think it was Dan Cajigas and Kathleen Steed-- actually went back into the data system and tried to pull that information for us. So we broke it down according to moderate and the high complexity. So if you look here on the top three-- quality control, quality assessment, numero uno. It's actually numero uno for both, moderate and high. We then had the proficiency testing, and then kind of a tie for training and competency and test verification.

This kind of makes sense. We are holding the lab director responsible for what goes on in their lab, and obviously, QC, QA, training, major, major issues for the lab to make sure it's taken care of. So we actually graphed it out here, too. And this is the high complexity citations as well. As you say, again, control quality assessment is the number one issue that we cited lab directors for.

So I'll talk a little bit high level about the PT proposed rule. As we've said, the comment period has been extended to June 4th, so if you have not commented on it, please do. We would welcome your comments and your suggestions on the PT rule, as we move forward, has not been done in many years. So this is a good opportunity to update it. So again, just CMS and CDC worked together to develop this. It's taken them a long time. It's a lot of work involved in doing this.

So what CMS and CDC are proposing to do is add 29 analytes to subpart I, and some of those would be CO2, PSA, and phosphorus.

CLIAC MEMBER: Are those the so-called regulated annual?

CMS EX OFFICIO: Yes. They're also proposing to delete five analytes from subpart I. One or two of the examples is LDH ISO enzymes, ethosuximide. We're proposing to update the types of services previously listed for each micro sub-specialty to reflect the required categories, such as antigen detection identification testing for each microbiology sub-specialty.

We have some other proposed changes, and I've split these up over two slides. Removing the list of specific example organisms from each sub-specialty, and adding a list of types of organisms to that, including bacterial morphology for gram stains, decreasing the required mix cultures from 15% to 25% for the culture challenges, and changes to anti-microbial susceptibility testing, direct antigen testing.

Accept its limits is a big-- we get a lot of questions about this. When we look at the criteria for acceptable performance, that is for the proficiency testing. We get a lot of questions from laboratories trying to adapt that to their own testing for regular testing, not just PT. So we're trying to clarify that as well, here in this rig.

Some other additional changes. Target values, definitions, and amending acceptance solicits, unacceptable scores reflect that if moderate and high complexity labs also perform waive tests, PT referral requirements apply. We have issues with waive labs that are doing PT, which is great. We like to encourage waive labs to do PT. If they fail the PT, it still comes under the purview and they still have to address their failures.

What we get is that, well, I ran it. Yeah, but you failed it, and you still need to do corrective action for it. And there's a lot of confusion about, well, I don't have to do PT. Well, if you do it, you have to take responsibility for what your actions and your answers are.

We've been very busy. We've done a lot of fees and [INAUDIBLE] and all kinds of stuff lately. So on 12/31 we published a notice with comment for a 20% fee increase across all of our certificate types. We have not updated fee since 1997. So far, we have not gotten a whole lot of comments back on that. So again, if you think you want to comment on it, please let us know what your thoughts are on that.

So I'd put a couple of slides in here on the workgroups. We also appreciate all the effort that has gone into these workgroups. It is a lot of work and takes a lot of time. So we're all looking forward to hearing the responses from the meeting and the presentations today as well.

And I have a couple of slides in here about the EUA. This is really great. We are so happy to be a part of this. Amy Zale is our representative to this group. And we have the charter signed, and we look forward to continuing the work on this group. Hopefully, we don't have a whole lot more of these emergency uses. We'd like to not have any. But obviously, with the way the world is now, we will probably have more, unfortunately.

So one of my goals when I took over as Director of CLIA is to go and look and see what we need to update in the regulations, because they have not, for the most part, been updated since the beginning of CLIA. So you can see that we have been doing a lot of that. We're doing PT, we've done fees, we've done some other-- did patient access. Obviously, it takes time and you can't do everybody and everything at the same time. So we're looking at what can we do moving forward.

So some of the areas we were looking at. Where are we limited in our guidance? Where are we limited in what we need labs to do? So we started looking at histopathology.

There's some new issues that have come up. We're not addressing slide prep and staining. We have molecular and immunohistochemical stains that are being classified as high complexity, but the personnel doing these are not high complexity personnel. There are also new polymer detection kits that negative controls are not necessary, but current regs require negative and positive control. So that's created some interesting issues for us.

We're also considering possible request for information or RFIs on histopathology, and some areas in microbiology, such as the reportable organisms and conditions, biological safety processes, contamination, and antimicrobial susceptibility testing. I also wanted to keep you aware, cytology was the impetus for CLIA. And I can tell you, these issues were all identified in the very beginning. We are still seeing a lot of these same issues. This past year, we have had many cases of where we've gone into cytology labs and found major discrepancies in the slides, no workload records-- just really not doing what we expect them do under CLIA.

So we currently have in-depth surveys for cytology. We have a team that actually goes in, actually does slides and read slides for us, and they're fully operational CLIA surveys. So these are some of the issues we've identified in the last year or so. Lack of knowledge regarding cytology regulations. No procedure manuals. Lack of the awareness that you need procedure manuals for your testing. Diagnostic discrepancies that range from unsatisfactory to carcinomas. Failure to document unsatisfactory specimens, and failure to document their workload. Individual workload limits are not established or re-evaluated every six months, if they have them. And prorating the number of slides when examining slides in less than eight hours.

I included some of the cytology proficiency since 2005. We're still seeing issues with pathologists who are reading slides without the benefit of a cyto technologist. The other two packed with cytologists and a cyto tech are pretty much consistent now. About 2% are not passing each year.

So we have some goals to try to improve our cytology oversight. We're going to continue our in-depth surveys. We think they're very beneficial to the lab when we go in. We're continuing to engage stakeholders through presentations, our Lab Excellence Mailbox. We're going to be focusing some cytology training for our state agency surveyors. And we're developing a surveyor tool, and we're also increasing state agency surveyor observation.

State servers hadn't been going in with the survey team, and we've now encouraged them to go at on site with the team so they can see how they do the cytology surveys. We don't expect them to look at slides, but they can at least see and observe the process.

When to follow-up on our FMS. It's a little small. I apologize for that. We started our new FMS process. This was a lean project that we did. Took us almost two years to totally revamp our process. We had regional office involvement with this. So we started this in January, so we're now just starting to see some of the benefits of that and going back and looking at what's working, what isn't working, so we can continue to revamp it.

So our improvements, we have one standard operating procedure for regional offices. What we found was everybody was kind of doing a little bit of their own thing. That's not good. We want everybody to be consistent when we're doing these processes.

So our regional office surveyors are utilizing a worksheet and a summary report form. We actually have them as Adobe PDF electronic fillable forms. So we've eliminated a lot of the paper forms and carrying them around. We have regional office identification of the surveyors' overall training needs. And the RO share, the assessment documents with us in central office to evaluate, so we can kind of gear our trainings and national meetings towards that. We also are developing some more quality monitors for that whole process.

So this is our criteria for who is going to require an FMS assessment on this in the state level. We're also really happy to announce that we now have a CLIA listserv. We just developed this within the last month. It's still very, very new. I think right now we have about 1,200 people signed up for it. We don't want to inudate people with emails, but we want to use this to get important things out to everybody.

So if you would like to spread the news about this, we would be very grateful. We figure we will use it for just policy changes, new regs, announcements, that type of thing. If you have some suggestions of what you would like to see for this, please let us know. Again, we don't want to inundate people with just tons of CLIA email.

And the link will tell you it's relatively easy to sign up for this. And these would be the slides from Dr. Ling. I will just real quickly go through them, kind of an overall look at what CMS is doing in regards to the opioid crisis. And that ends my presentation. Thank you.

CLIAC CHAIR: Thank you, Miss Dyer. I'm afraid we don't have time for questions, but maybe in the general discussion if there are questions for Miss Dyer, we can circle back to that. I will call now upon Dr. Peter Tobin. This is presentation number three for FDA update.

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

FDA EX OFFICIO: Good morning, everyone. In the interest of time today, I'm just going to focus on updates to a couple of areas that we talked about last time. Following up on the FDA innovation challenge for devices to prevent and treat opioid use disorder. A little bit of update on anti-microbial susceptibility tests. And a little bit update on the draft CLIA waiver guidances.

So last time I talked about a FDA innovation challenge that sort of built on a broader program that we have called breakthrough devices, where we work with device manufacturers in a very interactive way, help them from the beginning to design studies and to help ensure that they're moving in the right direction to bring new and innovative devices to market.

There was an innovation challenge specifically for opioid use disorder that was put out last year. At the time of the previous meeting, that applicants had not yet been selected. We had over 200 people apply, and the applicants listed here were selected. So CDRH, so Center for Devices and Radiological Health will be working with these applicants in an interactive manner to help bring these devices forward and help them design studies, so that they can apply for marketing authorization or clearance.

Another issue that we talked about last time was that we don't currently have any marketing authorizations for confirmatory drugs of abuse tests. We still don't have any of those, but we have had some interesting discussions with several test developers, and we're happy to work with them in a least burdensome manner to try to bring those devices to market as well.

I'd also like to provide a little bit update on several different steps that we're taking in the antimicrobial susceptibility test area. There's a number of actions and developments in this area that are going on. I'm only able to report a few of them so far, but we're going to continue to make more action in this area because it's an important area. We did recently publish a final guidance on the coordinated development of AST devices, along with antimicrobial drugs.

This guidance outlines how drug and device developers can work together. So basically in this situation, there's drug developers that are working with CDER, there's device developers that are working with CDRH. It's a lot of moving parts, and it can be really helpful to have a framework for all of these groups that work together, and try to make sure that we can get these devices on the market as soon as possible after the new drug has been approved. And following on from initial workshop in this area and some draft guidance. This approach already has been piloted between the draft guidance and the final guidance. And we've had some significant effects from this in terms of the availability of new AST devices after new drug approvals.

So the top area above the line shows some data for a particular drug approval and devices related to that drug after this new approach has been used. And the area below the dotted line shows some data from a few years ago, before there was this coordinated development in place. So you can see that it really does help to get these types of devices to market faster after the new drug approval.

One of the big areas that we were talking about last meeting was about the promotion of time and integration of updated antimicrobial susceptibility tests, interpretive criteria, breakpoints and device labeling. When those updates are changed, and this is including for not just new drugs but for existing drugs when those breakpoints are changed.

So we are, in response to the recommendation from CLIAC, we are looking into updating the guidance, as well as other approaches to address this issue. But one approach that we were able to implement right away was to use this idea of breakpoint change protocols to help promote the time, the integration of this labeling. So basically what happens in this case is the device manufacturer, in coordination with FTA can develop a protocol to address future changes to device labeling in response to when those breakpoint changes are recognized by CDER on the FDA STIC web page.

And then these protocols are submitted as part of a 510K and reviewed by FDA. And then if the criteria in the protocol are met, the manufacturer can update the labeling without the need for a new 510K. So this can speed the ability for these updates to be made, and it provides benefits to patient care, public health laboratories, and the manufacturers. For a little bit more information you can see the one decision summary from March that's listed here. And we know this is just one element to ultimately help promote the time and integration of these changes. So we'll be continuing to do further developments in this area.

Additionally, we reissued the CLIA waiver guidance as a draft. So I mentioned at the last meeting that we're planning to do this. These came out toward the end of November, and you can download the drafts from the link here. We also held a webinar in January. It went into more detail about the draft guidances.

We put them out again in draft to have comments from stakeholders because we did change them significantly from the previous drafts. The comment period for that did close toward the end of February, and we're currently in the process of going through those comments. And I'm just going to provide a real quick overview of some of the details in there, and then since we don't have a lot of time, you can look at these slides for some highlights, or you can also go to the webinar.

The main idea is that these guidances are a little bit higher level. We see quite a broad range of different types of IBD tests that apply for CLIA waiver. And so these guidances are really emphasizing looking at validating the accuracy of the candidate test is not meaningfully impacted by differences between waived and non-waive use.

And in general, we're relying more on FDA recognized standards, generally CLSI standards, instead of having particular information in the guidances that was not necessarily broad enough for the range of tests that we actually see for CLIA waiver. And also, those CLSI guidelines can be updated faster and kept up-to-date more frequently than-- it's easy to do with guidances. So for the rest of the slides, please feel free to take a look through those. We also have a CLIA waiver decision summary process that's now going strong. We have 16 decision summaries up there now, and we're going to continue to post these. And so for the rest of the few slides, since I think we're out of time, please feel free to take a look at those or the webinar.

CLIAC CHAIR: Thanks, Peter. Can we have the public comment now, before Dr. Campbell's presentation? And Peter, as with CMS EX OFFICIO, we'll get to questions when we do general discussion.

Public Comment

ROBIN STOMBLER: Good morning. Mr. Chairman, members of the committee, my name is Robin Stombler. I am President of Auburn Health Strategies, and I'm here today on behalf of the American Proficiency Institute.

API was pleased to see the proposed rule on CLIA proficiency testing regulations related to analytes and acceptable performance, issued in February. This proposed rule has been long anticipated, and forward movement is a positive development. By way of introduction, API is one of the nation's largest proficiency testing providers, serving over 20,000 laboratories. Widely accepted API clinical proficiency testing programs are approved by CMS, the Joint Commission, COLA, and all state health departments. The College of American pathologists also accepts most analytes for its laboratory accreditation program.

Established in 1991, API was granted ISO 17043 accreditation for operating proficiency testing schemes in 2018. API has formally commented in writing on several aspects of the proposed rule. In fact, API, along with other proficiency testing providers, voluntarily provided data to assist the government in its study of the analytes and acceptable performance measures several years ago.

Today this opportunity is appreciated to share with you one section in particular of the proposed rule that will have profound consequences for proficiency testing providers and the laboratories they serve. The proposed rule would amend Section 493.901(c)(8) to require, quote, "all functions and activities related to administering the PT program must be performed by a private non-profit organization or state," end quote.

Requiring contractors performing administrative responsibilities to be private non-profit organizations or federal or state agencies will significantly undermine proficiency testing operations. This proposed section would eliminate essential services on which private non-profit and state-run proficiency testing providers rely. From obtaining source samples, to customer shipping and delivery, to information management services, contracts with these for-profit vendors are vital.

In order to receive approval from HHS, proficiency testing programs must be offered by private nonprofit organizations or federal or state agencies. The current system for monitoring compliance has an annual approval process that is robust, and can ensure that the program is operated by a not for profit entity, as required by the statute. In fact, the proposal itself states that, quote "100% of PT programs are non-profit organizations," end quote.

While the proficiency testing programs themselves are administered by private non-profit organizations, components may be performed by for-profit entities or subcontractors. This business practice has been used for decades. Proficiency testing programs are sufficiently complex that no one organization can deliver every element of the process themselves. Contracts with vendors, some of whom are for-profit, are necessary.

This section of the proposed rule has the capability of significantly altering business practices by restricting contractual relationships. The availability of proficiency testing providers and programs may be at risk. At a minimum, this section requires careful clarification and full regulatory impact analysis. We urge CLIAC to join invoicing concern over this particular proposed section.

Thank you for your time.

CLIAC CHAIR: Thank you very much for that. Dr. Campbell, will you now give us an update on the CDC Office of Infectious Disease Board of Scientific Counselors meeting. And this is presentation number four. Time.

CDC OID Board of Scientific Counselors (BSC) Update
Sheldon Campbell, MD, PhD

DR. SHELDON CAMPBELL: Thank you.

The in-person meeting of the Office of Infectious Disease Board of Scientific Counselors had to be canceled due to the day of mourning for President G. H. W. Bush. So we met by teleconference on the 6th of December, and really had a focused discussion on three topics, two of which I think are of interest to CLIAC-- three of which-- I'm sorry. The issues around the recent outbreaks of Acute Flaccid Myelitis, and the Food & Safety Modernization Act surveillance working group, and future activities with the Infectious Diseases Laboratory working group.

As of the meeting in December, there were 460 confirmed cases of Acute Flaccid Myelitis, defined as shown on this slide, with a remarkable biennial distribution, a significant outbreak every two years in 2014, 2016, and 2018, with relatively low activity between those years. The average age of onset is 6.3 years. 61% of the patients are male, with an ethnic distribution similar to the US population. 87% of cases reported an antecedent respiratory or febrile illness more commonly than a gastrointestinal antecedent illness. 20% or 30% of these cases had enterovirus type 68 detected from a respiratory site. But there was no consistently identified viral pathogen.

So there is an Acute Flaccid Myelitis task force that's been formed with stakeholders from neurology, infectious diseases, and the laboratory community, academia, and public health as well, which is trying to understand the epidemiology pathogenesis, treatment and management of this condition. And there's considerable efforts in virology and pathogen discovery.

The viral trigger, the leading hypothesis is still that enterovirus D68 is at least an important viral trigger. However, it's a little unclear how long this virus is shed from the respiratory tract after an acute illness, and if it's six months, it's hard to say that that association is a real one. So we need better understanding of enterovirus epidemiology to really understand this association that exists. We have used many of our available discovery methods to try and detect a pathogen in the spinal fluid of these patients without consistently doing so, and the thinking is that it's likely to continue to be true.

Looking more deeply at antibody responses and immune cell receptor responses is hopeful. And so there are meaningful efforts to do both of these things to look at multi pathogen peptide micro rays, immune cell receptor repertoire profiling, and other ways of looking at the host response as a way of getting at the etiology of these cases. The kinetics of the disease, relative to antecedent conditions, suggests that antibody mediated pathology is unlikely. So autoantibody responses are not high on the research list. And there is also looking at examining host risk factors that may point to a pathogen as well. So it's very much a work in progress.

The Food Safety Modernization Act surveillance working group made a report, and we're still trying to put together the reporting and surveillance system for food safety, particularly in light, as CLIAC has discussed several times, of culture independent diagnostics. Culture independent diagnostics have had a clear impact on the case finding in foodborne illness. At this point, 50% of diagnoses of foodborne illness in California are made by culture independent diagnostic tests. This has increased detection, increased workload for public health laboratories without increased resources. We think this is overall a good problem since we're missing fewer cases. Several outbreaks have been detected over the last couple of years.

The Infectious Disease Laboratory working group, co-chaired by Jill Taylor and Susan Sharp, has been working with the Public Health Laboratory community on the response to culture independent diagnostics, and moving

food testing and Infectious Disease Laboratory testing into the next generation sequencing era, and managing the transition from culture, to culture independent diagnostic testing.

And this laboratory working group is looking at its role going forward as an advisory group, the CDC in managing the transition to culture independent diagnostics in channeling information and merging practices from industry and the professions toward CDC and public health community.

The Infectious Disease Laboratory working group does not have continuing funding, and so its role is still up in the air. So the Infectious Disease Laboratory working group feels like they still should and may have a role, and in managing this transition from the culture paradigm of diagnostic testing, to the culture independent paradigm. And so I think I'll leave reading the details here to the audience and give time for questions for all the speakers.

CLIAC CHAIR: Thanks, Dr. Campbell. We actually do have a minute or two for questions, which maybe we can-- if there's brief questions now, otherwise, obviously, this will be a topic for conversation.

Committee Discussion

CLIAC MEMBER: I have a question, going back to Ms. Dyer's presentation. You showed that 20% of citations for high and moderate complexity against lab directors were high, and moderate complexity lab directors were for proficiency testing related issues. I know in the past, one of the most common citations given is that the PT attestation form is not physically signed by the lab director. Inspectors have not in the past accepted electronic signature, a copy of the original signed form. You've talked several times about trying to modernize CMS and to current practices. Has it been thought about accepting electronic signatures, or copies, or not requiring that the physically signed attestation form is in the lab, to not be cited for PT attestation forms.

CMS EX OFFICIO: That's something we'll probably take under consideration with us.

CLIAC MEMBER: A similar question on the topic. Is there any follow-up on what happens after citation? Are there repeat offenders, as it were, or does any further disciplinary action follow?

CMS EX OFFICIO: As far as what?

CLIAC MEMBER: The citations to laboratory directors.

CMS EX OFFICIO: Well, they do have to have a corrective action plan. They have to fix what we've cited. And if they don't fix it, obviously, we continue with more enforcement on that particular laboratory. But we do try to work with them to help them come back into compliance.

CLIAC MEMBER: And what percentage? Does it usually happen 100% of the time, or 50%?

CMS EX OFFICIO: I don't actually have that percentage on hand. I mean, I would think it would be very high. Obviously, the lab director doesn't want to not have his lab. So they're going to want to try to come back into compliance as quickly as they can. So I think it would be a relatively high percentage that would come back into compliance.

❖ Presentations and Committee Discussion

CLIA Personnel Regulations Workgroup

CLIAC CHAIR: Thank you, everybody. Well, the first topic of the day is going to be the workgroup report from the CLIA personnel regulations workgroup, with a brief introduction by Miss CMS EX OFFICIO Dyer again, followed by the workgroup report presentation by the Chair, Dr. Lee Hilborne-- this is presentation number five. The workgroup is on the CLIAC website. Again, this is presentation number five. Does anyone in the audience wsh to address the committee during the public comment portion of this topic? I think we had one, two--

CLIAC DFO: Three. You've got three.

CLIAC CHAIR: I thought that we had three. Why do I only see two hands? Help me out here. Oh, here we go. Sorry. Fantastic. Well, good. Well, after public comments we will have a break, and then we'll begin our discussion. So let's see, is Dr. Bert Gold here?

CLIAC DFO: He's here.

CLIAC CHAIR: Fantastic.

CLIAC DFO: Did you want to do the public comments now?

CLIAC CHAIR: I think we'll do the public comments now.

Public Comments

DR. BERT GOLD: Ladies and gentlemen of CLIAC. I come before you today as a medical specialist who is highly skilled in molecular genetics and molecular pathology. Clinical molecular testing laboratories perform and interpret important genetic tests. Currently, CLIA 88 regulations allow general pathologists to serve as technical supervisors of these labs. CLIA 88 should be updated to require that these supervisory positions be filled by molecular specialists, such as those who are certified by the American Board of Medical Genetics and Genomics, the latter, a term coined in 1986, shortly before CLIA's adoption.

Molecular specialists are highly skilled in troubleshooting and interpreting molecular tests, and in counseling patients and their families about tests results. I propose that general pathologists who lack molecular training be excluded from acting as technical supervisors in next generation sequencing, and similar specialized laboratories. Only those specialists with expertise in molecular genetics and molecular pathology should be allowed to counsel physicians and patients on the meaning of the results of molecular genetic tests.

Why? Because general pathologists and others who lack a molecular certificate are not qualified in Bayesian statistics, or genetic counseling, molecular test troubleshooting, and the interpretation of NGS sequencing. In the United States, many recent startup companies in the field of health care are mainly or solely DNA laboratories. I have elaborated that there are many unique spheres of knowledge that molecular geneticists possess.

Some companies employ general pathologists who are not trained or competent in many of these areas. These companies may contract with outside specialists, including in other countries, through business associate

agreements, BAAs, to obtain a genetic testing expertise that they lack in fields, such as variant interpretation and counseling.

Currently, there are two opposing theories of medical test regulation. One theory, as manifested in CLIA and ISO 15189 takes the position that laboratory directors and technical supervisors are professionals who must take responsibility for their technical sections. These regulations acknowledge the credentials, training, and experience of qualified individuals.

The other competing theory of medical test regulation as manifested by the FDA and ISO 13485 rules asserts that a management representative, a regulatory expert employed by a company, may act as an interface between a company and a regulatory agency. Such management representatives are not necessarily medical professionals and may lack special credentials, qualifications, or skills. They may be beholden to venture capitalists, entrepreneurs, and corporate management.

Currently, the FDA adheres to the second theory of medical test regulation through the offices of management representatives. The College of American Pathologists, CAP, also advocates for the use of management representatives to regulate molecular diagnostics. CAP has taken a position that is not in its own best interests or those of patients. First, it does not recognize its own molecular pathology fellows as technical supervisors in the CLIA law, so that generalist pathologists can sign off on technical reports that they may not fully understand.

Second, CAP's policies enable labs to be represented to FDA as companies with corporate liability, rather than as practicing professionals committed to their patients. CAP is a powerful guild, but we must not allow them to trample on common sense. In the past few weeks I have come to realize there is a conflict between the principle of the Hippocratic standard of premum non nocera and physician greed.

The Hippocratic Oath implores physicians to put the patient first, and thereby to do no harm. Pathologists may do harm if they fail to recognize the special skills of their own molecular pathology trainees, skills that general pathologists may lack. The average anatomic clinical pathology, APCP, who may lack special training must not be permitted to sign off on complex genetic sequencing results and to provide genetic counseling, a practice that the CLIA law as written now permits.

In the last 30 years, the field of genetic testing has become more complex, thus necessitating that specialists with commensurate expertise oversee NGS and similar advanced genetic testing labs.

Bert Gold PhD, FACM, GG, CGMB, San Mateo, California. Thank you.

CLIAC CHAIR: Thank you, Dr. Gold. We'll proceed with the remaining public comments before the introduction. Is Dr. Luis Chiriboga here? Apologies if I mispronounced your name.

DR. LUIS CHIRIBOGA: Good morning, everybody. Good morning, committee. My name's Dr. Luis Chiriboga. I am a practicing histologist and a biochemist by training. I've been working in the CLIA laboratory field for about 10 years, and have most recently become a director of a clinical translational histopathology laboratory, and I'm here today representing NHS, which is the National Society of Histotechnology, to reinforce the need to make sure that histology professionals are being recognized under the CLIA guidelines for their professional standards.

My colleague, Claire Thornton, was here back in November, and she was fortunate enough to listen to Dr. Michael Laposata's presentation on diagnostic error, which actually strikes the point home all the way for the people in histopathology laboratory, because the specimens that we are beginning to see in histopathology

laboratories are getting smaller and smaller, with a higher demand of testing being required of that particular specimen. These specimens are complex in their nature, and they're difficult to obtain. It's not as simple as going back and drawing another blood sample.

And we feel that this is an important consideration that the individuals tasked with handling these specimen from the pre-analytical through post-analytical phases of diagnostic testing be certified and under the auspices of the CLIA guidelines. NSH is proposing that these individuals be required to pass an accreditation test. We understand, and we certainly appreciate, the issues in terms of the workforce shortage. So NSH is also proposing that CLIA provide some mechanism in terms of grandfathering to make sure that the-- excuse me-- to make sure that the histology workforce or the workforce in general is not depleted by these new regulations as they are put into effect. And we hope to be able to continue to work directly with CLIAC to make sure that these issues that we feel are very important in the histopathology field are addressed, and make the public aware of what's going on. Thank you.

CLIAC CHAIR: Thank you, Dr. Chiriboga. And finally, Barbara Caldwell from ASCP.

MS. BARBARA CALDWELL: Good morning, everyone. My name is Barbara Caldwell, and I am a Medical Laboratory Scientist. I was a former educator and a laboratory administrative director, and I'm representing ASCP and the ASCP Board of Certification this morning. ASCP and the BOC wish to thank the CLIA personnel regulation workgroup, and its Chair, Dr. Lee Hilborne, specifically for their thoughtful consideration of a number of issues surrounding modernization of the CLIA personnel regulations.

The ASCP and the BOC agree that all high complexity testing personnel must complete appropriate Baccalaureate degrees, such as a degree in medical technology, clinical laboratory science, or the biological or chemical sciences. Quote, "Medical laboratory science," unquote, specifically should be added to this list as well. The ASCP and BOC agree that individuals with non-traditional degrees should be considered when they have the required and appropriate science coursework.

We believe every Baccalaureate degree holder must complete at least 30 semester hours of coursework in the requisite sciences. Only those physical sciences and other degrees satisfying this standard should be recognized for purposes of high complexity testing. The ASCP and the BOC support the workgroup's recommendation that, quote, "all testing personnel should have experience and training," unquote. CLIA's high complexity personnel rules, however, do not currently, specifically specify that such a requirement is needed for individuals with Baccalaureate or higher degree.

ASCP is disappointed that certification was not in the scope of the discussion by the CLIA personnel regulation workgroup. We note that the November 2018 CLIAC meeting minutes stated that the workgroup should address the possible use of competency exams. While ASCP and BOC believe that patient care is best served by certified laboratory professionals, we also believe that the Board of Certification certification examinations could facilitate the employment of high complexity testing personnel, including those with non-traditional degrees.

When the BOC processes application for certification, we verify the academic education, including transcripts, clinical training, and/or the work experience of all of the applicants. As a result, the BOC has taken care of that burdensome process of determining whether individuals possessing non-traditional degrees have completed enough academic science training to successfully work in laboratory occupations. Therefore, recognizing certification could expand the labor market and help address personnel shortages.

The ASCP and BOC urge CLIAC to task the workgroup with considering possible roles that certification examinations could have in facilitating the eligibility of individuals to supervise or perform high complexity

laboratory testing. Further, we recommend that CMS outline standards for recognizing certification agencies, such as the BOC as Primary Source Verification, PSV, organizations for the purposes of verifying a laboratory professional's academic education, clinical training, and work experience.

Again, this would reduce the burden of documenting personal qualifications and competencies, which is, I can attest, a very burdensome process. For those individuals whose training programs have closed or who can no longer satisfactorily document their education training and/or work experience, PSV may be the best approach, Primary Source Verification. We recommend that CLIAC, the CLIAC workgroup, that CLIAC ask the workgroup to explore PSV as a tool for reducing CLIA's documentation burden.

The ASCP and BOC appreciate the workgroup statements for supporting the establishment of personnel standards for histotechnology professionals, like those currently in place for high complexity testing personnel. We urge CLIAC to adopt such a position and its recommendations to CMS. In closing, the ASCP and BOC thank CLIAC and the workgroup for its discussion of the CLIA personnel requirements. We strongly support the recommendations provided so far by the workgroup and encourage CLIAC to urge the prompt adoption of these requirements by CMS in a proposed rule.

We look forward to working with CLIAC on these goals, and thank you for the opportunity to provide these public comments.

CLIAC CHAIR: Thank you very much, Miss Caldwell. Miss CMS EX OFFICIO Dyer, would you like to step to the podium.

Introduction to Topic
CMS EX OFFICIO Dyer MT (ASCP), DLM

CMS EX OFFICIO: Just wanted to say thank you to Dr. Hilborne for chairing the personnel workgroup. [AUDIO OUT] --of what CMS may propose to change in the personnel regulations, or what may have appeared in the RFI. However, they are specific issues that we believe the CLIAC committee should discuss, and for which we would ask CLIAC to provide recommendations.

Our approach to potentially updating the personnel regulations is very focused. And we appreciate the thoughtful consideration that both the workgroup and CLIAC have spent in preparing the report and formulating recommendations to CMS. Are we going to go ahead and do the--

CLIAC CHAIR: Yeah, so a little technical check-in here as we get online again.

AUDIENCE: This is going to take a second [INAUDIBLE].

CLIAC CHAIR: So given that, at least-- I do not have internet. I don't know if others do. I wonder whether the Livestream has also been interrupted. So I wonder if it might take more than a minute, and I'm directing this question to you, Heather. Maybe we ought to take our break now and come back in 15 minutes or so for the exciting conclusion of the beginning here. Oh, I guess we don't.

AUDIENCE: Yeah. I think everything's rebooting.

CLIAC CHAIR: All right. Well, how about we take a break. It's-- Oh, we just got sound back. But we're going to take a break any-- wait a minute. I spoke too soon. I guess the AV system responds to threats. So bear with us, everybody. If we can get our video back up in the next minute or so, and internet back up, and if we have some confirmation-- Heather, maybe you have some confirmation of the live feed, or people around the table?

CLIAC DFO: Internet's still not up.

CLIAC CHAIR: Internet's still not up. Let's come back in 15 minutes. That's the easiest thing. So if everybody could plan to be back here at 10:10, and thank you for our presenters this morning, and for our commenters. See you at 10:10. Thanks.

CLIA Personnel Regulations Workgroup Report
Lee Hilborne, MD, MPH

DR. LEE HILBORNE: OK. So hopefully, many of you have the presentation. It was handed out. It was on the table there. It's available electronically online.

So I'm here to report on the Personnel Regulations Workgroup. And it certainly was a pleasure to work with all the members of the workgroup, so I really want to give a shout out to all of the group who really represented a broad spectrum of people involved in laboratory medicine-- the people from accreditation organizations, from the state organizations, people with specific areas of interest and specialties, et cetera. So I think we had a pretty robust conversation.

And probably more importantly, a big thank you to the HHS staff who really helped pull this all together. So Heather, who is pulling it together yet again behind me and the CMS and agency staff were really, really good. So CMS EX OFFICIO already introduced a bit the charge of the workgroup. The charge of the workgroup was to provide advice to us at CLIAC for considering and making recommendations to HHS on revising some of the CLIA personnel regulations. I'm almost afraid to touch it.

So basically, the workgroup was to advise on questions that were asked by CMS during the meeting in November. And again, that was a very focused set of questions as CMS EX OFFICIO Dyer pointed out. And I think there are probably other questions that the CLIAC may want to consider or may want to have others consider. And we heard that in some of the public comments as well.

So there were a series of nine questions. And I have each of these-- I think the intent is for me to go through all of them. And then, we'll have a discussion. So the first question was, what should be considered an appropriate educational background in terms of degree and curriculum to meet CLIA personnel requirements under chemical, physical, or biological science degree? So the first thing, in terms of the discussion, is we realize that physical science degrees probably alone would not be an acceptable degree under CLIA and the reason being that many of those programs, whether it's earth science, or physics, or whatever, may not have the other biological items that were important. So we thought that the removal specifically of a physical science degree as being qualifying was important.

And therefore, acceptable degrees should include chemical, biological, medical technology, clinical laboratory science degree. And we did hear from Barbara Caldwell also that medical laboratory science. But I think the concept-- our goal was really to provide it to CMS. I think that's an important clarification in terms of the degrees, at least in their title. And we'll talk a little more because the titles have changed.

But ultimately, the base requirement is that individuals who want to qualify to be laboratory personnel under CLIA need to have the necessary coursework to provide a foundation on which to effectively work in the clinical laboratory. So the acceptable degrees, as we list here, are chemical, biological, medical technology, et cetera, are acceptable because the course of study includes the relevant coursework. And therefore, those degrees really are a surrogate for the appropriate coursework.

So because degree titles have evolved and changed it's challenging to determine the acceptability solely based on the degree name. This was our discussion. And then examining transcripts for folks is really labor intensive. And course names can be misinterpreted. One of the things, in terms of specifying the exact or the general areas of education that would qualify, the minimum number of required semester units in the appropriate sciences is only included for high complexity testing personnel. So we think that that should be more generally expanded for clarity.

Also, individual's nontraditional degrees should be considered when they have the required education and background in those respective areas of education. So that's really the gist of it no matter what is that you need to have the requisite education. These degrees may be a surrogate for that. But the education is really the underpinning. And that would be the same situation.

If you had a degree in physical science, but you had the necessary underlying education, that would be sufficient. Same thing-- as I know the discussion has come up with nursing. The other things-- there needs to be a consistent approach to evaluate education. That's needed by CMS, the accrediting organizations for those states that are exempt and also for the Department of Defense.

We recognize that basically requirements, in terms of specifying the education, should graduate with a level of complexity and responsibilities the individual has. Testing personnel need one level, but as you move up toward consultant and director, et cetera, that those were important. Minimum education, I think we all agree, is necessary. It's necessary, and it gets you in the door, but it's not sufficient. And we'll talk in question two about the training and experience.

We want to also look at evaluating the educational requirements across certifying agencies so that there's consistency. Because there are multiple certifying agencies involved, and the requirements do change. We did hear, for example, from [INAUDIBLE] this morning with their set of recommendations. And then, we also heard this morning some consistent-- whether personnel requirements should be added for histotechnologists, histotechnicians, pathology assistants, and bioinformaticians. So those are all areas of discussion.

So the next question really moved from education to training experience and supervision. And the question we were asked is, what laboratory training or experience should be required for testing personnel and technical consultants and then supervisory experience for the laboratory directors and technical supervisors? The workgroup concluded that all personnel should have experience and training in the responsibilities listed for their CLIA positions at the appropriate test complexity. So that's all listed in the various components under CLIA.

Some discussion items that we had that we should discuss here, whether the issue of about training and experience should be in a CLIA-certified laboratory, whether the training should be from an accredited institution or organization. We also thought it was important. We did have representation from DoD, that the experience obtained in non-CLIA labs-- DoD, VA laboratories-- needs to be recognized as equivalent as they migrate to take on civilian roles. Also, in terms of experience, just the ordering of diagnostic tests alone doesn't qualify as laboratory training or experience. It's interesting, but not relevant for the experience to be a laboratory functioning person.

Personnel need to be trained in the areas they perform. And basically, one can grade that and move to higher level positions. The laboratory director should have experience directing personnel in a CLIA laboratory. That kind of goes with the training of people up above. We did recognize that training varies, that general training required for board certification versus specialized training in a laboratory specialty are different. The clinical laboratory experience, we believe, in terms of qualification, is implicit in the requirements for obtaining board

certification in laboratory medicine specialties. So that's pathology, the American Osteopathic Board of Pathology, or the other boards that are recognized by HHS for PhD certification, [INAUDIBLE].

The other piece that we were asked as part of question two is, what is the appropriate documentation to verify the training experience and supervisory activities? CMS really told us that-- and that they use-- transcripts, diploma, letters of laboratory directors that are official, include experience and time frames. But a CV alone is not sufficient.

We recognize that obtaining documentation can be challenging when hospitals or laboratories have closed. I think that that would dovetail into some of the comments we heard about primary source verification from organizations that have already verified that information, perhaps at an earlier point of time. That might want to be looked at. Templates or forms would be helpful. And then, consider making documentation and competency assessments in a way where in fact the experience can roll up and make it easy to pull together.

We had a long discussion about qualifications on laboratory director qualifications. So the question being, what is possessing qualifications that are equivalent to board certification mean? Well, there were a number of discussions. First of all, it was not possible to really evaluate qualifications equivalent to board certification in AP or CP by the respective certifying boards. So the recommendation really was to remove the option for meeting director technical consultant, technical supervisor qualifications by these routes from the regulations.

It doesn't mean that they wouldn't qualify. It's just that the issue of equivalency didn't really make sense. And it's very difficult to make that work, so the group, as a whole, recommended deleting that. We recommend that pathologists must be certified by the American Board of Pathology or the Osteopathic Board to meet the CLIA qualifications via board certification. So if you had another certification as a pathologist or a foreign board, et cetera, that they would still qualify, could still qualify, by other regulatory means that are specified, but not by virtue of board certification.

The other thing that was discussed was this whole issue of board eligibility. Most boards have gotten off of the definition of being board eligible. But in terms of this period, for somebody who completes their training who may meet their requirements, we concluded that perhaps the period of eligibility for certification may be given out for the purposes of identifying these individuals as directors. But the status of board eligible really wasn't meaningful.

The next issue that the group discussed-- was asked to discuss-- is the 20 continuing hours of continuing education. Should it be required for everybody, regardless of degree prior to qualifying for moderate and high complexity laboratory directors? And we saw some of the data that CMS provided us, that there are a lot of laboratory director citations for things that would suggest that perhaps the laboratory directors don't completely understand their roles and responsibilities. And this may be one way, in part, to meet that.

The group agreed that the requirement for 20 hours in laboratory practice that's consistent with being a director responsibilities should apply to all modern and high complexity directors except those who qualified by virtue of having board certification in one of the approved boards-- either the pathology boards or the HHS-approved boards, with the notion that those boards include training in the 20 hours that are already specified. And to that end, that it's important to assure that current and future recognized boards actually include the 20 hours of education and training in clinical laboratory operations to meet the requirement. We think that most of them do at this point, but it's worth looking because if, in fact, that's going to be a route to exempt from having to take the 20 CE units, then it needs to be inherent in their training.

The residency requirement for a one-year laboratory training during medical residency for high complexity laboratory directors who qualify through this route should specify clinical laboratory training, although we're

going to come back to this in a minute. I mean, the issue here was the specification was for laboratory training, but they could have experience in a research laboratory that had nothing to do with running a clinical laboratory. So the intent here was to be explicit, but we'll address that a little bit more. And then, I think we can discuss it.

The requirement right now that we talked about, well, who needs to do that the training, the 20 hours? It applies to certain moderate complexity laboratories, but really, for the reasons we stated that everybody should have that knowledge and it's important to get it. In terms of the available CE courses right now, there are two available. They're on the web to meet that requirement, so it's not a difficult climb to get there. And if, in fact, the expansion is required, it's very likely that other organizations who traditionally offer continuing education will do that. And the recommendation in terms of discussion was really to review already approved boards to ensure that they include that kind of training, which I already discussed.

We had a brief discussion. How often should a laboratory director be required to be on site at a laboratory? And there was agreement that laboratory directors of both moderate and high complexity testing should be on site a minimum of once every six months with visits not less than four months or not greater than eight months apart. So it didn't have to be exactly the time. But we didn't want, if there were two visits per year, for them to occur April 11 and April 12. Right? So we wanted it to be far enough apart that the laboratory director really saw what was going on in the laboratory for which they were responsible. And that tasks should include things that cannot be easily assessed remotely or delegated. And visits should be clearly documented-- pretty standard stuff.

That, in terms of the discussion, some states and accrediting agencies do have specific requirements requiring some minimum visits. In terms of our discussion, it may help decrease the number of director deficiencies that CMS EX OFFICIO Dyer discussed. Adding that 20 CE requirement may help move to that as well in terms of reducing-- for laboratory directors to really understand what their responsibility is. For those of us who have been laboratory-- or are laboratory directors at very large, complex laboratories where we're there all the time, I don't think that this is the issue. The issue is really for labs in most situations where there is less direct engagement. OK? And we talked about the timing issue.

OK? And the items that could be considered, things that would be done on site as opposed to remotely or delegated are the ones you see here. You know, the environmental conditions, physical conditions, reviewing the documents, assessing the staffing in the laboratory, et cetera. So those are key issues. And again, as was in the workgroup agreement, clear documentation was important.

So in addition to already required board certification, this question for doctoral degree directors, what other clinical laboratory experience should be required? So the workgroup agreed that for board certified laboratory directors-- why that happened-- should include directing personnel and CLIA-certified laboratories. We think basically that that's implicit, as I stated, that in the training for the boards that are recognized already. And we talked a lot more about that before.

So the next question we addressed is, what, if any, modifications should be made to the qualifications for a technical consultant? And the workgroup agreed that as an optional route to qualify as technical consultant by having an associate's degree in chemical, biological, or clinical laboratory medical laboratory sciences in two years should be a route to qualify. And this really had to do with the requirements for a technical consultant requiring a baccalaureate degree in the moderate complexity space where in the high complexity space, the general supervisor could have an associate's degree. And this was a route to sort of align them in a way that has meaning and ensures adequate experience.

The issues have surfaced because general supervisors, as I mentioned, do have an associate degree. And they can do competency assessments for high complexity but not for moderate complexity. It occurs in a number of

laboratories. It's also an issue for people coming through a military experience route, that basically, they may not have an earned bachelor's degree, but they certainly have the education and training that would qualify at the associate's level. The goal is, why are those personnel different for-- and somewhat a more complex or hire for-- moderate complexity in some cases than they are for high. So the goal was to think to align those.

The next issue was address mid-level practitioners and should the definition be expanded? And the reason for this is that the question of adding clinical nurse specialists and CRNAs to the definition of mid-level practitioner was addressed. They're really advanced practice nurses. There's four categories-- the nurse midwives, the nurse practitioners, the CRNA, the nurse anesthetists, and clinical nurse specialists. So we looked at the scopes of practice for the additional ones, the additional advanced practice nurses, and realized that it's conceivable that within their scope, they could do PPM-type services. And so we talked about extending that and are recommending that because it is within their scope of practice.

We didn't want to just use advanced practice nurses because there could be broad expansion of what might constitute an advanced practice nurse. So if, in fact, there are other advanced practice nurse type specialists that come forward, then we recommend that those be considered at the time. And then also, the same sort of proviso here about including DoD experience as qualifying.

And then the last question related to histopathology but not the personnel directly. But what frame should be considered appropriate for the pathologist to review the gross examination performed by individuals not a pathologist? This was discussed at the last meeting as well. We supported the comments that said having some policy with a time requirement wasn't really operational or valid and that having policies in place to assure quality was important. Depending on the specimen processing, there may not be anything to review after the specimen is grossed and submitted anyway. And that review would occur as part of the review of the prepared slides anyway.

So in a 24-hour period, reviewing everything in 24 hours made no sense if the grossing occurred on a Friday or Saturday and it was going to be reviewed on a Monday. What would be the point of Sunday? So the time-based didn't really make a lot of sense. OK.

We've sort of talked a little bit about this. Those were the questions that CMS proposed to the workgroup and what we concluded for discussion. But as the discussion went on, although it was impossible to herd everybody to just focus on those nine questions, we did identify other things that we think should be addressed and discussed by CLIAC and conceivably by a workgroup that might be addressing it. First one, as we mentioned several times, the military training and experience. It's very important to recognize that training as a route for future civilian laboratory professionals and to make sure that in all places, the military experience that's equivalent should be acknowledged.

The second thing that did come up was the doctorate in clinical laboratory science, the DCLS degree. It's a new degree that's coming forward. And so it's not really referenced in regulation at all because it hasn't existed. But basically, it should be added to the CLIA Interpretive Guidelines as an acceptable laboratory-based doctoral degree. There are only one or two people so far that have come through and have been granted the degree and are operating in that space. But that's expected to grow fairly quickly.

We've already heard this morning from NSH, but really, the issue about recognizing the specialty of histotechnologists as laboratory personnel. We did discuss that and believe that CLIAC should address that as well as similar consideration to pathology assistants. And then, potential topics for the future-- this was this was even farther beyond the stuff that was on our list.

Topics for discussion-- given the current and future technology in laboratory automation, discussed when the analytic process begins for the purposes of determining when do you need testing personnel that meet the CLIA requirements. Now you've got robotics that are loading instruments. We don't normally certify our robots to load the instruments, but we do have some personnel requirements that, if people do it, that that's a requirement. It's really to look at technology and how it's changed since CLIA was written.

The next one is kind of a can of worms. I don't know. I think it certainly makes sense. The many laboratory practice and technologies have changed since CLIA regulations were implemented. And when looking at personnel qualifications, consider whether the criteria for categorizing tests should be modified or be more relevant to evolving technology in the role of the laboratory. I think we're just acknowledging that we've got this complexity model and we've got this testing personnel model and so on. But laboratory changing has changed a lot in the last 25 years, and so maybe this needs to be looked at.

And then the last issue was the modes of communication and information exchange and how these impact laboratory testing and communication between laboratory providers and patients. Whether they're smartphones or other kinds of pagers, communicate internet device, none of that existed when this came forward. So things that may be appropriate communication now aren't really recognized in the current structure. But they could or should be.

So with that, I believe that that is the end of the workgroup. You have the written report as well. And I think I look forward to the discussion and appreciate also the comments from the public.

Committee Discussion

CLIAC CHAIR: Thank you very much, Dr. Hilborne. That's a tremendous amount of work that you and the committee did, that the workgroup did. The committee, I echo everybody's thanks for all of that hard work and for giving us an awful lot to discuss right now. So again, just as a quick reminder, this workgroup started because CMS brought us a bunch of questions and said, oh, by the way, could you guys answer these? And we took a look at them in the broad committee and basically said, there's just no way that we can do these questions any justice without dedicated discussion, which is what led to the workgroup.

What means that means for us, thinking about the work product of this committee, which is recommendations back to CMS and the other agencies, is we now have a set of answers thoughtfully summarized by Dr. Hilborne just now broken into two parts-- the part where the workgroup achieved agreement and then the part relating to other issues. So as we get into the discussion, which will span lunch by the way, meaning we'll come back to it after lunch, as we get into the discussion, I would like people to think about two things. First, of course, will be the many specific questions that I'm sure everybody has about what we just heard. But the second will be, how do we want to consider packaging a recommendation?

And [CMS EX OFFICIO] I kind of look to you also for a little bit of guidance about what would be useful for CMS to hear back. I imagine just having one enormous recommendation that basically has all of the areas of agreement as modified according to our forthcoming discussion might be a bit much. Another is to simply say, hey, take a look at this. Take a look at this set of slides with the following modifications might be too little. So that would be helpful just kind of a point of procedure. So maybe we could spend just a minute or two getting some rough idea about what we're working toward at the end of this discussion period and then actually get into the meat of it and ask questions and discuss.

CMS EX OFFICIO: As I said earlier, we are-- can you guys hear me? I was told I didn't talk loud at all. We want to update our regs. We want to make pretty much precise. We don't want to make things so global that we defeat the purpose. That's why we said we were doing very focused. And I thank the workgroup. I think was a

great job what you guys did. What might be helpful is maybe-- again, not doing a whole big list of it to go back to the secretary, but maybe try to prioritize them and maybe do like two recommendations.

CLIAC CHAIR: But two recommendations covering nine topics? I mean, it seemed to me--

CMS EX OFFICIO: We could do more. We could do more.

CLIAC CHAIR: I mean, in the limit, we have one recommendation per question, which I think we're happy to do. But just as a matter of timing and practicalities, is that the kind of thing that's going to be useful for you guys to see? And by the way, this is not just a conversation between me and CMS EX OFFICIO. If other people have ideas on this, please.

CMS EX OFFICIO: You can all join in. It is a lot of questions. So I'll be honest, I'm really not sure the best way to get that back as a recommendation. Some of them can probably be combined. But I think going along with what our questions were actually listed is probably the best way to go.

CLIAC CHAIR: Got it.

CMS EX OFFICIO: But I don't think there's any set way to do it.

CLIAC CHAIR: That's helpful. CLIAC MEMBER?

CLIAC MEMBER: What if CLIAC's recommendation was something along the lines of, we recommend that CMS create a proposed rule for CLIA personnel standards that reflects this following blob of information. Would that kind of a product be sort of what you could go forward with?

CMS EX OFFICIO: We were already planning to do that anyway.

CLIAC MEMBER: OK.

CLIAC CHAIR: Good. So the content of that blob will be modeled on the areas of agreement of the committee, et cetera, the workgroup.

CMS EX OFFCIO: I mean, the main thing is to put these out for a discussion for what the workgroup has talked about. If you are all in agreement with it, is there something you think needs to be different?

CLIAC MEMBER: Yeah, we're going to go there.

CLIAC CHAIR: Yeah, we'll definitely get there.

CMS EX OFFICIO: I would hope so. I would hope so.

CLIAC CHAIR: Well, then the broad structure, unless there are-- oh, go ahead, [ADVAMED LIAISON].

ADVAMED LIAISON: I thought that with the nine questions and then the SharePoint document where the recommendations are laid out as specific recommendations was a good start for each one of these could be. For example, in this first one, the CLIAC recommends, and then you had two points. The way whoever wrote this up extracted information did a very good job, I thought, to just say, this is what the CLIAC could decide to do. Do we agree on? And then recommend forward.

CLIAC CHAIR: Fantastic. Other thoughts? [CLIAC MEMBER]?

CLIAC MEMBER: I think I agree. If we pull these up one at a time, discuss them, come up with a document we agreed, that's 1/9 of our work, that seems like a reasonable length if we multiply by nine, it's a bit longer than our typical recommendation. But it would be nice to have all this work recognized after Hilborne and I participated and others. You know, there was a lot of work done. And so it would be nice if we can get this times nine as our work product.

CMS EX OFFICIO: That would be good.

CLIAC CHAIR: So endorsements of basically a default of recommendation per question. It's fine with me. [CLIAC EXECUTIVE SECRETARY] and then, [CLIAC DFO], you had something?

CLIAC EXECUTIVE SECRETARY: So I'll just kind of add from a historical perspective and from the perspective of the tracking recommendations. Different actions may be taken. Different parts of what the workgroup report showed. So the recommendations can be separated, that'll make that easier. Also, looking back to proficiency testing, when that workgroup report was given, there were 23 recommendations made. So you can go whatever way you choose, but it is important to have a committee deliberate on all of the questions that were asked.

CLIAC CHAIR: Fantastic. Anyone else about this procedural issue? [CLIAC MEMBER]?

CLIAC MEMBER: So procedurally, when you look at those recommendations, does it make any difference how we prioritize them in that as we say in these recommendations. Will it make a difference of, this is high priority and really needs to get done versus, this is a lower priority. Will it make difference then to the agencies how it's acted upon?

CLIAC CHAIR: I would suggest that if we are excited enough to put something in a recommendation, which I think we are based on CMS having asked us these questions, that they would all be looked at as effectively equivalently high priority at least in our recommending them. How the agencies prioritize will involve other externalities to this group. So we can always put in language saying, we really think this is important, but we want to be careful not to rob other recommendations from not appearing important simply because they don't have that, which would raise the question, well, then why bother making a recommendation?

CMS EX OFFICIO: And the thing to remember with the questions that we've asked were ones we have gotten a lot of comments for or request from laboratorians and from laboratories. So they're ones we really would like to get your thoughts and your views on in relation to what the committee has recommended.

CLIAC MEMBER: Does it make sense to conglomerate the four questions on laboratory directors so that it doesn't seem like nine? There's four questions, three to six, that really involve laboratory directorship. Could they be under one subheading with multiple recommendations underneath?

CMS EX OFFICIO: If you guys think that-- I mean, I would be OK with that if we can make them distinct underneath that recommendation. That would kind of make sense to kind of put lab director all together.

CLIAC CHAIR: So I propose that we work from a template of one recommendation per question and then as we review them before voting, if it seems likely that we decide to combine the four that have to do with medical directorship into one that we do it at that time. Well, good. Absent a revolt, I think we'll go with that. And hats off to staff and to our own Heather Stang for being the one who started us out in SharePoint this way. So with that, I propose that we now move toward attacking these in order. So questions about or discussion on the first

question. And I do anticipate many questions about all of these issues. I know I have several myself. So we will try to proceed. We'll try to give everybody time to ask and help us get to a consensus, but we'll also try to be brisk as we move through these. So one last procedural point. I might get up and walk to the podium to scribe a little bit. And if and as I do, [CLIAC DFO], I might turn to you to help call on people.

CLIAC DFO: Yeah.

CLIAC CHAIR: All right. So discussion question one. Thoughts? Comments?

CLIAC MEMBER: So it seems to me that the concern with number one is the educational background. The last half of the very last sentence seems to cover that pretty clearly. If we require science coursework with a minimum number of coursework hours related to clinical laboratory testing, then that resolves the issue completely. There are many professionals that have other backgrounds, but if they have the clinical laboratory education on top of that, I don't see that they need to acquire an entire new degree in order to meet those requirements.

CLIAC MEMBER: Yeah. And I agree. I think this is a great recommendation. And we had a great discussion and reach consensus. We had both public comments and in the workgroup talked about a number, the 30 credit hours being. And I guess the question I would have would we want to put a number, 30 credit hours, if that's the number in here or leave it up to CMS to pick a number.

CLIAC MEMBER: My other concern about the education is there is already a shortage of laboratory personnel, so it's important to be careful about how we frame it. We already have a shortage. If we lose what we have, that becomes more of a shortage. And it also makes it more difficult to fill the shortage in the future. But I completely agree. 30 sounds like a reasonable number. I know in a lot of fields, 18 credits in graduate studies are also sufficient. So I think it just depends on the level of education as well.

CLIAC CHAIR: So let me ask a question to Dr. Hilborne about the-- well, I guess something maybe I didn't understand. So I understand about the physical sciences being taken away. But you made a comment-- and it was in the discussion-- that part of the reason to accept named classes of degree is because it's too much work to go in and look at transcripts. And then, it's unclear what the course titles mean. And that was something that's come up at previous CLIAC meetings as well.

But there is also that thing that you say at the end which says, well, if you happen to have a physical sciences degree, it doesn't preclude you from doing this. It's just that the degree title in and of itself isn't enough. You would have to exactly find-- or more correctly, exactly go back to those transcripts and course titles. So could you flesh out, are we basically proposing that that is a thing to do or not? Or is it simply to say, you will have to do that provided you don't have one of these named course degrees?

CLIAC MEMBER: So that was basically it. I mean, one could have a specified requirement that you have just the minimum number of course hours that are defined and leave it at that, even take out all the other degrees. But I think that the message that we got was experience has shown that these degrees do have those credit hours, and so it really was a streamlined way to do it. But that, as you said, whether it's a physical science degree or an English degree or a nursing degree or something else, if you have those related courses, that that was sufficient to qualify to have an educational background. Theoretically, that statement alone would be sufficient without listing any of the degrees if there was a desire to be that general. But I think that we did this because having any of those degrees is an expedient way to do it, and the data have already shown-- correct me if I'm wrong-- that when you have a degree in one of these disciplines, that, in fact, you do have the requisite courses.

CLIAC CHAIR: Thanks.

CLIAC MEMBER: Is there is a requirement for stability of the coursework in those degrees? In other words, if someone wants to name a new chemistry degree but only have 15 credits, is there something stopping them at the university level from making those changes? So I agree they are where they are now, but maybe some language could be added. Those degrees, assuming 30 or more credit hours. Because the universities need some guidance as to-- they're cooking up new programs and catchy titles all the time. And I think if you're a university program director, you would need that guidance to know that you were going to be having that requirement in your degree.

CLIAC CHAIR: Do we need a list, an thorough list, or what would require us to move from the streamlined approach to the detailed approach? Because we say like, "human science degree, such as biology, chemistry, and medical technology--" what about biochemistry? That's not there, but it certainly seems to fit under the "such as." If I come in with a biochemistry degree, it requires a judgment call. And do we care to? And is there a practical way to avoid making people do the work of that judgment call in deciding?

CLIAC MEMBER: So I know that the certifying agencies have specific lists of what constitutes. When Barbara Caldwell said that there's 30 hours, there's specification as to what biology, chemistry, et cetera are included within those, the basic kind of courses, which would include biochemistry. And so, I think that what we wanted, what we generally wanted, was to be explicit about that for each of these. Look to the accrediting organizations, perhaps, for guidance and be explicit about what those are and what would be incorporated.

I think the point is well taken that we see divergence of degrees. And so at some point, specifying this is probably good. But what constitutes a laboratory and a diagnostic is going to be different 10 years, too. So it's also going to be important for us to keep up with that.

CLIAC CHAIR: There's a question over here somewhere.

CLIAC MEMBER: Yeah, I think I was going to maybe be redundant now. But a lot of the medical students that I teach are coming from arts degrees, but they have an exemplary amount of laboratory courses under their belt in order to be in what's historically called a premed track, which isn't actually a degree in most schools. So often, it becomes an arts focus with almost as much science credits in order to be MCAT eligible. And a lot of those students don't go to medical school. And a lot of them-- I actually now interact with her in clinical labs-- but they have B chem, O chem, P chem, physics, biology, cell biology, genetics. But their degrees says arts history or English.

Well, those are going to be the type of degrees you really need to look at the transcripts. And so should we be a little more prescriptive to say instead of the degree title, that the 30 hours are laboratory appropriate courses. Because you can take science courses that have absolutely no lab component. And so are those advanced physics courses-- have no labs-- actually helpful for running a lab? Well, that physics degree may actually not be as useful as a person who did you know affiliated health care focus with an English degree but took biology lab, chemistry labs for five semesters. So I think we might want to look at the nature of the lab time in their curriculum, not just was it a science course or not. Because some of the science courses don't always have lab components, especially in physics and some of those more physical sciences.

CLIAC CHAIR: So with reference to what's on the screen then, does that suggest a modification here to either talk about those work hours or-- not work hours-- of course hours? Or does it fall underneath the kind of broad umbrella of the second point there, which is basically, if you've done an English degree or a physics degree that matters less to us than what our review of your actual coursework states.

CLIAC MEMBER: In my mind, the actual laboratory and components of those science courses can often be more valuable than the classwork hours. I mean the didactic is very important to learn the theory, but if you've never held a pipette, you're not useful in a lab. I mean, as much as anyone can learn it, there is something to be said for having spent three hours an afternoon, four days a week in different biology, biochemistry, chemistry courses where you're doing this stuff hands on and actually getting an appreciation for weighing out reagents and pipetting accurately and doing basic calculations and stoichiometry. That comes into effect when you go into a laboratory. So I think that there should be some nuance about what component of that curriculum has a laboratory component.

CLIAC CHAIR: So while others talk, maybe you can propose some terminology that we can put up here. And it's SharePoint, so you should be able to also modify it.

CLIAC MEMBER: I mean, it seems to me like we're talking two pathways, sort of qualification by degree name and then a qualification by more detailed examination of a transcript. And the idea would not be to have to examine every transcript because the working group pointed out that's very labor intensive. And sometimes it is unhelpful because the transcripts are weird. But if we have two pathways-- the qualified by degree name, biology, chemistry, biochemistry-- you could probably come up with a pretty exhaustive list of names of degrees that would be OK just as they are. And then the second pathway is you have to examine that transcript and get somebody to agree that there is enough in there. And there'd have to be criteria for that.

CLIAC CHAIR: So do we want to list those or do we want to recraft these to make that more explicit? I think these two points carry that broad idea. We're explicit about physical sciences being out as the set of named degrees, but then the second point--

CLIAC MEMBER: But we can leave out "including those in physical science." I mean just other degrees may not have the requisites, and candidates for a position should be considered based on a minimum number of hours.

CLIAC CHAIR: And the--

CLIAC MEMBER: Because the "including those in physical science" makes you think that that's the direction we're going with that. And it doesn't include the art history people who had planned to go to medical school.

CLIAC CHAIR: So we could say something like-- sorry,

CLIAC MEMBER: Thank you very much. I agree with the comments from [CLIAC MEMBER] and how you framed them just a moment ago. The unedited version there a moment ago reflected those two pathways. And it seems that these recommendations really encompass the question, or answer the question which was asked, which is how to clarify some of this. And it seems like removing physical science and then specifying some degree, these human science degrees, will help out the majority of the questions that arise during inspections. And then for the, as you said, few times that people really have to go through transcripts, that should be relatively-- hopefully-- minimal.

But I think that what we should consider is, does this really help answer the question that was asked. I think this does provide the assistance for inspections. But it may not be that we find that out until this goes back to CMS and they flesh this out more with how they would like to change their guidance documents. But I think that this is probably the best way to frame it at this point. If we get into the weeds with reengineering a lot of this, it may not actually help them out through the inspection process.

CLIAC CHAIR: So, that's a vote for things as they stand on the screen?

CLIAC MEMBER: As they were originally. Yes.

CLIAC CHAIR: Have I changed them in some way that is--

CLIAC MEMBER: You were typing, so I wasn't really--

CLIAC CHAIR: Oh. So all that I really did is switch the order to kind of reflect our structure of thinking. Like the physical sciences being taken out something we have to say because it's there. But that's not the emphasis here. The emphasis is on this two- tiered description.

CLIAC MEMBER: Correct.

CLIAC CHAIR: So that's all I did.

CLIAC MEMBER: Yes, as is.

CLIAC CHAIR: And then I tossed in-- I thought I did-- humanities as well as physical sciences to make it clear-- and others-- to make it clear that we aren't singling out the physical sciences. And then the part I've highlighted is for Marc's benefit based on his question. Sorry, I don't know how to-- so to your point of the lab coursework being kind of clinical laboratory related, does the text as it was already in there not cover that in your eyes or do you think that that covers the issue that you brought up? Marc? Putting you on the spot.

CLIAC MEMBER: I guess I'm sort of hung up on practical laboratory experience versus just a science course that is all didactic. And I'm struggling. I've just rewritten the sentence five times. And I'm struggling with how to actually frame that comment to get the point across that the credit hours should have laboratory components not just three hours of cell biology lecture.

CLIAC MEMBER: Should it be a certain amount of biology, including at least this much laboratory?

CLIAC MEMBER: That's--

CLIAC MEMBER: Yes.

CLIAC MEMBER: Yeah, I think that's a reasonable approach to start with.

CLIAC CHAIR: OK keeping that in mind, let's go around the room because I think Dr. Hilborne can tell us what the committee was thinking about that-- the workgroup was thinking about that.

CLIAC MEMBER: Remember, this is question one which just talks about the educational background because the training and experience are addressed to some extent. And that area is addressed in question two. So this would be education that would be necessary, but it wouldn't be sufficient for laboratory medicine. I tried to apply for certification while we were talking on the ASCP website, and they specifically ask about microbiology training, biology training, chemistry training, et cetera, and the number of hours. And so they've specified that kind of thing.

And I think that's what we're trying to talk about. For the education, to be able-- now if you happen to go through a clinical laboratory science program, you will have the necessary laboratory experience. But if you don't, then the route would be to get that as part of the training and experience piece after you come in with your art history degree but these requisite courses.

CLIAC CHAIR: Thanks.

CLIAC MEMBER: So I wonder could one way to consider the outside coursework be to require certification or one of those degrees. Would that resolved the issue?

CLIAC CHAIR: I'm thinking about it. Let's see. So would that suggest something like-- where's my cursor-- "other degrees or certification." Something like that? Would that get the idea of what you're talking about there?

CLIAC MEMBER: No. Because that's indicating that the certification was not appropriate. I'm thinking on the other end of the sentence.

CLIAC CHAIR: Oh, sorry. But should be based-- what I meant is for that to modify the "should be based on" part.

CLIAC MEMBER: Maybe just add to the end of that sentence, "as specified in certification requirements." Someone help me out with that.

CLIAC CHAIR: "Should be considered based on minimum number of hours of coursework related to--" I mean you could say this. We can wordsmith in a second. But this coursework could come from post degree certification. Maybe something like-- does that get the idea?

CLIAC MEMBER: Yeah.

CLIAC CHAIR: OK. Fantastic. And I think [CLIAC MEMBER] was next. And then we'll come back to this side of the room.

CLIAC MEMBER: Well, look, I guess I don't understand. I mean to [CLIAC MEMBER] point, the certification and the clinical components of clinical laboratory tests in our kind of question, too. We're talking about the bachelors degree required to get into a board certification and/or be acceptable for any of the boards, including the subspecialty boards, right? So this is kind of the coursework and the undergraduate or graduate courses that need to accumulate before you can be considered for the board. Is that correct? So I don't know if post degree certification, you're talking about the board. And here, we're talking about the coursework. Right? And should it--

CLIAC CHAIR: Ah, I see. I guess it comes down to what--

CLIAC MEMBER: Or are you trying to combine it?

CLIAC CHAIR: No, no, I'm not. Or at least trying to read [CLIAC MEMBER] comments. I'm not trying to combine those. This is more of like a post bacc type of thing is what you're thinking of. So a certification, not board certification, but additional coursework. I guess this word curriculum, which was in the question, might be--

CLIAC MEMBER: Yeah, "curriculum" I think would be a better. Number one. And then just finally, I know there's a lot of other things that sort of have appendices. It may not be reasonable to list all of those degrees here. But to make it easier for CMS to review certificates, do we want to have sort of a list-- biochemistry, molecular biology, microbiology, allied health. Should there be some type of larger list that could be referred to here that would make the review of the coursework less onerous? Because someone might not realize that allied health is another word for medical lab science in some of the undergraduate courses. So just a thought.

CLIAC CHAIR: So, yeah. [CLIAC MEMBER], maybe you could reply to that. Go ahead.

CLIAC MEMBER: Just apropos to that discussion, when we look at nontraditional degrees in expansion-- I think it's not trivial because so many people now have those-- to make it challenging. But I wonder whether given what we heard earlier about accepting some of the certifying agencies like the board of certification as a primary source verification for the education and training may be a route to bring in another way to verify that from organizations that have been approved by HHS so that, in fact, that you don't have to go looking at the transcripts. Because those certifying agencies have already done that. It's just a thought as a way to do that. Might be an easier route, even for the ones who have the other degrees because they presumably, many, have certification.

CLIAC CHAIR: So two different points then on the floor. One is, do we want to give an exhaustive list? And the second is, do we want to point to a specific certifying authority to say whatever they say is OK is OK?

CLIAC MEMBER: Right. If you are certified by this agency, then you have done what's on that exhaustive list.

CLIAC CHAIR: So do we have proposals related to that? This always happens when a group has a long list of things to do, we always end up spending more time on the first thing. And then, the last thing gets short shrift, so I would like to try to draw conversation or discussion about question one to a close in the next couple of minutes. So if comments can be directed in terms of specific terminological updates or practical changes here, that would be helpful. I have to say, I'm a bit on the fence about both of those things. Unless you can name that particular authority, I certainly worry that a list is not going to be sufficiently exhaustive for us to come up with here to not avoid the very problem that the list is intended to solve, which is OK, well, what about this other degree that I had? Doesn't that fit?

CLIAC MEMBER: But we could ask CMS to make the list.

CLIAC CHAIR: So that's kind of why I like the phrasing as originally proposed here without those extras. It seems like our recommendation is clear. It is not-- how do you say-- perfectly specified, but they get the gist is my sense. Again, though, open. I'm here typing, right? So anybody who wants to change anything, let me know. I think we've had a couple of comments going around.

CLIAC MEMBER: So maybe some vocabulary issues because this is typically undergraduate topics we're talking about here. So at that level, we don't talk about human sciences because they could go into agricultural or veterinary, et cetera. So biological science degrees is I think what you're getting at. And then to Marc's point, I think the other terminology change we could have here is a number of hours of courses with laboratory components related to et cetera, et cetera. Back to the other point, I really do think that we're on the right track of saying that there are two tracks that this can be done by-- one that's following a biological sciences and then one which were non-biological, and that requires a number of hours of courses with laboratory components.

CLIAC CHAIR: So I've tried to highlight those changes, those proposed changes.

CLIAC MEMBER: Instead of course work, just call it courses.

CLIAC CHAIR: Hours of courses.

CLIAC MEMBER: Yes, because that's the technical word.

CLIAC CHAIR: Is it? Course hours? OK. Hours of courses. It's been a while since I was an undergraduate. OK.

CLIAC MEMBER: Yeah. Well, I kind of liked it better before the changes. I understand. And so I agree. We're looking at two tracks-- biology degree or, I guess, 30 credit hours of related, relevant coursework to clinical lab work. You know, our goal is to minimize the amount of transcript digging CMS and other groups have to do. And so I completely understand the point about, yes, you might be better prepared if you have biology and chemistry with labs. But then the question would be, well, how many credits of labs? How many credits of didactic?

We're all kind of moving in the opposite direction, so my preference would be to actually put it back to just the way it was with you either have biologic science degree or you have other degrees and demonstrate that 30 credit hours of related coursework and not specify how much lab work or if it's post-certification or pre-certification or those things.

CLIAC MEMBER: But inspectors going to have to have some guidance as to what that means, right?

CMS EX OFFICIO: I mean, right now, if we have questions--

CLIAC MEMBER: Right now, we don't.

CMS EX OFFICIO: Well, right now, when we have a question transcript, it an actual manual review of what that is and what they have and us making a good determination as to--

CLIAC MEMBER: But with no sort of written guidance as to what that means?

CMS EX OFFICIO: No.

CLIAC MEMBER: OK.

CMS EX OFFICIO: We have requirements in the regs, but they're the minimal requirements. And some of the courses are very creative when you have to try an interpret them.

CLIAC MEMER: Right. Yeah.

CLIAC MEMBER: OK. So my suggestion about the certifications was really more along the lines of what Dr. Hilborne so eloquently stated. There are different levels of certifications. I know, as PhDs, you're probably thinking of the higher level, but there's also the medical technologist, et cetera. So if we allowed a certification board to sort of filter out all those details, I'm sure that more certification abilities would be determined. And then it wouldn't be CMS's decision to filter out all of that. It would just be CMS's decision to decide which certifications are allowed.

CLIAC CHAIR: So that in response to [CLIAC MEMBER] point and this last parenthetical? By keeping it, basically, is what?

CLIAC MEMBER: So I almost wonder if we should remove-- so you could either add to that, the certification requirement, or you could just remove the entire minimum number of hours of courses and allow the certification to determine the minimum number of hours and the quality of the courses.

CLIAC CHAIR: All right.

CLIAC MEMBER: Well, my first comments were way back. But anyway, just to let people know, in the conversation on this committee, when it comes to is a person qualified to work in this laboratory, there was a a lot conversation by the attendees that at the hiring level, the supervisor of the laboratory director, it is a real problem for them to understand whether or not this person is qualified to hire and do that laboratory work. And that's why we had that statement about consider the minimum number of hours.

And we left that pretty open because the realization that there is no industry-specific or standard about what are those hours? What should they consist of? We have our certification agencies who provide those. But we also have a lot of people who come into our laboratories and find jobs who are not certified by certain things that probably [INAUDIBLE] certified. But they do have a lot of those laboratory components [INAUDIBLE].

So we were trying to get a statement there so that there would be some direction for people at the labs. How do I evaluate this person? And then the CMS evaluates it. But we didn't want to be too proscriptive because there is so much to consider in the industry right now.

CLIAC CHAIR: So, [CLIAC MEMBER], I think you've got the last word here.

CLIAC MEMBER: OK. That's right. So with respect to certification as being a route, that would be something that the agency would need to look at. There's certainly people who are not certified. The whole issue of DoD, for example, and corpsmen came up as items of discussion. But they may meet it. So the education would be required. Remember, we're talking-- this is the educational background to be able to participate in training and get experience. So it's not really necessarily-- the minimum number of the courses with laboratory components related to clinical laboratory testing can come in the training and experience. This is just the educational background. And so that's why we're talking about the really the basic stuff-- biology, chemistry, organic chemistry, et cetera. And so that's what this section-- because we're going to get to number two. The good news is some of the later questions won't take this much time.

[LAUGHTER]

We had that from experience from the workgroup, too. But this is really only the education to get into it. So I don't think we want to make it too rigorous. What you want to know is that somebody has enough science thinking to be able to do laboratory in the next phase. And the only purpose of looking to the certifying agencies in this place is a surrogate so when CMS comes to audit it, if you see that somebody is an MLS ASCP or any of the other certification organizations that would be approved by the agency, they have those education and training, so they don't have to go and audit course by course or diploma.

CLIAC CHAIR: So I know I promised you the last word, but because [CLIAC MEMBER] hasn't spoken yet, I'll give you the last word. And then, we will, I think, bring this to a--

CLIAC MEMBER: I just have one question. I remember in November when we were discussing educational background, there was a conversation about nurses being considered as biological degrees. And I was wondering if there was any discussion among the committee and if this would be the place that we need to be concerned.

CLIAC CHAIR: Didn't that come up in another question? I know I saw that in your presentation.

CLIAC MEMBER: Can I talk?

CLIAC CHAIR: Yes, please.

[LAUGHTER]

CLIAC MEMBER: So I will get the last word! The nursing education would not be a biological chemistry we don't think. They would still qualify if they met the minimum education requirements, much the same as a physical science. But what we heard is some nursing degrees do have the adequate number of educational courses, some of them do not. And so basically, to qualify somebody who has a BSN, for example, would be based on the education requirements rather than the degree alone.

CLIAC CHAIR: Well, thanks.

CMS EX OFFICIO: I have a question.

CLIAC CHAIR: OK.

CMS EX OFFICIO: From what I'm hearing, I just want to make sure I have it clear in my mind. When we're talking about something like ASCP or whatever the boards for the certification that we would recognize them as a standard approval for people. So are you recommending that we would look at them as prime source verification groups?

CLIAC MEMBER: I think this represents a personal opinion because we didn't discuss this as a specific workgroup topic. But I think that if CMS reviews the certifying agency requirements for specific certifications and the integrity of the process and believes that it's OK, then one could use that for primary source verification for the educational background as appropriate. That would help with the issue of programs have closed after, say, a certifying agency has validated, et cetera. And it would also eliminate the need for you to go through transcripts when, in fact, that's one the requisites to qualify for one of the certifying agencies, assuming you've reviewed it and approve them.

CLIAC CHAIR: Kind of like deeming for a laboratory accreditation.

CMS EX OFFICIO: When we did the prime source verification and allowed prime source verification, we, at that point in time-- it was going to be a business decision. And I think we've talked ASCP about that, that it's really a business decision for them whether they want to become one of these prime source verifications. So we really didn't want to go back and start having to approve ASCP and whatever boards. We can go back and look at that. But that wasn't-- when we did prime source verification-- it was not the intent to have us review everybody to say that they were. We were going to consider it as a business decision for that group. But we can certainly take it under consideration. I just wanted to make sure that's what I was hearing.

CMS MEMBER: OK so I'm not sure I quite understand the distinction. Before the agency would be able to prove them in lieu of demonstrating these other things, you have to make sure that if ASCP-- and I'm using ASCP because they're the largest certifying agency right and there obviously are others-- but if ASCP said that this person has an MLS, that means that the number of the things when I went in looked, the number of hours of biochem, if they say primary source verification that you're certified. And it sounded like the board of certification was willing to do that.

CMS EX OFFICIO: Oh, they are willing to do that.

CLIAC MEMBER: Right. Right. And I know that. And that the basically if they met those requirements, that CMS would take that in lieu of going through a whole long.

CMS EX OFFICIO: OK. I just want to make sure what I was hearing.

CLIAC MEMBER: I think that's--

CMS EX OFFICIO: OK.

CLIAC MEMBER: All right, everybody. So with that, I would ask, are there any deal breakers here? Are we happy with it? And if we're happy with it, I would entertain a move to a vote on this recommendation. No deal-breakers? We have motion. We have a second. We have a second.

CLIAC MEMBER: I do have a clarification question because nursing was just brought up. So CMS recently clarified nursing degree qualifies for moderate complexity testing, so we don't have to, in our point of care program, get 3,000 transcripts. I assume this would mean, as we're applying to nursing, if a nurse wanted to be a high complexity tester, or supervisor, et cetera, you'd have to go find those credit hours. We're not reversing the recent CMS clarification that nursing degrees do qualify for moderate complexity testing personnel?

CLIAC CHAIR: No. I don't think so. So we have a motion on the-- so [CLIAC MEMBER] unless it interferes with that,

CLIAC MEMBER: Where?

CLIAC CHAIR: Yes. Feel free, [CLIAC DFO], to interrupt, to speak up. Save you a trip. OK, so if we've got-- yes?

CLIAC MEMBER: To the extent the recommendation considered based on the minimum number of hours of courses, with the laboratory related to clinical laboratory testing, I don't think that's this issue. That's the next issue. That's the training experience.

CLIAC CHAIR: I was looking at that. Where was that? I mean, does it-- this is maybe just passing the buck a little bit, but does it hurt us to say it in two places? Or would it be contradicting ourselves?

CLIAC CHAIR: Well, so long as it's clear.

CLIAC MEMBER: Remember, this is education and not training. So education and the courses have a laboratory component. That's not training.

CMS EX OFFICIO: No.

[INTERPOSING VOICES]

CLIAC MEMBER: That's laboratory coursework.

CLIAC CHAIR: Yeah we've run--

CLIAC MEMBER: Excuse me. That educational coursework.

CLIAC CHAIR: Yeah, we've run afoul of words having multiple definitions here because we were been using the word "certification." but meaning an undergraduate or pre-professional level, so we've changed that to "curriculum." And then, we've got "laboratory" being used here, but not, again, in terms of professional hours, but in terms of a practical component or a lab component of your biology 100 type course.

CLIAC MEMBER: Right. So this is here related to clinical laboratory testing. In my biology class, we dissected nematodes. We didn't do--

CLIAC CHAIR: So my understanding here-- that's a fair point. My understanding is it's like with relevance to was the way I understood that. Maybe that clarifies it?

CLIAC MEMBER: Yeah, that's better.

CLIAC CHAIR: OK, very good. Thanks. I think these have helped make the recommendation better.

CLIAC MEMBER: One small wordsmith.

CLIAC CHAIR: Yes?

CLIAC MEMBER: It is "concerning educational background" or "describing educational background?" Aren't we describing what needs to happen to be able to apply for a board? I mean, it's kind of a nuance.

CLIAC CHAIR: Here? How about that?

CLIAC MEMBER: I would like people to know that we're describing the educational background that should be made to move forward.

CLIAC CHAIR: Is that better than "concerning?"

CLIAC MEMBER: Well, I like "describing," but "regarding" is fine, too.

CLIAC CHAIR: OK. I'm going to make an executive decision, stick with "regarding" and go back to entertaining our motion to vote and our second. Are those still on the floor? Hopefully Robert's Rules aren't looking directly at us. Motion to vote? Second? OK. So all those in favor? Any opposed? Abstentions? OK. We have a recommendation on question one. Only eight more to go.

[LAUGHTER]

CLIAC MEMBER: They get easier after number two or three.

CLIAC CHAIR: OK, first of all, take a full--

CLIAC DFO: Could I just ask-- For those members on the phone, do you want an opportunity to contribute to this discussion. OK.

CLIAC CHAIR: I'll take that as a yes. OK. So question number two. We can congratulate ourselves for a couple of seconds on question number one. So question number two, I'll open it up for discussion. So here, there was-- oops. Sorry. Give me a second. So here, this question was for the more professional part, like the post-undergraduate component of training and supervision. And let me ask. I'm thinking back to our public comment earlier about requirements on the molecular level. What we've got here in terms of agreement-- I mean, there's obviously many different types of responsibilities that require different training levels and the point of agreement was just that all personnel should have the appropriate training as I understood it. Do we want to be more specific? Let everybody read it. Refresh your memory. I can ask you, [CLIAC MEMBER], to what extent were your conclusions, were the workgroup's conclusions, different from what CLIA already says?

CLIAC MEMBER: Than what who says?

CLIAC CHAIR: CLIA.

CLIAC MEMBER: Oh. So basically, there's no specification of training experience. What there is is that there's roles associated with each of the tests in the complexity. So they're listed here. And if you go to-- I actually have all those somewhere here. That basically, in the list-- and let me see if I can quickly. Like in 1407, laboratories director responsibilities, it lists the responsibilities. Right? But the training and experience should be commensurate with those experiences.

What the workgroup was trying to do was link the roles and responsibilities with the training and experience. Just under 1207(e), basically, they must ensure that the physical plant, they must assure the test methodology that have been selected have the capability of providing quality results required for patient care. Verifications of procedure used, et cetera. So those are the roles and responsibilities. So the statement that says, "that are listed in CLIA for the appropriate test complexity shown" is to link those roles and responsibilities that they should have an appropriate education, training, and experience to fulfill those roles.

CLIAC CHAIR: Got it. So the table that you're showing us here is the mapping that you propose in order to make more explicit the general standards described in 1403 to 1407.

CLIAC MEMBER: Right. Because those are the sections that specifically address the roles and responsibilities for each of the people in the complexity category listed. Does that make sense? CMS EX OFFICIO, did I get that right. OK, good. Because if she says I'm wrong, I'm wrong.

CMS EX OFFICIO: No, that's where they were. 1407. For moderate [INAUDIBLE].

CLIAC MEMBER: So Lee, you're not wrong, but you're missing one key technical supervisor definition, which is 1449, which is the blood bank. The blood bank technical supervisor in the current CLIA requires a doctoral level scientist. And I was hoping your workgroup could have opportunities other than doctoral level scientists being technical supervisors of hematology.

CLIAC MEMBER: OK. So I need to call that up because I didn't print that section.

CLIAC MEMBER: It's 493.1449. It looks like an 11. No, it's and "i."

CLIAC MEMBER: 1449.

CLIAC CHAIR: What subsection, Valerie?

CLIAC MEMBER: It's on page 644 of this little book. And it's at the bottom column. It starts here.

CLIAC CHAIR: What letter and number?

CLIAC MEMBER: Well, it's got an "ii," but I don't know how far down the--

CLIAC CHAIR: The page. Page 641. "Have four years of laboratory training or experience or both." That? That part?

CLIAC MEMBER: Yes. But it's ii, "have at least one year lab training with high complexity testing." It's like a special with immunohematology. And then on the next page--

CLIAC CHAIR: Sorry, can you get closer to the microphone a bit?

CLIAC MEMBER: Yeah. On the next page, there's a note. There is a note that calls out this uniqueness. So if you go up halfway on page 644 on the right column, and it's Q. "If the requirements of paragraph D of this section are not met, and the laboratory performs tests in the specialty of immunohematology, the individual functioning as a technical supervisor" and then "(1)(i), be a doctor medicine, (1)(ii), be certified in clinical path, (2)(i), be a doctor of medicine and have at least one year." So these are all appear to be doctoral degrees. And certainly, we have specialists in blood bank. We have other highly trained folks who can clearly perform this function. I get cited on this in every inspection. That's how I know.

CLIAC MEMBER: Just a comment, that's the scope and the intent of the technical director used to be a terminal degree. So why isn't that addressed? Why do you want that exception I guess is what I'm saying. And I don't think it should be for personal reason.

CLIAC MEMBER: No, I think having a doctoral degree is a pretty high bar to be a technical supervisor for an area of the laboratory. And folks can achieve that either through additional specialty training with additional experience.

CLIAC MEMBER: OK. So it's (q)(1).

CLIAC MEMBER: I'm sorry. But I derailed this meeting. I'm sorry. Because that's an oddball one-off.

CLIAC MEMBER: I think you raise a good question. Because as you say, we have SBBs that have extensive training. I can assure you that the SBBs that trained me are much better in blood banking and immunohematology than I would ever be. I'm willing to admit that. You know? Spending more time so I think that-- I'm not sure that we can do this on the fly now, but basically to go back and pull the equivalent requirements here. But it may be that-- I am just reluctant to say, what about some of the other ones. You know, the histocompatibility would be the same thing. Right? And that's covered under (o)? (o). So maybe it's going to be important for us to go back and work with CMS to make sure that some of these subspecialty groups. These are the general categories, as you as you note. But it would behoove us to go back and identify the specific requirements for these subspecialties as well.

CLIAC MEMBER: I believe that I called out immunohematology but I think the carve out is also for oral pathology, histocompatibility, a couple other handfuls in there.

CLIAC MEMBER: Right. So most of these subdivisions would need the training and experience general ones listed in these sections that are here, but would qualify by virtue of their additional training. Really, the issue is whether they need a doctorate.

CLIAC MEMBER: Got it.

CLIAC MEMBER: Right? And so I think that the piece that needs to be looked at. Is somebody with a baccalaureate degree but having gone through an intensive SBB type training--

CLIAC MEMBER: And experience.

CLIAC MEMBER: And experience.

CLIAC MEMBER: But I recommend to get through this section, we table that discussion. It would be a follow-up action. And we just move forward with what we're doing.

CLIAC MEMBER: Yeah, I agree.

CLIAC MEMBER: Yeah. That's good. That's a huge--

CLIAC MEMBER: Undertaking.

CLIAC MEMBER: Undertaking. It would be this plus something else if you wanted to qualify through the non-doctoral route.

CLIAC MEMBER: And I don't know, again, when [CLIAC MEMBER] has mentioned the value of technical supervisor was designed and claimed to be the terminal degree. Technical supervisors can delegate a lot of the day-to-day competency and operations to a general supervisor. He doesn't need to have a doctoral degree. So it can be kind of a slippery slope if we start having carve-outs to technical supervisor requirements.

CLIAC MEMBER: So that raises the bigger question, why do we even have carve-outs? Why are these just not standard terms across the entire laboratory.

CLIAC MEMBER: Which term?

CLIAC MEMBER: I'm sorry. I don't mean terms. I mean qualifications. Why do we have unique qualifications for immunohematology, or for oral pathology, or histocompatibility.

CLIAC CHAIR: I agree that this is an important issue but also that it's one that maybe might best be revisited. What I'm struggling with is what the implications are for recommendations today. We had a question in the corner. Or comment?

CLIAC MEMBER: I was just going to comment about the blood bank and the requirement for doctor degree. Certainly in laboratory, we test specimens. But in the blood bank is one area we actually are giving out a blood product. And I think it's always been at least considered in our institutions to be a very high risk. So just thought I'd throw that out there.

CLIAC MEMBER: I would echo that comment and also say that also in the blood bank, there's a lot of patient interface, which is not necessarily a component of all the technical director components of other aspects of the lab. There's a lot of interacting with the patient and understanding pathophysiology of disease and implications of transfusion.

CLIAC MEMBER: So in 1449, it lists all of these alphabetical. So some of these disciplines do acknowledge people who don't have doctoral degrees and so on. So I think that what the request really is to look through all of these requirements for individuals who have don't meet a-- where the specification is at only the doctorate level, to ask the question whether in those situations there might be others. So it's not the whole 1449 A through whatever it is.

CLIAC MEMBER: Q.

CLIAC MEMBER: Q or whatever. But it's really just a limited number in that series that don't already acknowledge people with lesser degrees but adequate training.

CLIAC MEMBER: So, just a point of process. So I think this is a good comment, but I think it should almost trigger an automatic table. And then you guys round up and have another conversation. Bring it up after we finish with number nine, so it allows us to keep moving and we go on to three. Because it's a good point, but then work on it, resolve it, and bring it back later maybe, so we can talk more.

CLIAC DFO: That's a motion to postpone.

CLIAC CHAIR: I think that's a great idea. I think we need a motion to table. OK. And I don't know that we need a second and a vote I think. Motion to table?

CLIAC MEMBER: It's a motion to postpone.

CLIAC CHAIR: Motion to postpone?

CLIAC MEMBER: Because tabling would mean we'd have to bring it back at this meeting, and I don't think that will happen.

CLIAC CHAIR: Motion to postpone then.

CLIAC DFO: Are we asking the workgroup to readdress this, to address this issue subsequently?

CLIAC CHAIR: So I think I think we might want to do that. But it occurs to me that with no formal resolution on the floor, we can talk about whatever we want, so we actually don't need a motion for this. We can just move on to the next thing. Let's come back at the end to even answer that question. So let's just skip over it.

CLIAC MEMBER: There may be enough meat for the workgroup to chew on maybe by phone or if in person if needed. Let's wait and see.

CLIAC CHAIR: Thanks. Good idea. So I've now put discussion question three up on the screen. I'll give everybody a couple of seconds to refresh your memory on that one and then begin the discussion.

CLIAC MEMBER: So OK, can I just make a comment that there is that same 1449(q)(1)(ii), the technical supervisor for her immunoheme, which is not, as I understand it, a correct statement in this table. Because the preface to (q) does not include the statement, "possess qualifications that are equivalent." I'm reading this on the fly, so somebody correct me on that point. So my recommendation is you remove that single half row and everything else we discuss.

CLIAC CHAIR: Apologies.

CLIAC MEMBER: I take it back. It is there. I just read it. Strike the comment.

CLIAC CHAIR: So thoughts on the proposal as on the screen in front of us.

CLIAC MEMBER: I think it's very appropriate and makes sense. I almost think it was anachronistic. It was a comment talked about a long time ago. We kept saying board eligible or eligible. That's got to be behind us. We have to move on.

CLIAC MEMBER: So I'm not sure it's on here, but in the discussion, you talked about one of the lab director pathways as being pathology with anatomic and clinical pathology. I have fellows who are trained in internal medicine and hematology or internal medicine and infectious disease and then do hematopathology fellowship or a microbiology fellowship. And then they sit for American Board of Pathology boards in either hematopathology or microbiology. Where would they fit under that scheme because it's not a clinical pathology certification?

CLIAC MEMBER: Well, I'm only looking at (q) now, but they're similar in all the verbiage. As it says that the routes here would be-- there's technical. "So it must be a doctor of medicine or a doctor of osteopathy licensed to practice medicine in the state and be certified in clinical--" it says specifically clinical pathology not immunohematology. So maybe the ask is for these subspecialty areas to allow whether it's dermatopathology-- and I think derm path may actually say that-- but whether in fact, for all of these, if you have a subspecialty certification from the American board in that area. Because we're going to eliminate the equivalent.

CLIAC MEMBER: To be a lab director in that area. Right?

CLIAC MEMBER: What's that?

CLIAC MEMBER: To be a lab director in that area.

CLIAC MEMBER: This is technical supervisor.

CLIAC MEMBER: But also, what about lab director?

CLIAC MEMBER: Well I think it's the same. I'd just have to look.

CLIAC MEMBER: OK.

CLIAC MEMBER: So the other option, if you aren't certified by the American boards, is to be a doctor and have one year of laboratory training or experience. Or I think it's two for director, right?

CLIAC MEMBER: Well, in the case under discussion aren't you saying that they are then getting their American Board of Pathology certification?

CLIAC MEMBER: But not in--

CLIAC MEMBER: But not in clinical pathology as phrased.

CLIAC MEMBER: Yeah, but I think that's a small c not a capital C. It's, I know, a technical point. But the issue is that as long as they are certified by the board of pathology in an area relevant to clinical pathology, small c, it works.

CLIAC MEMBER: OK.

CLIAC MEMBER: So that's an interpretive piece. If I was certified by the American Board-- so it only applies the American Board of Pathology not--

CLIAC MEMBER: Not CP specific.

CLIAC MEMBER: That's how I read that.

CLIAC MEMBER: Right. So if I had certification in immunohematology from the American Board of Pathology, would you consider that to be certification in clinical pathology related to immunohematology?

CLIAC MEMBER: It should be. I just want to make sure it is. Yes.

CLIAC MEMBER: Well, then maybe I'm saying, is that worth clarifying? Maybe we should have the workgroup go back.

CLIAC MEMBER: It's a little more complicated because I think what we're saying-- if you did an infectious disease training, did a microbiology fellowship, passed the American Bar of Pathology, boarded in medical microbiology by AVP, you'd be qualified to be a high complexity lab director because you passed the boards, be qualified to be a technical supervisor in microbiology, but you wouldn't be qualified to be a technical supervisor for chemistry or hematology. So it's a little more complicated. But I guess there's a gap as it exists that isn't all drawn out and defined. It only says "clinical pathology." It didn't all the subspecialties what qualifies for technical supervisor and high complexity lab director.

CLIAC CHAIR: How would you propose that we change this in order to reflect that? I mean it is sort of an issue. Is like your subspecialty training, if you come from outside of a general training background, is for your subspecialty but not for the specialty.

CLIAC MEMBER: Yeah. I mean--

CLIAC CHAIR: Do we have to have a comment on the phone?

CLIAC MEMBER: It would have to be built in to each of those specialty technical supervisor requirements by subspecialty.

CLIAC MEMBER: Yeah, I think you could clarify it by just saying "or a subspecialty board certified to direct a subsection of the laboratory related to the specialty," something like that. But then you do have-- which was my actual question-- you have anatomic pathologists who are overseeing the entire APCP who have never had CP training. And you don't have the reverse. I'm just a microbiologist, so I don't want to get into that. But it does sort of draw that conclusion that if you're only subspecialty certified, are you able to direct appropriately an entire laboratory? And personally, from my experience, it's been a long standing question.

CLIAC CHAIR: So the chair would entertain modifications to the document here to reflect that. I think that is an important issue. And it feels like something that we could come to a conclusion on.

CLIAC MEMBER: So I'm confused, and maybe you all can help set me straight. The title of this question says "laboratory director qualifications." Is that what we are discussing? Or are we discussing every other laboratory personnel in this table? Because back to [CLIAC MEMBER] question, the laboratory director, if you look on page 630, it addresses everything we've talked about. So you're either somebody who is certified in APCP, or you're a physician who is certified by ACPC, or certified by ABMM, or AS cytology, or-- and then there's oral pathology and there's ABMM and other things mentioned in there. That's for the lab director. We don't talk about it for the other categories. So is this question around the lab director or is it around every category?

CLIAC MEMBER: Yeah. That's actually a good point because we actually address-- We actually addressed all the areas. And maybe that was a mistake because we launched into the issue of equivalent board certification as it related not to the director but to other positions. And so the general recommendation was to eliminate the

qualifications that are equivalent to board certification wherever it appeared. But that really wasn't-- actually, that wasn't the original question. Now I remember why it was so much fun being on the CLIAC with [CLIAC MEMBER].

CLIAC CHAIR: But, you're basically proposing that statement and answer to the specific question, "what should possess and qualifications that are equivalent to board certification mean," that there aren't qualifications that are equivalent to board certification.

CLIAC CHAIR: Right. There are still other routes of qualification.

CLIAC MEMBER: But they're not equivalent to board certification. They're more experiential than training related.

CLIAC CHAIR: And removing that statement-- it looks like, from that table, that you wish to remove that statement categorically.

CLIAC MEMBER: Right. And I think that's what happened. We sort of started to talk about the director. But then we kind of lost the focus and said, well, this is a problem everywhere. So I think the issue is still valid. I think, actually, we departed from the question that CMS originally asked.

CLIAC CHAIR: But not in this first half of the answer, unless I've missed your point, Valerie, which I might have. Because that takes care of that question, doesn't it? The top half?

CLIAC MEMBER: I'm sorry. I was responding to [CLIAC MEMBER] comment about what are the alternate ways to qualify for a lab director if you came in through a different medical or doctoral profession.

CLIAC CHAIR: So in our discussion--

CLIAC MEMBER: And not just a subset of this.

CLIAC CHAIR: Right. Right. So in our discussion, we've run afield. But the answer that we've got up there still is answering the question and relevant.

CLIAC MEMBER: Yeah, that's right. Well, the table refers to other than the director.

CLIAC MEMBER: I think it's what you said. Well, the table's OK. Because wherever that terminology applies. If you're functioning in this role, that that's still OK because these were roles that people with doctorates could do with boards, right, as a technical supervisor, or a director, or whatever. And for all of those, wherever it said that you could have equivalent certification, we just said, get rid of equivalent certification because no way to determine that. So the equivalent certification in the technical supervisor categories is actually because those were roles where a person who might qualify as a lab director is functioning in the role of the technical supervisor. And so we ended up pulling it all in, which I think is valid. But it is for somebody who is functioning in a role for the ones that are shown here that are not in the director role. Only some of them are directors. Does that make sense. Did I say that right?

CLIAC CHAIR: I think it's clear. And the question came up with a respect to directors.

CLIAC MEMBER: Right.

CLIAC CHAIR: But the answer is just like you know this holds everywhere. And so let's categorically list everywhere that this holds.

CLIAC MEMBER: That's correct.

CLIAC CHAIR: I don't know that that's a bad thing to have here. Unless you feel it's an overstep.

CLIAC MEMBER: Just a comment. Back to what did CMS ask and if it was pertaining to the role of the physician, that's where this issue came up in the regulation. So I don't know that all these positions you're talking about in this table are physicians.

CLIAC MEMBER: But these are the situations. They don't need to be physicians in all those cases.

CLIAC MEMBER: And I get that point. Right. But relative to what the question was and what this was referring to, it was referring to the physician and board eligibility in a different or an equivalent. And I thought you were trying to be narrow in that regard. And this is an expansion into all areas where many of these people may not be physicians.

CLIAC MEMBER: Which I think is OK. I mean, we talked. And I don't know that ASHI or Comac or any of the other groups also support this indefinite board eligibility, so we thought it really did apply to all doctoral scientists with all boards as far as we could understand.

CLIAC MEMBER: Yeah. Because the flip side of that is when you carve out some people just because they weren't physicians and say, oh, well in that case, there is a route that's board equivalent. I don't think we would say that.

CLIAC MEMBER: No. They would come through the other routes that are specified in there anyway.

CLIAC MEMBER: Yeah. Yeah.

CLIAC MEMBER: To qualify. What we heard was there's no way for CMS to determine equivalency, foreign boards, which foreign boards, et cetera. And so therefore, to remove that in any place where it appeared and for those people who therefore-- the few who might have previously qualified by equivalency would qualify by the experience route that exists in all of those categories.

CLIAC MEMBER: I perfectly understand what the workgroup's intent and completely agree with [INAUDIBLE]

CLIAC MEMBER: Glad somebody does.

CLIAC MEMBER: And we didn't specify to the workgroup, you should consider the question and only the question [INAUDIBLE]. So I figure we need to work to look where else that qualification could be changed [INAUDIBLE].

CLIAC CHAIR: So then as to the-- sorry. [INAUDIBLE] I don't think it's on. So as to the remaining bullet points there, what is the highlighted bullet point?

CLIAC MEMBER: Oh, that was just one that was there. That should have come out. It was just one I didn't think applied, so I took it.

CLIAC MEMBER: Slashed it there.

CLIAC MEMBER: Yeah.

CLIAC CHAIR: So tagged it, but it's not in the text.

CLIAC MEMBER: Yeah, we just never--

CLIAC CHAIR: So we can delete it?

CLIAC MEMBER: Yeah. Sorry.

CLIAC CHAIR: The remaining two bullet points up here. And I'm assuming people can hear me just fine. No? So the remaining-- I'll project until we come online again. So the remaining two bullet points up here, thoughts on those? What is the-- if I may ask about that now new second bullet point-- what is the context in which the experience route came up? What is the verbiage that we're now adding clinical to?

CLIAC MEMBER: It talked about laboratory experience. I am trying to do this by memory. But it talked about laboratory experience, laboratory training. "Have at least one year of laboratory training or experience or both in high complexity testing." We wanted to make sure that it was clinical laboratory experience just to clarify. I'm not sure, in all the sections, it's exactly that way, but just to make sure that if somebody was qualifying through the non-certification route that they got it through clinical laboratory experience rather than--

CLIAC CHAIR: You don't happen to have handy the reference so that we can put it here in the recommendation?

CLIAC MEMBER: I have on my screen here--

CLIAC CHAIR: I mean 493.1409 something.

CLIAC MEMBER: Oh. 493. Let me go back to 1409.

CLIAC CHAIR: And while you are-- well, I guess the next question would be to you. So I'll open it up again to the discussion. Other questions on these two points? I'm moving it along to the second two bullet points because it feels like there is broad agreement on the first.

CLIAC MEMBER: Assuming it reads the way he just spoke it, "clinical laboratory experience," it's just listed as clinical experience, which may not include any laboratory.

CLIAC CHAIR: Interesting.

CLIAC MEMBER: So how he says it is correct.

CLIAC CHAIR: So our meaning, that you are not in favor of it being clinical laboratory experience. You're happy with it simply going from experience, whatever that means, to clinical experience.

CLIAC MEMBER: No. I'm saying it should say "clinical laboratory experience."

CLIAC CHAIR: Ah.

CLIAC MEMBER: It should say what?

CLIAC MEMBER: Unless I'm mistaken, 493.1409 isn't the right reference.

CLIAC CHAIR: Oh.

CLIAC MEMBER: Well, so 1409 actually reads in others. So it's really not-- it's like 1411.

CLIAC MEMBER: 11 and 13.

CLIAC MEMBER: OK. 1411.

CLIAC MEMBER: And on page 633 sort of right at that point (ii) in the first column.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: Have at least one year of clinical laboratory training experience.

CLIAC CHAIR: Sorry. 493.1411, parenthesis, presumably a letter?

CLIAC MEMBER: Oh, let's see.

CLIAC CHAIR: Yeah. Sorry to put you on this. I don't have it up here in front of me.

CLIAC MEMBER: (b)(2)(ii). But yeah. Yeah. It's all over 1411.

CLIAC CHAIR: So in that case, we can say in--

CLIAC MEMBER: Wherever it says "laboratory training or experience," it should be "clinical laboratory training or experience."

CLIAC MEMBER: And then, there's other places in that.

CLIAC DFO: Yeah, it's more of a global change isn't it?

CLIAC MEMBER: It's kind of a global change.

CLIAC CHAIR: I see.

CLIAC MEMBER: It's really everywhere. I don't know why 1409 was in there.

CLIAC CHAIR: I put it in there. That's my fault. Throughout section 493?

CLIAC MEMBER: Yeah.

CLIAC CHAIR: Specify that the experience described under experience route should be clinical as in clinical experience. And then Donna had the point should that not be clinical laboratory experience.

CLIAC MEMBER: Yes. I think so because it's the intersection of the-- because clinical could be the practice of

surgery.

CLIAC MEMBER: It specifies that the laboratory experience described under the experience route should be clinical laboratory experience. Because it says right now-- it just says laboratory experience. And they want it to say clinical laboratory experience.

CLIAC CHAIR: Perfect.

CLIAC MEMBER: Right. But you need both. Because clinical experience could just be training in hematology.

CLIAC MEMBER: But go up and say that the laboratory experience described under the experience route should clinical laboratory experience. That's specific to [INAUDIBLE].

CLIAC MEMBER: Yeah. That's it. That's right.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: Right. Because laboratory experience could be research lab. Clinical experience could be--

CLIAC MEMBER: Clinics.

CLIAC MEMBER: Could be surgery. But what we're looking for is clinical laboratory experience.

CLIAC CHAIR: Perfect. Perfect. Good catch.

CLIAC EXECUTIVE SECRETARY: One more clarification.

CLIAC CHAIR: Yes? You might want to say subpart (m) other than just part 493, subpart (m) is personnel.

CLIAC MEMBER: Yeah. Good point.

CLIAC CHAIR: Like this?

CLIAC MEMBER: Section 493 subpart (m).

CLIAC CHAIR: Like that?

CLIAC MEMBER: Right. That's it.

CLIAC CHAIR: Very good. Well that leaves us with bullet point number three here. So who should-- maybe Lee can tell us what the genesis of this recommendation was.

CLIAC MEMBER: That basically the these are the boards that HHS approves. Now this is a link to the boards that HHS approves. And so these were the ones that could qualify under laboratory director if you weren't an American Board of Pathology or American Osteopathic Board of Pathology. There was a sense that to make sure that there is a clinical component that's inherent in those board certifications, if those board certifications are to be accepted, to meet that requirement.

There was a comment that perhaps one board may not be that stringent that's even currently approved and that current boards and future boards really should include the clinical component that includes the laboratory management and administration. Right? So that if you're going to put somebody in this position and say they have the training and experience and the route to that is the board certification, it's important to make sure that those boards only certify people who've had that experience.

CLIAC CHAIR: That's clear. That's helpful. Thoughts on that? Seems pretty non-controversial to me. Well, I would-- sorry,

CLIAC EXECUTIVE SECRETARY: No. I was just going to say one more clarification here, at the back, in your supplemental tables that we provided, there are listings of what the approved boards require.

CLIAC MEMBER: Who would be making the review for these boards?

CLIAC CHAIR: It's a good question.

CMS EX OFFICIO: Usually, they send information to us at CMS, and we have some forms we ask them to fill out. And then, we work with CDC to evaluate that. CDC does the primary evaluation, and then, we discuss it.

CLIAC CHAIR: So there's a standard route for that? Well, chair would be open to a move to vote on this second piece here for discussion question 3. Recommendation? OK, we have a motion. Second. Seconds. Second. OK. All those in favor? Any opposed? Abstentions? No? All right. Well, seeing none, this recommendation passes. And we are on to a discussion question four. I'll give everybody, again, a couple of seconds to just refresh your memory.

CLIAC MEMBER: So really, there's only-- the continuing ed, there's only one bullet because the second one we've just addressed as part of the last question.

CLIAC MEMBER: I'm sorry.

CLIAC CHAIR: This part here we just covered.

CLIAC DFO: We just want to make sure that we capture the votes of any members who are on the phone.

CLIAC MEMBER: [INAUDIBLE]. Can we just clarify that the-- would you please clarify that the 20 CE really relates to that one time first bolus of CE to qualify as a lab director? It's not related to the however many units you're required every year to maintain your license.

CLIAC MEMBER: Yes. That's absolutely correct. And I think that specificity may have fallen off.

CLIAC MEMBER: Is the word "continuing" confusing?

CLIAC MEMBER: Qualifying education. It's not continuing, right?

CLIAC MEMBER: Well, I think if we're specific about what the program is, it's offered as a continuing education course with CE credits, so that's why it's there.

CLIAC MEMBER: OK.

CLIAC MEMBER: I think your point is well taken. It's really an education course that, by the way, qualifies for continuing education that addresses laboratory oversight and management. That's probably better said that way. Because otherwise, somebody will just assume I can take any continuing ed. And right now, there are two programs, if I recall, that are approved that cover this 20-hour piece.

CLIAC MEMBER: So is there a proposal for changing the terminology here?

CLIAC MEMBER: Yeah. So basically, we should take the language, I think, out of 493.1405(b)(2)(iib). That they have 20 hours of-- it says here, "of CME credit hours in laboratory practice commensurate with a doctorate with the director responsibilities." And it probably should be something like that.

CLIAC CHAIR: So I would ask that either you SharePoint it in there or you dictate it to me because I don't have my book up here.

CLIAC MEMBER: Yeah. OK.

CLIAC CHAIR: I'm happy to take dictation.

CLIAC MEMBER: Do I? I'm not sure how to SharePoint.

CLIAC MEMBER: I've got it.

CLIAC MEMBER: I want to make sure I get it right. Have it 20 CME credit hours-- I think that would be OK, right-- specifically addressing laboratory practice commensurate with the director responsibilities.

CLIAC MEMBER: That's pretty good.

CLIAC MEMBER: I think I would have to call it up.

CLIAC CHAIR: So does that suggest that--

CLIAC MEMBER: That's the language that already exists.

CLIAC CHAIR: So then we want to do that?

CLIAC MEMBER: I'm sorry. What was that question?

CLIAC CHAIR: So the change that I've just made to then elide the two sentences, that's a description of the 20 credit hours that--

CLIAC MEMBER: Yes.

CLIAC CHAIR: Yeah.

CLIAC MEMBER: And in another section, it references where I got that language from. And in the full document that you have, the report [INAUDIBLE].

CLIAC MEMBER: I can help you wordsmith.

CLIAC CHAIR: Please.

CLIAC MEMBER: OK so 20 CME or CE credit hours. Blah, blah, blah, blah, blah. Laboratory director responsibility. Second sentence. Parentheses, (CFR.)

CLIAC CHAIR: Sorry where? Second line? Here?

CLIAC MEMBER: Second line. Sorry. Yeah. After "responsibilities." Parentheses, (CFR) 493.1407. There.

CLIAC MEMBER: I think the "and" in the very last line should be an "or."

[SIDE CONVERSATION]

CLIAC CHAIR: So if we are-- I'm sorry. I've started working on the residency requirement. Are we all satisfied with the continuing education requirement? Is anyone dissatisfied with it? OK. Very good.

So on to residency requirement. And what I've started doing is just combining these into a formal language--

CLIAC MEMBER: I'm sorry. Continuing implies continuing. Is that expected yearly or is that a prerequisite?

CLIAC MEMBER: It's one time.

CLIAC MEMBER: It's one time. So let's call it qualifying education, in part. Because continuing implies you have to keep doing it.

CLIAC CHAIR: I think that's fair. Opposition.

CLIAC MEMBER: No. That's good.

CLIAC CHAIR: Now this section appears to be in a similar vein to what we covered in our previous recommendation. Is it redundant with it?

CLIAC MEMBER: Well, this is talking about what they would do in residency.

CLIAC CHAIR: So is this statement that I've highlighted sufficient to capture that section?

CLIAC MEMBER: I think so.

CLIAC CHAIR: In that case, I'm going to dispense with this. Is this controversial to anybody? Yes?

CLIAC MEMBER: No, no, not controversial. But just where we added 1407, that is just moderate complexity lab directors, so you're going to have to add the high complexity one, which I think is 1443.

CLIAC CHAIR: Up here you mean?

CLIAC MEMBER: Yeah.

CLIAC CHAIR: 1443?

CLIAC MEMBER: Yes.

CLIAC MEMBER: Yes, that's right.

CLIAC CHAIR: Good. I'm so grateful to have all of these expert eyes, these eagle eyes on congressional record. So that brings us to, I think, the last part of question four, a proposed recommendation for a question four, which was about laboratory director qualifications. So no, this is, in fact, just a summary of the above, right? There is no-- excuse me-- there's no action proposed here. Correct?

CLIAC MEMBER: Right. I think that's just a summary.

CLIAC CHAIR: Yeah.

CLIAC MEMBER: Yeah.

CLIAC CHAIR: So I shall strike it. Eventually, it will be stricken. All right. In answer to question number four, about 20 continuing education hours as a requirement prior to qualifying, we've got these statements about the education requirement. I'm not even sure, that we need "qualifying" if that's what the question is.

CLIAC EX OFFICIO: it's actually just 1405 and 1443 because 1407 is what the lab director has to do, not their qualifications.

CLIAC CHAIR: Yes?

ADVAMED LIAISON: So in this section, the question was around continuing education, so as prior education, would those 20 hours count as part of your graduate work, your degree?

CLIAC CHAIR: I believe so because although they are talking about--

ADVAMED LIAISON: And those who would not necessarily be CME or CE.

CLIAC CHAIR: So they're talking about continuing education hours as just kind of like where to go to get this prior education requirement. So yeah, I think it is part of training.

CLIAC MEMBER: So if it was part of your regular training program and you were certified by one of these groups where that was already considered, that this 20 hours of this is inherent in it, then those people are exempt. So these are the people who-- internists who want to be a laboratory director but don't have any background directly in laboratory medicine in, say, in a moderate complexity lab. So they want to open up a lab, let's say, in their practice or their group, but they don't know what it means. That's when CMS sees all these citations because people are assuming roles for which they have no background. And so that's the kind of person for whom this is intended. If they had a formal laboratory training program that resulted in certification, then they wouldn't need it.

ADVAMED LIAISON: They'd have to go this route.

CLIAC MEMBER: Right. If they did a program but they never got certification, then they'd be required to do this.

CLIAC CHAIR: Does this bit of added text clarify in a useful way?

CLIAC MEMBER: Well, the last part of that defines pathologists except those certified by ADP.

CLIAC MEMBER: Well, because the other boards approved by HHS are not for pathologists.

CLIAC MEMBER: Oh. OK. That's true.

CLIAC MEMBER: So I think it actually messes it up.

CLIAC CHAIR: Right.

CLIAC MEMBER: Because there are there are non-pathologist directors that would be exempt.

CLIAC CHAIR: So then this is what we have. So any further discussion on this as a recommendation? Excuse me, as I put this in the appropriate format

CLIAC CHAIR: Just speak up if I'm looking down.

CLIAC MEMBER: Do we have to worry about the unintended consequences of this? I'm thinking about all the PPMP certificates. Those are all moderate complexity labs. Are we now requiring all of them or do they already have it? Is that the reason why there's so many citations? Because maybe the PPMP labs are not aware they're moderate complexity.

CLIAC MEMBER: Yeah, but the PPMs are under 1359. And so we're only talking about 1405 and 1403.

CLIAC MEMBER: So do the PPMP labs have a carve-out that they are not required to meet a moderate complexity lab director requirement?

CLIAC MEMBER: There's a whole section on them that does not have this.

CLIAC MEMBER: Essentially, yes, there is a carve-out that PPM lab directors do not have to meet the other requirements.

CLIAC MEMBER: I just want to make sure we don't have an unintended consequence here.

CLIAC MEMBER: It's a good point.

CLIAC CHAIR: It's a good point, but it sounds like it's taken care of. Any other discussion of this as a potential recommendation? Seeing none, the chair would entertain a motion to bring this to a vote. OK. I've got a motion on the floor. Second? We have a second. So all those in favor? All opposed? Abstentions? Anybody on the phone? We've been having technical difficulties, actually. I should ask anybody on the phone if you can see what we've been editing.

CLIAC CHAIR: Ah, well, that's unfortunate. OK. Well, here we go. At least we've got quorum around the table. All right. Well, passed then. Good job, folks. We're almost halfway done.

CLIAC MEMBER: We're more than halfway done in terms of time and complexity. These are only moderately complex. The last ones were high complexity.

CLIAC CHAIR: Yeah. So it is 12:30 and time for lunch, so I would propose we move to lunch. We can noodle on this stuff but not discuss until we get back. We will get back at, I believe, 1:30. And we'll continue this discussion. We'll have an hour to finish it up, and we'll see how we do. Thank you, everybody, and off to lunch.

---Lunch Break---

CLIAC CHAIR: Good afternoon, everybody. Could I ask that committee members find your way to your seats around the table?

Fantastic. And I think we've got quorum. Everybody enjoy the lunch? Good. Well in that case I think we'll pick up--

CMS EX OFFICIO: Did everybody eat?

CLIAC CHAIR: Yeah, did everybody eat? That's the question.

I think we'll pick up where we left off. We have about an hour remaining on discussion of this topic before I move on to a quick break and then the next one.

So I think without further ado, I'll just pick up-- we were at discussion question 5 of 9 for this topic. And I want to say that although we are within our purview to discuss broad topics, I'm quite gratified to be closing the loop on something that came up for the first time a couple of meetings ago, and then tasked to workgroup, and the workgroup came back with their report. And so it's gratifying to be able to close the loop on that with some recommendations based on it. So I think we'll push through questions five through nine. And I bet it's already up behind me. And indeed it is.

Question five, and I think five and six, were both about laboratory directors. Yes. Five being about on-site requirements. And there was a workgroup agreement about laboratory directors being on-site a minimum of once every six months, but not super together. So kind of averaged out to visits not less than four months, and not greater than eight months apart.

And on-site tasks should include or be defined as things that cannot be assessed remotely or delegated. And visits should be clearly documented. So I'm going to migrate up to the podium there so I can type, but as I do so I'll open the floor for discussion. So if you catch me looking down and you want to be recognized, just say something and I'll look up.

CLIAC MEMBER: I do want to revisit something on four at the end.

CLIAC CHAIR: All right.

I should also point out that we are not obliged to fill up the entire time on questions. If we find things are non-controversial, and you would prefer to move to a vote sooner rather than later, and a chair would entertain that, we certainly have things, as we've discussed already before, that we can come back to and spend-- make good use of the time discussing. Like, question two, for example. So don't feel obliged to fill up time. We generally have the opposite problem. Any comments here?

CLIAC MEMBER: So I don't know if we've got the right people at the table. I mean, there are parts of the country-- we're a really big country with some very spread out areas. And I-- there are parts of the country where pathologists are covering laboratories that are a long way apart.

I was in one CAP meeting five or six years ago that was talking about that. And I don't remember what we agreed as is the right amount of time or the right physical presence. I know that the world is changing and that you can do more at a distance than you used to be able to. I'm just a little worried about the impact on access to care in rural and underserved parts of the country of that, sort of, hard ruling.

CLIAC CHAIR: Do you think we are so far out of the realm of experience of rural or difficult-to-travel parts of the country, though, that these every six months, and not more frequently than four months, not less frequently than eight, could be satisfied?

CLIAC MEMBER: I'm saying I don't know and I'm not sure that anyone here does.

CLIAC CHAIR: This must have come up in the workings of the workgroup. Somebody rather than me, or you.

CLIAC MEMBER: Well, one of the things that did come up was that it was important for them to be-- for a laboratory director to, from time to time, put their paws in the laboratory for which they have responsibility.

CMS EX OFFICIO: Yes it is.

CLIAC MEMBER: And so we talked about how much. Whether it's weekly, monthly, or quarterly. And we, sort of, arrived at twice a year as being reasonable. The other reason that others stated why it was important to have that specification was that organizations that employ these laboratory directors to serve in that role.

If there is a regulatory requirement that they do it, then they'll pay for the travel and the oversight that's associated with it. So that was the other side that basically the regulatory specification would back them up.

CLIAC CHAIR: What's your representation on the committee from rural laboratories?

CLIAC MEMBER: We had some people that were a little more distant, but most of our people were in more urban kind of areas, I think.

CLIAC MEMBER: We did have that discussion about how distant some pathologists are from the laboratory that they oversee. But that's why we came to that six months' conclusion because twice a year we would like to be in Montana, Idaho, even Nebraska, South Dakota. You should be able to get there twice a year.

CLIAC MEMBER: So I'll kind of give two different perspectives. In the workgroup, we did have Beverly Rauch from New York State. And New York State requires directors to be site every other week. And it doesn't matter where you are in the state. So I would say that that was a good representation of a rural population, because they require that of the entire state, that directors are site every other week.

And then in my DoD experience, although not necessarily equivalent, we try to get our directors there once a quarter. And we do that even in Europe and Asia and the far reaches of the world, in addition to in the United States. And we meet that requirement not all the time, but every six months, we would certainly be able to meet it.

CLIAC CHAIR: Is that reassuring to your question?

CLIAC MEMBER: Well, it's not like CLIAC's making rules here. This will come out for comment, and I just wanted to make sure that we at least addressed that question. That's fine.

CMS EX OFFICIO: I understand distance between labs. But the laboratory director, being ultimately responsible for everything going on in that lab, to be there only twice a year-- I mean, from a physician point, you are all comfortable with that?

I'm just throwing this out. I mean, that, to me-- I understand that's the recommendation, but that does not seem like it's going to provide adequate oversight of a lab from my perspective. And feel free to disagree. But no, I don't think that that's a really good amount of time.

CLIAC MEMBER: But I think [CLIAC MEMBER], you may have said this, or somebody on that side talked about in today's electronically connected world, that doesn't mean the laboratory director only does things with the lab twice a year.

CMS EX OFFICIO: Right.

CLIAC MEMBER: I mean, there's day-to-day involvement, weekly involvement, however they define that-- via WebEx, or phone calls, or however they do that. But to be physically present in the laboratory twice a year didn't seem onerous for even these rural laboratories that we were discussing.

CMS EX OFFICIO: I guess I'm just old school. I think that really would be a little terrifying for me. And I understand telework and all of that, and remote everything. But sometimes, you can't get away from the fact that having somebody on site-- that presence on site to oversee things is not a bad deal. I mean, that's what their responsibility is. So I just wanted to put my thoughts out there.

CLIAC MEMBER: This was the balance, right? Between what would be reasonable, looking at all laboratories across complexity of testing, is that certainly, in my laboratory, I was there every day. Right? When I was the medical director, it wasn't an issue. But the point being is there's lots of things that can be done remotely.

CMS EX OFFICIO: Right

CLIAC MEMBER: You don't get out of your responsibilities of reviewing the QC and making sure that people are competent, and everything. But once every six months, roughly, in a difficult to access laboratory, we thought, was-- we're running the floor here, not the ceiling.

CMS EX OFFICIO: And I get that. I just--

CLIAC MEMBER: I'm still-- and then we had a great conversation in the workgroup. I was in the workgroup and we had a great conversation. I'm still struggling with what [CLIAC MEMBER] had mentioned, making a rule that works for everyone. And I think yes, you want lab director should understand what's going on in the staffing, the facility, the maintenance, and what's going on in the lab. A lot of that can be done remotely. I've done inspections where a lab director goes once or twice a year to a small lab, but is getting monthly quality reports and really understands what's going on at that lab. I've been to labs, and we discuss this, where there's monthly visits, but lab directors signing off out here, and really is not involved.

I'm struggling. There's no solution that's going to work for everyone. Twice a year, it seems reasonable. I mean, one idea for mitigating the distance and the requirement. The lab director is one person, the person whose name's on the CLIA certificate.

Could this be delegated to someone with lab director qualifications? That's an accreditation concept where either the director or someone who would be qualified director, who often is part of a group of pathologists or scientists-- and so that person doesn't have to travel 400 miles, because you're in that four-to-eight-month

window. Could that be delegated? And then I'm wondering just now, because I'm still struggling with making a rule that works for every situation, whether that could mitigate that somebody, who's involved in the operation of that lab, who's qualified as a lab director, but may not be the person whose name is on the CLIA certificate, might get there in that window of time.

CLIAC MEMBER: So I wonder if perhaps some clarification about ongoing essential contact-- the items listed, looking at the physical environment, reviewing and signing documents with today's document control systems, that can really be a remote activity. But the crux of it is is that the quality of time assigned to it, and the limit on the number of labs that somebody could be in charge of. So theoretically as it's written, if you'll only be someplace two times a year, then you would have 30 labs you could visit two times a year. But you might not be giving the proper one on one phone calls, and telling pathology conferences, and group meetings with video conference, that you should be doing as a laboratory director.

So I think it's a component of on site, but actual holding people to the responsibility level that's required that I think you're addressing. Is that there's a lot of ways to do this now. And we don't mention any of those other ongoing, continual things. So if somebody is just going to rubber stamp everything, and visit twice a year, that's not acceptable and we need to perhaps spell that out a little bit more with an expectation of true oversight, true responsibility, for the ongoing operations of the laboratory.

CLIAC CHAIR: In that respect, it might be helpful to note that the question was not meant to be exhaustive about what the responsibilities are of a director who will not spend most of their time on site, but just how often should they be required to be on site. So this is not saying that just showing up twice a year is sufficient. It's simply saying that it is a necessary condition. It's a floor, as Lee said. And I think Mark, we had you, and then-- yep. Mark, and then Annie.

CLIAC MEMBER: I may have retracted my thought, but I was wondering if we should consider the time spent, versus just a statement of twice a year. I'm speaking from an example of-- we have a local lab director who is never in his lab, and so he would probably check this box off. But in my mind, walking in for an hour every five months is not sufficient. So twice a year could be dangerous if it's literally someone walking in to say yeah, I was here, and leave. Would we want to consider a quanti-- an equivalent FTE, or an equivalent hours on task? And that's getting maybe a little too much, but if someone really doesn't care, and just wants to collect the accolades, they could easily show up, be there for an hour, and leave.

CLIAC CHAIR: So, presumably other oversight will prevent that from happening, but I wonder if also the second bullet point up there might bear on that. So it reads clear documentation of laboratory director on site visits should include validation that the laboratory is in continuous compliance with the current laws and regulations et cetera, et cetera. So as opposed to just saying that I'm here, I showed up, where do I sign my name, and then I continue on to my Greek island, or whatever, I have to at least certify that everything is working. And presumably that would mean whatever time is necessary to confirm that.

CLIAC MEMBER: So would the laboratory be documenting the number of days they're there somewhere? Or just the signature of those dates would be the documentation?

CLIAC CHAIR: So I guess it comes down to what problems specifically are we trying to get around or trying to solve? If we're trying to solve the problem-- or avoid the problem of gross negligence, I guarantee you somebody is going to be grossly negligent no matter what. They're going to sign that they were there for a week when they were only there for a day, or what have you.

CLIAC MEMBER: I mean, I've inspected labs for the CAP where the manager and technologists have been pretty frank about their frustrations with the lack of their director's presence. And it's typically been smaller hospitals, rural mountain west institutions, without naming names.

CLIAC CHAIR: What is the report showing? What is CAP inspections or the report showing as a result of that? Did they--

CLIAC MEMBER: Well, their signatures on everything that it needs to be, and the labs generally doing well because they have a good manager. But they're doing the job of the director essentially. So, I think there are situations where people are feeling unsupported.

CLIAC MEMBER: So the trouble is making a model that works for everyone. So I have-- we have three physician office labs in our practice. They're run centrally through our stat labs. Every other week I'm there looking at management, quality control, compliance, et cetera, et cetera. I literally do go on site twice a year for an hour to see those facilities. I mean, often times I have reason to be there. But, the onsite visit is really just physical space. Is it hot? Is it cold? Are there people? There's three staff there. OK.

Because I'm doing all the other stuff remotely, as was mentioned previously. So, I think it's dangerous trying to be too prescriptive here, because one model isn't going to work for everyone. There are people doing very good central management. And the point of this is there is a minimum bar we want to set, but we don't want it to be too prescriptive about you have to be there for a half day, or three hours, or two hours. Again, you can't force people to do their job. You can force them to be there two hours. Would that mean they're going to the lab director job any better than 30 minutes, or an hour, or a day?

CLIAC CHAIR: So other comments on this problem?

CLIAC MEMBER: Can I ask the committee members, was there any discussion about differentiating between a moderately complex lab and a high complexity lab, in terms of the number of visits, et cetera?

CLIAC MEMBER: Yeah, there was. And there was once a quarter, twice a year, that was discussed, the reference to what's required in some, states and by accrediting organizations. So, there was that discussion. And ultimately, we came to that given there's a spectrum of laboratories, and there's those that are in very rural areas, and different levels of complexity, that this was the floor. It wasn't meant to say, this is what it should be, that this is necessarily the best practice. This was the basic floor because there are laboratories where nobody is-- where the person who's responsible is never there. And so that was the basis for this recommendation, was really to say there has to be a floor, not to define what constitutes necessarily best practice.

ADVAMED LIAISON: So I think that's a good point because the regulation is the floor. And while you may have desired-- we may have to say we have people there more frequently, the lab director there more frequently, but this is the bare minimum. So that's why I have an issue with-- it says every six months, but then goes on to say not greater than eight months apart. If six months really is what we think the minimum frequency should be, then it should just be six months period, because if we're worried about the least concerned lab director, they will take it out to eight months. And then over a four year period they will have been there three times.

CLIAC CHAIR: I think that line is meant to avoid the following situation. So, you arrive there last day of June. That's your first six months, and then you stay through the first day of July, and that's your visit for the second six months. And so technically it's once every six months, but practically it's once a year, if I understood you right.

CLIAC MEMBER: That was to put some bounds on it so that it's plus or minus-- we don't want to require somebody to be there every 180 days.

CLIAC CHAIR: But nor did you want to have it so that you can establish that you have two six months periods, and then your two visits were just on either edge of it. I think that's all that that's stating. So if you were to visit greater than eight months apart, then your next-- meaning if you visited just in the first-- if you visited sometime between January and August, you couldn't buy another six months after that. You'd have to have your second visit somewhere in September or December. I think that's all that that's saying. So, average is six months a year, but they can-- yeah, I was trying to think my way through some loopholes here, and it seems reasonable to me. Helen?

CLIAC MEMBER: I have to agree though, when I read that, I thought the exact same thing. And I think if somebody comes in June and then they come in July, then they should again come in January within the six months.

CLIAC CHAIR: What we're basically asking is for you to be there twice a year, roughly.

CLIAC MEMBER: But it's not saying twice a year. It's saying every six months. So if they come early, then their next six months should start beginning that date. So then that would require them to come more than once, twice a year. And that's their option. It is just a minimum.

CLIAC CHAIR: So would you prefer something more like twice a year, with at least four months between visits?

CLIAC MEMBER: So I just want to comment. There's an analogy about how often we do our OPPE. And our OPPE, it says more than once a year. And then you define how often, but you need to do it at least once, and more than once a year. That's a very broad statement. But I'd like to pull it back even further. I mean, I feel like we're going backwards in time. I understand the concern, and you really getting at the lab director who doesn't do his job. But today we have ICU's that are managed by tele monitors. Those ICU docs never show up in our hospital. We're not going to mandate they come in once a year. So why are we doing that for lab director?

CLIAC CHAIR: Say that again. We aren't demanding--

CLIAC MEMBER: Pardon?

CLIAC CHAIR: I missed your sentence, your last statement.

CLIAC MEMBER: We are not demanding the tele ICU docs come into our hospital every so often to physically be on site. If the issue is the environment, you got robots running around with whatever, and you can look at the environment. You put temperature monitors on. You can webcam it. We've tried to do that. We've had some union issues around that but, there are other ways to look at the physical environment if that was the intent.

CLIAC MEMBER: Right, but I don't think just because another discipline has a low, quality we should drop ours to it.

CLIAC MEMBER: So that's a good point, but the quality data out about the tele ICU show that they're providing better care than the folks who were on site.

CLIAC MEMBER: I don't think it's discerned by the number of times the medical director is there, though.

CLIAC CHAIR: That's something to think about, but we would have to go into some detail to see how that would compare. But in light of these questions about frequency maybe I can ask a question back to CMS EX OFFICIO. When this question came up, can you remind us what led to it?

CMS EX OFFICIO: I think we were just seeing very long periods of time--

CLIAC CHAIR: Can you speak in the microphone?

CMS EX OFFICIO: I think we were seeing long periods of time between when-- particularly in toxicology labs where these people would have multiple labs.

CLIAC CHAIR: But this must also have been a concern. If everything was running hunky-dory-- so what was a concern about it being long periods of time?

CMS EX OFFICIO: Sarah, do you remember exactly what it was? I'm drawing a blank.

SARAH BENNETT: It has to do with the fact that we see a lot of variability within laboratory directors and that the noncompliance for laboratory directors continues year after year after year. We see that they're not fulfilling they're regulatory responsibilities.

CMS EX OFFICIO: So it's a compliance issue, but compliance with what?

CLIAC MEMBER: I think one of the other issues we talked about was, and you see these ads if you scan journal pages, ads for lab directors who are qualified. They've got a Board, and they've got their MD, and they will never set foot or really understand much about what's going on in that facility. And you're seeing more and more of those. I think that was one of the things we talked about in the group.

CMS EX OFFICIO: So can I take a straw poll at this point? Is this idea, maybe the sentences have recrafted it there, of two visits a year with this buffer to avoid playing the system-- does that generally sound OK to people? Or is this a deal breaker? Generally sound OK? A nodding of heads is fine.

CLIAC MEMBER: I have one suggestion to this. I think that we should leave off the four months, because now it looks like there's a penalty if they come more than three times a year. Because there has to be at least four months between visits.

CMS EX OFFICIO: Oh, I see.

CLIAC MEMBER: I think just leave that whole part off. If you're going to do this, just at least twice a year period.

CMS EX OFFICIO: I see. That is a problem if it's more than twice a year, but if it's only twice a year, then they can sell skirt the system as in my comments earlier.

ADVAMED LIAISON: I see your point exactly. I was going through that myself. But then I was thinking we're making a recommendation to HHS. If they can understand our intent for what we're trying to write, because we're not actually trying to write the regulation ourselves. And then I had, with what's now the fourth bullet, wondering about the term validation, because validation typically in the lab implies a higher set of requirements. And maybe that word is too strange. Should verify that the lab-- but again we're not writing the regulation. We're making a recommendation to HHS.

CLIAC CHAIR: So it's a validation because validation is a technical-- it's a term of art as opposed to verification?

CLIAC MEMBER: I didn't mean to talk over you. I was just saying the word demonstrate. It should demonstrate that the laboratory is in continuous compliance.

CLIAC MEMBER: How do you demonstrate though?

CLIAC MEMBER: And I'd like to ask again that because of the intent of what you were talking about, these absentee landlord type of directors that started this whole question in the first place, if we could tag on to what she said with the minimum at least requirements, but evidence of ongoing-- that demonstration of ongoing contact, or guidance, or something like that because I agree that on site-- I mean, I have 17 hospitals and we run around once a month doing the onsite visits. But we meet twice a week by video conference, and more often in per-- like once you know somebody, you could be guiding them. You could be verifying data. You could be doing all kinds of things.

But, I think to have the onsite, so that there's that personal touch, but demonstration of continuing and ongoing contact to be-- maybe not quite as closely defined. But there's all these people trying to put up CLIA labs in their garage these days and doing what exactly was discussed about just having all these labs and not really paying attention to them. So I think if we could have some kind of clause there, that would be the intent of the oversight. And being on site is not the end all be all of oversight, but there's got to be some expectation of continuity there.

CLIAC CHAIR: So my question back to you, would be-- so I take your point. Is that an issue that we expect to be taken care of elsewhere in regulations?

CLIAC MEMBER: I guess I'd say that if it was taken care of in the regulations, they wouldn't have had to bring it up to start with.

CLIAC MEMBER: So the only point, is we were asked to review specifically on site director requirements. As we cited before elsewhere, there are clearly director requirements that are already specified for what needs to be done. So the question that was posed to the workgroup, was is it OK to be an absentee landlord and just do this by cell phone or smartphone? And that was really where we went. So that's why it didn't address-- the assumption is that there is that responsibility that's covered by the roles--

CLIAC MEMBER: Does it refer to the section then maybe?

CLIAC MEMBER: Well, I think that could be a recommendation to look at for-- See, they're crafting the specific regulations to make sure it's clear that this specifically refers to an onsite piece. But doing this on site doesn't do anything to get you out of doing what your regular job is.

CLIAC MEMBER: I think that we should also, even though we're not crafting the law right now, that we should also comment or make a provision about technology, tele conferencing, tele governance, so that when the law is crafted the thought is not that we are out of touch with what's going on in our current healthcare environment.

CLIAC CHAIR: So does that- do these edits get at those questions? I see a lot of nodding heads. Are those heads nodding sufficiently enough to--

CLIAC MEMBER: Just one little correction. The last bullet point, it should say on site visits should demonstrate. Can you delete the word include?

CLIAC CHAIR: On site visits should include demonstrate. You don't like to include demonstrate?

CLIAC MEMBER: In the first bullet, can you change directorial to director? Because I mean, they're defined in CLIA as director responsibility.

CLIAC CHAIR: Perfect.

CLIAC MEMBER: I just would like to comment that the term “reasonably spaced.” It still worries me from our discussions on how that will be interpreted and used. So I think it has to be very clear in the regulations.

CLIAC CHAIR: Well, to the point brought up earlier about us not actually having to wordsmith the regulation, is there any chance do we think that CMS or anyone else at HHS would misinterpret what we're trying to say here? And the only reason-- I 100% agree with you Bonnie, I just worry that it begins to get very legalese to say it has to be at least four months, unless you're coming more than three times a year, in which case-- or three times or more in which case you don't have to worry about that, or maybe you do because you can't have two of them meeting-- you know what I'm saying? It starts you need to want to write a mathematical function for it.

CLIAC MEMBER: Let the regulators do the regulatory work.

CLIAC MEMBER: I think they understand the intent.

CLIAC CHAIR: With your vast experience, is the intent of reasonably spaced, pretty clear?

CLIAC MEMBER: Yes.

CLIAC MEMBER: Would it just make more sense to say at least one separate, or on site visit per six months?

CLIAC CHAIR: Again, then there's this worry that the first six months period is January through June. The second is July through December. And your two trips are broken up by going to the hotel in between the last day of June and the first day of July. There's your two visits once per six months.

CLIAC MEMBER: It is my impression having worked with the team from HHS that they're pretty smart and they understand the intent of this. So I think we should be OK.

CLIAC CHAIR: CMS EX OFFICIO how do you spot respond to that accusation?

CLIAC MEMBER: She agrees to being smart.

CLIAC CHAIR: Fantastic.

CMS EX OFFICIO: I have a great group of people.

CLIAC CHAIR: Well in that case, if Jared would entertain a motion to bring this recommendation to a vote? We have a motion. Second? We have a second. All those in favor? Any opposed? Anybody on the phone? Any abstentions? All right, motion passes.

CLIAC MEMBER: Yeah, I'm sorry. There's a delay on the phone. And yes.

CLIAC CHAIR: Oh, I'm sorry. If you would like to speak up, please. It's hard for us to insert you. So just speak up. Feel free to interrupt and we'll get you in common list.

CLIAC MEMBER: OK. Thank you.

CLIAC CHAIR: Great All right. Question six. And just nodding from the audience will do. Is everything on the screen large enough for people to see? OK, good. So discussion question 6. This is about additional doctoral experience. In addition to already required Board certification for doctoral degree laboratory directors, what other clinical laboratory experience should be required? And I think that I might turn Lee, to you because I feel like we've addressed this. So unless there is opposition from members of the committee to move on to discussion question seven--

CLIAC MEMBER: I told you they'd go faster.

CLIAC CHAIR: Don't jinx us. So discussion question seven, technical consulting requirements, something that was brought up earlier. So what, if any, modifications should be made to the educational qualifications for technical consultants? I will let the members of the committee read through these three bullet points.

CLIAC MEMBER: Really the only recommendation is the second bullet.

CLIAC CHAIR: Yeah So I'm going to simplify. Is it EB White recommends, "It is seldom advisable to tell all"?

CLIAC MEMBER: If this wasn't my first time doing this, I would have brought it to you this way. We worked really hard on this with short notice.

CLIAC CHAIR: And that's appreciated. Was it Lincoln that's supposed to have said if he had, about the Gettysburg Address, if he had had more time, he would have made it shorter? Variously attributed? Happy to be corrected.

CLIAC CHAIR: Yes?

CLIAC MEMBER: Since you're cutting and pasting that one phrase, do you want to change propose to recommend?

CLIAC CHAIR: Yes, and I want to undo what I just did. Thoughts on this requirement for technical consultant?

ADVAMED LIAISON: I move we accept it.

CLIAC CHAIR: We have a motion on the floor. Seconded? No discussion, right? OK so motion seconded. Then let's move to a vote. All in favor? Any opposed? the phone, sorry?

CLIAC MEMBER: In favor.

CLIAC CHAIR: In favor. All right. And no abstentions? No abstentions. OK, this passes. And brings us to discussion question eight about mid-level practitioners. Should the definition be expanded, and if so how? And this came about earlier about nursing anesthetists, and clinical nurse specialists. Again, this is a quick one to read. I'm just going to put the appropriate formatting here. And open the floor to discussion. I see nodding heads, but no comment.

CLIAC MEMBER: So again, remember this was to add the other two categories of advanced practice nurses.

CLIAC CHAIR: It's non-controversial in the committee, or in the workgroup? Excuse me.

CLIAC MEMBER: Once we understood the scope of practice of the CRNA, then it wasn't controversial.

CLIAC CHAIR: Discussion?

CLIAC EXECUTIVE SECRETARY: I'll just add again here, it's not obvious from the question, but this applies to individuals who are qualified to direct and perform PPM procedures.

CLIAC CHAIR: Do we feel that needs to be specified, or will that be understood as stuff is brought to my attention? HHS will have a transcript of our discussion, which should allay some concerns as least issues of misunderstandings.

CLIAC MEMBER: Maybe put PPM after CLIA. Modifying P-- PPM.

CLIAC CHAIR: Here?

CLIAC MEMBER: Yeah. Will that work?

CLIAC EXECUTIVE SECRETARY: Yeah, I was just mainly adding it to make sure everyone here understood where we were talking about.

CLIAC MEMBER: Better it should be there too?

CLIAC CHAIR: This is fair? Well if there's no discussion, if it seems pretty non-controversial then you know what my next question is going to be.

CLIAC MEMBER: I'll just say, there are many other-- we refer to them as advanced practice practitioners. And there are many categories other than those coming through the nursing discipline. So we are specifically just including the CRNAs and the CMFs and excluding the other APPs.

CLIAC CHAIR: Who else did the committee consider and turn down?

CLIAC MEMBER: So basically there were four categories. The nurse midwives, nurse practitioners, CRNA's, and clinical nurse specialists. So those were the four. And two of them were already listed as qualifying. So the issue really that we were asked was should these two additional advanced practice nurses be included? The group concluded after reviewing the scope, yes. If there were other groups that should qualify, we didn't want to just say advanced practice nurse because nobody knew where that might go. And so we wanted to be specific and just include these four categories for the purposes of directing the PPM lab.

CLIAC MEMBER: Would you end up excluding other APP's who are not nurses? I'm thinking we have PA's for everything. Neurosurgery. I mean, endocrinology. Podiatry.

CLIAC MEMBER: No, they would-- I don't think-- I guess I need to refer to my colleagues, but this had to do with the nurses, the nursing specialists that would qualify to be able to do this. Is that right?

CLIAC EXECUTIVE SECRETARY: Yeah. There is a definition in CLIA for who is included under mid-level practitioners. And this is just adding these two categories to that.

CLIAC MEMBER: I can't hear you.

CLIAC MEMBER: Sorry. We use the American Nurses Association. They're guidelines help us determine what [INAUDIBLE].

CLIAC MEMBER: I'm on the phone. Just a brief comment if you can hear me. It's not too disruptive. The distinction is that certainly in our setting nurse midwives and practitioners can sign off on charts. Physicians assistants, and while I agree with their previous comments because I don't know what to do about them, often they work under the auspices of the position and not necessarily are able to sign off on documents independently. And that perhaps is the reason for the distinction?

CLIAC MEMBER: Thank you. I was going to make a comment about the PA. The PA's are dependent practitioners. The PA's are already listed, as I read this bullet number one on the background. So, as I read this, there's no distinction between independent versus dependent practitioners.

CLIAC MEMBER: Thank you for clarifying.

CLIAC MEMBER: That's right.

CLIAC CHAIR: So we aren't excluding anybody. We're just explicitly including folks that we think we ought to. Any other discussion? All right, seeing none, I would be open to a motion to-- yes? Motion to-- To do what? Yeah, no, to vote on it. I'm sorry. Second? Second. OK. All in favor? On the

CLIAC MEMBER: In favor.

CLIAC CHAIR: Any opposed? No abstentions? All right, it passes. And that brings us to our last discussion question, and hopes that we'll even have a bit of time left over for other things that we have all been thinking about, but put on hold to get through these important points. So this is about histopathology grossing review. The question was what time frame should be considered appropriate for a pathologist to review the gross examination performed by an individual who is not a pathologist. And we commented on this. I was going to say this. This came up in our previous meeting and basically there's nothing additional to recommend from them. So, I think no action on this topic from us. So, I propose we go back to question two with our remaining few minutes.

ADVAMED LIAISON: Or are we going to-- there were other issues considered.

CLIAC MEMBER: Well, there are-- we do have the other issues. And then also, I wanted to touch on four. But if you want to go to two first, I [INAUDIBLE].

CLIAC CHAIR: No, I defer to the table. I mean, what do we feel like? Feel free to speak out of turn? Just what do people want to do with our remaining 10 or 15 minutes? We've got question four, question two, other issues.

CLIAC MEMBER: I would like to touch on the topics for future CLIAC discussion as well.

CLIAC MEMBER: Because that would be a matter of prioritizing future work of a workgroup, not necessarily this workgroup.

CLIAC CHAIR: Well, maybe then let's do-- let's look at other issues and future topics, as opposed to going back over the things that we've talked about already at least a little bit. Sound good? I see nodding heads. Good.

CLIAC MEMBER: I do want 30 seconds on question four though. Sarah reminded me of a discussion I was trying to find before.

CLIAC CHAIR: Please go ahead. Maybe now's the time.

CLIAC MEMBER: OK. So, and I was trying to find it while we were discussing it, but as we recommended that residency training should include clinical laboratory training during residency or fellowship. When we discussed this, actually we went back and forth about it. The accrediting agencies and the states had told us that frankly this doesn't happen very often. And at the end, on page nine in the discussion items, the workgroups suggested for moderate complexity laboratory directors or-- either for the high or-- the last two bullets, for high complexity or moderate complexity, eliminating that all together because very few people qualified through residency training. And if they did have the experience then they would qualify through the experience route anyway. Does that makes sense?

CLIAC CHAIR: I'm trying to bring up the recommendation to see if I follow.

CLIAC MEMBER: It's the last two bull--

CLIAC CHAIR: Oh, in the report on the slide.

CLIAC MEMBER: We went back and forth about whether to leave it and change it, or just get rid of it. In the end, if I recall, our conclusion was it probably didn't add much because the accrediting agencies told us that very few people qualify through that route. And those that do would qualify through the experience route anyway.

ADVAMED LIAISON: Did we vote on that one already?

CLIAC MEMBER: Yeah. So it's the second bullet.

CLIAC CHAIR: So you're proposing now going back to this recommendation, and deleting that second bullet?

CLIAC MEMBER: Well, to eliminate the route for residency education. So our first discussion was it should be clinical and then at the end, that we came back to the conclusion that for both moderate and high complexity, very few people qualify through this route. And those that do for the most part have the either the Board certification or the time. Well, the board certification wouldn't matter. It's really whether they have time in the moderate or high complexity. One or two years of experience.

CLIAC CHAIR: So the concern is that this might be-- I was going to say redundant, but that's not quite true. Just rarely applicable.

CLIAC MEMBER: Rarely applicable and difficult to manage.

CLIAC CHAIR: I suggest that having discussed it, and if it's not going to be grossly wrong, then maybe let's defer that until we've had a chance to discuss these other issues.

CLIAC MEMBER: I just wanted to make sure that I didn't gloss over that.

CLIAC CHAIR: The point's been heard and will be on the record. With that said-- and I apologize for not being able to know how to toggle back and forth between things easily here. There we go. Learning on the job. All right. So we still have a few minutes. And we have many more issues that the workgroup discussed. Then we're going to have a chance to discuss in detail. Are there specific things that we want to devote a little bit of time to now?

CLIAC MEMBER: Well, I would comment--. For the items that are on this slide, I think we've touched on them for the most part. It was making sure that military training and experience could map even if it doesn't meet the written requirements, but that the experience should crosswalk so that those who are completing their service in the military could fill the many holes we have on the civilian side by virtue of them receiving that training in the military.

So that's the first one. I don't think there's much controversy on this. The doctor at the DCLSs knew-- just were asking that it be looked at in the interpretive guidelines and be included. The third one, I think we heard both from public comments and in discussion about including our categories for these individuals, both on the histotechnology side as well as the PA side. I don't know that there's much to discuss here. I think the issue of priority is more the next slide.

CLIAC CHAIR: Maybe your comments on this slide touch on the next slide, which is what we want to talk about or recommend talking about next.

CLIAC MEMBER: But can I just-- back to the-- Yeah. On this slide, I guess I do have some reservations about the DCLS. And the issue of what we're saying is that in the same amount of time this individual will be able to be knowledgeable about all laboratory activities, as opposed to the disciplined training that we're receiving in say microbiology, or chemistry, or whatever. I just want to be sure is it correct though, that this individual, who has a DCLS, will still have to have a fellowship in order to be qualified and recognized by a Board?

CLIAC MEMBER: They still would have to meet it. It's just it's acknowledging that this degree now exists. And the education, the background, and training for that degree would be consistent with other doctoral level degrees that would be appropriate for laboratory science.

CLIAC MEMBER: But they still will have to have a fellowship after that in order to be able--

CLIAC MEMBER: They have to have whatever they have to have to be qualified. But the degree that this one would--

CLIAC MEMBER: Well, they would have to have a board. Again, that gets back to the previous conversation. With DCLS and a board, ABB, one of the Boards, you'd be qualified to be a high complexity lab director. Then the devil's in the detail of what, if any, technical supervisor requirement does this degree match to? But I think the conversation we had in the group was DCLS, plus a Board, you'd be a high complexity lab director. But then the hashing out of, well OK well then what technical supervisor duties would this pathway qualify for, or if any?

CLIAC MEMBER: But then that would be dependent on your training experience and your certification, et cetera. It's just that there's no reference for good reason because it didn't exist to the DCLS in the interpretive guidelines before.

CLIAC CHAIR: Maybe a good topic for a future meeting.

CLIAC MEMBER: Yeah it was just on DCLS. I just wanted to mention that since these documents were available on the web, I've received three emails and a call, in regard that this be reconsidered, as they do not feel in my discipline that this degree is equivalent to a doctorate, as research projects are not involved.

CLIAC MEMBER: Thank you. So my comment is related to the next slide. And it's regarding the modes of communication that have changed, especially the increase in digital type of communication. And I'd like for the committee to consider studying the significant and critical results, communication of significant and critical results, especially as it relates to diagnostic accuracy, as we talked about earlier in the last meeting with Dr. Lapasoa. I think that there's some synergy that we could create around looking at digital modes of communication of significant and critical results, and improving the language that's currently in the federal register about that, and also tying it in to diagnostic accuracy, and communicating these results.

CLIAC CHAIR: As a future topic?

CLIAC MEMBER: Yes.

CLIAC CHAIR: Other future topics that relate to work force?

CLIAC MEMBER: I'll bring up my little nit picky one that I bring up, which is automated blood bank platforms are FDA categorized as moderate complexity, but there's a little asterisk, unless used for transfusion. And they immediately revert to high complexity. And with a workforce shortage, with automation, with autoverification, we certainly would be interested in moving those platforms to moderate complexity period.

CLIAC CHAIR: Other thoughts and ideas for next time? Seeing none, I would like to congratulate the Committee on really thoughtful, and I think productive discussion, related to these nine points. It's gets nice to see the loop closed. And we've arrived I believe, at our mid afternoon break.

CLIAC MEMBER: I want to make sure that we thank the staff again because--

CLIAC EXECUTIVE SECRETARY: What about question two? Remember, you were going to go back to that?

CLIAC CHAIR: We were.

CLIAC MEMBER: That's old history now.

CLIAC CHAIR: So we can go back to question two now, and then have the break, or an abbreviated break, or we can basically not discuss-- not plan to discuss question two and fit it in if there's time at the end of other discussion sections. And [CLIAC EXECUTIVE SECRETARY] you burst my bubble. We were doing so well. But you're absolutely right. And before I forget, yes, thank staff for all their help in organizing all this stuff. And none of this happens without them.

CLIAC MEMBER: So are the other personnel issues, are we making recommendations on those today, or are they going to be bunted with the next slide to the next meeting?

CLIAC CHAIR: The latter.

CLIAC MEMBER: What was that?

CLIAC CHAIR: So do we want to talk about question two, or do we want to have a break and be back? In any event, we should begin again at 2:45. I'm happy to continue going straight through. But I really defer to the feeling around the table. And with my new found expertise at switching between things on Windows--

CLIAC DFO: Could I ask for some clarification?

CLIAC CHAIR: Yes.

CLIAC DFO: Before we leave the personnel topic, I guess I'm unsure whether CLIAC is-- whether the workgroup that was convened to address these nine questions has completed its task and we are disbanding that workgroup, or are there additional questions and issues that that workgroup that we've already convened should tackle or continue to address?

CLIAC CHAIR: That's a fantastic question. And I think it would be great to continue the workgroup if the work is amenable, in order to address-- I mean, that's a way to have them think through in some more detail some of these questions that they've already grappled with, the other personnel questions and then some of the things on the list of topics for future meetings relating to personnel. So I would be certainly amenable to that, to continuing and having them report back on the questions arising from this discussion in our last work. I don't know of procedurally how that happens, but I'm assuming that it requires at least some agreement by the workforce leadership and members.

CLIAC MEMBER: So I think that we didn't have an explicit recommendation one way or the other, because we weren't sure what would come out of this in terms of recommendation or next steps. There's clearly a couple of things that we've been asked, or that-- I guess it is a question two, to look at and specify some of the issues that the [CLIAC MEMBER] mentioned.

CLIAC MEMBER: Q.

CLIAC MEMBER: Well, Q. Just think she's just into Q, but there's a couple others where there's doctorate only. So I think we do need to look at that. There may be some other issues. I mean we can probably start by having a conference call before the next meeting. And then if in fact there are more issues, and some of them are for future discussions if want to be prioritized, we could reconvene this group with maybe some modification or additions to address those questions. It's really up to this.

CLIAC CHAIR: Should vote to task a-- yeah go ahead.

CLIAC MEMBER: So, I think that if we're going to ask the workgroup to keep on it's a good bit of work to get volunteers on the staff. You should really should prioritize a number of these things, mostly to work back to. I didn't really hear any burning questions we referred back to that would require the workgroup input. I know there were some questions that came up, and I don't think we really [INAUDIBLE]

CLIAC DFO: Yeah, I would agree. I think we shouldn't have a workgroup just to have a workgroup. There should be a pretty specific charge, agenda, objective. But if you have that, I mean, so we could either articulate it, or put this workgroup to bed.

CLIAC MEMBER: On the other hand, it's kind of useful having a bunch of people you can just dump stuff on.

CLIAC MEMBER: Thank you very much. But I think that maybe let's wait until we get to the end of the day and come back to that. There may be some issues that fallout of the subsequent discussions, it could be. Or

maybe this meeting and the next meeting, and then maybe we want to reconvene it, but in the meantime we might want have a conference call to deal with Q. And you're welcome to join us.

CLIAC CHAIR: That would suggest a formal agenda of dealing with Q for question two, which I would say it's not a bad agenda. I have some thoughts on adding-- adding to that, some of the specific recommendations around military personnel and around this other doctoral degree, as was mentioned. But the point is I guess, it wouldn't be nine questions, but certainly at least three that we could specifically task you with, based on topics that arose out of this discussion.

CLIAC MEMBER: Right. And while I understand Q, it's really anyone where there's a doctoral only level specification in that long list to at least look at, not necessarily change.

CLIAC MEMBER: I would like to broaden the charge because I'd be very curious on the discussion around why don't we just have single definitions standard for each of these categories? I'm sitting here thinking why do we have a technical consultant and a technical supervisor? Why are these not defined better? Why do we need more than one group in there?

CLIAC CHAIR: So, I'm going to interrupt the conversation discussion just for a second to ask whether staff is unable to write while I'm up here? So if this is all being recorded that would be helpful so that we can be efficient about providing a charge if we want to do something for the day. OK. Bonnie?

CLIAC MEMBER: I just wanted to say what Lee mentioned about going through the rest of the workgroup reviews and then decide because when we were talking review for NGS, there was a lot of conversation about how to do petitions and how we address those NGS. So I think the rest of the workgroups work also has as a lot to do with what we were working on in personnel. So I think [INAUDIBLE]

CLIAC CHAIR: So the answer to your question, the workgroup is not disbanded, but we haven't tasked them with anything specific yet. We've got a couple of bullet points off of the agenda but we'll wait to the end.

CLIAC MEMBER: Thank you.

CLIAC CHAIR: And with that, about a 10-minute break. And we'll be back here at 2:45 sharp. Thank you everybody.

--- Break---

Nontraditional Testing Workflow Model Workgroup

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

Nontraditional Testing Workflow Model Workgroup Report
Valerie Ng, MD, PhD

CLIAC CHAIR: So do we have any public comment? So this this afternoon will be devoted to discussion of nontraditional testing workflow model-- workgroup results. So we have one, two public comments. Any others? So in keeping with the way we did things this morning, I will invite the public commenters up to the front to the podium to give your public comments first. Either one of you can begin. Whoever's closer maybe, I don't know, whoever wants to. And please introduce yourselves. And again please try to limit your comments to five minutes out of respect for other commenters and the rest of the discussions. Thank you.

Public Comments

SHARON WEST: Good afternoon, I'm Sharon West, the Vice President of Legal and Regulatory Affairs at the American Clinical Laboratory Association. And ACLA is pleased to provide oral comments this afternoon. We represent local-- thank you-- regional, and national clinical laboratories throughout the country that employ pathologists and other laboratory professionals practicing in anatomic and molecular pathology, hematology, cytogenetics, and other specialties.

ACLA and its members believe pathologists and laboratory professionals should be permitted to read digital slides and images and interpret data in locations other than the CLIA certified lab without the need for a separate CLIA certificate. Review activities at the remote location would be covered under the certificate at the designated primary CLIA certified lab. As the workgroup recognized, pathologists routinely work remotely, given the sophistication of today's high resolution monitors, security protocols, and workflows.

CLIA, though, has not kept pace with the technology and workplace changes that are now standard of practice and commonplace. In fact, in many cases remote digital pathology is superior to viewing slides with a microscope. A laboratory can process slides in one location and scan the slides using whole slide imaging, allowing a pathologist to sign out a case, accessing the laboratory's imaging system, from virtually anywhere there is a secure internet connection and password-protected computer with high resolution screen.

A pathologist can click and zoom in on a section of the image, perform a semi-quantitative analysis, circle areas of interest, and select an algorithm from a drop down menu on the screen if needed. Unlike physical slides, multiple users in different locations can view a digital pathology image at the same time for purposes of a case conference. Pathologists may temporarily read cases remotely to assist with an unusually high volume of cases or on a regular basis from, again, of any location with an appropriate secure monitor. But for the physical location of the pathologist, remote digital pathology is indistinguishable from on-site digital pathology. The same quality and safety standards must apply whether an activity occurs in a CLIA certified lab or in a remote location. So as such, ACLA proposes guidelines including the following-- one, inclusion of telepathology and digital pathology in the laboratories' overall quality management program.

Two, conformance with HIPAA requirements which address message security, user log-in and authentication, activity logs, encryption, and access restrictions. Three, the laboratory validates systems and technology closely simulating the real world clinical environment. Four, equipment as laboratory issued owned and validated system equipment. Five, there's a process to ensure [INAUDIBLE] patient identification.

Six, there's access to all pertinent clinical information at the time the slide image or data file review occurs remotely. Seven, personnel qualifications are established and documented. Eight, role-specific training on the use of a system, including hardware and software, occurs. Nine, whole slide imaging user training includes pathologist and those responsible for slide scanning and digital slide quality assessment. 10, error rate monitoring occurs, as does 11, routine calibration and periodic maintenance of system equipment.

There are several commonalities between remote digital pathology and those instances where CMS has allowed for multiple sites under the CLIA certificate at the designated primary CLIA certified lab. The remote digital pathology locations would not permanently house instrument, equipment, or records. The use of instruments and equipment is not required other than a monitor and computer with access to the imaging system, and records are maintained on the main laboratory server or other remote storage means. With proper security and risk mitigation measures, a separate CLIA certificate for each and every remote pathology location is not necessary. So we're pleased the workgroup has provided CLIAC with input including offering an option that remote access is part of a single laboratory as an extension of the laboratory and not a separate laboratory. Thank you.

CLIAC CHAIR: Thank you. We have our second commenter.

MICHELLE MACPHERSON: Good afternoon, I'm Michelle Macpherson. I'm the chief business officer with Cell Works. We're a bio simulation and bioinformatics based company. I'm pleased to provide comments. Thank you very much the working group for all the analysis and the work that went into the documentation that we received.

Interpretation of wet labs has always been required. The thing that's changed now is that it's gone from being fairly simple, with the amount of data that needed to be interpreted being a single byte, may be a yes/no answer, to being an enormously more complex. Regularly we're seeing 52 gigabytes of data that's coming in for a single NGS report for a single patient at one time. We can probe more molecularly and we're probing more. And more data is being created. The difficult and the act-- the difficulty and the actionability is one of the requirements and complaints the physicians have regarding NGS reports. What do I do with it? How do I get something out of it?

The step between the wet lab and the physician, the interpretation, now becomes much more complex. It's much more civics sophisticated. Genomics has advanced at the same at the same time as Moore's Law has given us a lot more computing power and a lot more data storage. With those two combined together, we have a much more complex interpretation step-- which already existed, but now it's more complex. So what whereas it's not new, we are looking at a new environment in which it works. Working group question one regarding the test procedures that should be outsourced-- should include interpretation of test results such as NGS. It makes sense for the dry lab, that is providing the results to be CLIA licensed.

In posing the question about the wet lab outsourcing, it's interesting to note that it could also be the other way around. In some cases, it may be that the dry lab that outsources the initial step to the wet lab. In an ideal scenario, each would be separately licensed with their own CLIA designated certificate. Innovation will continue to occur in the interpretation of results because understanding and synthesizing the output of wet labs' enormous volume of data is complex. And different approaches will be valid. Each will need to be clinically validated. Innovation with the dry labs is with the dry lab, and FDA and CMS cannot outsource that job to wet labs who do not have the expertise to do the dry lab work.

For the dry labs, it would be advantageous to be individually licensed separate from wet labs. It will set of both types of labs to focus on what they do best. This will help with items that were addressed in question two concerning the risks of outsourcing and also the contractual questions. The interface between the two labs is in

fact the data. The data is the data as a specimen. And there are standard quality control measures and processes that can be implemented to ensure that the transfer of the data is secure, confidential, stripped of PII, HIPAA compliant, and accurate. Industry standards would allow for easier communication between the two kinds of labs, and we would welcome that. Question five addresses the accurate and timely results, that can best be achieved by allowing separate licensing and contractual agreements on turnaround times.

If it's acceptable, contracts will be signed and those contracts will allow the wet lab and the dry lab to work together and to reach their reach their common goal in turnaround time. With respect to proficiency testing, the question for cloud based bio simulation is-- it's different, because in the cloud-based biosimulation world, we use retrospective testing.

And we use it to be able to be able to validate the workflow models. There is a substantial volume of retrospective data. And with each software release it gets performed again to see that the results continue to be accurate and increase in accuracy. It's important to note that results may not be absolutely the same every time, because you're getting new information. When PubMed documents are produced and they are incorporated into models, the information adjusts, it changes, and it becomes more accurate.

In conclusion, the companies exist right now that can do this. And we'd like to bring this kind of technology to market. We need the wet labs as an input, we need the data as a specimen, and we need the dry labs to be CLIA certified and able to do the analysis they do best. If they're properly regulated and separate, we would have many more pivotal technologies available to the world and available to the patients and physicians that can use them in making their treatment decisions. Thank you.

CLIAC CHAIR: Thank you. So that I'll turn to Nancy Henderson to introduce our topic, and then Valerie Ng will tell us about the output of the non-traditional tests and workflow model workgroup. For those of you following along, these will be presentation 6 and 6A.

CLIAC EXECUTIVE SECRETARY: OK, I'll just do a very quick introduction, because some of the issues that the second workgroup addressed have already come up today and will come up again tomorrow. But recognizing the fact that the clinical laboratories are constantly changing and changing at a faster pace than they have done in years gone by, CMS actually came to CLIAC last April and asked for some input in assistance on appropriate oversight of testing scenarios, nontraditional testing in which the process is separated and one part may be done in a traditional laboratory and interpretation or other parts of the analysis are done in other locations.

So last April, CLIAC recommended that a workgroup be formed to provide some input back to CLIAC to help you in making formal recommendations to HHS. Dr. Ng chaired that workgroup. And it was a great group of individuals representing CLIAC, laboratory experts, accrediting organizations, exempt states, and industry. And we got some very useful information that you will-- and I'll turn the floor over to Dr. Ng to present-- again, there were a series of questions at the workgroup deliberated on and that she will go through for you. But thanks to all the workgroup members, and a special thanks to Dr. Ng for doing the great job chairing that workgroup.

DR. VALERIE NG: Thank you. And of course, a special thanks to Nancy Anderson for holding my hand throughout this. This was truly an august group that I had the deep privilege and honor to try to be the chair of. To just repeat, very wide diversity of perspectives that helped inform us. In terms of our regulatory partners, we were deeply grateful for learning about the concerns you have and why these topic is of interest.

And I would like to honor them with you seeing who participated. OK, so this was a charge to the committee. I am not a fan of reading to people. But if you'd like me to read along, we were supposed to provide input to

CLIAC making recommendation to HHS. The items that were raised include telepathology, digital pathology, certainly spoken to by Ms. Macpherson. Cloud based informatics certainly brought up multiple times.

Next generation sequencing, you'll hear more about that in tomorrow's workgroup report. And also focusing on toxicology using mass spectroscopy. All of these are the distributive model, where one lab may be generating some of the original data, sending it to another lab or another area to be analyzed, with a final interpretation report coming back.

So let's talk about what we have today. This distributive model is not new. It's been going on for at least a couple decades. And I diagrammed it very simplistically here in that the initial testing in the patient and the man is-- the cartoon is the patient-- is at lab A. Those results move over to lab B for additional testing or analysis, and then that goes on to lab C for interpretation.

And while the arrows are depicted unilateral here, they could be bi-directional, going from C back to B, from B back to A, but ultimately we are responsible for the patient. So lab A is responsible for understanding how that interpretation fits with that patient's clinical criteria and how we optimize health and safety. Inspection is a little bit at a disconnect because today's system has the licenses linked to geographic addresses.

So the distinction-- the inspections are in very discrete packets, where lab A is inspected separately from lab B and lab C, and there's no easy way right now to link them all together. I think you can also appreciate the difficulty this model has with proficiency testing, because you can't take a sample all the way through the whole process to understand where the defects might be.

So as a group, we all identified the points of handoff between the different laboratories as where the risk lies. And if you have multiple risk areas, ultimately how can you trust the accuracy of that final result? And of course most importantly, how can you assure that patient is being treated correctly? So the point of our workgroup was to try to identify the issues that could help assure accuracy in this distributed model.

So what types of tests, procedures or specialties may have parts of the testing workflow outsourced to another facility? Scenario we already have today, it will expand in the future, and potentially exist for every specialty or subspecialty. It's especially relevant when interpretation is required. So let me show you some examples of what we have today.

We have lab A, which is a rural hospital, maybe staffed by MLTs, where they can run a test on a hematology instrument. But if there's an abnormality, a camera takes a picture and beams it somewhere far away where an independent person will read it and make an interpretation. Be interpreted either on a computer screen or on a telephone.

What happens with anatomic pathology, as brilliantly discussed earlier, imaging can certainly happen at one location. The image interpretation can be read anywhere, including at home with your children off to the side. What about microbiology? Lab A isolates the organism. They send it to lab B for identification. Maybe some MALDI TOF maybe some sequencing happens. And then that data goes off to the cloud to some database, and then the organism is identified.

What happens in toxicology-- lab A may generate some data through mass spectroscopy, but nothing matches in the database the pattern that's obtained. So that goes off to the cloud or some other database to identify what the molecules are. For sequencing, which is kind of the hot topic right now, lab A may produce a sequence. Sequence may go off to lab B for the cloud. And then the cloud interpretation may go to a clinician in lab C to try to figure out how to interpret this.

Is it a variant of unknown significance? Is it thought to be benign? Or is it unknown? Or maybe it's pathogenic? And what version of what literature are you using to make that decision?

And probably the most glaring example of this is the serum protein electrophoresis, where lab A, which is a general lab, may simply do a total protein and albumin measurement, then send the sample of to lab B for electrophoresis, and then someone sitting in this room could be looking on their computer and doing the interpretation.

I'm pointing at [CLIAC MEMBER] because I've seen him do this. We all know there's a plethora of-- and he nodded yes-- so there's a plethora of connectivity options. And we all know the central question we debated is, what is the definition of a laboratory? Now with global access and connectivity, you can have the data being generated somewhere, pathologists as a second consultant, remote access, review, and analysis. And as [CLAIC MEMBER] was trying to point out, director can sign off electronically from any location. So what is the definition of a laboratory?

I put up this model. It was the Cleveland Clinic published in 2017, their Abu Dhabi partnership, where through a lot of hardware and validation of interfaces and transmission, they were able to improve diagnostic accuracy, improve turnaround times for consultation, and ultimately clinical care from clinic station in Abu Dhabi linked over to the Cleveland Clinic, which is somewhere in the US. So it's happening.

I'm sorry, just to pause on this model, we learned from our VA colleagues that the central lab where the original thing was done, regardless of who's reloading in from whatever, that that CLIA license lives in the VA system with that central lab. That the remote areas do not require a separate CLIA.

So with that backdrop, we moved on to question number two-- what are the challenges or risks to laboratories when they outsource parts of the testing? What do we do to assess potential risk? How do we mitigate? And how do we validate that our risk mitigation worked? As mentioned earlier, our overarching challenge is to assure that the total test process, especially at the handoff points, are assured to be accurate.

To define where the total test process begins and ends and who's responsible for each part of the process, proficiency testing remains an issue because some alternative assessments can be done just to avoid the risk of PT referral and sanctions. But it's not part of the total test process. Personnel requirements-- that's kind of a doozy.

We spent all this time talking about what I call the old model of test personnel, which is liquid reagent, liquid tube putting it together and getting a result. Now we need bioinformaticians. We need-- I jokingly said with my automated lab-- I need mechanical engineers to go in and fix my tracks or my pipetters. They need a different skill set than that conventional model.

Validation of cloud-based services and softwares-- how do I know your pipeline is protected? How do you know-- how do I know you got what I thought I sent? How do you know that I got back what you thought you sent me? Ensuring database and algorithm fidelity and version control. As new literature is published, interpretations change.

How do I know that you're using the most current version? What does that mean for something you analyze remotely? Do we go back and reanalyze it? Of course there's data security and transfer risks. There are patient safety concerns if something gets crossed in the wires. And I say new patient A data but it gets logged in under patient B-- oh, that's really bad.

And then of course risk of lawsuits, which is what your lab director is worried about if an incorrect result is reported. And then especially-- then of course you have to throw in the whole laboratory develop tests, the LDT discussion, because many of these are LDTs. And what are the challenges for the surveyors?

They have to decide what is part of the testing process, what is subject to CLIA? They have to figure out who are testing personnel? What are the competencies required for all parts of the testing process? How do you evaluate the accuracy and reliability of the final test results? And then for those models that cross state or global lines, those are clearly unique challenges for folks who are wed to a laboratory being linked to the physical street address.

We did talk about assessing and mitigating risks to perform risk assessments. The possibility of setting up contracts or defined agreements to specifically identify the steps to be taken as part-- and the expectations as part of the distributive testing process, and then clearly surveyor training is needed. Question number three-- what are the ways the originating laboratory can assure ongoing quality?

Well we talked about contracts and/or agreements. We talked about within that we need-- as an originating lab need to define the metrics for monitoring and ensuring the accuracy of testing. And the mechanisms for monitoring include tracer methodology, be careful of PT referral, to establish and follow the chain of custody and workflow, to monitor the quality control in two separate locations, and to use split samples if you don't want to violate any kind of PT referral thing.

I want to take a step back and make it clear that this group thought data was the same as a reagent and that data analysis was the same as testing. So when we talk about wet labs and dry labs we don't make that distinction. If we shoot a bunch of data over to you, as far as we're concerned you're a lab.

CLIAC CHAIR: Sorry, data is the same as a reagent, not an analyte?

DR. VALERIE NG: I'm sorry. So we'd have to talk offline about your distinction between an analyte and a reagent. Question number four-- what special considerations are needed to ensure that bioinformatics are providing accurate, reliable information results? Well, we've got to ensure quality, transparency, and traceability. Analytical validity of test performance, clinical validity of interpretation.

The laboratory that performs the analytical testing and the bioinformatics facility need to be part of the test validation. What are your record retention requirements for the bioinformatics part of the process? How do we ensure data transmission fidelity? What is the difference between VPN access to data versus remote data transmission interpretation and reporting and the regulations around that?

Consideration of data as a sample or a reagent-- you notice we did not use the term analyte, -- including storage and maintenance. What's the fidelity of the storage and how do you maintain that? What's the potential for the original data to be reanalyzed and/or reinterpreted including for different purposes than originally intended? What is the lifespan of a digital slide or the data?

What do we need in terms of documentation and version control of databases, algorithms, and monitoring the use of artificial intelligence, which is evolving with every case analyzed? When do you draw the line between data interpretation versus the practice of medicine versus part of the testing algorithm? And then finally, what are the personnel responsibilities, and what are the knowledge and skills they need for performing data analysis and interpretation? That gets back to personnel requirements and competency assessments.

Question number five-- I know it's a lot of stuff, but this is a big subject and it's very complicated. So if originating labs are anywhere in the chain, you're going to set up a contract or an agreement with an outsource

facility. What should be in that agreement? Well, we threw out-- first we need to determine whether or not a separate CLIA certificate is required for every facility. That is part of the testing process, and this may require defining what is a test.

So two options were suggested. Consider the total testing process as a single laboratory with one lab holding the CLIA certificate and responsible for all aspects of the test, including those that are outsourced. In that model, that would mirror the VA model where the central lab-- folks dial in remotely and the CLIA license is housed within that single lab. The other extreme is to consider the remote sites at different physical addresses that perform data analysis or interpretation as separate laboratories.

That's what exists today. That's what that plethora of separate CLIA license has since ensued. But regardless of the option, a contract or agreement needs to include the details about how this model works and what the expectations are. And the contract agreement should include the mechanism or process for tracking a specimen through the total testing process. Quality measures to ensure accuracy and reliability of testing and data analyses, expected time frames and other relevant circumstances, policies for data management or retention, including provisions if the company or the outsource facility becomes obsolete. Consideration of whether the contracted facility is monitored by the FDA. And then other unique considerations that apply to the distributive workflow model.

Question number six-- proficiency testing. What PT programs are currently available for this type of workflow? If it's not available, how do laboratories using this model conduct the alternative assessment? There was uniform agreement that PT is the best external assessment of testing. And there was agreement that treating PT samples as patient specimens cannot be completely met in the distributive model because of the risk of PT referral.

CAP, the College of American Pathologists, happens to have PTs available for next generation sequencing and other tests and sends out data-- not the total test process, but just sends out the data for interpretation. But performing PT on only a part of the testing process does not evaluate the total testing process, right, doesn't evaluate those risky points-- the handoffs.

Internal PT and alternative assessments can be performed by retesting known but de-identified patient specimens. PT materials can be used for quality assurance after cutoff dates for results mission. And as laboratory medicine moves more towards distributive testing models, PT programs should develop models applicable to this type of process.

And we asked whether or not CLIA would consider allowing an exemption or relaxing of PT requirements for the distributive models, especially because of the consequences of PT referral. What other issues should CLIAC consider? Well, the one that's brightest in our field of vision is that medical errors occur most often at the point of handoffs, where communication gaps can occur.

All involved in any part of the testing process need to be aware what the other people are doing. So [CLIAC MEMBER] kind of raised the issue of how do we make sure how we communicate effectively? And I can tell you in today's world, we cannot guarantee a report that we have beautifully formatted in our system will land in somebody's EHR in any type of comprehensible, intelligent fashion.

And this is just a small piece of what we're trying to get at here, that what you intend to happen actually happens. As a result of-- because we can't rely on that, we need to build in safeguards as part of the non-traditional workflow models to ensure optimal patient care. And as the use of artificial intelligence evolves, we need to consider specimens or data that could lead for actionable reports and affect future patient care.

We considered the CLIA applicability to specimens stored in a bio repository, when future information be obtained that can affect patient care. I want to pause right here because many of us-- we hold our paraffin blocks for 10 years, right? We talked a lot about, should you ever go back to that database and re-analyze given the new information available with various bioinformatics and algorithms, how do you know that that paraffin block prepared at whatever point in time was in a DNA or RNA free water bath?

And that the sections didn't follow another case that had tumor in it? And the cross contamination of specimens? How do you know that the paraffin didn't degrade over time and altered the ability to generate a sequence? We don't have answers for these, but we identified the problems. Consider how to handle metadata as laboratory information systems and electronic health records.

I mean, they are not set up to do this. So how are we going to handle that? Determine the accuracy of data if changes are made within EHRs. and EHRs are pretty much tinkered with and configured every minute of every day. So how does that affect that data you thought you deposited accurately? Ideally revised or future regulations will accommodate future trends, including situations where part of the testing process can occur outside the US, and although not subject CLIA, how do you ensure the quality of distributed models of public health testing performed for surveillance purposes? And that's the end of that summary. So we're open for questions.

CLIAC CHAIR: Is that all? No, thank you very much Valerie, for a wonderful summary of a tremendous amount of work. And listening and thinking back to when this first came up, which was just about a year ago is when we first started talking about what the agencies would need to know about non-traditional workflow testing models, having a hard time coming to an easy answer in my head about what we, just as a structural thing, about what we would want to report back.

As I was thinking about it, my first answer was, well everything. We want to tell them, like, you know we have thought, you have thought through all of these things. And basically say, whatever you come up with, incorporate all of these points. But then I put myself in the shoes of the agencies on the receiving end of all of that information and it's like a drink out of a firehose. It's an awful lot.

And so maybe a bit differently from our strategy with this morning's discussion, where it seemed fairly straightforward to just go question by question and then just basically discuss-- have a little discussion and kind of an up or down vote with some modifications about the consensus that the workgroup had arrived at on each question, here I feel we've got a much more open-ended beast to discuss.

So I am going to assume that after at least a little discussion, having heard what Valerie's just described to us and hopefully having had a chance to take a look at these documents, this presentation and the accompanying text summary before, to just throw-- to open the discussion by asking, again, a broad question-- what and how-- what do we want to package for the agencies and how do we want to do it? Keeping in mind again that the initial guidance to us was, hey guys, hey CLIA, how do we think about legislation around these things? So it's kind of a broad purview of a huge, rapidly changing and fast growing area. So how do we want to think about that? Tom I think you had a point.

CLIAC MEMBER: Oh, I was just going to mention I agree, it's a rather large body of work. But there are certain specific areas that I think we could address and be helpful by providing a recommendation. And one example that I think is the digital imaging and remote signing out of slides, which seems to be permeating the-- certainly pathologists, anatomic pathologist world.

CLIAC CHAIR: So there's a there's a bit of feedback. We could try to move the microphone back, actually, a little bit. So say that again? Digital pathology and--

CLIAC MEMBER: I think digital pathology would be one thing that we could provide a recommendation on.

CLIAC CHAIR: Other thoughts?

CLIAC MEMBER: So really fantastic work. I think one thing that we as pathologists have to understand that what AI is going to be doing is my view is the practice of medicine. It will be practicing medicine. When we talk about self-driving car, AI driving a car, it's driving the car. There's no discussion. It's the same kind of discussion that's the AI will be practicing medicine. I don't think there's room for distinctions.

Many of us are trying to figure out how to stay up on that, copy these changes. And so I think [INAUDIBLE] licensing environment, everything is going to change dramatically for dermatologists, for oncologists, for radiologists, [INAUDIBLE] And I'm not sure that any governmental agency I don't think we are going to be able to keep up with the pace of change of things. So although I think we would like to get out front of the [INAUDIBLE] changes to CLIA, I'm really not sure actually how [INAUDIBLE]. Things that looked like they're far out, and you think they're going to take a while to come, [INAUDIBLE].

So I think it's a great question to try to anticipate some of these things. I think we can do that if some of these suggestions around are we going to have CLIA licensing [INAUDIBLE] same thing. That's happening right now. Those algorithms are performing tests at [INAUDIBLE] not under our control. These are bioinformaticians that are basically interpreting this and changing this data and thus the practice of medicine, too. Some of these places are software companies [INAUDIBLE] So there's so little of this that's going to be under our control at some point, I'm just [INAUDIBLE] I'm not sure.

CLIAC CHAIR: So I might I might offer a bit of a counterpoint to that, which is while I completely agree that the specifics of the technology will change and continue to change and change quickly. I equally agree that like the self-driving car, you know what they say about the future. It's already here, it's just unequally distributed. For almost everything that Valerie touched on, and then indeed some adjacent activities, there are examples published in research journals, being done by private companies in a demonstration basis.

Rarely at this point done as the main-- as the main way of doing things. And in a health center. But I mean-- granted that they exist. But I'm not sure that means that the answer is that we would just have to kind of throw up our hands, grab our surfboards, and just kind of be along for the ride.

Because as I look for-- as I think again back to what Valerie described, there are certain commonalities which I think that no matter what the details of the technology are, no matter how widespread or niche those technologies are-- or I should say not technologies but workflows are-- and the task was to discuss workflow-- there are certain commonalities that maybe there's something useful that we can report back about.

The distributed nature is one example. The split between things which we currently think of as medical, requiring medical people with MDs or related, and software companies and things which we currently think of as nonmedical, and bridging those two things. Going back to one of your first couple of slides, the pipeline-- is there something useful that we can report about what needs to be regulated from that perspective?

To say, it doesn't matter what the pieces are, there's going to be-- so long as there's going to be something that you recognize as medical and something that you recognize as nonmedical and these handoffs of data, what's the saying-- medicine has become an information technology. That feels like there must be some guidance around information technology.

Now, when I thought about that, it made me think, well, OK, well what are some other places where information technology has invaded-- I shouldn't say invaded, it's not necessarily a negative thing-- it's

transformed other ways of human activity, including doing business. It kind of made me feel a bit sad, A because I didn't know-- I don't know a whole lot about the regulations surrounding them.

And B there have been so many stark failures of that kind of thing when it comes to social information lately, where it's clear that the rest of the federal government-- I'm sure committees not unlike this just outside of the medical field-- have not managed to get ahead of these things. I mean, who should own your social network and data and why and what are the uses that it can be put to and stuff?

I mean, these things are actively being debated with very different points of view, say, between the US and Europe. So those of you who've been on the committee for a while know that something I often ask is, OK, well who's already encountered and solved this problem? I don't know who's already encountered and solve this problem for-- that we can just say like we should recommend that the agencies kind of deal with this like those other places dealt with their problems.

But that said, it feels like something surrounding the distribution of data and practitioners and the distribution between fields that we consider today medical and fields that we consider today nonmedical, that there's got to be some useful statement that we can make emphasizing-- and now maybe this might be my own editorialization, so open for discussion-- there must be some statement that we can make that says, this entire loop, this brain to brain loop, as they describe it, no matter where that information goes and who it ends up in front of on its way from the patient back to the patient and their physician, that's all got to be considered of a piece in the same way that we consider the brain and brain loop inside the laboratory. So I'll shut up now, but those are maybe my counterpoint. Other thoughts?

CLIAC MEMBER: So well actually I flew out here with a colleague of mine, he's on the American Board of Radiology. So maybe there's an answer to who's done this. But that wasn't what I was intending to say. There's-- to me the heart of the question and ideally a recommendation would be the question of what is the lab and who needs to have a CLIA certificate?

And there is both an overlap and a major potential gap between the discussion we just had about lab director on-site visits and this question of what is the lab in the distributive model? And you could make one extreme that the lab could be, in the interpretive service, a computer monitor reading gel electrophoresis, mass spec, chromatographs, digital slides, there could be five or 20 or 100 locations participating in specimen collection and technical testing.

If we go to the extreme of that model, the lab would be the computer monitor and therefore by what we just recommended an hour or so ago, the lab director has to go to the computer monitor twice a year. But the five or 10 or 100 places doing the specimen collection, the testing, no one ever has to see that to know if anybody's there trained, space-- what does it look like? Are there any fire extinguishers, et cetera.

So I mean the heart of it is the lab. And I agree we shouldn't have CLIA certificates in our living room to sign out and we should be allowing those digital pathology other activities, bioinformatics. But the heart of it is a lab person who has a CLIA who's going to take responsibility, has to really be in a position to be able to assume responsibility for the collection, pre-analytic, analytic, and post-analytic processes.

And not just say, well, there is a contract with 100 places that are actually running these gels, and I'm sure there's good people out there somewhere. How are you going to put that into a recommendation and a find that, I don't know. But to me the heart is what is the lab and who is in a position to take that responsibility that can therefore alleviate the need for the CLIA certificate in the living room for someone signing out remotely, but not allow the extreme distributive model of 100 testing sites, what we consider labs today, that don't need clear certificates or oversight.

CLIAC MEMBER: I think that one of Valerie's earlier slides about the lab that connects with the patient and the tissue, maybe that's where the lab is with the distribute model, and that's where the reimbursement and the Oversight and the responsibility for QC should lie. Whoever is going to take ownership of incorporating the disparate data results and be reimbursed for that and take the risk that's associated with bringing all these different disparate pieces of data together in order to impact patient care and affect outcomes.

CLIAC CHAIR: So, I'm going to insert myself. So something interesting, an interesting theme I heard in those two comments, does it suggest-- is there a solution which is for CLIA to throw all of this responsibility back on the current CLIA director? In other words, is there-- maybe I misheard or I'm drawing the wrong, drawing the wrong line between these two comments, but to basically say hey, you're all you're all medical directors.

You oversee your labs. What happens between when the sample which contains the information comes out of the patient and when it gets put back in the chart is your business. If you don't get it right, we'll dock you. But at least that's kind of the-- what is it, the 1,000-- shoot, I forget what the what the phrase is. But distribute-- let us experiment. So instead of us--

CLIAC MEMBER: 1,000 points of light.

CLIAC CHAIR: 1,000 points of light. But there's a-- is it incubators of democracy or something? Laboratories of democracy, or something like that. So like 1,000 laboratories to figure out what the solution is. Is that kind of where you guys are going with that? In other words, I'm a lab director of medical-- of microbiology. And basically CLIA it might turn on our recommendation to me and say, you figure it out. But just FYI, you're responsible.

And then I say, oh nuts, I'm responsible. I need to look into how to figure this out. And then I might go across to Valerie and say, hey Valerie, I'm struggling with this. How are you doing it? And Valerie may have figured out a way that's better than mine. And with-- it's evolution. Variation and then we'll select from that. Is that the direction of the proposal?

CLIAC MEMBER: I'd like to hear this comment.

FDA EX OFFICIO: Yes, so I'd just like to add another thing to discuss potentially that's related to this, is that I think it's not just the question of what is a lab, in particular it's a question of what is a test under CLIA? Because a lot of the way that CLIA is set up it's based on the complexity of performing particular types of tests, and what is the complexity of that test, and therefore what kind of personnel requirements are required to perform that test?

And if you have a test that's being done across different distributions, is that a single test? Is that multiple tests? That informs a lot about-- there could be pros and cons to interpreting it different ways. So I think it could be interesting to have discussion on, if you're-- what is a test or what should be a test definition under CLIA and what would that mean in terms of down the road pros and cons for what would that mean in terms of personnel requirements for people performing that piece of a test if it's considered a separate test.

Or whether you have a whole test. And that affects us in terms of, if we're trying to categorize a test system, historically it's a complete test system. But if you're-- we have-- certainly there's a lot of interest in people trying to develop things that cut across multiple complexity categorizations that-- what if you have a some piece of a test that they want to do in a moderate, and some in a high, or some in a waived in a non-waived. How do we-- how should that be addressed within CLIA? So I think those are a lot of good things to discuss as well, besides just the laboratory.

CLIAC MEMBER: So personnel, I would agree in reimbursement and maybe tiered, tiered results based on the type of test and the potential for what that diagnosis yields. I mean, what's an actionable result that's necessary to treat the patient or an actionable result that would be treatment beyond the standard of care? At a different point in the patient's clinical course. Those are the other types of issues that we need to consider as well.

CLIAC MEMBER: So I'd like to sort of pull things back to some kind of an example that we are familiar with, because there's a lot of things to grapple with. And that if you look at the fact that now we send specimens to reference laboratories, there is a process for ensuring the same sample arrives that you sent. There is a process by which the data comes back to us. And we as medical directors combine the esoteric tests with the routine tests we do on site.

And we deliver a result and actionable interpretation back to the providers and the patients. But in this scenario, I really-- we don't have all of the expertise necessarily about the data transfer. We don't know how to do barcodes. But there are established standards for lab interfaces, for digital interfacing, that people have gotten together and said, well there needs to be HLA standard-- or the HL7 standards for data transmission.

So it seems to me like there's expertise out there in the form of the companies that are doing the sequencing and this interpretation that we really need to group with, kind of see them almost as a digital reference laboratory, if you will, that would have requirements that we might not be the right people to make those standards, but somebody out there knows what they are.

There are groups, including mine, that do this, that send out sequencing, get the variant data back, and deliver that to the patients. And I would think that there'd have to be some kind of a group that would set those kind of data transfer standards and that the end method verification has to be all of those things as somebody mentioned. You can't-- I can't just arbitrarily use a different swab.

So I shouldn't arbitrarily be using a different data group if I've validated a method with one. So I think these general broad concepts could be laid down by the committee. I mean, same with proficiency testing. Right now we're saying, how are we going to do proficiency testing if the nonprofit PT organizations have to use only other non-profit suppliers like transport and vendors? What are we going to do with proficiency testing with this digital data?

And that's another thing we'll have to grapple with. But I think the cradle to grave approach, and building subspecialties in those transfer units and seeing that circle from patient to patient has to be in there. And there's got to be a call for data standards that maybe don't exist yet, but we could look to other organizations that are doing this and try to get best practices designed and report back to the committee. That would just be how I would kind of look at it.

CLIAC MEMBER: So I had been thinking through your model and your idea. And I think that's what we're saying if you want to look at the classic example of what you're talking about. So for digital pathology, where the most logical model is there's a hospital that has tissue processing, histology lab, infrastructure to do anatomic pathology, there are people who want to be able sign out remotely. The most logical model might be the hospital holds a CLIA certificate but there's conditions and contracts and agreements about what's needed to sign out remotely.

Your idea about this 1,000 highlights as well, if somebody wanted to say, pathologist wants to say my living room is a CLIA certificate, theoretically that's possible if they could prove that they could oversee and guarantee all the things that are supposed to be happening in the hospital, the tissue processing and histology, are happening correctly without having that facility hold a CLIA certificate.

I guess that's what we're saying? It's an interesting concept to grapple with. But if the inspection process works and somebody has to inspect that CLIA certificate, it should become apparent what is that person in their living room can really-- is really assuming responsibility for all the parts of the process of the collection, testing, and analysis.

CLIAC MEMBER: I think I'm probably going to end up saying much the same as is being said here. But we live in a distributed model anyway. I-- my instruments are built by somebody else and their reagents are made probably by somebody else yet. And then the LIS that it works on is made by somebody else. And my job is really to ensure, and document that I've ensured, that all the pieces are working together properly. And so if-- I mean, this still begs the question of what's the lab? What's the lab? Because is the bioinformatics company a CLIA lab? And maybe it is, maybe it's not. I don't know. But if each lab that's part of a distributed testing thing is responsible for making sure all the pieces work-- and that may mean that each of them has to maintain redundant documentation effect. But if the model is, I'm, as a lab director I'm responsible for documenting and ensuring that all the pieces work, then I think that should be what we're striving for.

And not a rigid model where you have to do it in a particular way because there's going to be too many particular ways to do that with. So even though my lab only takes the sample and carves it up and sends it to an NGS place and then that goes to a bioinformatics place and then it comes back and goes out under my name, I still have to document that each of those places is doing their job.

CLIAC CHAIR: So it seems like that suggests a division-- and this echoes some of the other comments-- I'm trying to find the optimal distance. You guys all probably hear some reverb. So I'm going to go as far away as possible from the microphone, and suggest that you do the same, so long as there isn't any reverb and you can still hear. But the past several comments suggests maybe a logical separation of the problem into one which is purely geographic and one which is process related.

And that makes me feel good. It might be something interesting and worth reporting. Meaning, if I could paraphrase what you just said Sheldon, and Donna you were also saying something like this, the-- kind of the whole cycle or end to end looping making sure that the information goes all the way around is something we do anyway. What the lab is is, it seems to me, a question which is almost orthogonal to that.

If all the processes work, it doesn't matter if I'm in my living room making sure it works or reading it out or whatnot. If the parts work, the parts work. The issue of the decentral-- of the physical decentralization of the reading part of it seems to be this geographical wrinkle about what the lab is. But to Sheldon's point, the manufacturer of-- I don't use any names, but the manufacturer of a particular device-- that manufacturing plant isn't a lab.

And the fact that that happens, that that machine happens to sit in my shop versus at a reference lab is less relevant to the end user than making sure that the process works all the way around. So maybe then a component to a recommendation might be something like, look, let's just recognize that no matter what the technology is, notwithstanding Greg's introductory comment of AI changing everything and that this is all happening, irrelevant, we could start by saying.

Our role is still to just maintain that the process, that the information flows all the way around works. And that at least lets us split off as an independent issue, which I don't have a clear answer for, about where precisely that happens and why and how. And mostly it's an issue of like, you know, my living room or wherever and whenever I and my computer happen to be. It's almost that the issue of geography is the fact that it can be moving around. As opposed-- because right now the geography is distributed. Just that the reference lab is in one place. It's not moving around all the time. We'll just go around the room, I think.

CLIAC MEMBER: I have a question may be directed to [CMS EX OFFICIO] first-- how far into the regulations or even into legislation does the statement that it has to be by address go? That a CLIA license is by address or CAP certification is by address? Is that something that administratively can be defined? Or is that in legislation at some point?

CMS EX OFFICIO: We actually have to have a specific address.

CLIAC MEMBER: Right, but did you say it? Did CLIA say it? Or it was CLIA directed to say it by legislation?

CMS EX OFFICIO: We have it in our regs, I mean it's…

CLIAC MEMBER: You can change it is what you're saying.

CMS EX OFFICIO We could, if we want to.

CLIAC MEMBER: Well, I mean we'd need to make the case that you want to. But we need to know that we don't need Congress to agree.

CMS EX OFFICIO: No, we would propose based on the recommendations that you give back to us, we would make proposals and put it forward as a proposed rule. So it would not necessarily have to go back to-- the only way it would go back to Congress if we wanted to change the actual law.

CLIAC MEMBER: Is there a law that says it has to be by address?

CMS EX OFFICIO: I don't know if the law actually specifies that. I think that's in the regs. The law is more of an overview of CLIA, and the regulations actually get down to the specifics.

CLIAC MEMBER: As we're scoping this out, that's one of the things I think we need to know more about. And the second observation was, I guess in my own mind, a laboratory test is a report. And then the question is, how many reports? So if I do a screening test, I issue a report. I need a CLIA license. If I send it to his laboratory for a confirmation, I need his report.

But I guess I'm also thinking back in all the digital imaging and NGS, what elements of it have reports? And that's maybe another address-- or another approach to take in addition to answering the question about the address.

CMS EX OFFICIO: We have to find in the patient access reg-- we defined it in court as when all of the testing is done. So that was defined in patient access.

CLIAC MEMBER: And that has to have one address, correct? I mean it came out of --

CMS EX OFFICIO: Well for a test report it actually has the address of the facility where the test was done.

CLIAC MEMBER: But what's done is what we're getting at. And I'm saying what is done is the report.

CMS EX OFFICIO: And what we've thought, and what I think we've encouraged and required, is that if you have five different places where some of that test being done, you need to have all this for each one of those parts.

CLIAC MEMBER: Yes. And that's what we're struggling with.

CLIAC CHAIR: So it sounds like a suggestion might be, a recommendation to-- and I'm putting words in your mouth, but hopefully not too different from the ones you're thinking-- to recommend relaxing the address when thinking about what a lab is. Maybe a lab is just an authority that oversees a testing process, and the only relevant addresses the address of the overseeing authority.

CLIAC MEMBER: Of the reporting entity. Excuse me, the reporting entity.

CLIAC CHAIR: Of the reporting entity.

CLIAC MEMBER: I think we also have to be -- we have to be cognizant of state laws and practicing medicine across state laws. Because if you have a hospital or a record, and that hospital consults with these different entities, then you're not practicing across state laws. But you have to-- state lines-- but you have to be very clear about how the distributed model is created and enacted to make sure that you don't run afoul of state law.

CLIAC MEMBER: We'll continue going around the room.

CLIAC MEMBER: Yeah, so I like your idea of splitting, although I can see some lumping here. I really do believe there is a difference between the digital image and transmission of a digital image in the viewing and interpretation by a physician or pathologist. And I can kind of separate that from big data-- next-gen sequence bioinformatics-- where the interpretive component is a little different.

You're presenting an image, and whether it's an Gram stain or histology, instead of your office next to your laboratory across the street or what have you-- which if it's across the street, yes, you need another CLIA license, and we've got a lot of those-- we could somehow recommend that, in the case of the propagation and interpretation of a digital image by a pathologist, that that is an extension of that laboratory where the actual processing, imaging, and transmission is performed. And the interpretation, whether it's in a home or an airport, is an extension of that laboratory.

In the workgroup, we even talked about if the laboratory issued a laptop or a phone with the proper resolution or what have you, all of that doesn't seem to be that much of an issue anymore. But certainly, there are places where your home is a CLIA license, and all you're doing is an interpreting, it just seems like an excess amount of work to go-- anyway, I just think this splitting idea would be helpful, because we might be able to address one without trying to detach…

CLIAC CHAIR: So just as a data point to consider in light of the difference between-- as you sketched it-- between images and next-generation sequencing data. For example, there's a grad student who took written sequence-- just printed out sequence, ACTG's nucleotide sequence-- and took a screenshot of it and threw it at a deep learning image processing machine, and it was able to call out SNPs. And it's an extremely like Rube Goldberg way to try to do things. But I give that example to say that I think it might be easier in this case to lump and to just say, data is data.

CLIAC MEMBER: I guess I would push back a little bit on that, because we currently have physicians practicing medicine-- they're not practicing law-- where they do take data points, whether it's remotely, and they change therapies and make management decisions of patients. That interpretation is done by the training of the physician, not by AI or algorithms. And so it just seems like there might be a bit of a difference there. Your point is well taken, though.

CLIAC MEMBER: Thank you. So I didn't mean to scare anybody. But I do like the distributed way of process related, and I think eventually no one will have to be process related. And I think we can only be sure of certain processes now [INAUDIBLE] lab [INAUDIBLE] by the conventional process we have now, contribute to [INAUDIBLE] results [INAUDIBLE]

What I was trying to highlight is it's not happening right now but coming in the future. But we won't have any ability to assess what happens in some of these other venues. The personnel requirements or personnel evaluations that'll do software or algorithm requirements where we just didn't have the ability to really [INAUDIBLE] information [INAUDIBLE] images, data, whatever will be interpreted [INAUDIBLE] analysis, whatever.

But that's part of the test is outside of our control and outside of our understanding of what needs to happen And I'm not sure that what we're getting back is the same quality of results. And sometimes things happen I'm not sure NGS sequencing, the algorithms [INAUDIBLE] refuse to do that. So there are things that could be happening now that I'm not sure[INAUDIBLE].

CLIAC CHAIR: I think you wanted to say something as well-- let's pursue that for a second and see if it either crystallizes the problem or possibly helps deal with it. So here is a sample, and the sample goes to—[CLIAC MEMBER], we're going to use you. It goes to your lab, and let's assume that it's fully automated and no human touches it. It's like those old Tom and Jerry cartoons, or Jetsons cartoons, and a machine drops a tube and literally the package gets torn open by the package tearing open machine, and then it kind of goes from there through the rest of the machine.

And back comes serum sodium is 140. And you say, well, jeez. How do I know? Who do I talk to? How do I make sure that that's the case? Well today, you've got a CLIA license for your lab that has inspected that. And going to the proficiency testing and just validation portion of the comments that you summarized from the workgroup, you imagine that you could take a bunch of samples and send them all to [CLIAC MEMBER]. And if they all kept coming back OK, [? one ?] way to look at it is like, well, it works. And I'm satisfied.

It's not a black box from [CLIAC MEMBER] perspective, but it's a black box from yours. But regardless, it works to your satisfaction. And now you might say, well, I think this works, because I've sent 30 samples, and that's enough to validate. And they cover the dynamic range and all the rest of it. And then somebody in your organization might come up to you and say, no, I don't believe it. And then presumably, the conversation would be, well, what could I do to prove it?

And I imagine that the answer is going to be something like more or broader range controls. Does that logic not automatically carry over to everything that we do? Here's a slide that I hit transmit on, and the image goes somewhere. And I'm not even sure that this machine took a picture. I didn't hear a shutter or anything, but I'm assuming that it went over there. And it came back and it said DCIS. Well, it's like, well, how do I know?

And I'm not asserting that that's the case. I'm just trying to sketch out possibilities. So it's a complete black box. In this case, it goes off to a quite literal physical black box that's sitting somewhere with some kind of an AI on it, and back it spits an answer. And I don't know how it works. We currently have that problem in a lot of fields when it comes to understanding what, for instance, a deep net does. And people are working on it and trying to figure out how to open the black box [INAUDIBLE]--

CLIAC MEMBER: Let alone how a pathologist actually under-- reads a slide.

CLIAC CHIAR: Yeah. Well, one is tempted to bring up the study of pigeons, who do pretty good at diagnosing breast cancer. Now we've seen all that stuff. Something is going on, right? But is the answer-- is it true that a

universal answer is, if you can come up with a sufficient set of controls, your golden, notwithstanding the fact that in-- especially deep learning and some of these things. You guys have all seen the studies that show how you can fool deep nets in certain ways, exactly because we don't understand it. I showed this particular bit of static to Google's inception algorithm, and it said, this is absolutely a lion with 99.9% probability.

And you and I look at it, and it's just like, it's static. And it's just that we've pushed the pixels in an appropriate way based on, say, reverse engineering or something. That could happen. But one imagines, although less likely, that it's also possible that you send something in the mail, hemolyzed blood or something-- you're going back a couple of generations before we understood these as problems-- it is possible that you take your blood sample, send it to the predecessor of a lab, and get back a completely meaningless result.

And that's-- there's always going to be something new that you don't expect. But keeping that in mind, is the answer not just, generally, come up with the right list of controls, and then Bob's your uncle. Who cares what it's doing? And I say that provocatively for a reason, because I want to know whether that works or not. OK.

CLIAC MEMBER: That was really well said. What I wanted to say is that change breeds uncertainty. It's something that happens. And usually it brings about more change. And when we started discussing this topic, it made me think of radiology, how we had to allow radiology technicians to control an environment and take the x-rays and then be able to send the images off to be read. And they're being read distantly.

And it's different than pathology, I know. But I'm sure when that process first began, it was very hard for doctors to let go of someone else taking over that role. I think that this kind of change is inevitable. It's bound to happen. And whether or not CLIA has a say in some of the delivery of it is what we really need to focus on today.

CLIAC MEMBER: So getting back to your geographical versus process, I do think what they're talking about with digital imaging, or-- might somebody in a remote space looking at agar plates through digital imaging and sending a colony off to a mass spectrometer at a central lab, is more of a-- the central lab owns that function. They send it out to a pathologist who is board certified, or they send it to a microbiologist who can read a plate and is competent digitally.

That seems to be under the umbrella of more of the centralized CLIA laboratory license. The sending of data to an external data firm who has its own industry standards and expertise, to me, is more like Sheldon's example of reagents. We don't know how reagents are made, and yet there's good manufacturing processes. There's good laboratory practices. There's ISO guidelines. There's FDA requirements. Sending off to a data center is kind of like sending it off to a reference lab or a manufacturer.

The difference is, is that we don't know what those good data standards are. I assume that industry has some and that we-- our role is to say, we want somebody from that industry to put together data transfer protocols, and all the things that Valerie talked about, to ensure, much like a barcode, that the data is coming back and that it's interpretable, and that we will validate it as a single process just like we would another method verification.

And we wouldn't be able to change data processing any more than we would be able to change a swab if we decided without some kind of a method verification. So I think splitting it up somehow and then getting the industry partners to provide that guidance, or whoever in the government that would have those good data practices.

I don't know if CDC has them or who makes those, but I think we need to recommend that they exist someplace, somewhere in the future, and that laboratorians can rely on those just like we rely, more or less, on

an FDA approved test or a good manufacturing process reagent that comes to our laboratory. So I think that's our role, is to make sure that same infrastructure gets put into place.

CMS EX OFFICIO: Just to interject real quick, I think we need to be very careful about assuming that those places with the black boxes have standards, OK?

CLIAC MEMBER: But that's our role to say that they should, right? I assume there's some really, really good laboratories that have standards, and then there's some version of a lab in a garage that exists in the data world as well.

CMS EX OFFICIO: Yeah. You just have to be very careful because you can't make everybody happy.

CLIAC CHAIR: So as we make our way back across the room, so question to [FDA EX OFFICIO] on that point. And by the way, [CLIAC MEMBER], I love the reasoning by example approach, because it's-- again, if this is actually not a new problem but a well recognized one, that kind of makes the unknown a little bit less scary. But [FDA EX OFFICIO], so here's this black box again, which is bought by Aico, which is-- some people say the global leader in AI, and others say is a fly-by-night organization and they don't even know what they're doing. But there's this box, and we're going to use it to analyze our images. That box has to be presumably FDA approved for its use that we're going to put it to, correct?

FDA EX OFFICIO: So I think that there is the area of digital health and what is a medical devices is definitely evolving as well, along with all these technologies. So I think it's something that we're certainly looking at. We have a group within the Center for Device and Radiological Health that's a digital health group that's kind of looking broadly at this issue beyond AI and things like that-- beyond just IBDs. And then within [INAUDIBLE] we're also looking to this area as well. And so I think it's an evolving area. Certainly certain types of systems likely would be medical devices, and others may not be. So I think it's an area that is important and is an evolving area as well.

CLIAC CHAIR: So it's not yet settled, but maybe we could recommend to the FDA to keep doing what it's doing, I guess, on it. Because it turns out this box, if you break into it, it's actually got a pigeon. And that pigeon is doing all the diagnosis. It's doing a great job, but it is a pigeon.

CMS EX OFFICIO: Is that better than a squirrel?

CLIAC CHAIR: I don't know. I haven't seen the data.

CLIAC CHAIR: So, OK. OK. So now we're back on this side of the room. I don't know who-- oh, no. [CLIAC MEMBER], and then that side of the room.

CLIAC MEMBER: So I just want to flesh out a little bit more about the conversation of the workgroup. The three points-- which lab is ultimately responsible, right? I think we've heard around here, lab A in that cartoon, where the patients showed up, that lab director has a conscience. Ultimately, that lab director is the one accountable, because that's where the clinical validation happens. Does that result match what you think is going on with that patient, and was the treatment appropriate? And as we commented in the workgroup, that if and when that lab director gets sued, everyone in that distributed model is going to be in court together.

CLIAC CHAIR: So everybody in that distributor model is going to be--

CLIAC MEMBER: Is going to be in court together.

CLIAC CHAIR: Oh, yes.

CLIAC MEMBER: Right? So everyone's held accountable, but it's going to be that lab director at lab A which will identify the problem.

CLIAC CHAIR: Yeah, it sounds like this is a case of stool sample flows downhill. So the person in the lab A get sued, they're immediately going to say, but, but, but. And then, [INAUDIBLE]--

CLIAC MEMBER: And that happens today, right? That happens today. The second thing about how the handoffs occurred, there was a very active discussion around what are the quality programs that need to be in each of the labs? And how do the two labs across the divide peer across that curtain to say, are you meeting these overarching sort of quality ideals, even if we don't know the technicalities of that? So that certainly would have been in the contract or the agreement between labs. That would be followed with periodic monitoring.

And then the PT-- the alternative PT workflow, where the specimen would follow the total test process outside of conventional PT so we don't run into PT referral risk. And then just a final moment, when we talked about the databases, the versions, the algorithms, we were hopeful that the FDA might have a role in that, because as I read CLIA, CLIA governs any testing related to the human condition, right? And this is a human who's being tested. And so it was thought a logical place to put that oversight would be with the FDA.

CLIAC CHAIR: I'm pretty sure FDA stands for Food, Drug, and Artificial Intelligence, right?

FDA EX OFFICIO: Maybe eventually.

CLIAC MEMBER: So I think I can-- your question about-- well, the example. So I think the heart of discussions item five was, there's two options. Either each lab involved in a piece of the process is separately CLIA certified, or one lab takes responsibility for all the testing processes. So you, a few minutes ago, gave an example of, I send a tube of blood out to a black box, fully robotic, no human beings there, I get a sodium back.

Well, the heart of the idea, I think, was that either one of two things happened. I decide to send that tube of blood to a CLIA certified black box, in which case somebody has got to inspect that black box every two years to make sure all the stuff that's supposed to happen for sodium testing is happening. Or, I decide to send that to a non-CLIA-certified black box, in which case I am taking responsibility for all of the processes involved in that test so that when the CLIA inspector comes to my lab every two years, I have to prove to them, how do I all the stuff that's supposed to happen for sodium testing is happening in that non-CLIA certified black box?

So I think that is the heart of the model. You have these two options. And there are situations-- labs-- that won't be able to take responsibility for all parts of the testing process, and we want to continue to leave them the option of, find another CLIA certified lab to do the pieces you can't. But if you choose to use a noncertified-- or there's parts in the process that do not involve another CLIA certified lab, that you, if you are taking responsibility for that test-- you are the lab-- have to ensure all the pieces are there.

CLIAC CHAIR: So that's interesting, because it makes it sound like there is an option. There is this black box, and either that black box is in your CLIA certified lab, in which case I say, thank you for handling that part of it. Or it's sitting in the middle of a field somewhere, in which case it's my business. And we just hope, per our previous statement, that the FDA--

CLIAC MEMBER: I think that's the heart of what we talked in the workgroup is, there are two pathways, two options.

CLIAC MEMBER: Two extremes.

CLIAC CHAIR: But is it an either or? Or is it-- I mean either or in the sense of, do we expect or even want a prescription from on high saying, thou shalt either choose a or b, and the other shall be illegal punishable by jail? Or are we saying, look, guys, we're just letting you know there are two ways to get to the mountain. And so, just letting you know that both exist. Here are the strengths and weaknesses of each. Which of those is it? It sounds like you're talking-- hopefully, you're talking about the second.

CLIAC MEMBER: Yeah, I think so.

CLIAC MEMBER: I just wanted to comment that we are mixing apples and oranges here. And I just want to make sure the-- there's a lot of details, and there's a lot of devils in the details. When we talked about the licensure business, when we talked about a single license that people can remote in, the understanding was, all of that information, all of that technology is hosted by the laboratory to which everyone's dialing in, and that that central laboratory is responsible for the platforms, the connectivity, the pipeline, whatever, to verify people can get in, and they're seeing things the way they need to look.

This other distributive model with the different CLIA licenses is when pieces of it are hosted at each of the laboratories. And then since you're testing humans, it would seem the current CLIA regs around each of those sites would still be applicable, and that the gaps that we need to bridge today are how the handoffs are occurring to a lab using a technology we don't understand.

CLIAC CHAIR: The pathologist in her living room, I would argue, is more like the latter.

CLIAC MEMBER: I would pose that the pathologist in the living room is dialing in through a VPN, and he's going into a virtual desktop. And that's hosted with all the stuff he needs, that he's seeing it the same way as if he were in that laboratory looking on a computer monitor.

CLIAC MEMBER: Yeah. So a lot of concepts out here. I'm not sure I can even wander through them all. But I guess, first of all, start off by saying, depending upon who you're talking to, i.e. a doctor, we are a black box. And so they don't even necessarily know what's going on in our shop, and it's maybe not nearly as complex as some things we're talking about. So depending upon where you're entering into the conversation-- and when we first started doing digital imaging, at one point, we wanted to know, well, do we have to license or verify that they're using the right stitching algorithm?

Well, that's gone away now. And then we said, well, how about compression technologies? Do we have to verify that? So I think we're at a different-- we're at the very similar concept of saying, we don't know enough about all these things, but we will eventually know more about them. How much did we know about quadrupole mass spec when it came out, or even MALDI TOF. So yes, NGS might be a little different, but I think as we go through time, we're going to learn it and know more about it. It won't be as scary or as much a black box.

There was a day where I went in and looked at a variant file, and somebody said, well, it's a black box around that area. Well, I was thinking, black box this way, but they're thinking black box meaning, no, no, you aren't accurate in that pipeline area. So over time, I think we're going to be able to work through these issues, but it comes back then to the responsibility of the originating laboratory.

And since I'm sitting between two laboratory-- reference laboratories-- they should know that when I'm in the business of selecting them, I send them comparison samples. It's not just price. I actually want to know, how do they perform when they are actually getting the same darn thing in two different places? And I think that's,

again, going to be the responsibility-- in the way that we work this out as we go through all these other technologies.

CLIAC CHAIR: So you bring up two things I want to follow up on. But the first one is, maybe I can ask you to comment a little bit more about these elements, like verifying-- or validating the compression algorithm or not. I was trying to think of a realistic example to put this in and couldn't, unfortunately. But it's a kind of thing like, have you validated that Microsoft Office is working correctly? Or have you validated that your email appropriately sends? Or have you validated-- let's be ridiculous about it and take it to, what is it, reducto ad absurdum-- do you validate that the gravitational constant is really the same as what it's reported--

CLIAC MEMBER: Did you validate the ink in your pen?

CLIAC CHAIR: Yeah. Or, the ink in your pen. Fantastic example.

CLIAC MEMBER: You signed it. I got it. Did you validate that?

CLIAC CHAIR: So, what point is it that we all look at each other and say, come on. That works. And I'm not asking rhetorically, like when it comes to things like compression or transmission.

CLIAC MEMBER: I use the phrase, performance over time. And of course, the first time you do it, you may not know, or you may not be certain. But by the amount of time and when you build up an aggregate of experience, you know what is working and what is quality. And I still believe then that the originating lab is responsible for making sure that is the case.

CLIAC CHAIR: So I'm tempted to say that that is conceptually similar to the, just do more samples and look for failure modes.

CLIAC MEMBER: Yeah, but you use the word controls. I think it's like controls, only a different couple words.

CLIAC CHAIR: I have a second thing that I'd like to bring up related to-- well, if there are other comments, I'd like to hear them first.

CLIAC MEMBER: Yeah, my comment is along the lines of that control. So having some experience in this field, when you're feeding in data into a machine learning or a digital microscopy type algorithm, there's a few things that you can consider. One is, before you've gotten to the point of actually testing on patients, you should have thoroughly vetted from the front end and the back end, in other words, what's coming back from the lab, which in most cases are not going to be lab, they're going to be software suites in the cloud.

So I don't know how we'd give a CLIA license to that, because it's not a lab. But you're validating that process by feeding in known specimens, or known images, that you've either scanned yourself or scanned in a second suite, and manually interpreted the results that came back to you. If those results are accurate, and you've validated that that software that you are choosing to adopt is functioning correctly, there is an ongoing validation process that I think is maybe not being appreciated here, in which on some regularity, defined by the director of that testing or suite, should be feeding in challenge specimens that are not patients to challenge that software that it's not changed and that there's not drift.

And there are some nuances to that that most end users may not be aware of, like the same exact slide scanned twice-- a good algorithm will never fail. So you want to change that control or that exemplar of data that you send through, or else you're basically stacking that manufacturer's software to not fail. So there are controls, and it's the same thing that [CLIAC MEMBER] is saying, is I test out the labs, right?

If I want to send something to Quest to make sure that a test that I'm running in an area is accurate, I'll often send stuff to Quest disguised as a patient. But it's really that I'm not sure if this is the right result because of something I've seen, so let's triangulate. And I think that that's going to be where this is going to have to go is, you may do your initial evaluation. You're going to do validation that the end result comes back as you expect.

But you're going to want to continually do that, whether that's a daily scan with an upload or a run scan. But I think the director is going to have to determine, what is the metric that makes you confident that that process is ongoing and accurate? I think just saying that you're never going to verify that product again is a bit away from what we do on a daily basis in laboratory medicine. We can have some control on that.

CLIAC CHAIR: Would it basically be whatever the high-dimensional version of Westgard rules?

CLIAC MEMBER: Pretty much. Yeah, drifted over time. .

CLIAC MEMBER: So I wanted to kind of just talk about another place where tests is similar type of process, which is in pharmacy. So there are a lot of different pharmacy models right now, where on the outpatient side, the patient will go to pharmacy, they will submit their prescription. And then they come back a couple days later and pick it up. They don't know what happened to it. And in fact, sometimes it's still there, and other times, they want to mail order and it got filled somewhere else. And then it just showed up at the pharmacy, to say that it's either.

And ultimately, the responsibility of that falls back on the pharmacy that's dispensing. And it's the same within a hospital. So sometimes all of the patients were in a different hospital, the patients were in the same system and had access to their different verification [INAUDIBLE] I'm able to verify something for a patient that's three hours away and do it from home.

But ultimately, the responsibility falls back on the dispensing pharmacy, so that hospital pharmacy. I don't know if that even sounds like a very similar concept. And then with respect to the data and where it will live eventually-- is the committee trying to standard what the data infrastructure looks like, or just to make sure that hospitals or laboratories are standardizing their own infrastructure?

CLIAC CHAIR: I would argue it's a bit of neither. So it's less about the infrastructure standardization than the process standardization. And I draw the distinction, because who knows where and how the infrastructures will change as various types of information storage and/or access become more expensive or cheaper?

CLIAC MEMBER: Yeah, or the process.

CLIAC CHAIR: Well, in that case, yes.

CLIAC MEMBER: It seems to me like there are two possible ways of doing this. One is to pick the reporting entity-- and I think that's a real good way of parsing it-- and say, if you generate reports for patients, then you're under CLIA. You have to have a CLIA license. And there are all these different ways you can organize yourself, but you are the CLIA thing. The other option would be--

CLIAC CHAIR: Sorry, the final report that the patient sees? Because otherwise--

CLIAC MEMBER: Yeah, well the report the provider sees.

CLIAC CHAIR: The final the provider sees.

CLIAC MEMBER: What the provider sees. The other would be the everything is a lab model. And so everything is a lab. So any entity that takes either a sample or data generated from a sample and contributes to building a report has to have a CLIA license. OK. So in that model, the cloud software would be a lab. And I'm not sure that that's wrong, because cloud software isn't a thing. Cloud software is run by people who are billing for that, and they're an entity. It's not just an autonomous piece of software.

And you can imagine doing it either way, but I think those are the two ways you can do it. If it's a reporting entity, that puts a lot of burden on small to medium sized laboratories that don't have a lot of academic expertise to get all of this shit right. And also, I don't know how it fits with the statutes. I don't know how a company that runs a piece of software in the cloud that takes an image off of a stool specimen, a cervical cytology specimen, gets away from being under CLIA in terms of statutes, even if it's just taking that data and feeding it back to a lab that then parses it and reports it. Statutorily, what does CLIA call that? I don't know.

CLIAC MEMBER: Is it generating a result, or is it generating a--

CLIAC MEMBER: It's generating part of a result.

[INTERPOSING VOICES]

CLIAC MEMBER: It's generating something that is then processed into a result.

CLIAC MEMBER: I think it depends on the intended use of the software and the algorithm. If it is doing interpretation and a natural result, I think that is different, and I'd agree with you. Then that becomes akin to a laboratory. But if all it's doing is gathering information and presenting it an easier to digest view, I don't know that you can call that a lab.

CLIAC CHAIR: But it's logically difficult to tell the difference, isn't it?

CLIAC MEMBER: It is, except if it's --if a human has--

CLIAC CHAIR: From a Turing machine sort of perspective, right?

CLIAC MEMBER: If a human has to put together the final result, though, then has the software really generated a result?

CLIAC CHAIR: If the human programs the software. I don't want to get philosophical, but--

CLIAC MEMBER: True. You're right, but I mean, a human's validated that the software is doing what it wanted it to do.

CLIAC CHAIR: I would ask a slightly different question and say, is it that-- so I don't have the answer about what falls under CLIA or not for whether the machine that's upstream that provides a component, but that we aren't considering a lab-- does that fall under CLIA? But presumably, it would or could-- and Peter, I keep looking at you for this-- it would have to be FDA certified for that use. Although again, there's a bit of a slippery slope, where at the other extreme, to [CLIAC MEMBER] point about like the ink in my pen, if that contributes to a report, is that not covered by CLIA if the ink is bad?

CLIAC MEMBER: A perfect example would be a piece of middleware, OK? In lab parlance, right? It's not a lab itself, but it's within a lab and under a CLIA license. Could you have middleware that was just autonomous and not under a CLIA license? Would that be a thing?

CLIAC CHAIR: Sorry, when you say under a CLIA license, be bit more precise about that.

CLIAC MEMBER: Well, my middleware is inspected under the lab general informatics chunk of the CAP checklist that is, in turn-- CMS EX OFFICIO signs off on. Yeah. It's all your fault.

[INTERPOSING VOICES]

CLIAC CHAIR: Not to parse hairs too much, but only when you're using it. If it's just out there used for whatever reason, for instance, suppose I'm using it for a laboratory whatever, then it's not under it.

[INTERPOSING VOICES]

CLIAC MEMBER: --laboratory, it's not.

CLIAC CHAIR: So it's insertion into that process that brings it under the CLIA umbrella. And who's CLIA umbrella? Yours, if it's in your lab.

CLIAC MEMBER: Right.

CLIAC CHAIR: And somebody else's if you're sending it another place or something.

CLIAC MEMBER: Right. But it seems that that middleware, if it's in that process, ought to be under a CLIA umbrella.

CLIAC CHAIR Yeah, I think I would agree. [CLIAC DFO] has kindly actually found the current statutory definition of laboratory, that maybe you could read to us.

CLIAC DFO: Yeah. So this is from CLIA '88. But I think it still holds, right? OK. So it's one paragraph. The term laboratory or clinical laboratory means a facility. So this is the law, by the way. Not the reg, the law. The term laboratory or clinical laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

CLIAC CHAIR: So the words that stick out in my mind are facility, examination of materials for generating information. Generating wasn't the word.

CLIAC DFO: Purpose of providing information.

CLIAC CHAIR: Provide. So something to think about is whether the nongeographically localized perspective that we talked about in an earlier part of this conversation can be shoehorned into this--

CLIAC MEMBER: Facility.

CLIAC CHAIR: --law. Yeah, we talked about the facility of being good at mathematics. That's a facility, right? I don't know. Let me ask one question here to the group. And then I think maybe we'll pause and kind of step back for a second and see where we've gotten after the first hour of conversation here. It's been a fantastic conversation so far. I'm not sure how much closer we are to a recommendation, but I'm also not sure that we necessarily need a recommendation on this topic at this point. And I would love to hear people's thoughts about that.

Just before that, though, let me return to something that was touched on but maybe taken a slightly different direction. And apologies. This might be just a bit involved. So people are always decrying at a big picture that, oh, no, you know, artificial intelligence and machine learning and all the rest of it is going to take all our jobs. A counterpoint to that is, no, it'll simply free us up to do things that we aren't otherwise able to do.

In medicine, in particular-- and this touches on the diagnostic error question that we've touched on a bit today and then heard in detail about last meeting-- one source of that error is that only one person ever tends to look at one sample. You don't get a second or third opinion routinely on every single analyte or every single slide that you get. I remember-- I think it was Lucian Leap said something which was televised, and so it's probably on record somewhere, saying that-- what was it-- I think, every cardiac echo ought to be looked at by two people.

And he said, the cardiologists will hate me for saying so. And I thought, really? I thought that they would rather appreciate it. And you say, well, why that, and what does that have to do with what we're talking about here? Well, if two independent algorithms-- two independent brains-- are looking at something and come up with the same conclusion, then it makes it more likely that that diagnosis is correct. And insofar as pathology is a diagnostic specialty, wouldn't it be great if you could look at everything twice routinely?

So what does that have to do with what we've been talking about in terms of these black boxes and the fear of the unknown that we are going into whether we like it or not? Well, if you have a black box, and it is really a black box from our perspective-- from your perspective sitting there like, well look, somebody might understand the details of how this works, but I certainly don't. What if there were just two black boxes that you could send every multiple controls to all the time?

So in other words, what I'm saying is that if AI will make things cheaper, ultimately, by taking away the requirement to spend gazillions of dollars and many years training humans in order to make diagnoses, the human might be freed to look at many independently trained machines, or independent machines, to reach a consensus conclusion.

In the end, you can always step back and say, I'm just going to draw a bigger circle around these multiple machines, and say whatever the consensus of those multiple machines is my machine, and that's my test. But for the time being, imagine that if we don't know how a particular new test works, that we'd just send our test to multiple-- like, my slide image goes to one AI, and it goes to another AI, and so on and so forth around, and--

CLIAC MEMBER: Don't send it to mine. It won't go well.

CLIAC CHAIR: It'll go to the pigeon. And we'll see how-- and on that basis, hopefully avoid some of these novel edge cases, like the picture in the static. Can't fool them all. And I bring that up as a topic for discussion, because I wonder whether the committee thinks that as a general rule-- and I'm again trying to overstate the case here just to kind of push back into-- asymptote to the right answer.

But as a general rule, should we be looking at thinking about, or recommending, or at least have on record for the agencies, a point of view that everything should be looked at multiple times in multiple ways? And that

actually might help us navigate these various unknowns. So I just throw that out there. Feel free to shoot it down. But a thought.

CLIAC MEMBER: Well, I think that we're going to have this general principle of, the CLIA director has to make sure everything works. But with the different models, we're going to have to be more granular. We talked about chemistry QC is not the same as microbiology QC. And we're going to have to provide guidance to the laboratory director on how to do this kind of QC for different types of nontraditional testing models. We're not going to escape that easily. Nice try, but no.

CLIAC CHAIR: Should this be a goal for us?

CLIAC MEMBER: Yes.

CLIAC MEMBER: I think that's a good idea, but I'm concerned about that longitudinally, that it defeats the whole purpose of using this technology if we have to do redundant processes to get to the same answer.

CLIAC CHAIR: So a random forest is many votes that come up with a consensus. So is the logic not similar?

CLIAC MEMBER: Right, but to what end? At what point do you draw a line in the sand and say, we trust what is happening. Versus if you continue to do-- I'm going to take my Pap, and I'm going to send it to three different places to always make sure I'm right. And I'm getting the same answer. At some point, you might as well just read it manually, because you're going to be paying three--

CLIAC CHAIR: At some point, you might just--

CLIAC MEMBER: You just might go back and read your Pap manually, because you've now paid three licensing fees and three independent scans and interpretations to get the result that you feel 100% about every time. But you've not gained efficiency. You've not gained cost economics. All you've done is made absolutely sure that these prediction algorithms are correct. So I agree with doing that to get to a point. But at some point, if you don't get to a state in which one system can be your system, I don't think you've gained anything.

CLIAC CHAIR: So a thought experiment. Suppose that each of those licenses is cheap enough that even doing all three is still cheaper than having a human read, and that the error rate goes as a cube, basically, in that way.

CLIAC MEMBER: If we can get to an altruistic society in which that's true, yes. Absolutely. My guess is that it will be cost prohibitive.

CLIAC MEMBER: And it's farther off than we need to deal with right now.

CLIAC CHAIR: Fair enough. Well, in that case, let's pull back for a second. So huge topic, as we said at the outset. We've been talking about it for an hour, or a little over-- around, something like that-- just about an hour. There's a lot more to talk about. Are we inclined-- so we end at 6, so we've got about another hour and a half that we can spend on this, or other topics, for that matter. Do we feel after this hour that we've discussed that there is something that we should recommend? Is there a shape of a recommendation in this discussion so far?

There need not be. If there is, that's fine. Or is it simply that the value of the discussion itself is what we will sort of deliver to the agencies? What do people think? We've talked about processes. We've talked about splitting processes from geography. We've talked about the importance of controls-- a number of other things. But-- thoughts?

CLIAC MEMBER: So I'm not an attorney, but I slept at a Hampton Inn last night. And I just might wonder, should we ask or recommend a legal opinion about what [CLIAC DFO] read? And is DNA and/or the information from DNA a material, and therefore already covered by the definitions in the law, and therefore its analysis by other laboratories is already defined as a distributed testing method already in the law? And there is no variation or no interpretation left for us.

CMS EX OFFICIO: DNA is a sample withdrawn from the human body.

CLIAC MEMBER: Is it a material?

CLIAC MEMBER: What about a DNA sequence, though.

CLIAC MEMBER: Is the sequence of--

CMS EX OFFICIO: You have to have DNA to do the DNA sequence.

CLIAC MEMBER: That's where I'm coming up with--

CLIAC MEMBER: The sequence is

CLIAC MEMBER: That's where I think a lawyer should say that answer.

CLIAC MEMBER: --that information. I understand the DNA. It's like any other component that we've derived. It's like the sodium or anything else. But once you've got the DNA sequence and you've got data--

CLIAC CHAIR: Is data a material?

CLIAC MEMBER: Right.

CMS EX OFFICIO: Seriously, people.

CLIAC MEMBER: Well, that's what the law says, right? So is that covered under the current word in the law?

CLIAC CHAIR: But to be explicit, is data a material in that particular example? Because nobody would disagree that the--

CLIAC MEMBER: Derived from DNA, derived from the patient, yes.

CLIAC CHAIR: Right. Because the DNA is certainly a material. The laboratory is a facility for examining it. Deriving the information is the examination. To provide information, that's fine. But it doesn't-- I've paraphrased what you had. Does the examination have to happen--

CLIAC MEMBER: It's in all our books, page 551.

CLIAC MEMBER: Page 551.

CLIAC MEMBER: Facility for, not in.

CMS EX OFFICIO: It's on the definition [INAUDIBLE]

CLIAC MEMBER: Page 551.

CLIAC CHAIR: 551, beginning at the first column, bottom of the page. So it doesn't say that the examination must happen in the facility.

CLIAC MEMBER: No. That then gets back to distribute testing on page 550.

CLIAC CHAIR: Please read that.

CLIAC MEMBER: Yes. Page 550 on the second column, two thirds of the way down. Distributive testing means laboratory tests performed on the same specimen or an aliquot of it that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final report, blah, blah, blah.

CLIAC CHAIR: But the trick there is when such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing. So does that mean if some information goes outside what is currently a CLIA certified location, it is no longer distributive testing?

CLIAC MEMBER: Well, that's why we're in a circle here. Because then that takes us back to the materials, and DNA, and is that a laboratory.

CLIAC CHAIR: So we can change that.

CLIAC MEMBER: That can be changed.

CLIAC CHAIR: But you have the law here.

CLIAC DFO: I read the law.

CLIAC CHAIR: You read the law. And this is good. But the law is not so-- OK. We're talking about two different things.

CLIAC DFO: There's a difference between the law and the reg. Law, we have to go to Congress to change.

CMS EX OFFICIO: The regs you come to us to change.

ADVAMED LIAISON: So I can think of an example where, I know two different labs-- or I call them labs-- two different companies that are in the space of analyzing sequence data to make a determination of the disease state. In one case, the lab-- the company-- you can send them your samples, and they'll send it out to a wet lab. And then the wet lab will send back the results, and they'll analyze it using their patented algorithms. And they have a CLIA license.

I know of another company that doesn't have a CLIA license. They say their whole business is their algorithms. You don't send them your patient sample, you just send them their data. So they never receive the physical sample, where the other company does. In the second case, they don't have a CLIA license. They don't consider themselves a laboratory. They're a business. Two companies doing almost the same thing, one that believes they need a CLIA license, one that believes they don't.

So I think the question will always remain out there that without clear guidance from somebody, you could almost make a case for either one. And I think it would be whether HHS or CMS is asking us to actually make a recommendation around this or just provide some of our thoughts for them to go back and think on is kind of the crux of it. But where there is a greyness, companies will find. Labs will always find a way to-- if you're quality-minded, you'll find the way to provide the best quality product. If you're profits-oriented, you'll find a way to do it with the least amount of overhead.

CLIAC CHAIR: But that will be true whether or not they have a CLIA license or not. So forget about algorithms or analysis that way. Somebody sends you a sample where you-- what's an example. All I'm saying is that first company's decision to have a CLIA license might not be motivated by best practice. They might just be motivated by fear of law, and they're otherwise like a fly-by-night cutthroat folks, where the lab director doesn't come by more than once a year, and so on and so forth.

ADVAMED LIAISON: I would agree. But I would say that labs or accrediting bodies or surveyors also have this greyness and question of, where does it fall? And I think that's what's kind of arising out of bringing the questions to us. What do we as CLIAC think that the agency should do or should interpret, and guide for the best quality patient care in thend.

CLIAC CHAIR: Does anybody here think that both of those labs shouldn't have CLIA licenses?

CLIAC MEMBER: Well, that's something we could test. I mean we could put out a recommendation and see how we would vote on it. That is if you understand the word material to be processing of data from a specimen, that it requires a CLIA license.

CLIAC MEMBER: But conceptually, though-- I take your point which is the importance of each of those labs in the information flow sufficient that whether material appears or passes through that lab is irrelevant to whether it should need to have a--

CLIAC MEMBER: That's what he's saying, have a resolution that--That data is material under the clear code. And so that if you're managing data for diagnosis, et cetera that's also material.

CLIAC CHAIR: Correct. Does anybody-- does anybody believe that, that second company in this example is under similar overall requirements to provide as good care as the first? Or as good data as the first. In other words, is the-- I'm assuming in the second--

CLIAC MEMBER: Is anybody looking at the second company?

CLIAC CHAIR: Well, so that was going to be my question. So in second company--

CLIAC MEMBER: Is anybody looking at the second company?

ADVAMED LIAISON: I didn't hear it. Is anybody what?

CLIAC MEMBER: Is anybody looking at the second company.

CLIAC CHAIR: He means anybody-- would anybody use the second company is what you're asking.

CLIAC MEMBER: No, no what is--

CLIAC CHAIR: Oh, is anybody looking at it as oversight?

CLIAC MEMBER: Of the second company--

ADVAMED LIAISON: I can answer that. I would--

CLIAC CHAIR: I mean not in this case, but continue with a hypothetical.

ADVAMED LIAISON: A good lab, or a director-- a good lab would be, before they contract, would go through some sort of process to verify --

CLIAC MEMBER: You would think-- so until their administrator tells them to take the lowest bidder.

CLIAC CHAIR: But --I mean there's another way to look at it. Suppose that your lab comes along. You're now a CLIA certified lab at a major medical institution. And you're looking for a service provider. And you have the choice to go through-- go for lab A or lab B. There are-- the simplicity of just having to send information is what attracts you to the current non CLIA certified lab. You are only going to use them if you are confident about their behavior.

CLIAC MEMBER: Or if my administrator forces me to take the lowest bidder.

CLIAC CHAIR: Or if your administrative forces you to take the lowest bidder.

CLIAC MEMBER: If I can't come back to them with a regulation that says, no, I can't send to these people because they're violating the law.

CLIAC CHAIR: But is this sort of like a-- does this sort of lead to the libertarian crisis, where you say, well, you know, it sucks to be you if you made a bad choice, but nobody has to regulate them. That's up to you, personal responsibility, et cetera, et cetera. Or is there a simpler, compelling reason to say no, no, no, that that lab ought to be made to conform to something beyond your CLIA license and your responsibility.

CLIAC MEMBER: I don't think that data is that different from the DNA that generates it. And so in terms of the overall intent of the CLIA law, that both of those laboratories are doing essentially the same thing.

CLIAC CHAIR: So I persist in this point, because it does, I think, lead logically to a recommendation that material-- excuse me-- that information is a material, but that seems quite a major recommendation to make. Not that I'm against making major recommendations, but one would have to-- I think I've probably set a record for recommendations in my chairmanship, which makes me happy, I think. But the issue is just then, back to points that, you were raising is like, where-- or maybe, it was you again, but-- what is sort of the unit of information that makes it clinical information? Or at what point does Microsoft need a CLIA license to sell us Microsoft Office.

CLIAC MEMBER: Right.

CLIAC MEMBER: So I'll follow up on that. I was actually thinking, [FDA EX OFFICIO], maybe you can answer this. If a digital imaging or sequence predictive algorithm for NGS or otherwise is submitted through the FDA and classified as a medical device, how does that work? Is that a lab now? Because it's a medical device, that you would just be tapping into at a remote site.

FDA EX OFFICIO: So are you asking about-- I guess it depends if you're asking what does it mean for CLIA?

CLIAC MEMBER Well, so I'm trying-- I'm still trying to get a grasp on how can something be a lab when it's just a bunch of IT guys sitting in a warehouse factory in an industrial park and doing computerized high throughput image analysis through software. And so if that software was put through the FDA and cleared for its intended use, and all the user is doing is feeding in the image data, isn't that a medical device at that point? That the user is using, as opposed to a CLIA lab?

FDA EX OFFICIO: I mean, I think there probably can be different models. You know, I mean, on the one standpoint, there might be something that where the software is a medical device that has been cleared or approved. And I would expect that perhaps under CLIA, you would just have to verify its use rather than validate it, like any other medical device. But you may also have circumstances where it's not that simple.

Where you have some bit of software that pieces of it may be a medical device, pieces of it may be an LIS. You may have a person in the loop that's maybe practicing medicine or maybe somehow involved in changing the outcome.

So, there are a lot of possible scenarios where as you go away from a situation, where you have a defined algorithm that's been cleared or approved and is a medical device, I think you get more and more into the realm of where it is potentially a laboratory that you need to validate like you would validate some other type of testing procedure in some way, depending on if data is considered [INAUDIBLE]

CLIAC MEMBER: Is it not inherent in the total testing process-- in the analytic portion of the total testing process? If you can't get a result without it? And if so, then is it-- is it really in a laboratory because it's part of that testing process? Is that a way to look at it?

FDA EX OFFICIO: So I don't know if I can define what's in a laboratory I guess.

CLIAC MEMBER: The laboratory's in the regs, or the law in the regs.

CLIAC MEMBER: 551

CLIAC MEMBER: I have two questions. Many of the regulations in CLIA are [INAUDIBLE]

CLIAC CHAIR: Sir, could you--

CLIAC MEMBER: I'm sorry. I was saying that it seems like a lot of our regulations use information in a lab that we can't decipher how to store it, how to transmit it, things like that. So we're already treating information that way anyway.

So I think that that information will be sent out to a bioinformatics company, where they manipulate it and do something to it, is acting just like a laboratory and there should be no clear difference. That's the point I was making earlier about algorithms, and the deep learning, and how they operate, it's just they take it where that information is [INAUDIBLE]

CLIAC MEMBER: So I think if we had an opinion about the word material, it'd be very appropriate to make a recommendation. And after all, it's only a recommendation. And when the rule goes out there, there'll be all kinds of comments and protests launched. But we should take a stand.

CLIAC MEMBER: I have a second recommendation, and this is a great conversation we're dealing with-- weighty issues of what is a lab, and what's a test, and a specimen. [CLIAC MEMBER] mentioned that the current PT referral models preclude developing distributed PT models.

So a simple recommendation that would allow that models to be developed while we're tackling all this would simply be that we recommended that CMS approve PT providers be allowed to develop distributive PT models for non-regulated testing. And that's a simple recommendation, that if followed through would allow some of the PT models to be developed while we're dealing with other recommendations that we might carry forward.

CLIAC MEMBER: And before we vote on these motions, I just want a-- a piece of history-- I thought on the space where those two companies are in, that I thought there was some decision that there would be no regulatory oversight of genetic testing for non-actionable things, like, why do you look the way you are?

Where did your ancestors come? I thought that was not something they were going to regulate, which kind of doesn't meet the all-inclusive intent of CLIA. But if that were the case, would the motion be modified to say, we are making this recommendation for actionable results?

CLIAC MEMBER: Well, for the diagnosis, prevention or treatment of any disease or impairment.

CLIAC MEMBER: Right.

CLIAC MEMBER: But they have this other thing-- or any other condition. So you would actually narrow.

CLIAC MEMBER: Yeah, I think condition in this case means a disease condition or a genetic condition, not necessarily blue eyes or where your ancestors were. I don't think that's a condition.

CLIAC MEMBER: I think also the--

CLIAC CHAIR: Sorry, could I pause you just for one second. Could everybody just cover their microphones for a split second? Thanks. There's been a lot of-- it's been a reverb afternoon.

CLIAC MEMBER: It's about 2,000 hertz, if they want to know.

CLIAC MEMBER: Yeah, no problem. I think looking at the alternative of doing nothing-- in a way, what happens when good people do nothing-- I mean, it's a tough decision. However, the only reason that [CLIAC MEMBER] says that we get to say we want to send our reference specimens to a CLIA certified laboratory is because there's a regulation. Otherwise, financers across health care would be saying, send it to the cheapest lab, we really don't understand what your quality's about.

If we don't make some kind of a stand-- if we didn't have that, we'd have people with labs in their garages all over America. So again, I kind of get back to the fact that maybe we don't dictate or mandate, but [CLIAC MEMBER] group has listed many sort of just common sense things that we could put up there as potential best practices, and also by defining it in the purview of the whole laboratory testing system. By default, it forces some level of quality.

You know, if we don't define some level of quality for these data folks, then good businesses who want to do the right thing are competing with people that don't. And so, if there's not some kind of balance there, how will we choose a good laboratory data, if we don't-- data processing house, warehouse-- if we don't have that? So, I

don't know what all the answers are, but I do think there should be some recommendation that they be included in the cradle to grave laboratory test system.

That would theoretically allow us to develop these guidelines with professional organizations, government organizations, industry organizations. Just like reagents have evolved and instruments have evolved, it seems to me like we've got to do something. I don't know that we can solve everything today, but there's some things here that are pretty common sense. And there's-- a ton of thought went into this document, so I think there should be some things we could say definitively that we would like to see happen.

CLIAC MEMBER: I think we could add to that by saying, if we don't and they then there was one lab, one group, that doesn't comply with regulations and another that does, then the cost of the relationship between them is markedly different. And we may be forced to use this one because it's got lower cost.

CLIAC MEMBER: So, I have to send that outI know that there's a lot more to it but having been in genomics discovery when we were first starting human genome, and just understanding what we were doing with our bioinformatics and who did it, and how we figured it out, and it was pretty much a cowboy operation out here in Cambridge.

But things kind of change a whole lot when it comes to how we assure who's doing the bioinformatic analysis, whether or not they really know what they're doing, whether or not they're qualified or not in what they're doing, and whether or not they're using good libraries and human resources for the information that they're gathering, to interpret, to get back to us, to treat that patient.

So when we talk about this data and who it goes to, I do strongly believe that it should be a CLIA certified facility or activity. The other thing that I think we need to be aware of and keep in mind too, there are several journal articles out there-- the Journal of Micro Diagnostics has a special article on standards and guidelines for next gen bioinformatic pipelines.

CAP has a huge paper out there on standards and guidelines that I think we need to keep in mind. And get the information put together so that we can use what's out there in the industry right now to understand at least some standardization and understanding how to maintain that quality. Because you're exactly right-- if a laboratory-- some of these people who choose these providers, they don't know the standard in how they should choose them.

We do. And when someone says I can give you this information tomorrow, it won't cost you very much-- why not? They don't know any different. But at least if it's a CLIA certified laboratory, we have some baseline standardization involved.

CLIAC CHAIR: So I'm just writing-- bringing up a recommendation by [CLIAC MEMBER] of a similar-- bringing some-- it's basically editing-- building on that to just make explicit a bit more restrictive definition of what data should be. Hopefully, getting around the sort of atomic idea about well, this fragmented-- this datum, or whatever, does that count as data or not. And then also, putting up a couple of other things that were mentioned. [CLIAC MEMBER], if you're in agreement with this second thing here, then I'm happy to just delete the first.

CLIAC DFO: Since there's a pause, I want to just ask a question. What would CLIA certification of a bio informatics company look like? How would you-- how would the government think about test complexity, personnel requirements, proficiency testing, which are all the basis of achieving and maintaining a CLIA certificate?

CLIAC MEMBER: I'll take the bait. So they'd have to have a medical director, a technical director. They'd have to have standards for their employees, training. They'd have to have a procedure manual. I mean, they'd have to have the whole nine yards, and why shouldn't they?

CLIAC MEMBER: So I'll just add, they have to have a quality management system, including if the black box ever gets waived categorization-- how to handle that.

CLIAC MEMBER: Just look at the general CAP checklist, for instance. You know, there's conditions for air conditioning, and fire, and data redundancy, and all the kind of good data practices. Just if they did that, and then, I'm sure there's personnel qualifications, and procedures, and data backups, and things like that, that are already sort of in our checklist, but just not extended.

I like the woman's comment about sort of a wet lab and a dry lab. I mean, maybe people don't call it a laboratory. They call it a data center. But in our requirements now, there's lists and checklist items that relate to hospital data that really shouldn't be ignored when it comes to, I think, the general data warehouses that we're talking about.

CLIAC DFO: So we'd have to create a different type of certificate then? Basically, right?

CLIAC MEMBER: My question is this. Looking at that first bullet point, does that open every physician who looks at diagnostic data from home up to have to get CLIA clearance, because they're a laboratory, since they receive medical images, genetic, and protein sequences, and O mixed data? Does that create a whole new bucket load for areas outside of the laboratory field?

CLIAC MEMBER: I thought we had a good comment, when somebody said, but they're really only-- their office is really connected to their main laboratory. Yeah, do you want to respond to that?

CLIAC MEMBER: I'm sorry-- if the data is all hosted on the primary lab, A, and they're just dialing in. The proposal, that would mirror the current VA model, that there's a single CLIA license around that geographic VA site. And everybody's just coming in from all over

CLIAC MEMBER: But it would disallow some random person setting up a TV-- a digital monitor in their house and saying they're pathology consultant, because that would mandate that they all go through the core VPN.

CLIAC MEMBER: I would be careful with that, though because you could essentially eliminate the services that a lot of you in this room use for free, such sending something unusual or parasitic images to myself and my colleagues. Right?

CLIAC MEMBER: We should be--

CLIAC CHAIR: But you're not using those for--

CLIAC MEMBER: We're not paid for that, but I'm saying people like Bobby [INAUDIBLE], and Blaine Matheson, and myself, do a lot of exactly what we're talking about. So it's a slippery slope. And there's a lot of that type of stuff. We're not issuing a diagnosis, but--

CLIAC MEMBER: Sounds like a business plan to me.

CLIAC MEMBER: You could force us to basically have to not help anymore. And that's what I worry about, over-regulating some of these things that if you start saying that everyone's home PC's are now-- my lab in the middle of the night can no longer send me images of a gross section of a worm or a blood smear with an unusual merozoite structure on it I have to come in and look at it.

CLIAC CHAIR: Will everybody on ClinMicroNet be raided by the feds and thrown into prison?

CLIAC MEMBER: I know that's hyperbole, but with anything federal, that goes down a slope, you never know.

CLIAC MEMBER: It's a butterfly effect. But if you do decide to submit this, I think that that has to be included in the verbiage. Because we're talking--

CLIAC CHAIR: As an explicit exception?

CLIAC MEMBER: I'm sorry?

CLIAC CHAIR: As an explicit exception?

CLIAC MEMBER: Yes.

CLIAC MEMBER: No, I think you would have to be affiliated with a CLIA certified laboratory, in the same way we had to work through this issue with CDC when it was issuing reports from the laboratory and they said that didn't have to comply with any federal regulation, because it was just an opinion of a public health laboratory.

But if it got in the chart, as many of those did, they had to be regulated. So I'm saying-- if you're-- and it's a wonderful service-- all I'm saying, is then I think you should be an affiliated with a laboratory and comply with issues related to quality assurance and documentation.

CLIAC MEMBER: But that's regarding laboratory specimens. Remember, if this goes into effect, it's going to affect more than just laboratory people.

CLIAC MEMBER: But I think the second bullet, in part, answers that concern about that in the first. So if images are regulated by CLIA, but the laboratory isn't confined to a geographic area, the laboratory can take responsibility for the data security and fidelity of everybody who wants to dial in and use that image or diagnosis. So the points together, I think addresses.

CLIAC MEMBER: OK, I've been thinking something simple. And it might seem stupid, but can't we just treat this light reflex testing?

CLIAC CHAIR: How so?

CLIAC MEMBER: Hmm?

CLIAC CHAIR: How so?

CLIAC MEMBER: So if we-- I've looked at the definition in the book too-- reflex testing needs confirmatory or additional testing that is automatically requested by a laboratory under a standard operation procedures for

patient specimens. This is how they begin when an laboratory finding indicates that they need other tests. So if we need to get a complete test result, this is all part of the process, in my opinion.

I'm thinking simple. And so, if they're going to another lab to complete our test results, couldn't we just treat it the same way? And also, another way of looking at it, if we actually had equipment in our own laboratories that provided us the same information, we would want it also to be CLIA approved, whether we had a box now that-- you know how things evolve.

We have this box in our lab that gives us the same information. Can't we think forward in how we would treat that? Wouldn't we treat it now in this same way, until that little box get built, approved by FDA, and is in our laboratory? It's simple for me.

CLIAC MEMBER: If everyone will just angle your mics down, that might mitigate the feedback a little bit. Just try that. It didn't do a thing-- oh, well.

CLIAC MEMBER: I'd like to make a couple comments. I don't want us to build a brand new, separate edifice. I think currently existing regulations cover most of this. And the gaps include the definition of materials that we've put up there. And then the PT that follows the total test process.

I don't want to get hung up on the bricks and mortar definition of a laboratory. I want to instead focus the definition of a laboratory as something that tests stuff from human people. Then you can decide is it a brick and mortar or is it an extension, hubs off of central lab. So I would recommend we remove that second bullet. And then I think if--

CLIAC CHAIR: But don't we already have-- so, then I guess the question is not what a laboratory is, but what a facility is.

CLIAC MEMBER: Yeah, I personally don't want to touch the facility issue. I think it's the role of all the laboratories involved in this total test process to come to an understanding that each one of them is providing a quality service. And to me, that's governed under current CLIA laws.

CLIAC CHAIR: I'm not sure I follow. Because it seems like this-- so, we have we have the process issue and then we have the geography issue. And if you don't touch the geography issue, then we're back to what Mark was worried about, in terms of where or what a laboratory is.

CLIAC MEMBER: Well, if we say each part of the process has to meet these quality regs, then that, by definition, if that facility, if that information, testing or whatever is happening at that facility, which is at a different geographic location, by definition, they need a separate license.

CLIAC CHAIR: But do you have to define everybody's living room as a lab?

CLIAC MEMBER: The living room example is related to images. And I would prefer the central hub with the spokes model, where there's only a single license, and people are dialing in to information that is hosted within a single lab.

CLIAC CHAIR: What if I download sequence data?

CLIAC MEMBER: No.

CLIAC CHAIR: To my machine?

CLIAC MEMBER: No, but now you're downloading, and now you're bringing that data into your system.

CLIAC CHAIR: I understand that. So what you're saying, basically downloading is illegal.

CLIAC MEMBER: Now you're a laboratory.

CLIAC CHAIR: I'm a laboratory.

CLIAC MEMBER: You're a laboratory.

CLIAC CHAIR: Is there precedent for that in regulation? If not, that sounds like it might something we could clarify, that you can [INAUDIBLE]

CLIAC MEMBER: That's tied into the definition of materials. Because right now, materials implies a primary specimen. But if you just had in your version materials in the CLIA 88 definition of a clinical laboratory include, and you just say any data derived from a primary specimen, parenthesis medical images, genetic sequencing, et cetera. Because the point we want to make is data is a specimen.

CLIAC MEMBER: So it includes data such as medical--

CLIAC MEMBER: Yeah, in parenthesis.

CLIAC CHAIR: Yeah, I worry about making the definition of data too broad, because again, you have this atomic definition of data.

CLIAC MEMBER: Well, remember, it has to have come from a CLIA sample.

CLIAC CHAIR: I took a CLIA sample. I started sequencing. The first nucleotide that showed up was a T. I transmit that. Are you a lab? Or is that T-- does that T, because it's a thymine that was sequenced from this patient --

CLIAC MEMBER: Am I going to use it to contribute to generating a result?

CLIAC CHAIR: That's a good question.

CLIAC MEMBER: Yeah, I think it's a specimen, because--

CLIAC MEMBER: It's going to be used for diagnosis, treatment.

CLIAC MEMBER: You sent a T, but I got a G, right? How do I know you sent me a T?

CLIAC CHAIR: No, just simply saying does that T-- does that T count as a material?

CLIAC MEMBER: I would say yes.

CLIAC MEMBER: It does, but it only falls under T if you're going to use it to generate a result that's used for diagnosis.

CLIAC CHAIR: Well, in that case, are we happy then removing bullet point two? So [CLIAC MEMBER] got the view that bullet point one automatically makes any place with the data a lab, and therefore, unless you want to make your living room a lab, just don't download stuff.

CLIAC MEMBER: That requires too much creativity. Having bullet point two there makes it explicit. Yeah, I mean, [CLIAC MEMBER] point might be true, but I'm not that bright.

CLIAC CHAIR: But then it sounds like we should change around bullet point two, because bullet point two is no longer quite-- it's different from what [CLIAC MEMBER] suggesting.

CLIAC MEMBER: Right, because--

CLIAC CHAIR: Because if I'm sitting in my living room, looking at DNA sequence, or imaging, or anything else, at my lab, then my living room isn't a lab. And just because I'm there looking at it, doesn't make it a lab. That's what [CLIAC MEMBER] is saying, if I understand you right.

CLIAC MEMBER: Yes. So that's a unique carve out, right? You have your virtual--

CLIAC MEMBER: You're the lab. I mean, [INAUDIBLE]

CLIAC CHAIR: That's what I've said here. But that's why I'm saying those two things are different. In one case, I'm not the lab. I'm simply, going to the lab. I'm going to the lab via my computer screen. In the other case, I am the lab, [INAUDIBLE] wherever I am, the lab is, because I am the lab. So which of those two views do we wish to espouse.

CLIAC MEMBER: I think there's a nuance here, though, that [CLIAC MEMBER] was getting at earlier. If I right now remote into my virtual desktop, I'm in the lab.

CLIAC MEMBER: Yes.

CLIAC MEMBER: But if I use web mail, and the image of the blood smear is on web mail, I'm no longer in my lab.

CLIAC MEMBER: Correct.

CLIAC CHAIR: Because then Microsoft Uplink is the lab.

CLIAC MEMBER: Correct, and it's locally on here.

CLIAC MEMBER And how do you know Microsoft Outlook did not corrupt or distort that image? Whereas you know from your internal virtual whatever that it is faithful.

CLIAC MEMBER: Because it was sent to Outlook on my work PC, so whether I'm going to the virtual PC to look at that Outlook versus web mail Outlook-- see that's what I mean, that's regulatory at that point. If you're saying it's a virtual PC, because that's still in the lab, I'm with you. Draw the line and say that's the case.

CLIAC MEMBER: I just want to comment, what's flying around ClinMicroNet used to be what was flying around DPDX. And DPDX ultimately made us complete requisitions and go through a formal--

CLIAC MEMBER: Only if you wanted it in the chart. To this day, you can still get a non official result from DPX with non charting.

CLIAC MEMBER: Yeah, they won't do that. They said, we're not touching it until you send me the form.

CLIAC CHAIR: So let's-- so one thing at a time. Do we like that first bullet point? Or do we want to go back to making it more general? To [CLIAC MEMBER] point, that's also a subtlety, but I think 100% right that that T is medical information, but not covered by CLIA unless somebody is diagnosing somebody based on it.

That pixel is medical data, but it's not covered by CLIA unless somebody is making a diagnosis based on it. So in that case, do we want to go back to making bullet point number one more general? We'll return to bullet point two in a second.

But I think if we can get rid of-- well, not get rid of-- if we can settle on bullet points one and three, then we can spend the rest of the time on two if necessary. That's the most expansive, I think, I can--

CLIAC MEMBER: How about all data derived from a patient's specimen? Because we don't want to govern--

CLIAC CHAIR: Yeah, but should it be though? All data derived from a patient specimen? I guess, because then it's not a medical issue, but it's a CLIA oversight issue, is that where you going with it? You took my history as a patient, and that clearly would fall under this rule, but not under CLIA.

CLIAC MEMBER: Because I'm seeing the stuff for data derived from a patient showing up in our EHR as AI and how to intercept evolving sepsis, things like that. I don't want to get to regulating--

CLIAC MEMBER: How about derived from patient material?

CLIAC CHAIR: Well, then it's a bit self-referential, right? Because material includes stuff derived from material, so it's material.

CLIAC MEMBER: OK.

CLIAC MEMBER: I still think that if you're going to say it does not fall under CLIA, because it's being housed in the facility, that that needs to be stated. Because you're asking them to draft law. And it should be that specific.

CLIAC MEMBER: Can you say that louder, please? It's either too loud or too soft.

CMS EX OFFICIO: Have to hold that thought.

CLIAC MEMBER: So what I was saying was, if we're proposing a consideration of change in legislation, and we have decided that where the data is housed determines where the laboratory is, that needs to be stated. Otherwise, you're opening the umbrella for CLIA.

CLIAC CHAIR: Hopefully just changing the regulation, which [CMS EX OFFICIO] can help us with, as oppose to a change in legislation, which-- I don't know-- something about a filibuster.

CLIAC MEMBER: Well, are we even changing regulations? We're just adding it an interpretation of the word material.

CLIAC CHAIR: Unless-- maybe not. But, we might want to make it explicit somewhere. It will presumably not going to just be explicit in our regulation. It will have to be accepted in some way by HHS. So I imagine it would-- that would feed into a change in regulation.

CLIAC MEMBER: I just want to comment on why I want to use that word specimen. Because we had years of arguing about pulmonary function tests and breath testing. And if it was still connected to the person, we would not regulate it. But if it came out of them, and it came to the lab, then we would be regulated by CLIA.

I would also ask whether we be more broad about the examples, images, genetic, and protein sequence, and similar all-mixed data, instead of-- and similar all-mixed data, consider some big, broad term, much as the original CLIA term used materials. But it's anything any data derived from any sample, something very broad.

CLIAC CHAIR: Is that better?

CLIAC MEMBER: Yeah.

CLIAC MEMBER: Other.

CLIAC MEMBER: It's good enough.

CLIAC CHAIR: So what I'm going to write down, I think is going to over-do it, but hopefully that will lead to a brief discussion. So thus, any repository of such data is a-- shall be considered a laboratory. And here, the reason why I think that that's-- so that that's what you're getting at, [CLIAC MEMBER]. But I think this gets to the [CLIAC MEMBER] exception, which is what about my email. I guess is that email server always housed at the hospital? In which case, there's a hospital site that is not the lab, part of the lab.

CLIAC MEMBER: It's probably in the cloud.

CLIAC MEMBER: Web mail's retrieving from the server, that's at the lab.

CLIAC CHAIR: But is web mail always at the lab?

CLIAC MEMBER: It's in the cloud some damn place.

CLIAC CHAIR: Worse-- or maybe not worse, but if I get on the phone and I describe-- and I read this sequence to Valerie, that sequence is now traveling through whatever fiber optics or whatever, from my phone to Valerie's phone, is that fiber optic cable transmitting part of the lab.

CLIAC MEMBER: But if you send a specimen in a box to my lab, is the box a lab? Let's not go there.

CLIAC MEMBER: I just want to avoid the-- I just want to avoid this sort of what about-- I think is the most obvious, but what about box, or dropbox, or whatever your hospital certifies--

CLIAC CHAIR: But, again, I don't think CLIA has ever tried to regulate except from a safety and specimen integrity perspective, whether a box that you're sending us serum specimens in through the mail is part of your lab or not. I mean, I think maybe we can leave the absurdity out.

CMS EX OFFICIO: It would be acontainer

CLIAC MEMBER: It actually speaks to that in the regs, and says that it does not include that.

CLIAC MEMBER: Oh, really?

CLIAC MEMBER: Yes.

CLIAC CHAIR: So email is a box. I like it. Not to be confused with box, which I think is soon going to allow email. OK, so then, I've deleted the second bullet point. Unless there are exceptions to that. And folded it in through this parenthetical to the first. Is that--

FDA EX OFFICIO: I don't think it's a repository. Because when you-- if you look at the existing definition of the laboratory right now, if your facility is collecting and preparing specimens, or both, they're only serving as a mailing service and not performing testing, they're not considered a laboratory. So you have to be doing testing, I would think. They're not just holding data or moving data around.

CLIAC MEMBER: Right, you have to be doing something.

CLIAC MEMBER: Any activity associated with such data shall be considered a laboratory.

CLIAC MEMBER: And again, I think we really still need put point two. Because we really do, I think, want to be able to say that a pathologist who's reviewing specimens in their living room is, at that point, and in a meaningful way, part of the laboratory. And you have to validate that. His air conditioning system doesn't need to be in inspected, or her air conditioning system doesn't need to be inspected.

CLIAC CHAIR: So this is a fundamental tension with [CLIAC MEMBER] point earlier. Does looking at data that is held at a laboratory, make you, wherever you are looking at it, part of the laboratory or not. [CLIAC MEMBER] says no, you say yes. For the record, I say yes.

CLIAC MEMBER: I mean, I think we need to-- I think people need to be able to do that. That's a valuable, productive activity.

CLIAC CHAIR: Well, they can do that--

CLIAC MEMBER: Without having their own CLIA certification.

CLIAC CHAIR: Yeah, in both cases they can do it without having goddamn CLIA certification. In both cases, you're sitting there. It's the equivalent of me staring through the window at a lab, I guess. Or it's equivalent of me going to a lab.

CLIAC MEMBER: So let me just tell you what my idea is. I think it should be as a separate element and not under this category. The category, the current category up there is geographically decentralized information flow. So we can try to think about word smithing. Because it's information and interpretation kind of flows, each piece is doing something differently.

But what I think we should have is a separate issue. Where remote access allows folks to view things that are-- I don't how do to even write this. But a laboratory-- is the laboratory hosting all that information?

And with assurances that however you're accessing it, preserves the fidelity of how it originally looked. Whatever they issue you-- a phone, they give you computer specifications, whatever. And that's the only exception to this separate CLIA like system.

CLIAC MEMBER: Can I ask, [CLIAC MEMBER], how do you issue a report or your interpretation? Do you issue a report? Or is it all phone? And can we incorporate the word report into all of this?

CLIAC MEMBER: For what specifically are you talking about?

CLIAC MEMBER: When you were saying you were looking at cross sections of worms, et cetera.

CLIAC MEMBER: Oh, I mean, this is something that's been done by email for years as a formal collegial favor that we should really be billing for, but we just don't in our field.

CLIAC MEMBER: But is it a report?

CLIAC MEMBER: You can call it what you want.

CLIAC MEMBER: Do you think your results ever get put in a chart?

CLIAC MEMBER: Constantly, constantly.

CLIAC MEMBER: So it's a report.

CLIAC MEMBER: But it's not, it's an opinion.

CLIAC MEMBER: It's what?

CLIAC MEMBER: It's my opinion. If you want to put it in the chart, that's on you.

CLIAC MEMBER: Oh, well--

CLIAC MEMBER: Because you're not paying me for a service.

CLIAC MEMBER: It does get translated through another provider.

CLIAC MEMBER: And back to the point, when the CDC learned it, its reports, even though they weren't so-called regulated reports that were going into the chart, they had to be compliant.

CLIAC MEMBER: The fact is, people can send specimens to me and they'll pay for it. But, right now, they just get it for free. It's a dirty little secret that's not secret among the micro industry. But in the end, it's someone's opinion. And your name is on that result. There's no formal result. It's no different than having a beer with me, and me saying, you know, I think it's this, but do whatever you want.

CLIAC MEMBER: Right, but that-- I mean, there is a difference between somebody formally sending you an image in an email and say, I'd like your opinion on this, that goes back to a chart, and somebody putting a picture on Twitter, that you say, hey, it looks like this. Well, that's not going back into somebody's chart. So, to be honest--

CLIAC MEMBER: Yeah, are you practicing medicine?

CLIAC MEMBER: By email, I don't know if that's a formal test requisition, talking to someone by email. I would say no. I mean, if you show me an antibody panel from Quest and ask me for my opinion, good luck charting that. That's my opinion. I mean, the Quest generated, that was all you asked me for, my interpretation.

So I don't know. I think that's a tricky subject. I don't think I could ever be responsible for something that I in an email said I think it's this, but there's no result, there's no formal request. That's a whole area we just opened up that we probably didn't want to.

CLIAC MEMBER: Well, I'm sure it's not unique to microbiology. I'll bet you there are list serves where the anatomic people share images and say, what do you think this weird thing is, right? So, I mean there is an informal culture in everything, I suspect.

CLIAC MEMBER: The curbside consult.

CLIAC MEMBER: Yeah, the curbside consult, yeah, exactly.

CLIAC MEMBER: But, I just want to comment, you know, the Cleveland Clinic, Abu Dhabi study that I had in one of my slides, they went through the entire infrastructure that was necessary to assure fidelity of images. So, it's not just email. Here's a picture of my iPhone over the scope, and what do you think it is, right? It's like a formal way to get the right answers.

CLIAC CHAIR: Can I take us back to this second bullet point. And all I did is I just split it off of the first, as [CLIAC MEMBER] suggested. Because it occurs to me that it does not actually distinguish between the viewpoint that [CLIAC MEMBER] was describing and the one that [CLIAC MEMBER] was describing.

Because again, go back to that living room, where you're looking at-- you're looking at the image or sequence data, or what have you, from a CLIA certified laboratory. Nobody's just got that up on their computer for its artistic value presumably. The pathologist viewing it is taking some activity.

So just because the data is still in the laboratory, by this terminology, that I've got up on screen here, that still makes the living room the lab. So how-- so there are two things. The first is-- and this gets all the way back to [ADVAMED LIAISON] point about guidance on this point would be useful for lab a versus lab B, to know what are we to do.

So I think we do need an answer to it. So is a living room a lab or not? So [CLIAC MEMBER], if the person in the lab is doing something with this data, even though the data is on-- even just cogitating, coming up with some conclusion, typing something in, even though all of that activity is being piped back to the lab and recorded in the lab, the fact that the human is part of that information gleaned, information, of course, being material, ipso facto, the first point there, does that have to make the living room part of the lab? [CLIAC MEMBER] shaking her head no.

CLIAC MEMBER: I was just simply commenting this is the VA model. This is not a model I dreamed up. But that is their current model, that the human brain, even though it's living in a living room, is tied into that virtual desktop. And therefore, that license is with that central lab.

CLIAC CHAIR: So if we go back to [ADVAMED LIAISON] company-- not [ADVAMED LIAISON] company, but this hypothetical company that doesn't have a CLIA license, all it's got is the information, what if the information isn't actually sent to the company? What if the information stays at your CLIA certified lab.

And all that you are allowing that company to do is log in to see your data in the same way that I might from my living room?

CLIAC MEMBER: The data has to go into [INAUDIBLE]

CLIAC CHAIR: Well, but not necessary. Well, yes and no, right? Because then you can also have these-- so what would the-- I forget if it's the VA, it might be CMS, where you can get access to an awful lot of claims data, for example, but you can't download it easily. What you can do, though, is spin up an instance on their cloud, copy your program to their cloud, and although you're sitting at your computer, the program and the data are still in the same [INAUDIBLE] just not local.

In [ADVAMED LIAISON] increasingly hypothetical company, that's exactly what they do. They upload their software to [CLIAC MEMBER] cloud, where [CLIAC MEMBER] data lives and do their stuff. But by [CLIAC MEMBER] definition, they're still a CLIA lab. They're not getting out of it that easy. [CLIAC MEMBER], by her definition, they aren't a CLIA lab anymore because all the work is happening in your location.

CLIAC MEMBER: I'm lost in all the cloud analogies. I'm sorry.

CLIAC MEMBER: [INAUDIBLE] do that.

CLIAC MEMBER: No, but that--

CLIAC MEMBER: That's, right our firewall's

CLIAC CHAIR: So the hamster that's running our firewall won't let us either. But in principle, this seems to be at the crux of the issue. Because if the location where the human brain interacting with it is what you advise you deem a laboratory, then this kind of company would definitely be a laboratory and needs a CLIA license.

But by that same argument, the living room is a laboratory. I guess the difference is, in the living room, it's just [CLIAC MEMBER] going home at the end of a long day from his CLIA certified lab, to which he belongs, and simply is now an extension of that same lab. Whereas, [ADVAMED LIAISON] company is not an employee of your lab.

[INTERPOSING VOICES]

ADVAMED LIAISON: I think we may need to be amenable to the different meanings, if you add onto that second bullet, something to the effect of be it a unique laboratory or an extension of the originating laboratory, something along those lines. That allows for the [INAUDIBLE] into the laboratory system to view it, and not be a separate site, or a separate company seeing the data is a separate laboratory.

And I think, again, being just a recommendation to CMS or HHS, this long discussion being recorded is certainly playing into how we think about what this really means.

CLIAC MEMBER: And don't you want to clarify the data that is used to inform an actionable laboratory result? Because--

CLIAC MEMBER: In bullet point two, involving such data related to a formal laboratory result, or generating a laboratory result, because it's not just-- anybody can send a string of Ts and Gs, but if it's not going to be used to inform a laboratory clinical laboratory result, that's where the distinction comes in.

CLIAC CHAIR: And I'm going to ask you again, what was the terminology surrounding the use of the information for a patient something or other?

CLIAC MEMBER: Diagnosis, prevention, and treatment of disease was in the original.

CLIAC MEMBER: Or something else about other health conditions.

CMS EX OFFICIO: Assessment.

CLIAC MEMBER: The assessment of human health. Or assessment of human health.

CLIAC DFO: Providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

CLIAC CHAIR: All right, any site at which an activity involving such data is performed, provided that-- provided that that activity-- I'm going to parenthesize this, just because it's too many commas-- to the diagnosis. Provided the activities are related to the diagnosis, prevention, or treatment of any disease, or impairment of, or the assessment of the health of human beings.

CLIAC MEMBER: Yeah, that's what it says.

CLIAC CLIAC: Shall be considered a laboratory, whether that site is an independent laboratory or an extension of an existing CLIA certified laboratory site. Are we happy with bullet point two?

CLIAC MEMBER: Instead of "that that," can we say "that the"?

CLIAC CHAIR: Say what?

CLIAC MEMBER: That the.

CLIAC MEMBER: So as I read this, this means the living room requires a CLIA certificate, is that correct?

CLIAC MEMBER: I think it's--

CLIAC MEMBER It's an extension. It's an extension of your laboratory.

CLIAC CHAIR: Yeah it's an extension of a of an existing laboratory. I think I'm inclined to lean increasingly heavily as the hour draws near that the agencies will read the transcript.

CLIAC MEMBER: I'm not saying I agree or disagree with the extension of a laboratory by CLIA, does that mean I will get inspected?

CLIAC MEMBER: Yes.

CLIAC MEMBER: I think it doesn't. I think we're implying a lot about extension of existing laboratory. I mean, the laboratory is the hospital, histology lab, AP department. And they're assuming responsibility for anybody accessing that data as an extension of that lab, that there's data security, there's image fidelity, et cetera, et cetera. I think we're implying all that. That's a lot to imply. But I think that's what the intention was.

CLIAC MEMBER: Well, again, it had come out of some kind of draft rule. Have fun.

CLIAC MEMBER: Remember us fondly.

CLIAC CHAIR: Well, please noodle on whether there is some clarification or wordsmith thing that will simply and easily, Obviously, make your living room sacrosanct. But while we do that, and we've got plenty of time. So it's not like-- we don't have to vote on, we don't have to agree, so-- Bullet point three, what are thoughts?

CLIAC MEMBER: I wish I knew. I probably should. I probably--

CLIAC CHAIR: That's you. That was your point. Do you want to--

CLIAC MEMBER: Yeah, I think that's-- I think that's fine. HHS approved distributed PT models for non regulated tests. I think that's basically they either approve or they allow.

CLIAC CHAIR: Would you like to offer some verbiage around maybe describing the distributed proficiency testing? I mean when it came up for us, it was, well, it has to be-- it can't be bound by just open source stuff, I think, was your initial point. Can we clarify this or provide a little bit of context on this bullet point?

CLIAC MEMBER: Well, what we really want is them to-- well, that HHS not allow development of distributed PT models for non regulated analytes. I guess that would be allow development of the models so that we're not doing PT referral sanctions for trying to develop models. But would challenge the way samples are actually handled in a distributive model.

CLIAC CHAIR: Say that again.

CLIAC MEMBER: So I guess HHS allow the development of distributive PT models for non regulated analytes.

CLIAC MEMBER: I like allow the development of. That's much better than approve. Unregulated, you mean for the not-- not for the regulated analytes.

CLIAC MEMBER: Yeah, I mean that's another question we could say. Well, maybe there'll be a need for distributive model for a regulated analyte. The point of non regulated was, again, the CLIA only refers to PT requirements for regulated analytes. So these are things labs are doing voluntarily, and then they want to try to treat them like a patient sample. And then they get punished. So I think it's fine to do non regulated at this point.

CLIAC CHAIR: Is that an improvement? Nodding, yes? Any further thoughts about the living room? Capitalize the first word?

CLIAC MEMBER: Well, if I wanted to be extreme, you would take the final phrase, whether that site is an independent laboratory, comma, excluding extensions of an existing CLIA certified lab. And then we can haggle over what an extension is.

CLIAC MEMBER: Well then, whether needs to be whether or not, something.

CLIAC MEMBER: How about if that site is an independent laboratory site.

CLIAC MEMBER: If that site is not an extension of an existing CLIA certified laboratory.

CLIAC MEMBER: So delete all that, backwards. And so to the comma, laboratory.

CLIAC CHAIR: Yes.

CLIAC MEMBER: And what did you say, [CLIAC MEMBER] If that site is not an extension--

CLIAC MEMBER: Of an existing CLIA certified laboratory.

CLIAC MEMBER: Yeah. Can I wordsmith this bullet? We want absolutely the availability of PT for distributive testing models. We don't want to allow development. We want it. So I would reword this as HHS allow proficiency testing.

CLIAC CHAIR: But that's less of wordsmithing. I think it's—

CLIAC MEMBER: but HHS doesn't develop PT. HHS oversees it, but PT is developed by other, by CAP and others so they would provide the framework for it, bless it, provide guidance perhaps.

CLIAC CHAIR: But not oppose it.

CLIAC MEMBER: So actually, if we wanted a little more specificity, what we're asking is HHS allow CMS approved PT providers to develop--

CLIAC MEMBER: Or I wonder we should even say HHS will develop guidance for the development of. That way it's not whatever they want to do. Is that-- I mean, I defer to you guys on what we should do.

CLIAC MEMBER: Well, if the goal is we want to have some sort of PT that covers the whole test cycle even in the distributive model, why do we have to include HHS or the regulatory piece of how that gets-- how that happens? Why can't we just recommend we want PT covering the total test cycle in the distributive test model.

CLIAC DFO: Yeah, say that. If that's what you want.

CLIAC MEMBER: Instead it's HHS.

CLIAC MEMBER: And that gets back to what's the purpose of this conversation.

CLIAC MEMBER: It's the quality of the whole test.

CLIAC MEMBER: It's the quality of the cycle. And this is an integral part of it. So therefore, that's what we want to do, is improve-- is assure the quality of the entire process.

CLIAC CHAIR: So as currently edited?

CLIAC MEMBER: I think I got a second wind.

CLIAC DFO: I don't see that saying what you said.

CLIAC MEMBER: So I'll give it-- OK, so it starts with proficiency testing. So delete development of distributive-- proficiency testing covering the entire test cycle of the distributive workflow. We can wordsmith that later.

CLIAC CHAIR: Or words to that effect, thank you.

CLIAC MEMBER: Period.

CLIAC MEMBER: That's not a sentence. That needs a verb.

CLIAC MEMBER: Well, then help me.

CLIAC MEMBER: Yeah, it doesn't give a direction. I think we can do it one of two ways. We could have HHS develop guidance for how to do distributive PT for non regulated analytes, or we could have HHS allow CMS approved PT providers to develop those models. One option, you're saying rather than have the PT providers Carte Blanche to try things. If it's an non regulated and distributive model, you'd have HHS say here's how you can do this and not run afoul of PT referral.

So one option, HHS develops guidance, gives it to CMS, to approved PT providers, say here's how you could do this without running afoul. The other is HHS just says if it's not non regulated, you can do what you want. So I think we can go either way. HHS develops the guidance or HHS just allows CMS approved PT providers to do it themselves.

CLIAC CHAIR: So I'm liking the highlighted version on the screen right now, thoughts?

CLIAC MEMBER: That would work. It would accomplish, I think, what we want to do.

CLIAC MEMBER: I would recommend some sort of clause say to ensure the quality of the entire test cycle.

CLIAC MEMBER: Then I think-- I mean not to put words in your mouth, but much of the recent changes in PT have been not-- will have been not only to improve laboratory quality, but to decrease the likelihood of gaming and frauding-- defrauding PT. And I don't think anybody else is going to think about that as carefully as CMS is. And CMS is going to have to second guess them anyway. So you might as well start off by providing some guidance.

CLIAC MEMBER: OK, a little wordsmithing. The last bullet, HHS develop guidance to allow the development. Can we say HHS initiates guidance.

CLIAC CHAIR: I'm sorry, say it--

CLIAC MEMBER: Instead of HHS develop, can you say initiates? We're recommending that HHS initiates guidance to allow the development--

CMS EX OFFICIO: We wouldn't really initiate guidance. We would develop guidance.

CLIAC MEMBER: OK, I'm just seeing the word development twice, and its making me--

CLIAC MEMBER: Well, we could do-- we could put the develop back-- HHS develop guidance to allow distributive PT models. So take out the second development.

CLIAC MEMBER: And do you really care about the non regulated? Because remember, we're having distributive CDC interpretations today. Somebody is taking pictures and shooting them somewhere else. And

those are regulated. So to allow distributive proficiency testing models to assure quality across the whole testing cycle.

CLIAC CHAIR: How about that?

CLIAC MEMBER: No, I would delete that phrase.

CLIAC CHAIR: We felt a bit strongly about it earlier. What does the rest of the committee think? The fate of this clause is in your hands.

CLIAC MEMBER: And don't forget the SPET model, where the albumin and the total protein are regulated and the rest is not. But that's part of the--

CLIAC MEMBER: Well, we ask these questions all the time. So CLIA, the law, requires PT for regulated analytes, and then there are regulations about that. And so how much of this-- I think for non regulated, and then CMS has made it-- HHS and CMS made an interpretation that CSS approved providers, they can regulate how they do PT for non regulated analytes. So how much-- we get into those questions, is it-- it's an interpretive question about allowing distributive for non regulated, but would require a legislative or other change to change how we're handling the PT for regulated analytes. That gets to be the tricky question.

CLIAC CHAIR: I'm inclined to leave it as it is. They are different enough things that they deserve separate mention, at least to remind CMS that we've thought about it. Even though the ultimate goal, direction is the same. So with that said, I would entertain a motion to vote, now that the living room is under control and all kinds of other things.

CLIAC MEMBER: There's a fire in the kitchen.

CLIAC MEMBER: I move we accept the recommendation as written.

CLIAC CHAIR: Is there a second?

CLIAC MEMBER: Second.

CLIAC MEMBER: There's a second. All right, all those in favor? On the phone? OK, nobody on the phone. All those opposed? Any abstentions? All right, so recommended. All right, everybody, I feel like even though we've still got-- we've still got a little time, and we could use that, I feel like this afternoon's discussion was especially intense. So what I will say is if there are additional points that people want to discuss, and remember the time is yours, including for discussion of possible topics for next time, I will entertain that. But if people are of the opinion that we pat ourselves on the back and adjourn a couple minutes early for dinner, I would also entertain that.

CLIAC MEMBER: I've been asked to let everyone know who is going to our dinner this evening that several of us do have cars. And so if you'll meet out at the front, we can all write together. And we'll get Ubers for anyone that we can't fit in. And I want to thank Heather for arranging the dinner.
CLIAC CHAIR: Thank you, Heather. Yes, you're here. Sorry, that's leaving from the front of this building, not the hotel. Very good. So dinner it is then. All right, so let us break for dinner. And see those of you who we'll see at dinner at dinner. And everybody else, tomorrow morning, bright and early. Thank you.

April 10, 2019

Call to Order/Roll Call

CLIAC CHAIR: I'll ask committee members to take your seats, and we'll get started on our second day. Thank you all for a wonderful and exciting set of discussions, very productive, fruitful set of discussions yesterday. Sorry, we still have music-- no, excuse me, that's something else. So thank you all for an exciting and fruitful and productive yesterday, and I have every confidence that today will be just as exciting.

I'll start with just a few remarks. So members are, again, reminded that it is important to remain in attendance for today's full meeting to ensure a quorum, until all matters before us are addressed and the meeting is adjourned. I will do my best to make sure we get out on time, as I know that a lot of people have flights very soon after. If you have a flight that you need to leave for, please just get up and leave discreetly, and that'll be fine.

If anyone in the audience wishes to address the committee, the public comment periods are as noted on the agenda, and they are the proper forum to do so. I might switch those two ahead of the introduction, as I did yesterday. Are there any public comments-- show of hands, please-- not already acknowledged yesterday? One.

CLIAC DFO: Two.

CLIAC CHAIR: I don't see the second-- where is-- oh, I see. Two. Thank you.

CLIAC DFO: We are scheduled to go until one o'clock today. We do have a planned morning break. As a reminder, copies of all PowerPoint presentations and other media materials are posted on the CLIAC website. Also, as a reminder, the meeting is being webcast and audiotaped to system prepare an accurate and written summary of the proceedings. We ask that when you speak, please speak into a microphone at all times.

Information for accessing the webcast is available also on the CLIAC website. We also ask that all sidebar conversations be restricted to outside the meeting room and you silence your cell phones. We need to now do roll call.

CLIAC CHAIR: Sure. So, Sheldon Campbell?

CLIAC MEMBER: Here.

CLIAC CHAIR: Marc Couturier.

CLIAC MEMBER: Here.

CLIAC CHAIR: Keith Davis is not in attendance. Susan Gross is on the phone, I believe? Do we have anybody on the phone?

CLIAC MEMBER: Yes, Susan is on the phone.

CLIAC CHAIR: Oh, fantastic. Nice to see you, Susan.

CLIAC MEMBER: And hi, good morning. Jordan Laser.

CLIAC CHAIR: Oh, it's Jordan. Thank you.

CLIAC MEMBER: Good morning.

CLIAC CHAIR: Morning. Lee Hilborne?

CLIAC MEMBER: Here.

CLIAC CHAIR: Steve Hendrichs?

CLIAC MEMBER: Here.

CLIAC CHAIR: Brad Karon?

CLIAC MEMBER: Here.

CLIAC CHAIR: Tom Lorey?

CLIAC MEMBER: Here.

CLIAC CHAIR: Sharon Masingale?

CLIAC MEMBER: Here.

CLIAC MEMBER: Here.

CLIAC CHAIR: Helen Mills?

CLIAC MEMBER: Here.

CLIAC CHAIR: Valerie Ng?

CLIAC MEMBER: Here.

CLIAC CHAIR: Katherine Perez?

CLIAC MEMBER: Here.

CLIAC CHAIR: Bonnie Rubin?

CLIAC MEMBER: Here.

CLIAC CHAIR: Greg Sossaman?

CLIAC MEMBER: Here.

CLIAC CHAIR: Cynthia Wilkerson?

CLIAC MEMBER: Here.

CLIAC CHAIR: We have everybody who's on the phone, right? OK. Donna Wolk?

CLIAC MEMBER: Here.

CLIAC CHAIR: Andy Quintenz?

ADVAMED LIAISON: Here.

CLIAC CHAIR: Ren is here. CDC EX OFFICIO?

CDC EX OFFICIO: Here.

CLIAC CHAIR: CMS EX OFFICIO Dyer?

CMS EX OFFICIO: Here.

CLIAC CHAIR: Peter Tobin?

FDA EX OFFICIO: Here.

CLIAC CHAIR: Nancy Anderson?

NANCY ANDERSON: Here.

CLIAC CHAIR: Fantastic, thank you all.

Recognition of Outgoing Members:
• Dr. Ramy Arnaout
• Dr. Sheldon Campbell
• Ms. Helen Mills

CLIAC DFO: So it's my pleasure to recognize our three outgoing members at this time. And the first to be recognized is Ms. Helen Mills. Ms. Mills' experience in the nursing field and as a nurse educator contributed a unique perspective for many of the issues that CLIAC has discussed over the past four years.

She's provided the educator's viewpoint during the CLIAC discussions on waived testing, the clinical laboratory workforce, laboratory quality, and laboratory data usage among many other topics. Ms. Mills also volunteered to serve an important role as the CLIAC social chair, coordinating CLIAC dinners-- which is much more difficult than probably she ever anticipated.

[LAUGHTER]

We appreciate her serving in that capacity and thank Ms. Mills for her service to the committee and just really appreciate her overall very friendly and happy demeanor. And she's brought a lot of light to CLIAC, so we'd like to recognize Ms. Mills for her contribution at this time.

[APPLAUSE]

Our second outgoing member is Dr. Sheldon Campbell. Dr. Campbell's experience as a clinical pathologist and medical microbiologist in the VA health care system provided a valuable perspective to a variety of CLIAC discussions. In addition to his commitment to the committee, Dr. Campbell served as the CLIAC liaison to the CDC's office of infectious disease board of scientific counselors, which helped to ensure that the voice of the clinical laboratory was represented during the BSE discussions. Serving in this capacity also brought important information back to CLIAC through periodic updates.

We thank Dr. Campbell for his service to CLIAC and his contributions to many discussions that resulted in CLIAC recommendations on laboratory-- in particular, on laboratory biosafety and quality. Sheldon has been a fantastic member of the committee, a great friend to many of us. And he has a way of contributing really insightful remarks to our discussions. And he's just been a wonderful friend and a great colleague.

So thank you, Sheldon. And what we would like to do-- and what Sheldon has agreed to do-- at his last meeting at the CLIAC is to perform for us. We should be performing for him, thanking him, but he's asked to play some guitar and sing a song. So Sheldon, the floor is yours.

SHELDON CAMPBELL: My mic isn't working, so can you hear me?

AUDIENCE: Yes.

SHELDON CAMPBELL: Good. I've been singing songs about microbes for medical students for many years. I started with (SINGING) oh, give me a home where the parasites roam, where the worms play in cheerful delight.

And it's kind of gotten out of hand.

[LAUGHTER]

I have songs about test validation, verification, and quality control, point of care coordinator blues, drugs and abuse testing blues. But this is one that I did relatively early on. And the tune is by Stephen Foster-- always acknowledge the songwriter. And it is a sing-along. So I'm going to [? turn ?] the chords and I'm going to expect people to sing along. If you don't want to be heard, just back away from the mic.

[LAUGHTER]

[MUSIC PLAYING]

(SINGING) Tis the song of the immunocompromised. Fungi, fungi, come again, no more. Too many antibiotics and other drugs I've seen, oh [? fun ?] John, come again, no more.

So that's the chorus. Tis this song if the immunocompromised. Fungi, fungi, come again, no more. Too many antibiotics and other the drugs I've seen, oh fungi, come again, no more.

That'll come around several more times. You'll have a chance.

[LAUGHTER]

And now, I have to remember the first verse. I know what organism it's about but I don't know how it starts.

(SINGING) There's a pale grouping-- no that's the second verse. Oh no. Well, I'll start on the second verse.

[INTERPOSING VOICES]

(SINGING) There's a pale grouping maiden who's glucose is too high so her blood pH has fallen through the floor. And she cries as the [INAUDIBLE] grows behind her weeping eyes. Oh fungi, come again, no more. Tis the song of the immunocompromised. Fungi, fungi, come again, no more. Too many antibiotics and other drugs I've seen. Oh fungi, come again, no more.

There's a man from Indiana with T cells gone astray from a needle whose better days were over. There's still plasma in the marrow makes him feverish all the day. Oh fungi, come again, no more. Tis the song of the immunocompromised. Fungi, fungi, come again, no more. Too many antibiotics and other drugs I've seen. Oh fungi, come again, no more.

In the unit lies a woman who buy-a-truck was rent and after six weeks of [INAUDIBLE]. And a dog is growing in her from the [INAUDIBLE] event. Oh fungi, come again no more.

Tis the song of the immunocompromised. Fungi, fungi, come again, no more. Too many antibiotics and other drugs I've seen. Oh fungi, come again, no more. Oh, fungi, come again no more.

[APPLAUSE]

CLIAC DFO: OK. And the last person we need to recognize is our chair, Ramy. So I have both a paragraph to read and then a few slides to show. We do a little extra for our chairs because we ask a lot of our chairs.

We're grateful to Dr. Arnaout for his service to CLIAC and excellent leadership of the committee. His diverse experience in clinical microbiology and pathology allowed him to provide thoughtful insight and critical input on many topics during his first year as a committee member and subsequently, almost three years as a chair. Dr. Arnaout has led the development of numerous recommendations on a variety of topics, including informatics, laboratory interoperability, the role of the laboratory, and improving diagnoses and the opioid crisis. Thank you Ramy for your time and important contributions to the committee.

So he's been a chair for five meetings from November through April of this year-- November 2016 through April of this year. And he said this yesterday-- I don't know if anyone caught it-- but he definitely set a record for CLIAC recommendations. And under Ramy's leadership I think-- and a few people confirmed this for me last night-- is the CLIAC has really moved from a body that discussed lots of important topics and had interesting meetings to a body that has become much more focused on identifying specific issues that the government needs assistance with and providing very specific recommendations that have persuaded the government to move in certain directions.

And so these 19 formal recommendations-- and that was prior to yesterday and prior to today. so the 19 was already a record, so whatever we're doing today is just adding to that record. And so it's just a very impressive, very focused and goal-oriented approach to CLIAC, which we are extremely grateful for.

I mentioned some of these already, but I have two slides. I won't read them all. But not only has CLIAC over these last three years pushed out a number of recommendations is that the scope of the topics of these recommendations is extensive.

So from communication to interdisciplinary health care teams to specific interventions by the laboratory community to reduce diagnostic error, a number of recommendations on a variety of interoperability topics, a

recommendation on increasing the amount of funding intention to autopsies, the need for a non-punitive confidential system for reporting laboratory associated biosafety incidents and infections, the impact of culture independent diagnostic tests on public health surveillance, the need for a specific laboratory workforce analysis and report, new approaches to laboratory workforce shortages-- and these specific three workgroups that we're now spending this meeting focusing on.

I think CDC EX OFFICIO mentioned this yesterday, but I'll highlight it. Never before has CLIAC held three specific groups and reported on the results of those workgroups between two subsequent meetings-- between a November meeting and an April meeting or an April meeting and a November meeting.

So previously, our standard was to not do more than one workgroup at a time. And so reflecting on sort of the drive of Ramy and CLIAC now, we pushed out three-- and thanks to all of you-- three workgroups and three very substantive reports over the last six months. And much of the credit is Ramy's for that.

So not only all these recommendations, but a number of specific outcomes-- and again, this is just since November of 2016 which is really not that long ago considering how long CLIAC has been around and how long CLIA has been around. So in addition to the three CLIAC groups, as a result of CLIAC CDC cosponsored a major international forum on culture independent diagnostic testing-- a significant improvement of engagement of laboratory professionals with various federal and national interoperability initiatives, a significant increase in the engagement of all three agencies in working to strengthen clinical laboratory safety, and most recently ensuring that all three agencies take an active role in the brand new federal interagency workgroup on improving diagnostic safety and quality.

So significant outcomes and significant work by Ramy-- and not only outcomes, but I think we all really appreciate the way that you run these meetings, how you engage us both in terms of ensuring that we finish and complete specific recommendations but also, the way you engage us on more substantive higher level intellectual topics such as yesterday afternoon's discussion was.

So thank you Ramy. We're very grateful to you and we really appreciate your dedication and the work that you've put into CLIAC. And we want to assure you that all your work has been well recognized and much appreciated. Thank you.

[APPLAUSE]

But for you, we have a small token of our appreciation as well as our standard certificate.

[APPLAUSE]

RAMY ARNAOUT: Well thank you Helen, Sheldon and Ren for that very, very touching presentation. I'm full of gratitude. I'm trying to decide whether to say this now or to hold off to the end. Maybe I'll say it now because toward the end, everybody will be rushing off.

You know, I feel after those comments that the conductor or the orchestra often gets an awful lot of credit. But the conductor is nothing without the orchestra. It's all of you and the committee members who have come before and rotated off who have-- in my eyes-- really done all the work. You make my job very, very easy. Wren talked about all of the recommendations that we've made. Those recommendations weren't my recommendations, they were our recommendations or your recommendations.

And the content and the journey to get to the content of those recommendations is impossible without all the time and effort and attention and energy that you all put in in these discussions we have. The groups especially,

I did not do those. So thanks especially to the leaders of our workgroups, to everybody who's participated in them. You all are the committee. You all have made this exciting and enjoyable for me and hopefully, for each other.

And I wish everybody the best of luck and am confident that the committee will do just fantastically in coming meetings, first under the leadership of Dr. Valerie Ng who will take over for me as chair, and in subsequent meetings. And I'll be eagerly tuning in and WebExs and looking at the transcripts and following the progress.

This has been a lot of fun for me, personally. I thank Bill McKenzie and Ren and staff for the opportunity. I'm trying to figure out where in the analogy of the orchestra the staff goes in. But until you are a chair, you have no idea how much of what I do is really just the staff kind of feeding me the appropriate stuff to say and do.

Heather, Nancy, others-- our ex-officio members-- do a fantastic amount of work behind the scenes. And you know, we are all the kind of people who are sometimes affectionately-- sometimes not so affectionately-- termed as the subjects of the herding cats statement. So that's what staff has done, done so ably, and continues to do so expertly. So thanks to everybody. Thanks to CMS for hosting us and to FDA and CDC for hosting us previously. And gosh, I feel like it's an awards ceremony acceptance speech. But really, just give yourselves all round of applause before we get on with the day's work.

[APPLAUSE]

Next Generation Sequencing Workgroup

CLIAC CHAIR: So with that, the topic of the rest of the day is the workgroup report from the next generation sequencing workgroup with a brief introduction by Dr. CDC EX OFFICIO Fitzgerald.

CLIAC DFO: Do you want to follow the path we followed yesterday?

CLIAC CHAIR: Yeah. You know, let's do the public comments first. So maybe we'll have the two public comments.

Public Comments

CHRISTIN HANIGAN: Good morning. My name is Christin Hanigan. I'm the senior specialist for advanced molecular detection from the Association of Public Health Laboratories. APHL is a member organization that works to strengthen laboratory systems serving the public health and US and globally. Our members protect the public's health by monitoring and detecting infectious and food borne diseases, environmental contaminants, terrorist agents, and genetic disorders in newborns and other diverse health threats.

We appreciate this opportunity to comment on the next generation sequencing workgroup report. And yes, technology has been utilized for our many different applications from infectious disease characterization to genetic disorders to cancer genomics. Our member laboratories are moving to use this technology for infectious

disease detection, characterisation, and surveillance, and newborn screening. Any guidelines, requirements, or regulations must account for the diversity of genomes being sequenced and the variety of NGS applications.

This report reflects the unique challenges and considerations around NGS. The report thoroughly addresses the challenges related to human genetics, including those that may be relevant to newborn screening-- an important program of APHL Member Laboratories. While it includes references to the unique challenges inherent of NGS of microbial organisms, we would like to emphasize differences between microbial and human NGS related to quality assurance, quality control, validation, data management approaches, as there may be deleterious consequences for the work of public health laboratories if these differences are not accounted for.

The points we would like to highlight are delineated as below. The workgroup recommended that the validation be driven by the use case in the test of the clinical context. We'd like to emphasize this as unlike the testing for human genetic disorders and cancer, there are often no commercially available or gold standard materials for some microorganisms.

There was a recommendation to use standardized and commercial PT programs. This would not be feasible for many infectious diseases as no commercial test is available. The workgroup did note the need for more my microbiology NGS PT. But this lack of commercial test and widely available standards should be noted when making any guidelines or regulations around PT.

Also in reference to validation and PT, we appreciate the workgroup noting that an all-inclusive guideline is challenging as there would be a fear of it being too prescriptive. Our members would welcome guidance, but hope it would be flexible enough to accommodate not only the differences in human versus microbial genetics, but also account for the differences in the diversity of microorganisms tested by our member laboratories.

Within QA and QC, it is noted that some of the metrics need to be organism specific and experience is needed to define these metrics. We concur that beyond the delineation between human and microbial genetics, flexibility and allowances for differences within microorganism is imperative. The workgroup posed the question of whether laboratories could utilize the individual quality control plan, ITCP, to determine the proper amount of QC needed. And our members also concur with this suggestion.

The lack of clear guidance around bioinformatics was noted in these findings. This aligns with the public health lab's experiences in microbial genetics. The report noted that there needed to be harmonization and curation of databases. These databases often determine the output of the bioinformatics pipeline and the lack of harmonization and databases or specifying which databases are being utilized remains a challenge for microbial genomics.

Data management is a substantial challenge that results from the amount of data generated by sequencing. Data retention policy-- including which files should be kept and for how long-- should take into account the different type of organism. Given the differences between genetic testing around human versus microbial samples, any guideline or regulation around data storage should take into account these differences.

The report states that the guidance regarding what files to store raw versus processed versus intermediate files. We would also like to emphasize this point, taking into account around the policies and procedures for re-analysis of any overall data be given the updates of the software code and the database changes that may occur.

Bioinformaticians are our new segment of laboratory workforce. And as stated in the workgroup summary, there are no personnel requirements for bioinformaticians as the current CLIA personnel requirements do not fit into the clinical bioinformaticians. If regulations are added regarding these bioinformaticians, the definition of a bioinformatician should be examined. Particularly as in a public health laboratory staff who wear many hats,

some may review analytical outputs and interpret the data even if they are not responsible for the creation of the analytical pipelines. We thank you for this opportunity.

CLIAC CHAIR: Thank you. Can we have our second comment, please?

GLEN FINE: Good morning. My name is Glen Fine from the Clinical and Laboratory Standards Institute. And just moving off script for a second, that if Dr. Campbell wants to make a song out of this three minute introduction, CLSI will donate it royalty free.

[LAUGHTER]

The Clinical Laboratory Standards Institute-- CLSI-- is a US based fully accredited not for profit standards development organization in the field of laboratory medicine. Our standards and guidelines are developed through a highly structured, open and inclusive voluntary consensus process that balances stakeholder participation and approval among government industry and health professionals.

For over 50 years, CLSI has been creating and revising the standards and guidelines that drive quality test results, support regulatory and accreditation requirements, and improve patient care globally. CLSI offers a number of consensus guidelines for molecular diagnostic methods, including infectious disease identification, [? ontological ?] applications, quality management, and proficiency testing. CLSI also publishes guidelines on specimen collection, transport, preparation, and storage.

Of note, CLSI is currently revising our document MMO9 nucleic acid sequencing methods in diagnostic laboratory medicine. This revision will be titled Human Genetic and Genomic Testing using Traditional and High Throughput Nucleic Acid Sequencing Methods and will focus on next generation sequencing NGS. In particular, the guideline will describe how to perform activities in the NGS testing lifecycle including test design, optimization, validation, as well as cover quality management. NMO9 will provide necessary guidance for industry and laboratories to implement current best practices and facilitate standardization of NGS test development and validation procedures.

In addition to providing guidance that can be formally recognized and used by regulatory organizations such as the US FDA, the revision of NMO9 will harmonize US test best practices with global standards. Molecular diagnostics is one of the most rapidly developing disciplines in laboratory medicine and CLSI has specifically identified NGS as a high focus area, and no doubt is likely to be one for CLIAC for the foreseeable future as well.

CLSI is pleased CLIAC has commissioned the next generation sequencing workgroup and eagerly looks forward to evaluating its output as a resource for consensus guidance that will improve laboratory medicine and practice and patient care globally. Thank you.

Introduction to Topic
CDC EX OFFICIO Fitzgerald, PhD

CLIAC CHAIR: Thank you. So now, Dr. CDC EX OFFICIO Fitzgerald will give us a brief introduction to the NGS workgroup.

CDC EX OFFICIO: Good morning, everybody. The committee will be pleased to know that I will not be singing this morning.

[LAUGHTER]

A next generation sequencing session was held at the Spring 2018 CLIAC meeting. Dr. Ira Lubin, Ms. 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. CLIAC made the recommendation to form the NGS workgroup.

We want to say huge thank you to Dr. Jordan Laser who chaired the NGS sequencing workgroup. We also thank the workgroup members for sharing their time and expertise at the meeting. There were 22 subject matter experts on the workgroup. Members represented a diverse range of expertise, including heritable oncology and infectious diseases, different laboratory professional organizations including the American Society for Microbiology, the Association of Pathology, accreditation organizations, commercial laboratories, public health laboratories. There was a consumer patient advocate and industry also participated on the workgroup.

The workgroup was given 12 questions to frame their deliberations. And their charge was to provide input to CLIAC in developing recommendations to CDC, CMS, and FDA for assuring the quality of next generation sequencing based testing in the clinical laboratory setting. Dr. Laser's energy and enthusiasm for the topic area got the workgroup through all of the questions during the in-person meeting on January 16th and 17th of this year. A lot of ground was covered those two days.

There was some common themes that were discussed here yesterday in the personnel and the nontraditional testing workflow model discussions, so I'm going to hand it over now to Dr. Laser who's going to be providing the workgroup update report. And I'm hoping Dr. Laser is connected.

Next Generation Sequencing Workgroup Report
Jordan Laser, MD

CLIAC CHAIR: Yeah, Dr. Laser is joining us by phone. And for those following along, these are presentations 8 and 8A. Thank you, CDC EX OFFICIO. Jordan, are you with us?

DR. JORDAN LASER: Hello?

CLIAC CHAIR: Hello. Can you say a few words? We're trying to gauge the quality of the line.

DR. JORDAN LASER: OK, you can't hear me right now?

CLIAC CHAIR: We can hear you. I think you might be forced to enunciate very clearly. The line isn't the clearest.

DR. JORDAN LASER: OK. But [INAUDIBLE] please let me know. I can probably dial in on another line.

CLIAC CHAIR: Yeah. Jordan, actually just even from that, I think maybe you could dial in from another line. I don't think we're going to be able to understand everything you have to say on this line.

DR. JORDAN LASER: OK, give me one second. I'll take of it right now.

CLIAC CHAIR: Sure, we'll play some elevator music.

[LAUGHTER]

Dr. Campbell?

[LAUGHTER]

SHELDON CAMPBELL: I don't do elevator music.

CLIAC CHAIR: We're happy to wait a minute.

[WHISTLING]

HEATHER STANG: So I'll make a brief statement about travel reimbursement. So travel-- since we're all seasoned CLIAC members now and we don't have any new members-- it'll be just like last time. I'll send an email out. You don't need to complete a form or anything. Just send me your receipts. Of course, no receipts for dinner so just any Uber, Taxi, Lyft fares that you incur, even if you did it for dinner-- since there is not a restaurant in the hotel, the dinner is taken care of. And then hotel, if you checked a bag, all the standard receipts. We'll get an email, get that sent, and we'll reimburse you as soon as possible.

CLIAC CHAIR: Thanks, Heather. Sorry Jordan, say again?

DR. JORDAN LASER: Is it better?

CLIAC CHAIR: I think so. I apologize for the micromanagement here. Can you get a bit closer to the microphone and we'll see.

DR. JORDAN LASER: Yes, I'm right on top of it.

CLIAC CHAIR: Fantastic. I think this will be fine. Again, just bear with us on our end. Our audio is not the best in the room. So maybe just extra slow, extra careful just for our benefit. You can't hear what it sounds like in here, but that would benefit us.

DR. JORDAN LASER: Absolutely. And if you need to, just please feel free to drop in. So I apologize for the faulty start but thank you CDC EX OFFICIO for the introduction. And you shared some of the insights from the workgroup already, so I do appreciate that. That's a nice background.

So again, I'm Jordan Laser. I'm the workgroup chair for the next generation sequencing workgroup. And as CDC EX OFFICIO just said, we had a really wonderful diverse group of volunteers going in day and a half session to talk to 12 questions. So here they are again. I want to thank them all for their participation and their wide breadth of expertise they were able to share.

Equally if not more importantly, I'd like to thank all of the HHS workgroup members and the subject matter experts. Certainly without all of them, this event could not have taken place. And they are the reason it was very successful so again, I want to give a very special thank you.

So CDC EX OFFICIO did go through the charge already. The only thing I wanted to add was this specific workgroup task which we were to accomplish is to identify the challenges of applying the existing regulatory framework. Identify the challenges and gaps and to suggest strategies to address these gaps and challenges, and

finally to suggest strategies for assuring workforce confidence. So again what was previously mentioned, there's some significant overlap with some of the presentations from yesterday.

So I'm going to go through the questions one by one. And before I do, I just want to give a little background. It was a day and a half session. It was truly action-packed. And it was reported in the workgroup report and there is a 20 page report that has been provided to everyone and is available online. That is the distillation of the conversation that occurred over that day and a half. This presentation is a distillation of that discussion. So we really did cover a tremendous amount of ground. And these are the hot topics that followed up for a 30, 40 minute presentation.

With that also, you'll see throughout the slide deck, I have work clouds. So the work cloud is our beautiful way of presenting some of the key features of the conversation. And the larger the word, the more times that word was said. And some of these words clouds really nailed the conversation beautifully. Some you'll see were a little less contributory. But I'll comment on it as we go through.

So with that, I will move on to the first question. Then, we'll start going through them so the question number one, what consultation or other assistance does the laboratory provide to help clinicians order the appropriate test for that patient? So again, here you see the word cloud. We have them enlarged for those of you who may have the slide deck on your computer or printed out.

And one of the main ways in which laboratories for this workgroup has spoken about laboratories can assist providers-- the first level was the directors providing the advice directly, either typically through phone conversations in order to be able to order the correct test. So of course, we recognize with a modality when the provider typically initiated contacts and helped with what test was appropriate. And so in one way, this is somewhat unilateral. And in another way, the question about capability was also something that was discussed in terms of providing that level of consulting.

Many laboratories also have hired genetic counselors. Genetic counselors as you may know are educated individuals in genetics and genomics and frequently are employed by laboratories to provide this level of support in terms, I did here to the workforce that consists of client services. Many laboratories do have client services. Their educational background tends to be less genetically advanced than maybe the director or the genetic counselors themselves. And they typically are referring to tech compendium and clinical interpretation that may be published or online.

From a support perspective, we really felt that support from the laboratory to providers is critical. We recognize that many of the providers practicing these days were trained in pre-genetic and pre-genomic effort. And providing a level of education and support is absolutely critical to make sure that the right patient gets the right test at the right time.

Also, the operation surrounding genetics and genomics has become increasingly challenging over the years as payers have initiated requirements for prior authorization. The agents have been asking for benefits investigations about out-of-pocket expenses. And a [INAUDIBLE] to laboratories provide that level of operational support in terms of provided information to the patient. Of course workgroup brought up a conversation-- this is obviously very resource intensive. And we were discussing some of the implications for small laboratories who may not have the same level of resources as larger laboratories.

[BACKGROUND COUGHING]

At this point in the conversation, switch to an interesting topic-- making sure that everyone understood the difference between medicine and between diagnostic yield. Checking the perfect setting that you

[INAUDIBLE] is where clinically you [INAUDIBLE] the ability for a to change [INAUDIBLE]. Diagnostic yield is frequently referred to as the hit rate of tests. So the percentage of time that the test will be positive.

And a perfect example to describe the difference between a child in NICU say with a [INAUDIBLE] medical genetics is involved in a very big sense of what may be going on with this child. There are [INAUDIBLE] some sequencing where in that particular setting, the diagnostic yield may be as high as 80%. However, the clinical utility tends to be significantly lower because, again, the medical genetics professional's involved. And the necessary change the amount [INAUDIBLE] may not be as attractive.

And the alternative circumstance where, again, a child in NICU does not necessarily have plastic or [INAUDIBLE] easily recognizable dysmorphic issues. And while the diagnostic view [INAUDIBLE] some deeper thing in that Maybe it's [INAUDIBLE] and the [INAUDIBLE] that. The clinical utility of such a result will be significant because in the absence of upfront expectation or anticipation of a genetic disorder, this type of result would drastically change the patient's clinician.

So in terms of a needs perspective, a standard definition that is based should itself be very important. And where location, location, location is what's critical in real estate, for genetics and genomics it's education, education, education.

So, discussing question number two, quite similar. In consultation that the laboratory provides is understanding the NGS based test result. The bottom line here is a little bit sparse right? So, I think it reflects that the conversation was less rich, largely because you'll see that a significant amount overlaps during question one and question two.

So again from the personnel perspective, a lot of the systems in interpreting or applying the result is that the director, the CEO or PhD, with or without boards also can contribute to the interpretation of these results. However, once the [INAUDIBLE] are in session that the scope of practice of genetic counselors was previously defined by state regulations and law. So, they may not be able to do all of the same work depending on the state in which they reside or are employed by. And this also becomes an issue for laboratories that have clients and/or patients that are from multiple states.

From a methodology perspective, phone calls being the most common. This is both a proactive and the reactive state. The reactive state is perhaps the provider calling up the laboratory and saying, hey I need some help interpreting this result. Proactive is more along the lines of the laboratory proactively reaching out to providers for the annual results. Many laboratories also provide online resources. Again, I mentioned test menus that could be published online. And many of them include clinical interpretation, diagnostic algorithm, indications for this particular test. So there are some significant online resources, as well.

This last methodology is really probably more focused towards the hospital-based or institution-based laboratory. But limiting the interdisciplinary style of the will be frequently known as genome boards. This can also be applied in the setting of inheritance and genetic testing, where again the interdisciplinary groups can get together to review the results and talk through management decisions, et cetera.

But of course the primary method in which we convey results and interpretation is by our report. And maybe the genetic and genomic tests are very complex. And as a result the reports can be upwards of 50 pages long. And there was a good conversation about the first page, about that if it's not on the first page, it's not going to make sense. So then, it's critically important to remember and consider that first page phenomenon and make sure all of the critical information that can be provided is put on that first page.

In addition to that, many of these tests are considered esoteric. And in the world of electronic medical records, many of these tests are not interfaced. As a result, these providers, their typical workflow is that they receive these reports either by email or fax, snail mail. And there's some front office staff that typically ends up scanning them into the EMR and tasking it to a particular provider to review.

It's well known that there are lots of technicality in some of that information throughout the process. Again, largely related to the fact that some of these reports are very long. And frequently only that first page gets scanned into the report into the EMR. Why that's important is usually on the second page and beyond is where some critically important information it gives in terms of performance characteristics and tests of the patient.

So question number three, what are the challenges with developing and performing NGS test validations. As you can see here, this is a very rich conversation. Importantly, in terms of validation, there are some guidelines that are available, However, the group clearly felt there was a need for more. That was discussed yesterday with the typical NGS analytical process include the both wet and dry components. The wet being a laboratory sequencing main component. The dry being the bioinformatic pipeline. To be complete the guidelines should encompass the entire analytical process to get involved with wet and dry.

And next generation sequencing has a methodology. That was something else. It's important to remember that NGS is a method, not a test. And these are complex tests that are recently viewed as complex tests. As our medical knowledge base changes over time and technology improves over time-- in terms of being able to identify different types of various guidelines surrounding, what are the triggers for revalidation? What does revalidation look like? Do you only need to validate what you've added to the test or do you need to go back and revalidate the entire test? So to me a lot of questions in terms of guidelines or needs in terms of guidelines in that revalidation phase.

Performance characteristics, again our group has identified stages. And they need to be determined and fully and clearly communicated to those that are using these in clinical care. Again referring to that first page phenomenon.

We also recognize very quickly that while the important characteristics are really fine because you use challenging specimens to really challenge this test and challenge the methodology, due to a general paucity of challenging reference material and commercial material to be able to really put the performance characteristics, it's hard to really, again, determine the extremes of those performance characteristics. And it was just mentioned again in the public comments, and obviously we think we agree, in the event that the methodology, the tests, the application is very specific and therefore the performance characteristics should also be application-specific as well.

In terms of performance characteristics where the very clear definition of what this has to test, I think probably equally if not more importantly, what the test does not test should be included in what those limitations of that test say offers.

And given the complexity of this methodology, the oversight by experienced professionals is obviously critical. Many laboratories in the-- there are many laboratories in the United States that use next generation sequencing methodology. And testing expertise is needed. There are many well-qualified inspectors already out on the circuit. However, there is a need for an increase in that bandwidth.

Also given this methodology can be used as-- or some laboratories can use it in a way where basically you just have one test. And from that one test, you can report some sets of genes given the clinical scenario. And you can easily envision a world where that single test is either a sequence or a genome. And at the end, you just report on that subset of a clinical scenario.

So one of the main points that was suggested to me-- a minimum set of standards for what these really large tests-- so some minimum standards available again, such as exomes, genome.

And I mentioned before in terms of reference materials are challenging. They're challenging to come by-- particularly challenging ones, which you are calling throughout the day educate. I did want to just call out the CDC Genetic Testing Reference Material Program, which has been a great resource for some of these challenging cases. But again, there is a need for greater assessment, acquisition, and availability.

Question number four, what are the challenges for clinical laboratories in performing NGS quality control and quality assurance? Great conversation where you see metrics as a critical component of this discussion.

Right off the bat, we recognize that quality control and quality assurance is an extremely resource-intensive process, not only financially in terms of acquiring quality controls and meeting the regulation, but also from a personnel perspective. Refer to a couple times in this specifications as the traditional quality management that we associate with CLIA and non-NGS based tests.

We differ in NGS based tests. And there was an interesting discussion about whether positive and negative controls really are the best or the ideal control for this type of methodology, even though we must do it to meet regulations.

Again, as mentioned earlier, quality control, given that NGS is a methodology and not a test or a single test. It's going to be very hard to come up with a set of quality control standards that encompasses or standardizes all the individual applications of this methodology. In terms of the current quality management framework, that has been-- again, referring back to that-- the positive/negative controls and maybe even considering alternate quality metrics surrounding the quality of the sequencing itself, may be a super method for quality management with this method.

I don't want to paint the picture of doom and gloom. Guidelines do exist and the associations for molecular pathology and College of American Pathologists. Do you have a guideline out there or other guidelines that are out there? Their particular guideline about validating the bioinformatics pipeline, completely in a need for more application specific guideline. From a need perspective, I try to keep these needs broad as we think forward to the very near future where we're coming up with recommendations, that the NGS really requires appropriate quality management definition and/or recognition that it may be different from the traditional quality management metrics that we associate with non-NGS tests.

And regardless, again referring back to that concept that NGS should be considered more of a living test. We would need an agile framework to be able to keep up with the pace of our available knowledge seeking and also how the technology advances over time. Discussion question number five. What reference materials, are thought to include projecting domination and quality control procedures. This is where one of word clouds is just absolutely perfect, where you can see just reference materials needs.

Again, not all doom and gloom. There are more materials that exist. For example, genome in a bottle, microbiome standards. And you can read the rest of that, as mentioned, GeT-RM program already.

That said, it was really a call for more of those challenging cases, those edge cases, to be able to stress the system and really learn the true performance characteristics of the test. Some needs that were discussed in the discussion about clearinghouse. So the need is for the GeT-RM program or a national sample clearinghouse containing large data sets, or maybe challenging cases that can be stored up in the cloud and posted by some organization, be it the government, societies, or industry. And it can be pulled down by laboratories to be able to push through their pipeline and have their performance captures, at least from the drawing side, from NGS.

And as I mentioned several times already in this presentation, the depth of the available reference materials needs to be expanded, in terms of homozygosity, somatic testing, a quantitative reference materials, and certainly more of those edge cases that tend to be more challenging to pick up by this methodology, such as structural variants and edge cases.

Discussion question number six, what proficiency testing programs or alternative testing schemes are available for NGS? As you can see here, a very deep, rich conversation. And referring to the wet and dry components, they felt that a good proficiency testing program should encompass obviously the entire analytical process.

There are many-- there are several PT programs that do exist. College of American Pathologists is probably the leader in that space. CDC PulseNet also has a PT program, particularly for public health laboratories. And there are a variety of other resources that are named here.

Consensus in the room was that these PT programs are generally too easy, again, not because PT people were trying to make it easier. It's that the creation of these proficiency testing examples for next-generation sequencing is extremely challenging.

Teaching methodology spiking samples. But they tend to be really obvious from the bioinformatics pipeline. And cell-line creation of rare structural variants is limited not only by cost, but the frequency in which we come across those types of variants as well.

But another really interesting conversation where both NGS and certainly the non-NGS test, the general sense is that a formal PT program, probably a commercially-available PT program, is superior to alternative assessments. But given the challenges in acquiring challenging PT cases, and the challenges of overcoming a lot of the matrix of that effects particularly in the microbiology space. Alternative assessments, at least for the time being, may be a superior method for this in quality management, where both the laboratories can maybe share the set of sample of unusual or challenging cases. And that could be, again, a superior way of assessing quality.

PT, as was mentioned in yesterday's discussion, is also challenging. This next-generation sequencing is frequently involved in some form of distributed model, where maybe Lab A did the wet component, and Lab B did the dry component. And whenever you're participating in a distributed model, you struggle with the balance of following patient workflow and making sure that you are not participating in PT referral.

So that's also something that needs to be addressed over time. So again, unique highlight of very high-level summary. We need more of these PT samples, more challenging, and some way of being able to address the distributed model.

Question number seven, what are the challenges in developing, establishing quality control, and implementing a bioinformatics pipeline in a clinical laboratory setting? Again, very rich conversation. But when it comes to the quality control in the pipeline, there are some regulations and standards that already exist.

However, again, you're referring to the typical positive and negative controls. And what are those values in a next-generation sequencing methodology, where quality metrics that particularly surround the quality of the sequences and steps may be a superior way of ensuring quality?

From a personnel perspective-- and again, it was mentioned before—bioinformatics has become a critical component of developing a pipeline, moving the massive amounts of data around, and also are involved in some of the analysis as well. Currently, guidelines do not recognize bioinformaticians. And that, obviously, will be something that we would recommend moving forward.

Pipeline, again, you'll see themes come up over and over again. Next-generation sequencing is a methodology. Again, the pipeline that it's creating, there is no ideal pipeline. And it has to be well-tailored to the use case. And bioinformaticians are a huge component in tweaking, developing, and validating that pipeline for that particular use case.

Databases are-- external databases are frequently-used resources, in terms of the interpretation and the analysis of the data that comes out. And the quality and the ability to identify the good external databases from the bad external databases is sometimes not as transparent as we would like.

Versioning was thought to be a best practice, and certainly the best thing a quality pipeline particularly just to document all changes that occur to the pipeline over time. And if for some reason there needs to be a correction back to a previous pipeline, you can do so.

An interesting need that was brought up was, again, the concept of training methods, where there could be, again, that clearinghouse of data that some organization can consider to be the bare minimum of types of structural variance or types of copy-number variance or simple point mutations and indels that these laboratories developing this pipeline could then pull down, push through that pipeline, to ensure that they're getting the correct results, and as an external source, to be able to validate their pipeline.

And given the complexity of this methodology, expertise in the laboratory that are trying to get into this space, expertise in the setting of consulting would also be a need that could be filled.

Discussion question number eight, what are the challenges associated with using and assuring the quality of external data? Again, this is a data cloud has been formed by this analysis. So guidelines are out there. And there are guidelines on how to use them.

But the most common databases that are used are ClinVar and HGMD. There are digital databases that are used as predictor models, such as SIFT and PolyPhen. But we felt that could be able to really enrich the power and the reliability of these databases is the data behind the data, or the metadata.

And when we speak about metadata, it's really understanding, what was the sequencing platform that was used in order to create that data and make that interpretation? What are some of the clinical parameters, the clinical characteristics, of the patient behind the data?

This would obviously quicken the pace of our medical knowledge base, and be able to provide better interpretations in a more rapid fashion. However, the object of the discussion here became, the more clinical metadata we attached with the data added into the database have to be very carefully balanced with privacy concerns as well.

Our medical knowledge base is forever expanding, and it's actually considered a best practice where variants are interpreted each and every time you encounter them. Even if you've encountered them in the past, proper curation of databases and your reports is critical.

In terms of needs, I'll pick metadata. I think I've covered that well. But quality control for input into these databases, these external databases are frequently populated by the individuals by the diagnostic programs or laboratory community. And another need is showing, having a great level of transparency about the quality control steps for ensuring that the quality data is actually being inputted into these databases would be something that would be interesting to this group.

And finally, we were toying around with the idea of a mandate recognizing that the sharing of this data will quicken the pace of the generation of our medical knowledge. And should there be some kind of mandate to share, and some various characteristic models to encourage sharing this type of data?

So I will say we kind of lied before, that there are 12 questions. There are 12 questions. However, we broke question nine up into two components. So in reality, we'll have 13. So question 9A, what are the laboratory practices and challenges NGS software and data management? And in this particular subquestion, we're going to be focusing on data sharing. One that we've spoken about are data sharing with the patient. We all now know that there is a federal law that the laboratory, on patient requests, needs to share the results and the patient data with that patient, within 30 days. There are other programs that actually quicken that communication time period, such as Meaningful Use.

So no one here was questioning the value of sharing data with patients. But the details are what really needed to be fleshed out. So for example, what files are appropriate to share with the patient? Obviously reports, of course. But if the patients were requesting files, what files? Are they the raw unprocessed files, the ASCII files, the BAM files? VCF files or the FASTQ or the final file?

What's appropriate? And the concerns that we had were-- and you see this in the lay media as well-- patients can then take that data and bring it to third parties interpretation patient platform, where they may get clinically actionable results from that third party. However, it could be on the backbones of unvalidated data from the laboratory that performed the original analysis. Again, these cases have been highlighted in the lay media as well.

Sharing information between professionals we felt was absolutely critical information. As I mentioned before, the more sharing we do, it quickens the pace and the growth of our medical knowledge base. And sharing with professionals improves the curation and the metadata that surrounds our interpretations.

There was a concern about interoperability, and that many of the members of this group felt that LOINC had been the chosen path for interoperability. And they did express some concern that there are other meaningful ways, or systems, to be used, other than LOINC, to improve interoperability and having meaningful data on the back end. So that was something I wanted to mention here as well.

And in terms of consenting and sharing data-- right, this is the patient's data. If you were going to be sharing it with anyone else, you need their consent to do so. So very often the way we do this, most laboratory organizations have either opt-in or opt-out, health programs, data sharing. And this group also highlighted another layer of complexity in terms of the environment. One model may be better suited for either the inpatient environment, as opposed to the outpatient environment.

Question number 9B, which is the same question, however, this time, we're specifically referring to the data and software storage retention and upgrades. So from a storage perspective, there was really no consensus The College of American Pathologists has a flag in the ground of two years, and the intent behind that is really surrounding re-analysis.

But again, [INAUDIBLE] sharing data with patients, there is some fleshing out that needs to occur. Again, the question is, what kind of files should be saved? Should it be processed files, the raw files? When you store files up over time, there's a degree of data loss, or lossiness. So standard criteria is, what is an acceptable amount of lossiness? Some files may have more susceptibility to have more data corruption. And latency, or the time in which it takes you to retrieve that file. Obviously, stored locally, the latency would be quite short. And stored off-site in a data warehouse, it could be quite long. So we felt that, whatever the storage guidelines created,

what should be discussed and figured out first is, what is the intent behind the storage? If the intent is re-analysis, you may have a different set of parameters, as opposed to the intent being for some other reason.

Also, it's important to recognize that many states have retention laws. If I remember this correctly, in the state of Georgia, you have to keep all data till seven years after majority. CAP accredited, you must keep it for two years. If you're doing CLIA you're going to be keeping that data for the next 25 years.

From a software perspective, I get these are living, breathing tests for methods, so any modification, there is considered to be a best practice that has a development environment and a production environment. For that development environment, you'd perform all of your unit testing and regression analysis and testing to ensure that the system is working appropriately before putting it in production. Similarly, from the versioning, perspective, it's important to keep those versions of your pipelines and your data to make sure that you could always revert or regress back, if need be. Similarly, as I mentioned earlier, next-generation sequencing methodology is a living test. What types of changes, particularly to the pipeline or software, should trigger a revalidation? And what would that revalidation look like? Is it the entire test or just modification itself? Similarly, in terms of storage and software management, we felt it was very important to make sure that everyone came to a consensus of understanding why we're storing it and worked backwards from there. And of course, there was a gap, in terms of guidelines. And guidelines would obviously help the community at large.

So coming down the home stretch, we have question 10, which are, what are the real-world and recommended practices and challenges in reporting clinically-significant secondary findings that are not related to the test that was ordered? We had a really nice conversation about the secondary-- the difference between secondary and incidental findings. See some examples here.

I think the classic secondary finding, which we have guidelines surrounding, an adult patient with a kidney disorder gets a whole exome sequencing, try to elucidate the genetic findings. Meanwhile you find out that the patient has inherited cancer syndrome. Incidental findings-- which, again, is really common in medical practice, particularly within radiology, the incidental [INAUDIBLE] is a well-documented [INAUDIBLE]. And we would have a similar finding here in genetics and genomics well. Here's the example of a patient who would have colon cancer, doing rapid testing or testing, and meanwhile you find a mutation within that gene that's associated with a different disorder, such as Noonan syndrome.

The conversation then switched to the existing guidelines for secondary findings, ACMG. And there was a good consensus-- sorry, a reasonable consensus about maybe it's time to re-evaluate these guidelines. They've been very helpful. They've been around for a few years now. And this re-evaluation should be to learn from that experience so far. Should we refine the list, increase the number of genes that are on that list, or decrease? How is the consenting processing been working over the last years what we learned from it?

The reporting has been-- what have been the impacts of the reporting of these secondary findings for patients, the impact of the reporting on providers? And is there a need for additional resources for either patients or providers when receiving these secondary findings? So again, this was about learning from the experience, a few years after ACMG came out with these guidelines.

Question number 11, what training and competencies are performed or considered essential to demonstrate that qualified personnel are testing specimens and analyzing data? So this was a great conversation, where we felt the wet components of next-generation sequencing was really well covered by CLIA, from a personnel perspective. And as has been mentioned before, the dry component, there are gaps in CLIA, particularly surrounding bioinformaticians, again.

Bioinformaticians touch this process in several ways. They develop the pipeline and the design and the manipulation of moving a large data set, and the back end, in terms of providing the first round of interpretation. And validating the data or not, they also depend upon where they touch the process. So maybe we could debate whether somebody who's developing the pipeline is part of the analytical process. And certainly the analyst is part of the analytical process. But that also may change given the environment, where in a laboratory, a developer or scientist or analyst could be considered part of the analytical process, and therefore within CLIA. And many say that manufacturers [INAUDIBLE], which would more likely fall within FDA's jurisdiction.

So we're going to be making, I think, a very strong recommendation to inform the agencies to push out a survey to laboratories that are performing next-generation sequencing tests, collect their job descriptions for their bioinformaticians that they may hire, qualifications that they expect of these personnel, and their educational requirements. Similarly, that may be a workgroup that can get together to define these bioinformatician categories, again, push them out. There may be others, or they may need to be refined. And crosswalk maybe in CLIA. Personnel requirements, or suggest the creation of new ones.

And question 12-- I promise you this one will be quick. How does the laboratory determine the total annual testing volume for NGS? For continuity I have included the word cloud. And here, we had a clear consensus that laboratories should, and generally do, count their annual volume by testing over any other reporting method. Why this is important, as you know, there are many NGS tests that have anywhere between one, two, five, 400, or maybe 20,000 different genes in which they test for. And there could be an opportunity to count your volume based upon the genes. But on the other end of the spectrum, whole exome sequencing typically uses three patient tests-- the [INAUDIBLE], the mother, and the father-- and those three samples come in to give a single report. So the consensus was, again, to continue the annual volume for any laboratory at the report level, not the gene or the specimen level.

So with that, I will conclude this presentation, and I'll turn it back over to the chair to discuss or take any questions.

CLIAC CHAIR: Thank you. Thank you very much, Jordan. Appreciate it. What a whirlwind of information. You know, it's only next generation sequencing technology, after all. It's a fantastic amount of work you and the workgroup have done. Your summary, both written and oral as you've presented it to us today, are really fantastic and a huge amount to work on.

I appreciate, especially for the middle questions, how you placed your answers in the context of resources that are already available. It often happens, or at least sometimes happens, in some of these forums where just because we are thinking about it, we tend to fall into-- we're tempted to fall into the pattern of thinking that we're the first to think about it. And we clearly are not in NGS. And so having that context is useful, especially as it bears on what our responsibilities here at CLIAC are, which is to recommend to the federal government what to do based on what exists and what gaps still exist.

With regard to that goal, I am struck, first and foremost, by the fact that we've got about-- let's say about three hours to discuss these 12 topics. And my sense, based on yesterday and just the amount of thoughtfulness and care and detail that you and the workgroup have put into your report, that we are not going to get through all of that in any way that does it justice.

I was taking notes as you went, and I counted at least a half dozen possible recommendations, none of which are obviously the best or right way to go about what we have to say. And also, at least two or three potential novel workgroups. To give these issues their due, and I'm looking across the table here at the next chair, I would suggest to the committee here that this conversation-- that we plan for this discussion to continue into the fall.

That's not a no-brainer for me, though, because we only meet twice a year. So meeting in the fall means that we put off any action that we're going to recommend to the agencies for at least that long. That said, I'm not sure how to resolve the tension between the amount of stuff we've got to talk about and the amount of time that's remaining, so maybe just a minute or two, before we get into details of this high level, thoughts from the committee or from you, Jordan, about what we should plan to do with the next three hours.

CLIAC MEMBER: I know we typically have discussion and then we have our recommendations towards the end. I think there was some low hanging fruit in terms of workgroup recommendations or agreement that was predicted and suggested by this group. Maybe we could tackle some of the low hanging fruit first, then engage in a little bit more discussion to see if we can flesh out any additional ones. And if it carries over into the fall, certainly I think that's appropriate as well.

CLIAC CHAIR: Jordan, are there things, in addition to being low hanging, are there things that are especially timely or would benefit most from lead time? If we're going to go into the fall, maybe we could make use of the intervening several months that way.

CLIAC MEMBER: Yeah, I think that's a great way of looking at it as well.

CLIAC CHAIR: And I'm thinking specifically about the--

CLIAC MEMBER: and then we'll need more time. I think typically the more time will include-- suggesting where CLIA would need to address distributed model and NGS testing and also some of the personnel challenges around bioinformaticians. I think those are the short term possibilities but we'll benefit from that.

CLIAC CHAIR: So I was thinking, there were a couple places there where it seemed like-- and again, obviously, we'll discuss it as a group-- but where a commission of a survey or a request for more information was recommended by the workgroup. And I personally agree with those recommendations. So that feels like maybe we could recommend a workgroup, a new workgroup of our own, in order to do that survey. It's either us doing that and trying to get answers in six months, or I'd task an HHS with doing that, but I feel like that's something that we can do for them and don't need to ask them to do for us. So I agree with that. We had some hands around the table for thoughts on what to do for the next three hours.

CLIAC MEMBER: I just glanced through the first part of 42-493 looking at all the different areas and subsections. And there isn't yet a molecular anything. It's been a long time since a whole new discipline has been regulated. And it feels to me like this needs to be treated as a whole new discipline to write regulations around, cautiously and with humility to start with, because it's evolving and we don't want to get ourselves in too deep.

But it feels like we need an outline of what this regulation needs look like. And maybe this is starting to be-- I guess you're asking the questions to do that. But that seems to me, that maybe the next step is to have an outline of what these regulations should look like for NGS-based testing. And that'll encompass all of the areas of the regulations personnel, and competency, and proficiency testing, and quality management.

CLIAC CHAIR: Great.

CLIAC MEMBER: Two quick questions taken off of [CLIAC MEMBER] comment. So there are some accreditation standards now, CAP around molecular. And these should be based on interpretations of CLIA which should jive with periodic assessments by CMS. So I'm wondering how is that developed and what is-- where did that come from? You said it doesn't appear to be clearly a molecular category in current CLIA low so how that might have developed and CMS do that?

CLIAC CHAIR: [CMS EX OFFICIO]?

CMS EX OFFICIO: Well, actually, CAP can be more stringent than CLIA, so they can go and develop their own, as long as they meet a minimum of CLIA. I mean, we could certainly talk with CAP and look at what they have and utilize the information that we have here.

CLIAC MEMBER: I mean, CAP's got an NGS checklist. How do you read that? Because we have to submit everything to you guys for signing off.

CMS EX OFFICIO: What do you mean how do we read it?

CLIAC MEMBER: Well, how do you sign off on that section that really isn't directly driven on it? Do you just look at and say OK, it's OK? Or--

CMS EX OFFICIO: We actually do it for CAP every time they come in for approval or re-approval. We go through all the checklists. We go through everything.

CLIAC MEMBER: But how do you go through that one, which is--

CMS EX OFFICIO: I have subject matter experts that have experience in molecular.

CLIAC MEMBER: So that's non-regulated testing, so CLIA basically says twice a year, APA-- it's like any other non-regulated test. So CAP-- any accredited agency can make requirements in addition to that. It will meet CLIA if you say you got to validate it. You got to do something twice a year for alternative performance assessment. And that's all that CLIA would apply now.

Your point about-- that's because there isn't any other detailed information. There isn't a specialty or a regulated area that applies in CLIA.

CMS EX OFFICIO: And as far as having a specialty, obviously it takes a while to do regulations. This is a constantly developing area. If we'd have done something five years ago, by now it would be obsolete.

CLIAC CHAIR: Well, I kind of-- I question that a little bit.

CMS EX OFFICIO: You can do that. It's OK.

CLIAC CHAIR: Because there are-- I guess maybe it would be true from five years ago to now, but might not be true from now going forward in the sense that if we understand-- what we understand now that we didn't five years ago, or at least what we understand better are the principles required for this kind of work. And it feels to me, especially based on the results from the workgroup, that we could craft or regulations could be crafted that would be sufficiently flexible and yet sufficiently useful to handle the novelties of NGS. But let me ask--

CMS EX OFFICIO: And this is probably an appropriate time to start doing that. I would agree with that.

CLIAC CHAIR: So in that context, in the context of [CLIAC MEMBER] comment and [CLIAC MEMBER] proposal, [CMS EX OFFICIO], you heard the presentation. How would it be most useful to CMS? Well, first of all, let's ask the obvious question. Is it useful to put a section into, or recommend there be a section in CLIA regarding NGS? Or I guess the alternative is to say, continue on with checklists like that from CAP but leave it unregulated. So is that useful? Is that something that you think the agency would want?

CMS EX OFFICIO: I think that's useful. I think we would need to take it back to how we would craft that, how we would develop it in the terms of creating regulations. I've never created a whole new subspecialty or specialty, so I don't know if we have any history of how to do that or what we need to do. So I would need to research that as well. I think the information that's provided with the presentation and all is probably a good start for us to do something like that.

CLIAC CHAIR: So since this is such a large topic, is it useful to have a recommendation coming? Again, this is not jumping to the conclusion. I'd love to hear thoughts from around the table. But would it be useful to have a recommendation from us so broad as to say, CLIA, we recommend that HHS have an update to CLIA, a whole new section including NGS, based on the workgroup recommendations made to CLIAC? And then leave it at that?

CMS EX OFFICIO: Yeah. That would be-- if that is what the workgroup would recommend, then we would take that under advisement.

CLIAC CHAIR: Without-- because again, there are many, many specific things which Jordan talked about which, again, we are happy to help with in certain ways, but--

CMS EX OFFICIO: Us developing a reg would take a while, particularly because we would probably be coming back to the committee again. So the fact that we're going to use some of this in another meeting and maybe another workgroup, all that information would feed into what we need as well. So maybe that recommendation would be fine.

CLIAC CHAIR: So now purely for informational or procedural purposes, roughly how long is a while?

CMS EX OFFICIO: Yeah, that's the crux of it. It would probably, for something like this, I would think probably to do it right would probably take about a year to craft it. And once we craft it, then it goes into the clearance and proposed rule stage. Usually that's a 60 day comment period. And then we take it and finalize it. I would think, from start to finish, probably about three years. If we're lucky, we would be done in about two. But I think three would probably be a good estimate.

CLIAC CHAIR: So let me ask around the table. You had some question. And I'll ask this generally. Is this a good general strategy for us? Because if it is, then the next set of questions, maybe what we do with our time—[CLIAC MEMBER], as you said, there's some low lying fruit, but maybe we could focus specifically on that stuff which would provide information that we expect CMS-- HHS and CMS specifically would need in order to make this happen fast.

CLIAC MEMBER: So I think it's great to address it. I guess I would play a little bit of a devil's advocate in that, saying molecular techniques are a tool. They are also a subspecialty. But 20 years ago, we might have said, do we need a serological section of CLIA? Do we need-- and I posit that perhaps we have molecular microbiology and molecular hematopathology to create a subspecialty that's out of the bounds of the existing ones. I think we should be careful because what next? What if nuclear magnetic resonance technology comes into the lab? Do we need a another section for that? Dog sniffing infectious disease, do we need a section for that?

So there's just so many techniques, ELISAs, FAs, that were groundbreaking at the time and now it's like, well, that's a part of chemistry or microbiology. So I think we need to keep both components in mind, calling out the fact that it is a very unique subspecialty, that having directed an MGP fellowship for a decade in a former job-- these fellowships are one or two years. And you're pulling in oncology, microbiology, genetics. It's just too broad. And my fear is that if we call it out as its own specialty, do we lose the subspecialty expertise? And somehow we have to be cognizant of the fact that we have to marry those things together.

CMS EX OFFICIO: What we currently view this as--

CLIAC MEMBER: So I think those points are very well needed. I think the-- and although we did not enjoy exceptionalism. But in this case, this particular methodology, I think what this workgroup has highlighted in the attempt at applying the existing framework is there are clear gaps. And I don't know if the existing framework could be applied to laboratory testing as well. But I think that's the fundamental difference, not that it's [INAUDIBLE] but that the application of the application of the current regs doesn't fit. We're pushing a square peg through a circular hole.

CLIAC CHAIR: So [CLIAC MEMBER], if I may paraphrase, it's less about making it its own specialty than about recognizing the set of issues that the techniques in this area bring which are different and not covered well in current CLIA, including personnel. And personnel, for instance, a bioinformaticist is not the same as a medical microbiologist, but it's more like a type of technologist. And covering those issues, if we do it right, would cover not just NGS but some of these other things that might come along.

CLIAC MEMBER: Yeah, I think that's well said.

CLIAC CHAIR: Thanks.

CMS EX OFFICIO: Thank you. Currently, how we treat this is that we have it you know chemistry immunology. And we have always felt that a lot of what we already have regulations for cover a lot of what is done. So the other alternative would be not necessarily crafting a whole new specialty, but maybe cleaning up or adding to what's already existing, to maybe be a little more specific. Because we already have an excellent framework. Do we really need to do a whole new one? I mean, we can always look at that. That's not-- we're not going to say no. But if we don't need to do all of that, we can probably get something like that done probably a little bit quicker than a three or four year process to get a whole new subsection.

CLIAC MEMBER: So that would be-- that might be more like what? A year or two instead of three?

CMS EX OFFICIO: No, it would probably still be about-- by the time you do the NPRM process and then the final process, it's still a good two years.

CLIAC MEMBER: I think we need to be very specific about what we're asking HHS, CMS to do, what we're recommending. I mean, it sounds like what we would recommend them to clarify is how personnel standards apply to this test team, whether you're making a new specialty or not. You're asking clarify how personnel standards apply to labs while using the methodology of NGS because we've heard bioinformaticians don't qualify as high complexity testers. And they don't fit. Clarify how validation requirements apply to these technologies because par AA, applying that to NGS and you're validating each gene, each disease, how do you do that?

And then clarify how quality control requirements apply because we just heard that one pos, one neg every 24 hours, which is all there is in CLIA. It is hard to-- probably not helpful to begin with, and hard to apply. So I think if we direct, here's what we want HHS, CMS to help clarify. I don't know. I don't have a strong opinion. You can make it a different specialty. You can clarify with an existing-- oh, but here's how it applies to labs that use this technology. It may be premature to ask CMS and HHS to clarify PT requirements. The way they would generally do this is look at what are provider's grading? And what's possible now? And there aren't any graded surveys that I know of out there now, but I could consider whether we recommend in PT. It may be too early for them. And maybe [CMS EX OFFICIO] would comment on-- actually, because there's so little out there, they may not be able to gather that data and figure out how PT should work.

CLIAC CHAIR: And let's keep in mind that it's not just CMS but CDC and CMS jointly on CLIA, and that's where, of course, the workgroup questions came from.

CLIAC MEMBER: I just want to add my voice to [CLIAC MEMBER] comment that I'm uncomfortable with regulation around methodology instead of clinical application. What I heard Jordan say is that the application of this method crosses all medical disciplines and the development of those assets has specific case uses. And because of that, a single, general theme around the methodology probably is not going to be adequate. I just want to raise-- it brings up a lot of issues. These are high complexity tests. CLIA already has a way to manage that. The personnel requirements, I keep asking you to simplify. We do have the lab director, ultimately responsible. The technical consultant or supervisor, whatever you want to call that, the clinical consultant, and then the test personnel. We can probably figure out a way to put in the bioinformaticists somewhere in there.

I want to comment that these tests today are probably LDTs. So [FDA EX OFFICIO], you're probably going to get dragged in, especially if they cross state lines in that business. So I wanted-- I'm always trying to fit that square peg in the round hole. I would like to leave-- the existing processes we have today can be massaged to incorporate this in each of the current medical disciplines under CLIA.

CLIAC MEMBER: Yes, I think what we're talking about now is the right strategy, recognizing that NGS is a breakthrough technology in multiple ways. But really, in terms of regulation, we should identify where is it, really not been already addressed. Where is it transformational? And make those identifications. And I think CLIAC could do that. And then that would result in specific recommendations, leaving the technical issues to such organizations like CLSI, et cetera. But we could identify where we need to emphasize or make new changes in or recommend changes in regulation. So for example, we've heard in personnel, we've heard possibly in controls. That situation also exists possibly for such things as defining what is the metric? And you heard from the committee, we think the metric could be the lab report. And so saying things like that and making recommendations along those lines, I think could be very valuable.

CLIAC MEMBER: I think that one of the things that the committee could do to provide value is to provide consensus guidelines based on the three major use cases for the test, the NGS test. So oncology, infectious disease, and constitutional clin. And I think if we considered looking at the existing consensus guidelines that exist but putting them in oncology, ID, or constitutional with newborn hereditable disorders would help clarify what the needs are for CLIAC to go forward and to ask the interagency group to provide clarity. I think right now with focusing on the test and the distributed model of it without focusing on the patient in each of these three categories which had unique testing requirements, PT requirements, and communication of the results to the patient requirements, I think it'll be too big of an elephant to break off. So that would be my recommendation, to split it into three different use cases.

CLIAC CHAIR: Sorry, could you say again what the three are?

CLIAC MEMBER: Oncology, Infectious disease, and constitutional.

CLIAC MEMBER: And another major application is HLA testing. If you're going to do the use cases, that's probably a fourth.

CLIAC CHAIR: As you say those use cases, I think back to the section in Jordan's presentation about canvassing to understand what labs, current volumes and specific use cases within those areas, are. So when you say that, I think maybe that's a good thing to start a workgroup around, to try to do that survey.

But maybe - And then I want to turn it back to [CLIAC MEMBER] to get, [CLIAC MEMBER], your list of what you would prioritize in the next little while to talk about. And then we'll go from there.

CLIAC MEMBER: So I've been listening to this, and what it seems is there was more commonality between the three workgroup reports, maybe, than originally thought. I mean, as we talk about-- the personnel workgroup talked or addressed bio informatics as a discipline, for example, in others. But it seems to me that as we look at it, it may be along the lines of what [CLIAC MEMBER] was saying as well, is that maybe we need, as we do this, to look through all the sub parts that exist in the context of NGS. But I don't want to call it that because that's a method. But--

CLIAC MEMBER: So sorry, sub-parts of what? Of CLIA?

CLIAC MEMBER: Yeah, of 493. And say, where are the situations where things have not been up to date for which there needs to be perhaps a change, or a new item added to it rather than blow the thing up or create a whole new section? I don't think it's that different.

I mean, bioinformatics is probably a personal item that needs to be addressed, for example. And so I think it may be worth getting people who've thought about all the pieces together to start to say, well, where does this now, in light of the fact that it's 30 something years later, where does it now fall short? And are there ways to fix it?

CLIAC CHAIR: And it sounds like, then, a general recommendation from CLIA might be a good starting point to let the agencies know that this is our strong feeling. So we basically had in Sheldon's introduction saying, how about a new section? And then the counterpoint is, well, how about just updating the subsections as appropriate? Which, per [CMS EX OFFICIO], might have the benefit of being as much as a year faster.

CMS EX OFFICIO: Possibly.

CLIAC CHAIR: Possibly. I mean, you never know, but possibly. That the unifying theme is, look, everybody sit down because this is going to be revolutionary what I'm about to say, that perhaps CLIA needs to be updated to handle these new things.

CLIAC MEMBER: Whoa.

CMS EX OFFICIO: I had been trying to do that for five years, OK?

CLIAC CHAIR: But I've thrown-- I guess it's up there on the screen. We'll try to make it a bit bigger for people. Just a general recommendation along those lines, touching on some of the points raised in the worker group report. Certainly not the only thing that we would say or do, and certainly not the final thing that we would say or do, but just as a placeholder to say, hey guys, guess what? We think this is actually super important and here are a bunch of specific things that we think we could think about. I didn't make reference to the workgroup. I probably should add that right now. But just to let people know that that's up there. And then Sheldon, you've put something up there as well. Do you want to briefly mention it? It's behind me. I can't multitask that much.

CLIAC MEMBER: Somebody else, though, I think had priority in speaking to me.

CLIAC CHAIR: Oh, sorry. Yes, And then you?

CLIAC EXECUTIVE SECRETARY: Mine isn't a priority but actually [CLIAC MEMBER] was a perfect setup for what my comment was going to be. We couldn't have planned this better. I was going to say that there are, within certain sections of CLIA that already exist, section 12-56 which are the control procedures, there are unique requirements based on methodologies. So if there would be something that needed to be added there to address this type of methodology, that could be done. And there would be cross cutting, regardless of what

specialty was being considered. And perhaps adding on to that, there's nothing in 12-53 for verification and validation. I don't know. CMS and CDC can certainly discuss whether something else is needed there. So I agree with [CLIAC MEMBERS} that I think there are ways, within what exists now, that some of these needs could be met.

Historically, I've been around here long enough to know that back almost 20 years ago now, there was a thought to create a genetics specialty. And CLIAC provided a number of recommendations. There were some workgroups, and then it was decided that that was not the way to go and that individual requirements could be inserted within the context of what already exists.

CLIAC CHAIR: Thanks. There seems like an emerging consensus on change, don't add.

CLIAC MEMBER: I think we should give a recommendation that's suitably vague that it doesn't push in one direction or the other. And I suspect that this will-- that the right way to do it will present itself as we go along. But when I was in high school, I was buying a suit. And picked out the suit and took it to the tailor, and the tailor started marking it up, the sleeves, in the back, in the shoulders, and the pants. And he looked at me and he said, you've got the wrong suit. Because he was going to have to alter everything. And when you're talking about altering PT, personnel, quality management, validation, verification, you probably got the wrong suit. It's still-- I mean, it's still a suit. It's not a dress. But you probably are going to have to write its own thing.

I will quote you from the book of Isaiah. See, I am doing a new thing. Now it springs up. Do you not perceive it? I am making a way in the wilderness and streams in the wasteland. So I suspect we're going to end up with a new section, myself.

CLIAC CHAIR: It's a fair counterpoint. So [CLIAC MEMBER], with all of that, and again, from a procedural perspective in lines of what we should do with the rest of our two hours and 45 minutes or so, channeling the workgroup, what do you think? And especially in light of your-- you had some specific low lying fruit.

CLIAC MEMBER: So in terms of this particular topic, I would suggest that the recommendation would be for the agencies to explore whether it is appropriate for a new category to be-- subsections to be created, or changes in the existing categories based upon the gaps identified by all three workers. I think, and I don't know if you think this, but in that recommendation for the agencies to work with a CLIAC workgroup-- so that the second recommendation would be the creation of that CLIAC workgroup to specifically provide that level of guidance to CMS and CDC. Now, I'm saying that out loud and recognizing we probably can't do that because workgroups don't relate to CLIA. But I guess that what I was trying to accomplish there was so that the agencies had a resource to guide them during identification of new categories. Should it be new categories or simply changes in the existing regulations?

CLIAC CHAIR: Sorry?

CLIAC DFO: Could I-- could I respond to that?

CLIAC CHAIR: Yeah, sure.

CLIAC DFO: What a CLIAC workgroup can't do is work directly with the government to craft regulations. It's the responsibility of the government to draft regulations. What a CLIAC workgroup can do is to focus on a specific task, or specific question, or sets of questions, and provide very specific guidance to CLIAC. And CLIAC may give a series of recommendations to the government. So what these three workgroups have done is focus in these three areas, distributed testing, NGS personnel, but what I would suggest the three groups did not do specifically was provide guidance to CLIAC about how CLIA could or should be revised, looking at it more

globally. So I guess I'm both supporting the idea of a new workgroup with a new tasking, but not supporting the idea that the workgroup would be tasked with providing guidance to the government on revising the regulation.

CLIAC MEMBER: So could we still have a recommendation where the agencies explore even the existing reports from the workgroups to CLIAC, that the agencies explore whether they're needing a new category in the existing framework? And the personnel workgroup specifically focused on what changes should be made and that to be reported back to CLIAC? So it's kind of a parallel process. They're both moving forward at the same time.

CLIAC DFO: Sure.

CLIAC CHAIR: Yeah, that sounds good to me. Apologies for the latency. I am attempting to multitask here. So to just repeat what was said as I attempt to craft some terminology around that, the proposal would be to recommend-- these are two slightly different things. And [CLIAC MEMBER], I guess I should say I don't know if you're able to have the SharePoint document in front of you because your proposal is similar to the third point of proposed recommendation that [CLIAC MEMBER] has put up on the SharePoint document.

CLIAC MEMBER: So I'm in SharePoint, I just can't find the document.

CLIAC MEMBER: It's called NGS CLIAC Recommendation. So let's think here. So what was just mentioned was the recommendation that the agencies report to CLIAC about-- what was it? What would be-- this is not wordsmith at all, but about what would be necessary-- let's think. Sorry, two different things here. So one is create a workgroup about how CLIA should be changed to reflect the output to reflect non-traditional testing workflows, personnel issues, and NGS testing which is covered by the three recent workgroups. But the second is the agencies report to CLIAC about what would be necessary or preferred for updating CLIA? And I'm looking around the table because it is multitasking here.

CLIAC MEMBER: So your cursor is actually what I was going to suggest, shortcut past the workgroup and then ask CLIA-- you already have the underpinnings. What tweaks do you need to do to address the identified gaps in each of the workgroups that were reported out this session? And because a lot of the impetus for the workgroups was based on, how are your surveyors going to look at laboratories performing these methodologies? Well, I think you would be best positioned to answer that question.

CLIAC CHAIR: So what would happen then is we would have, I guess in November, we would have a presentation by the agencies saying something to the effect of-- if we ask for this-- saying something to the effect of, we heard you and have read your reports, and read your recommendations, and read the transcript of your last meeting. We get that you want to update CLIA. We see that there's overlap as [CLIAC MEMBER] just mentioned among these three workgroups' output. Here are a couple of ways that one could change CLIA, and here are the specific questions we have to you, CLIAC, that would help guide us about what would make the most sense. Is that the basic idea?

CLIAC MEMBER: Yes, and with the proviso that CLIA was meant to be very broad and continuously evergreen.

CLIAC CHAIR: Continuously--

CLIAC MEMBER: Evergreen. So we cannot anticipate what the NGS of 2020 is going to be. So whatever we're doing today has to be broadly adaptable to whatever that next methodology is.

CLIAC CHAIR: It's whatever the robots want to do. So is that a--

CLIAC DFO: I guess I'm uncomfortable with that. I mean, I think-- I think the purpose of CLIAC is for the members to provide advice and guidance to the government. I don't think CLIAC can ask the government to go off and think about various ways of changing the regulations and then come to CLIAC and lay out a number of possibilities and ask for your vote. It doesn't-- rulemaking doesn't work that way.

CLIAC CHAIR: Well, then the alternative is that we use just our best judgment from reading CLIA ourselves about how we feel like that--

CLIAC DFO: Yeah I mean, I think-- exactly.

CLIAC CHAIR: --which we can do. The proposal was hopefully to streamline that a bit more by saying, well what hits the realm of possibility.

CLIAC DFO: Right. The question here is, does CLIAC want to make a general recommendation for changes to CLIA along these lines and allow or that encourages the government to respond. And the government has the discretion of responding. But, essentially, what that does is it allows the government to respond in the way the government feels is most appropriate. Or does CLIAC want to take a more assertive stand and dig into the details a little bit and make more specific suggestions on how CLIAC thinks the regulation should be changed.

And now that doesn't guarantee that CLIAC's recommendation will be taken, but the more specific the recommendation is, the more-- one way of looking at it, is it provides more assistance to the government.

CLIAC CHAIR: So two things in response to that. So, first, that sounds like that's more like what I've highlighted in gray up on the screen here. [CLIAC MEMBER], I don't know if highlighting-- if you see my highlighting. I've just highlighted the create-a-work-group section. OK, so one option is to create a workgroup, tasking the workgroup, basically, with integrating the results of the three current workgroups with a specific eye on CLIA regulation and what specific places things ought to be changed. That's one option. A not mutually exclusive option is something like this top proposed recommendation where, [CLIAC MEMBER], I would suggest-- I mean, it's yours, so I direct this point--

CLIAC MEMBER: No, it's ours.

CLIAC CHAIR: --you. OK, it's ours. That in light of current discussion, in light of your own point about keeping things vague, we just change 'developing a section' to something like, 'updating.' And that leaves it-- that leaves it open per, especially, [CLIAC MEMBERS] points about, does it have to be its own section or simply a thorough update. And then that pretty much captures what I had said down here. I'd just put in a couple of--

CLIAC MEMBER: So if you look at that close. I was going to ask you to go down to the bottom one here. So, if we wanted to get more into what we usually do as a recommendation, this last one we recommend-- CLIAC recommends HHS thoroughly update CLIA to incorporate the issues. And, if we added a sentence at the end of that one, this may or may not include development of a new section or development of a new section or area. Then, that would be more of direction of what we do. We define the problem, and we say, you ought to consider this, but we're not directing them come back and tell us what option A, B, and C, or, it's just direction, and here's the problem and here's one thing to consider and now you take that an figure out how it works.

CLIAC CHAIR: All right, so we can put in that as options to show them that we have thought about through this update may include new section, revising existing sections or other alternative. I don't know what those others would be, but if it's not A, it's not B, it's not A, not B.

CLIAC MEMBER: So - There are two prompts. One is, we're basically asking CMS and CDC to begin the process of updating the regs. And run it through a timeline of three or four years. So we're asking them to move forward. To update without necessarily giving them the specifics of update.

CLIAC CHAIR: Yes, which we can also do, by the way, another recommendations.

CLIAC MEMBER: While that process is underway, one of the input will be CLIAC, and CLIAC will get their inputs from the creation of their workgroup, that's going to combine the sub-workgroups. And the output of those workgroups is that workgroup is going to be consuming the output of these three workgroups and put them into specific, CLIA suggestions or regulations. Which will be presented to CLIAC, which CLIAC will then present back to CMS and CDC who will already be working down this road. Correct?

CLIAC CHAIR: That's my understanding, yes.

CLIAC MEMBER: What is the Wayne Gretzky quote? We're playing to where the puck will be?

CLIAC CHAIR: Sorry, I didn't catch most of that. Say that again, please.

CLIAC MEMBER: There's a Wayne Gretzky quote, where you're playing to where the puck will be, not where it is.

CLIAC CHAIR: Oh, yes. Yeah, we're playing it where the puck will be.

CLIAC MEMBER: So, I would keep that to keep the puck moving forward, and we'll hit them with the pass from the next workgroup.

CLIAC CHAIR: Sorry, [CLIAC MEMBER], I'm going to assert myself for a second. So, what may make sense, then, is if there is general agreement on this strategy, this kind of being like the overall strategy, we might move sometime before the break to approval of a recommendation that is some combination of one and three. And, again, they mostly say the same thing. It just comes down to wordsmithing. Also propose a working group to synthesize the work of the three workgroups that reported to us at this meeting. Again, as, [CLIAC MEMBER], you said, with specific eyes, specific changes in CLIA and then spend the rest of our time at this meeting on the low-lying fruit, on preparing for where the puck will be, [CLIAC MEMBER], and specific recommendations that came out of the workgroup report. How does that sound to the committee? I see nodding heads. Any vociferous, angry opposition? None. OK, so let's plan on doing that. [CLIAC MEMBER], do you have a point to make on this?

CLIAC MEMBER: Yeah. I just had to reorient myself to the charter of this committee. It's on 6, 6, 7. And we are simply there to advise and make recommendations on technical and scientific aspects, right? We can't require anything. So, I would say, if you want-- there's a whole spectrum of what we could advise on, but, if we want to get very granular, then we would just propose recommendations based on the gaps, the very specific gaps that have been identified, and recommend that CLIA address them however CLIA wants to do that. So CLIAC recommends that CLIA, or however you want to do the HHS business, address new issues raised by NGS, including personnel, quality-control, et cetera.

CLIAC CHAIR: I take that point. We're not tasked with providing regulations, also as [CLIAC DFO] said, but when-- I think what it is is when there are so many technical issues that we want to advise on that just like work, you know. Let's summarize for you agencies. The technical issues effectively warrant-- this is what it's going to take. That's not our-- we're not talking about regulation or legislation. We're saying there are many, many technical issues. Fair enough. So, do we want to take a few minutes then and smush these two things together?

CLIAC MEMBER; [CDC EX OFFICIO] had something.

CDC EX OFFICIO: Well, just before you jump into the fine tuning here for this recommendation, I just wanted to propose out to the committee. You know, we heard from [CMS EX OFFICIO] that it might take a while for this to come to fruition. And I'm thinking back to the workgroup report, I heard in that at least development of full guidelines. And we nicely heard from Christin Hanigan at APHL that there are some major gaps and challenges for labs today. And, so, [CLIAC MEMBER] did suggest at the beginning, too, that there might be low-hanging fruit, and, if there is time today, I would just ask the committee to also consider what that low-hanging fruit might be so we can provide some practical help to laboratories now.

CLIAC CHAIR: Absolutely. And, as chair, my plan would be-- I don't think it should take us more than five or 10 minutes to get this part out of the way-- and then we spend all the rest of the time on exactly that low-lying fruit. I just want to get this out of the way to--

CLIAC MEMBER: Oh, OK. So, heard loud and clear, [CDC EX OFFICIO]. So shall we smush these together? I'm happy to take dictation. I'm happy to work in silence trying to smush them together myself.

CLIAC MEMBER: If I'm not mistaken, the third bullet point is illegal. And I never wrote that. You didn't see me.

[LAUGHTER]

CLIAC CHAIR: So thoroughly update versus begin the process? I'm sorry, go ahead. Somebody was saying something.

CLIAC MEMBER: First bullet point. Since we're talking about the merger of the common themes of all the three workgroups, wouldn't we want to add NGS working group and workforce and the three groups there?

CLIAC CHAIR: Yes, definitely. And let's think how to do that. How about we do this? Raised by next generation sequencing. Non-traditional work flows. And evolving personnel needs? Including, for example, the definition.

CLIAC MEMBER: I'm curious the items that are called out in this portion that's being revised. Are those the low-hanging fruit you were referring to?

CLIAC MEMBER: No, not the physical hanging fruit. I think the fruit that needs to be picked, but it's a little bit harder to pick. I was thinking more along the lines of what [CDC EX OFFICIO] was mentioning before, in terms of calls for guidelines. Personally, I'd like to see that they get our GeT-RM program maybe be expanded, maybe compensating technical work, I thought those were easier, crisper recommendations. That make sense?

CLIAC MEMBER: Yes, thank you.

CLIAC MEMBER: Fourth line from the bottom. Do you want to say verification and validation? Those are two separate things.

CLIAC CHAIR: removing proficiency testing? Or--

CLIAC MEMBER: Add verification and validation. Then make proficiency testing its own semicolon-ed out section.

CLIAC EXECUTIVE SECRETARY: And a reminder that CLIA doesn't use the word validation.

CLIAC CHAIR: What would you want to say under proficiency testing? Or, will this do?

CLIAC MEMBER: I mean, I just think in terms of the sentence structure, verification and proficiency testing are separate things.

CLIAC MEMBER: Yeah.

CLIAC MEMBER: And so you shouldn't combine them and that's only if proficiency testing is the last thing.

CLIAC CHAIR: I don't remember what the official names of these were. Personnel.

CLIAC MEMBER: Personnel and regulations.

CLIAC CHAIR: Say it louder, please.

CLIAC MEMBER: Personnel and regulations.

CLIAC MEMBER: Oh, sorry, well, whoever is on the phone, maybe you could mute when not contributing. So how does that look? It sounds like we ought to-- how about-- Since this is now subsumed. Yes?

CLIAC EXECUTIVE SECRETARY: So, you've made this very general or you broadened to capture the three word groups, which I think is totally appropriate. But all the examples there are NGS examples. And, being the ex officio on the distributive testing, non-traditional workgroup, I think, those categories, there are other things that go beyond the scope of just NGS that maybe either should be added as examples, or else take away all the examples. But, I think, if this is really going to be something that thinks about all three workgroups, they should all have emphasis where appropriate.

CLIAC CHAIR: That's a great thought. I'm happy to-- I'd prefer to add, rather than subtract, here, actually. I mean, this is the umbrella recommendation, and we're about to get into more specific details.

CLIAC MEMBER: But there was a lot of stuff in personnel, too, that isn't relevant. And we did have separate recommendations on those workgroups. This one really is our NGS recommendation. I don't know that we need to be encompassing. I mean, maybe we need to mention some other things in terms of CLIA updating, but that might open a can of worms that we would prefer not to chase around the room.

CLIAC MEMBER: Well then perhaps we could do something like that, making this the umbrella recommendation for NGS, but by asserting that this update should--

CLIAC MEMBER: There's stuff in all of them that applies.

CLIAC CHAIR: --yeah. And, as you pointed out, we have made a number-- as pointed out-- we've made a number of recommendations on those other issues. So that it's not like they're missing.

CLIAC MEMBER: Yeah. I feel the suggestions, and, if I remember correctly, this is the only recommendation that's specifically asking for an update of CLIA.

CLIAC CHAIR: Yes.

CLIAC MEMBER: And there are needs for updating CLIA in all three presentations and all three report outs. So, I like the recommendation of keeping it actually short and sweet, saying CLIAC recommends that HHS thoroughly update CLIA to incorporate new ideas raised by the three groups. And then just use that last sentence. Delete everything else and say this update should capture the recommendations by the CLIA Personnel, Non-Traditional Workflow Model, and NGS workgroups reports as presented. Because it's short and sweet saying, update CLIA. These are your choices.

CLIAC CHAIR: So I must say I'm of two minds on that. I hear what you're saying. I also hear-- sorry, buzzsaw has just started in the room. You missed earlier when there was a celebration next door, so it's a non-stop fun here. So I hear what you're saying, and this kind of echoes [CLIAC EXECUTIVE SECRETARY], which is, you don't want to leave the others out. Actually, maybe I'll turn to the ex officio members. If you received, or if the agencies are to receive something short and sweet, yes, but also quite general, will the thrust be missed? No?

CMS EX OFFICIO: I don't think so.

CLIAC MEMBER: OK, well, in that case, I'm happy to go with the short and sweet. Sorry, Please.

CDC EX OFFICIO: We'll have the recording. And we'll go back to the summary.

CLIAC CHAIR: OK. Well, that's not going to miss anything. And that sufficiently emphasizes to the agencies the extent to which this is not just a general or milquetoast recommendation, but an attempt at a summary of an awful lot of specific issues, then I am on board with it. But I look to the room and to take the temperature of the room on that, keeping in mind that we want to move on to all the specifics, the low-lying fruit and so forth that we were describing earlier.

CLIAC MEMBER: I mean I would wonder again. I know these recommendations take time to move through and people move on and off CLIAC. The nice thing about having the longer version is at least somebody on CLIAC or even five years from now when many of us are off CLIAC and we want to know what happened, that has a nice summary for us, for our purposes. What we were asking the government to do.

CLIAC CHAIR: So is it a compromise or is it a useful compromise to--

ADVAMED LIAISON: What if it's a general recommendation to take in account, to incorporate new issues, based upon the reports of the three workgroups, and then, because this is the NGS section, maybe a sub-bullet that says, for NGS specifically, these are the topics of interest in the CLIAC. Something along those lines.

CLIAC CHAIR: Thoughts of the room? Is that going to-- that won't end up marginalizing the other two?

CLIAC MEMBER: No, because they're addressed in the other workgroup reports.

CLIAC CHAIR: Fantastic.

CLIAC MEMBER: It almost empowers them. It almost empowers them because it--

CLIAC MEMBER: But in the other workgroup recommendations, didn't we break them out as individual, separate recommendations here? We've lumped like five into this one sentence.

CLIAC CHAIR: Yeah, I think we're going to go back. So the broad-- the strategic view here is that there are many more recommendations and actions that CLIAC can and wants to take than we are likely to be able to take

in the time allotted. Instead of getting through a little bit of those and, therefore, leaving the agencies with sort of a piecemeal, slapdash set of recommendations, to point out to them that, stepping back, we think there is this larger framework that these specific recommendations that they're about to receive fit under. Therefore, let's just get out of the way, first and foremost, that, hey guys, this is a big, all-encompassing hole. Here that is with a couple of examples. And hopefully, in the next couple of minutes, we'll move to supplementing it with those specifics.

The structure of these recommendations certainly would have gone differently if we had had all of the reports first without any discussion and then discussed everything as a whole. But, you know, I don't think it's a problem that we didn't have the complete context in going through those. So that's why the structure is a bit different, but, I think, as CDC EX OFFICIO pointed out with the transcript and the rest of it, it should be clear what we're thinking of. So it's not a problem to have those specifics here and yet go on with further specifics later.

CLIAC MEMBER: Would it be appropriate to add precision medicine or biomarkers at the title for proposed recommendations so if someone querying this in the future looking for those-- or are including it in our recommendation, to know that the end result of the test will be the biomarker result delivered to the patient and their provider regarding therapy?

CLIAC CHAIR: How would you propose-- yes, interesting-- how would you propose I modify this, or, if you have SharePoint in front of you, if you could make such modification? And I do apologize, multitasking, again, is not best. But here, at least, I think I have summarized. I've incorporated the comments to this point for that top part. So, [CLIAC MEMBER] what would you propose I modify?

CLIAC MEMBER: First line, perhaps. New biomarker issues. New biomarker testing issues. I mean, again, personnel, PT, QC, but it's not just-- I think, as far as providing guidance and a consensus statement, as we've said multiple times, we're not talking necessarily about the test and using just the test, may limit its utility of this guidance in the future. We're talking about precision, medicine, biomarker testing, and precision

CLIAC CHAIR: Does that incorporate or encompass the personnel needs, though?

CLIAC MEMBER I believe so, because we have to have the right people in place in the lab in order to perform, and, as we've talked about today, as well, and I think a big gap is communicating the results.

CLIAC CHAIR: Does it limit any of the other topics discussed under personnel yesterday? Like, for example, or for that matter, the nontraditional workflow, such as imaging?

CLIAC MEMBER: No, it does not limit.

CLIAC CHAIR: I'm not sure I see how imaging would fit under that. What did the rest of the committee think? So you propose we do a new biomarker testing issues. Like that?

CLIAC MEMBER: I do. That would be my recommendation.

CLIAC CHAIR: Thoughts from the group? Please, just speak up if I'm looking down.

CLIAC MEMBER: Could you leave it biomarker testing and emerging technologies or new technologies, something like that? Then that encompasses.

CLIAC CHAIR: So that needs to be wordsmithed now.

CLIAC MEMBER: Maybe address issues?

CLIAC MEMBER: Add workgroups at the end of means.

CLIAC CHAIR: Sorry, I couldn't hear.

CLIAC MEMBER: Sorry, workgroups at the end of that sentence.

CDC EX OFFICIO: Maybe add regulations after CLIA.

CLIAC CHAIR: Well, if that is the case, then what we should do is we should just put-- shouldn't we just do this? But now, we're responding specifically to the issues raised by the workgroups, as opposed to the issues themselves.

ADVAMED LIAISON: What if you ended the first sentence after new technologies? Just to recommend the update to regulations to address that. And then, the update may include a new section revising existing sections or other alternatives. And then, the last sentence, reflects the three. I have to say you should come back to CLIAC in the future to be the scribe at the podium.

CLIAC MEMBER: How's your typing [CLIAC MEMBER]?

CLIAC MEMBER: Awful. I can't--

CLIAC MEMBER: You need to-- I shouldn't say that because, otherwise, open mouth, insert foot. But you need to deputize a typist.

CDC EX OFFICIO: In the NGS examples, we took out the word validation, but we should put it in the language in the regs- establishment and verification of performance specifications, in the examples. We took out validation earlier. Could we add back in the language that's in the regs? Establishment or verification of performance specifications.

CLIAC CHAIR: Establishment or verification of perform--

CDC EX OFFICIO: Establishment and verification of performance specifications.

CLIAC CHAIR: And I apologize to people. There is a fan coming from somewhere that you hear when you're at this computer. So, when I can't hear you guys, that's why. All right, let's step back and have a read.

CMS EX OFFICIO: [CLIAC MEMBER] on question two, there was some discussion on the reporting. Should there be some language in there on reporting?

CLIAC MEMBER: I'll defer to the wiser, collective consciousness of the group. I think that first paragraph is perfect. I think that's it. I think by increasing the level of specificity here, by us forgetting something, as you're pointing out, could imply that it's not an issue. I think you're safer by just not having any specificity. That first paragraph's perfect, as a recommendation.

CLIAC CHAIR: All right, what do folks think of the second paragraph? Any opposition to the second paragraph?

CLIAC DFO: One other consideration would be to make it a second recommendation that's specific to NGS.

CLIAC CHAIR: So what do we think of that idea given that we hopefully are about to go into a number of specific recommendations?

CLIAC MEMBER: It makes your record even harder to break.

CLIAC CHAIR: It's true, but it's so referential to the first paragraph, that I wonder whether it might just be better off sticking in there?

CLIAC MEMBER: Is there any reason to split them?

CLIAC CHAIR: Yeah, I'm happy with my record, so we can keep it.

CLIAC MEMBER: In terms of responses and stuff?

CLIAC CHAIR: No. So if we're happy--

CLIAC MEMBER: Just a little wordsmith thing.

CLIAC CHAIR: Yes?

CLIAC MEMBER: Third line down from the second paragraph. It says controls to controls. Was that intentional?

CLIAC CHAIR: Unfortunately, it is intentional and technically correct. It's just-- catches the eye. Yeah it's weird. I mean, I could say this. How about that? OK. So I think at this point, perfect being the enemy of good enough, I would entertain a motion to vote.

ADVAMED LIAISON: Are we still doing, if you scroll down, are we still doing the next recommendation?

CLIAC MEMBER: No, we're going to treat these two things as separate, I think. I think it is fair for those to be two, because--

ADVAMED LIAISON: I would agree, I just wasn't certain if you're getting rid of that third paragraph.

CLIAC CHAIR: Oh, no. It's just not part of it. And, actually, [CLIAC DFO], again, remind me. We don't recommend the formation of a workgroup. We can just form a workgroup, correct?

CLIAC DFO: It helps to have a recommendation.

CLIAC MEMBER: OK, so we should do that. So maybe that'll be a second, hopefully non-controversial, quick-

CLIAC DFO: The idea would be to articulate the tasking objective of the workgroup.

CLIAC CHAIR: Got it. OK, so one thing at a time then. These will be two different recommendations. The first recommendation being the two paragraphs you see on the screen. For those following along at home, it's the first two paragraphs. I'll entertain a motion to bring this to a vote.

CLIAC MEMBER: So moved.

CLIAC CHAIR: So moved. Seconded. We have a second. All those in favor? Any opposed? What about telephone?

CLIAC MEMBER: I'm in favor

CLIAC CHAIR: OK, and [CLIAC MEMBER]?

CLIAC MEMBER: in favor

CLIAC CHAIR: Fantastic. OK, so none opposed. No abstentions. All right, passes? Let us quickly, I hope, move to this second, I think, noncontroversial recommendation and then what we'll do is we'll take a-- I think it's almost time for a quick break. It might actually be time for that break. And then come back after the break and deal with specific recommendations. So, if you will humor me, this is, let's see, CLIAC recommends creation of a CLIAC workgroup with the charge of advising on how CLIA should be changed to reflect these things. How CLIA might specifically be updated, how about? Integrating and reflecting. All right, again, perfect being the enemy of the good, what do we think about this? And then I guarantee you we will move to a break. If no discussion or opposition, I will entertain a move to vote. We have one by [CLIAC MEMBER] or is it a comment?

CLIAC MEMBER: Oh no, it's a comment. I got to noodle on this first. Do we want to-- sorry, this is semantics-- do we want to create a new workgroup or do we want to continue the existing workgroups?

CLIAC CHAIR: I think a new one. Different charge.

CLIAC MEMBER: And do you-- your second line might specifically be updated. You may not need to update CLIA, right? There may be a creative way to apply the existing CLIA.

CLIAC CHAIR: Sorry, we may--

CLIAC MEMBER: There may be a way to apply the existing CLIA to address these, so would you consider wording it on how CLIA might address, not specifically be updated, but might address the issues in the reports by the personnel regulations?

CLIAC CHAIR: So, in my role, not as chair, but as drafter of this, I kind of like the 'might specifically be updated.' It's still got the 'might' in it, so it gives the option to say, no, unnecessary. And I like that the charge include that we had updating in mind. Further discussion?

CLIAC MEMBER: Can we add something about inclusion of some of the other workgroup members? Because I kind of feel like this workgroup would need some historian from the other three. And I don't know if that's too specific, but, maybe when they're making a decision on the workgroup, I think there'd be a lot of lost time if there wasn't some input from the former groups for continuity.

CLIAC CHAIR: I agree with that.

CLIAC MEMBER: Very good. Other discussion? All right, seeing none. Motion to vote? Several. Seconds? Several. All right, all in favor? On the phone? All right, any opposed? None. Abstentions? None. All right, let's thank you all.

CLIAC MEMBER: I wonder if we could ask [CLIAC MEMBER] to make a list of low-hanging fruit for us for the next session? During the break maybe?

CLIAC CHAIR: That would be fantastic. Sorry, I spoke over you. What was your answer?

CLIAC MEMBER: Sure, absolutely.

CLIAC CHAIR: Great. All right, it is now 11:10. We are slated to get back at 11:15. I propose we push that to 11:20. If everybody is in favor with that, we'll break till 11:20 and be back here prompt and work through the low hanging fruit. Thanks.

---Break---

CLIAC CHAIR: Oh, it's still not on. So thank you all for coming back. Our mics are not on. I will yell until they do come on. There's been an inquiry about a photo. The policy is-- there we go-- not to have photos unless there are new members. But I'm happy to have a photo. I think what we will do is make the photo a reward for ourselves for finishing ahead of time. So--

CLIAC MEMBER: I just wanted to make a comment about the last motion recommendation that we approved. The last motion we approved - I wanted just to make a comment on that.

CLIAC CHAIR: Yes.

CLIAC MEMBER: So I took that to mean that [CLIAC DFO] comments that it would be helpful if we as a group considered how CLIAC had input on-- basically, what if you were starting from scratch, right? How would we reimagine and how would we want CLIA, that was in the contract with [INAUDIBLE]. But with current state of technology, what we know now on a personal scale as things have changed. How would we want to look at CLIA now? So my interpretation of what was being asked when CLIAC was-- can we attack that.

And I think it's not just with what the current law says. But it could be starting fresh right now. So I didn't want to generate too much discussion right before break on that. I'm hoping that that part of the charter-- that idea can be incorporated in that recommendation. I was hoping.

CLIAC CHAIR: Sure. I would say that the word "update" can be interpreted with as much latitude as you want. And to paraphrase what [CLIAC MEMBER] said, I think he said he is volunteering for the workgroup.

CLIAC MEMBER: Absolutely.

[LAUGHTER]

CLIAC CHAIR: Fantastic, and thank you. Right. So we have now about an hour and a half. If we finish early, we will try to do an impromptu photograph to memorialize the occasion, which will be right outside if we manage to get it done. But between now and then, what we, I think, want to set our minds to are the low-lying fruit that [CLIAC MEMBER] mentioned before the break. Again, I had been taking notes during his

presentation. And based on the workgroup report, there's, as I'm sure all of you have found, like, a number of specific things that we can usefully recommend, including things not just that are low-lying fruit but that have lead time that will inform the next CLIAC meeting in November. So I propose that we now focus on that. And with that, [CLIAC MEMBER] , are you back with us? You probably never left.

CLIAC MEMBER: Yeah, Yeah, I'm here.

CLIAC CHAIR: Fantastic. So what I would suggest is if you have the SharePoint document open and you have a list of low-lying fruit, that maybe you go ahead and drop those in if you haven't already. And sorry, I'm looking in front of me and behind me at the same time. And then we work from that list.

CLIAC MEMBER: I did already. Tell me if you see them.

CLIAC CHAIR: Yes, we see them.

CLIAC MEMBER: You see them. OK, good.

CLIAC CHAIR: Mm-hm. So in the name of efficiency, I propose we just start right in on this list. Would you like to introduce point number one, Jordan?

CLIAC MEMBER: Sure. So again, I don't know how good I am or poor I am at writing. But I wrote basically that CMS and CDC send out a request for a guideline developing a professional society which could include but are not limited to oncology, inherited testing and microbiology applications of next generation sequencing. Recommendation topics for the guidelines include-- now we're specifically focusing on revalidation. But I separated it to kind of be the wet part and the dry part. When you make any changes to these areas. What does that validation guideline look like, and revalidation in terms of software updates, changes to the software that's in the pipeline. Those probably should be separate guidelines. I quickly went through the presentation again to see if there was anything else. That was what I came up with quickly. And I don't know if this is even an appropriate or possible mechanism. I don't know CMS or CDC has never done anything like this or a request for guidelines-- essentially a request for information.

CLIAC CHAIR: Maybe--

CLIAC MEMBER: So we just want this to go to professional societies or also organizations like CLSI and others-- CAP.

CLIAC CHAIR: So [CLIAC MEMBER], let me ask, so suppose we end up with the proposed or the referenced guidelines. What would be the next steps? What would come of that?

CLIAC MEMBER: Well then, I'm not sure these would be really leveraging HHS to share information with the community at large, reflecting that specific community that guidelines are needed. I think if any of the professional societies or other organizations step up to create those guidelines, it should then benefit the community, not necessarily CLIAC or HHS. That said, whatever guidelines come out, who'd be useful resources in our other recommendations of updated CLIAC.

CLIAC CHAIR: So is the ultimate goal then HHS as a mouthpiece to broadcast this need and also as a clearinghouse for these in a way that individual societies cannot do?

CLIAC MEMBER: I didn't think of it-- I was thinking about it just request. I didn't think about the clearinghouse. Has HHS ever functioned in that capacity? Certainly, clearinghouses are beneficial.

CLIAC CHAIR: All right. thoughts?

CDC EX OFFICIO: I mean, we could be part of the guideline development, too, as well as just the call out.

CLIAC MEMBER: Hi, this is Sue on the phone. The only thing to beware whenever you do a clearinghouse for guidelines is there has to be something in place to maintain those guidelines. In other words-- not maintain the guidelines, but whenever there's a change in guidelines, no matter how minor, it has to be updated in that clearinghouse. So someone there is just... That's a wonderful idea that actually benefits everyone-- patients and laboratories. But so this is something to think about, I think.

CLIAC CHAIR: So devil's advocate, let me play devil's advocate for a second. So suppose I am a member of one of the aforementioned societies. And I'm sort of maybe a foul-tempered person. I come back and I say, well, the nerve of those government types asking for guidelines, we've-- oops. I think I've done something to the computer here. The nerve of those government types. They already have guidelines. In fact, they have our guidelines. So you know, what's the point of this exercise? You're only making it more complicated for people to know what to do because we had our perfectly good guidelines. And now they're getting guidelines from us and others. Everybody knows ours are best. You're contributing to confusion-- typical government, et cetera, blah, blah blah. So that's a devil's advocate position. But we would come back and say the utility of this is--

[LAUGHTER]

CLIAC MEMBER: Well, there was the guideline clearinghouse for clinical guidelines. It closed down. It's to every-- I can tell you clinicians, it was really, truly painful. It was an amazing thing to have a repository of guidelines. And unfortunately, that's no longer with us, may it rest in peace. So it's true that-- I see the point. But from a practical point of view, again, it's a wonderful thing. The issue is it's an enormous amount of effort to maintain it. And I suspect that's why our clinical guideline clearinghouse was shut down. I think budgetary, as I recall.

CLIAC CHAIR: But you found it useful.

CLIAC MEMBER: It's more of a practical issue.

CLIAC CHAIR: But you found it useful, I guess what, in order to compare guidelines from different agencies looking for commonalities and differences?

CLIAC MEMBER: Exactly. It was magnificent. In fact, it was so good because it also included guidelines from outside the country. Many of the guidelines when you read them will have a scientific assessment. So for those who are really serious about guidelines, it was a wonderful thing to-- it was a literature review, especially the current one-- and to see, again, maybe for the average rank and file clinician out there, may not find time and just follow-- your point is correct.

If let's say I'm a member of a certain society and for-- and [CLIAC MEMBER] and the others will know this very well-- from NextGen, we have the ACMG, the guidelines that direct our various activites in classification. So there's certain guidelines that just take over the community. Furthermore, people who belong to a certain society even follow the society guidelines, by and large. However, for those in labs or more scientifically inclined to see how the various societies come up with their guidelines could actually be very informative. But again, the worst thing you can do is take responsibility, have a clearinghouse, and then not have a way to ensure

that every single guideline is up to date. Because it can actually harm-- there is real harm to an outdated guideline. And if a society changes it, then it's gone.

CLIAC CHAIR: Got it.

CLIAC MEMBER: Then you've got people practicing poor care. So again, many of us were absolutely outraged/heartbroken. But I understand that the budget wasn't there to maintain a clearinghouse. It's just not there.

CLIAC CHAIR: Understood. And then to [CDC EX OFFICIO]point, if I'm understanding you correctly, when you say the CDC would be happy to jointly develop guidelines, would that be sort of consensus guidelines based on these others?

CDC EX OFFICIO: Yeah, well, best practices. I mean, like I said earlier, I mean, I think there's just a clear need to provide help to the laboratories right now-- certainly, public health laboratories. And I think it was noted in the report that additional guidances are needed for microbiology and for infectious diseases. So I think it could be best practices or guidelines.

CLIAC MEMBER: Yes. Again, just piping in one more time. I really love that idea because both the clinical and the lab community really look to CDC. And often, you'll see other guidelines simply reframed or even cutting and pasting. So CDC has a lot of weight, yeah. And I understand if you can just clarify for me best practices versus guidelines versus recommendations because I know each of those words carry meaning.

CDC EX OFFICIO: Yeah. So I think FDA uses guidelines. At CDC, we have recommendations and best practices. And you know, there's different routes and clearances and ways of gathering data based on the approach that's taken. I don't know if Peter wants to mention that.

FDA EX OFFICIO: Yeah. I think most frequently recently, we have guidance.

CDC EX OFFICIO: Yeah.

CLIAC CHAIR: So [FDA EX OFFICIO], could use a microphone?

FDA EX OFFICIO: Yeah, most frequently we recently would have guidance or we may recognize various consensus standards.

ADVAMED LIAISON: So I'd just like to clarify. [CDC EX OFFICIO], you're saying that-- I thought you were saying that CDC would be interested in creating guidelines or guidance.

CDC EX OFFICIO: We could be part of the group.

ADVAMED LIAISON: Like, up here, the comment is that you would maintain a clearinghouse for all these. And I'm not sure that's what you were--

CDC EX OFFICIO: No.

ADVAMED LIAISON: All right. Because I think the challenge is asking a federal agency to maintain a clearinghouse is not within the scope of what they would normally do. That would be a professional association or other organization. The federal agencies would create rules or educational components or something like

that. And then organizations like CLSI could be involved in creating guidelines or standards to meet a regulation. So I think we're kind of blending things in this number two.

CLIAC CHAIR: So as you were as you're talking, [ADVAMED LIAISON], I modified number two to reflect that. It seems to me that if the government were to create guidelines, there's no harm. And in fact, based on [CLIAC MEMBER] comments, probably utility to also including other related documents. So in that sense, maybe it's a bit of both.

ADVAMED LIAISON: And just be careful about the word "clearinghouse" because as previously mentioned, clearinghouse is about maintaining, updating, and all related to that.

CLIAC CHAIR: Is repository just as bad?

ADVAMED LIAISON: I would prefer it if one the agencies would comment on repository.

CDC EX OFFICIO: Yeah, I mean, we post all of our materials that are cleared that these guidances would be publicly available on the website. So it wouldn't be a repository, per se.

CLIAC CHAIR: I see. But would you maintain, say, a link to CAP's guidelines or AMP's guidelines in addition to your own? So shaking your head no. So again, I want to get back to members from the workgroup and say I'd like us to be precise about the use case or utility. Sorry, somebody's got their hands up.

CLIAC CHAIR: Oh, sorry. You can't hear me. So I'd like to be precise about the use cases that the workgroup members see this going to. I'd like to make sure that a proposed recommendation, whether it just be the development of new consensus guidelines or best practices or some reference to existing or previous ones, serves one of the essential gaps identified by the workgroup in response to one of the questions. So would somebody from the workgroup like to respond? [CLIAC MEMBER], I would be looking at you if you were here. But anybody who is on the group can respond.

CLIAC MEMBER: So I'm not sure I get it? Could you repeat it?

CLIAC CHAIR: So again, use case-- so what is the specific gap that these recommendations fill, and what specific question does that respond to?

CLIAC MEMBER: So just expanding on the A and the B part?

CLIAC CHAIR: I guess number two because I think we're folding in one and two together. Is that--

CLIAC MEMBER: So for number two, I mean, it came from the NGS workgroup, right? So I think from a scope perspective, having it related to NGS would be appropriate. But if there's already going to be funds to maintain that guideline repository. I think it needs to be limited somewhere. So that's why I suggested laboratory organizations.

CLIAC CHAIR: I see. So that shouldn't be NGS?

CLIAC MEMBER: If there was a guideline about D-dimer testing, if the infrastructure's already there, and put it in there.

CLIAC CHAIR: And things like choosing wisely, which has got D-dimer in it failed for what reason? Again, I'm trying to understand what specifically does requesting such a thing add.

CLIAC MEMBER: I was actually putting it out there because I was hearing the conversation.

CLIAC CHAIR: Ah. So what I heard is more like blending one with two, so going beyond number one-- going beyond sending out a request for guidelines and turning number one into number two. And these specific regulations are about NGS, as you've put in number one. That's what I understood from the conversation. Maybe I missed something. What does the room feel?

CLIAC MEMBER: So I just think strategically, I'd prefer them separate only because one as a core. If it's only the request, you call out, hey, you know, we had this workgroup. And there's clearly the community standards for guidelines. We're asking societies and other organizations to push out guidelines. If one guideline is produced because of that call-out, I think recommendation one is already a step. I just necessarily want to tie it to the creation of the repositories because this step requires funding and approval and all of that. So I just want one step to be tied to the successive two. Does that make sense?

CLIAC CHAIR: Understood. Further discussion in the room of one and two, or shall we take a quick survey of the others? So I take lack of comment as let's take a quick look at the others and come back to one or two.

CLIAC MEMBER: There are two two's.

CLIAC CHAIR: I know there are two two's. I'm going to change them now two three, four, and five. We're all sufficiently numerate to handle that.

[LAUGHTER]

So I'll let the room read briefly three proposed recommendations-- three, four, and five-- which again, are part of the low-lying fruit that the workgroup identified. And then as soon as people are done, just please speak up. And we will discuss whatever the committee feels they want to discuss.

CMS EX OFFICIO: I have a question.

CLIAC CHAIR: Yes, [CMS EX OFFICIO].

CMS EX OFFICIO: This is [CMS EX OFFICIO]. I have a question about using LOINC since that's what everything is going. Is there any other computer type language that would be appropriate for genetic testing?

CLIAC MEMBER: So I think you could probably guess by the shortness of that recommendation is that that's a interesting topic. I'm going to give you another standard that would be appropriate. I was just reflecting back the group's concerns about whatever organization was used that SNOMED needed to be incorporated.

CLIAC CHAIR: Well, what were the group's thoughts on SNOMED?

CLIAC MEMBER: Yeah, so I was at the committee meeting. And that's exactly the point made. So I thought it was made quite strongly that LOINC would not be sufficient and that SNOMED would have to be incorporated and that there's great international progress in that regard. So I think you should list them both. And it will be resolved in other groups over the year.

CMS EX OFFICIO: I was going to suggest they had to do SNOMED, too.

CLIAC MEMBER: Yes, using LOINC and SNOMED as the standards.

CMS EX OFFICIO: I'm just not so sure that the way LOINC is done and set up would really work for genetic sequencing.

CLIAC MEMBER: No, you're very perceptive. And that's exactly the concern.

CMS EX OFFICIO: Yeah, I mean-

[LAUGHTER]

CLIAC MEMBER: Although, I would like to point out for NGS for microbiology at least, the end point is an organism ID. And so while the rest of it needs to be mapped and annotated, that end point result still needs to be able to be standardized in the medical record for data acquisition. And the LOINC for microbiology is probably by organism name and the RxNorm codes that are associated with it. Because some of these companion diagnostics might have to pull in RxNorm codes as well. It's just a thought.

CLIAC MEMBER: It actually works across both microbiology and genetics. And the issue there is that the LOINC term would be is staph aureus present. And the SNOMED code would be yes or no and was detected by such and such. So it actually has to have a combination of LOINC and SNOMED to answer the question correctly.

CLIAC CHAIR: And is the concern of the committee not just about LOINC's shortcomings but also that SNOMED has equivalent or complementary shortcomings? Or is this meant more to be a vote in favor of SNOMED and against LOINC?

CLIAC MEMBER: I think you should stay out of that and just put it in there. And let the chips fall as they may in the next two years. Actually, it would be SNOMED International, so SNOMED is clear enough at this point.

CDC EX OFFICIO: And there's a HL7 genomics workgroup. And as I remember from the meeting, there was a discussion there would need to be some engagement with that group moving forward.

CLIAC MEMBER: So if you wanted to throw in data exchange and then HL7 or Fire, you're really getting into the weeds here. But you could say inter appropriate data transmission standards.

CLIAC MEMBER: So just a little bit of wordsmithing in terms of we're not necessarily sharing concerns anymore. Now we're supporting the use of LOINC and SNOMED for incorporation of standards for interoperability and data usage.

CLIAC CHAIR: Yes.

CLIAC MEMBER: Right.

CLIAC CHAIR: OK.

CLIAC MEMBER: So it's not like you have concerns about LOINC and SNOMED. We're actively supporting. I don't remember who is the target audience for this support. Who decides what to use?

CLIAC CHAIR: That's a good question. Do we have answers?

CMS EX OFFICIO: It's almost been more industry. It's kind of pushed for, like, LOINC and SNOMED.

CLIAC MEMBER: That's a very interesting issue.

CLIAC MEMBER: How would they support the use of one of these?

CLIAC MEMBER: So actually, [FDA EX OFFICIO] and a group at FDA are really leading the way in this whole area. It's known as Shield. And it can be incorporated in a number of ways, either by referring to a standard table outside of a so-called FDA approved process, or it could be incorporated into the test as it's being developed. So that in itself is also a subject of ongoing activity. [FDA EX OFFICIO], do you want to say more about that?

[FDA EX OFFICIO]: Yeah, I mean, I think it's obviously a broad effort that involves a lot of stakeholders in order to move it forward. I mean, that's the biggest thing. It's not only the people here. But I think that there are roles that CDC, CMS, and FDA can play to move forward interoperability along with a bunch of other partners, including the firms that develop EHR software. And it goes beyond just the laboratories and the device developers. It's a pretty big group of people that have to be involved. But I think we can all contribute to advancing interoperability.

CDC EX OFFICIO: Yeah, but maybe the specific concerns around NGS can be brought forward to Shield more directly.

CLIAC CHAIR: So again, I come back to the question-- not always playing devil's advocate-- only sometimes playing devil's advocate-- but just wanting to be explicit about which problem identified by the workgroup LOINC plus SNOMED to address this. So is the issue here just interoperability-- just having a standard where currently there isn't a very good one?

CLIAC MEMBER: It depends what you mean by interoperability. So it also is relevant to the issue of clinical interpretation and linking data to sets of various types. For example, in the anatomic world, the ability to add a LOINC and SNOMED to the anatomic term and make it computational is the real goal. And then by linking that through LOINC and SNOMED to your genomic and genetic testing, you're really adding capability. So it's much beyond operability. It's really usability of the data sets and the ability to then make them computational when in the past they were just English terms.

CLIAC CHAIR: Other thoughts?

CLIAC DFO: I'll say it. I think it's sort of out of scope because it's not related to the clinical practice and the sharing of information. But to the extent that once those interoperability classification codes are identified, the ability to link and improve and better refine the relationship between them and ICD-10 and probably CPT is probably relevant. That's another side of this building. But I think it's worth, as the group looks at this, to get better clarity amongst all these ways that we report different kinds of information about these services. So it may be sort of out of scope because it's more about the billing and the reimbursement side. But it is something that we all struggle with.

CLIAC CHAIR: But it need not be restricted to that, as [CLIAC MEMBER] was saying.

CLIAC CHAIR: It's all kinds of capability. It's certainly, I mean, historically, billing is what's driven coding but from the perspective of clinical informatician. And in fact, the late Warner Slack who, with Howard Bleich,

built one of the first systems in the country for that. Their goal of building an infrastructure was not for billing at all. It was purely for clinical outcomes. And their experience was it only happened to be the green visored money people who ended up paying for it because they found they could bill for it. So if the issue is this is out of scope because it's only billing, I would push back a little on that.

CLIAC MEMBER: Well, yeah, and maybe that was overstated. Because obviously, the same data are now being used to generate quality and performance and so on. So it's not irrelevant. I just want to make sure that it's kind of on the list. Because as we struggle in real laboratories to try and get the information and all the information that we need for the multitude of purposes that ICD, CPTPs. And the MolDX Z codes for those that are under MolDX and others do create a level of complexity that maybe developing a single vision could help streamline.

FDA EX OFFICIO: Another possibility is that maybe take it up a little-- another higher level-- and just say something about support the use of standards of interoperability for genetic and genomic testing and for interoperability or at least just maybe not say specific ones because there are additional standards that may also be useful or just to promote the general approach to how should we be using these types of standards for this type of testing. But maybe not specify which exact standards, even if it may be that these are two among maybe a few more that might all be used together ultimately. But rather than if there isn't a strong desire from the community to specify these particular two.

CLIAC MEMBER: Well, maybe that's why I reacted because we struggle on the other side every day.

CLIAC MEMBER: So if you want to go back to four, taking that into consideration, CLIAC recommends the support of interoperability or the importance of interoperability. And then that addresses [FDA EX OFFICIO' point to maybe take out just LOINC and SNOMED as the only examples, unless you want to put them in as IE, LOINC, and SNOMED.

CLIAC CHAIR: And [CLIAC MEMBER] could you wordsmith a little of that for me again, Please?

CLIAC MEMBER: CLIAC acknowledged the importance of interoperability and the incorporation of standards for interoperability in genomic and genetic testing. And in addition to interoperability, could you add standards for data usage and interoperability. So in front of interoperability, put-- OK, fine there, too. There you go.

CLIAC CHAIR: So an acknowledgment is useful. I wonder if there's a specific recommendation, though, to the agencies based on that. I mean, we're telling them it's important. But is there something we want them to do in this revised version?

CLIAC MEMBER: OK, well, sorry. I'm really getting goofed up here. So then CLIAC recommends the incorporation of data standards then for the achievement or interoperability for the utilization of data and interoperability for genetic-genomic testing. And as [CLIAC MEMBER] pointed out earlier, it's also microbiology. So I don't know if you want to then say in NGS or something like that. [CLIAC MEMBER], how would you incorporate that?

CLIAC MEMBER: I think if you just say across the clinical laboratory subspecialties or something like you have there. You might want to say across the subspecialties focusing on the most pressing clinical laboratory needs in oncology, genetics, microbiology-- something like that.

CLIAC CHAIR: So I don't know what the keyboard shortcut is to redo. And I don't see an edit menu. But is this the gist of it?

CLIAC MEMBER: Yeah, across the laboratory subspecialties then, I think.

CLIAC CHAIR: So then the specific mention of specific standards like LOINC, SNOMED, and HL7 and Fire is no longer necessary, correct?

CLIAC MEMBER: [FDA EX OFFICIO], you agree?

FDA EX OFFICIO: Yeah. I think it's kind of better to have it a little bit more general. That way it leaves room for future development-- fast moving area.

CLIAC CHAIR: Fair enough. I propose we go through these first and then return to a vote just in the last few minutes. Is that all right? Again, seeing no violent opposition. Can I ask what the committee thinks of recommendation 5? Yes, [CMS EX OFFICIO.]

CMS EX OFFICIO: CMS normally does not do surveys of our laboratories where we usually are not encouraged to do that. And I don't think we are allowed to. So this would actually be more a CDC function that we could work with them on. They do have more of an ability to reach out to labs and get that kind of data from the groups and from facilities. But we would definitely work with them on looking at that data.

CDC EX OFFICIO: We can do that.

CLIAC CHAIR: [CDC EX OFFICIO], yes?

CDC EX OFFICIO: Yeah.

CLIAC CHAIR: Fantastic. So I must say personally I like this recommendation quite a bit. We can make better decisions with data and two places where data is sorely lacking the workgroup found was in who, what, and just all the details regarding bioinformaticists. The second, which is not up here but I might put up here if we get time, is surrounding the volumes and details of what tests are done, which was another thing that [CLIAC MEMBER] summarized in his report. Do you have a better idea about-- well, I'll just leave it at that. We can come back to that. But what do you folks think of five.

CLIAC MEMBER: So I think that is a great question to ask. And I'm wondering, since-- or maybe we don't have a bioinformatics service to last. But I'm wondering where it'll slide into bioinformatics that would be able to try to updatet everything that's [INAUDIBLE] companies that would be traditionally called academic setting provide support in an academic setting, if not actual function in a laboratory. So overall broad coverage is needed.

CLIAC CHAIR: I love that idea, especially given that it's these other organizations. And I might have made it even broader than what you intended by just saying and other organizations. But the options for job offers for people trained in bioinformatics include broadly speaking clinical environments but also things that have very little to do with direct patient care. And seeing as that's the competition on the market that we best know about that. So for instance, if Acme Co., one of the world's leaders in pharmaceutical development, employs bioinformaticians with the same NGS skills that say our local laboratory does, and for instance, they have different responsibilities, different educational requirements, or slightly different educational requirements that subsume what we've traditionally looked at in our own little hospital but are paying twice as much, for example, or only ever think to employ a bioinformatician level 2 with the following nonbioinformatics like sysadmin types or whatever, that kind of information is useful for us to know. There was another hand, I think. Another hand. So five seems pretty uncontroversial. Four also seems to be pretty uncontroversial at this point. Or is there more discussion on four? I'll try to put-- I'm going to leave--

CDC EX OFFICIO: Sorry to interrupt you. Should you change HHS to CDC then in number 5?

CLIAC CHAIR: Sure. Thanks, [CDC EX OFFICIO]. So I'll try to keep as many of these on the screen at a time as possible. And I will entertain discussion of any or all of them or others at this point now that we've seen, like, the main ones here. We are going to come back to two.

CDC EX OFFICIO: So on number one, as we looked through that or heard from [CLIAC MEMBER] report out, the data management retention and sharing might be another guidance example we might want to put up.

CLIAC CHAIR: Sorry, it might be A?

CDC EX OFFICIO: Another guidance underneath the A.

CLIAC MEMBER: Yeah.

CDC EX OFFICIO: Maybe there's a C that we might want to have. I don't know what the committee would think about adding that.

CLIAC CHAIR: Well, [CDC EX OFFICIO], we'll take-- if you can, I guess not formally propose something, but if you can say some words, and I can take dictation. And then we can ask the committee. What would you say?

CDC EX OFFICIO: So maybe the-- where it says recommended topics for guidelines includes-- so maybe the revalidation piece needs to go with A to B, and then there's--

CLIAC CHAIR: Sorry, I'm too slow for you here. Recommended topics for guidelines include revalidation or changes to--

CDC EX OFFICIO: So the revalidation is related to A and B.

CLIAC CHAIR: Mm-hm.

CDC EX OFFICIO: And then maybe the next one on data management retention and sharing.

CLIAC CHAIR: Whoever's typing, thank you.

CLIAC MEMBER: Yeah, I'm typing. [LAUGHTER]

CDC EX OFFICIO: Thank you.

CLIAC CHAIR: And [CDC EX OFFICIO], could I ask that you lean closer to your microphone?

CDC EX OFFICIO: Sure.

CLIAC CHAIR: So like that?

CLIAC MEMBER: Do you want to include providers in part D?

CDC EX OFFICIO: So [CLIAC MEMBER], in the sentence that starts recommended topics for guidelines include the revalidation following changes to is related to A and B.

CLIAC MEMBER: Correct? Yes.

CLIAC MEMBER: Maybe this?

CLIAC MEMBER: Now I'm just getting obsessive.

CDC EX OFFICIO: Maybe while [CLIAC MEMBER] is typing, I just wanted to bring up one more thing I had just discussed with [CMS EX OFFICIO] at the break about-- as we're thinking about the low-hanging fruit. I'm not sure this isn't a recommendation, but options for modification to the existing interpretive guidelines so that while we're waiting for the new rules to come, is there any change that we can make now in those guidelines? Because that's another quicker win.

CLIAC CHAIR: Thoughts of the committee?

CLIAC MEMBER: Can you say that again? I'm sorry. I couldn't hear you.

CLIAC CHAIR: I think all our microphones are too loud, and yours is too soft.

CDC EX OFFICIO: So I had brought up the suggestion and I had a discussion with [CMS EX OFFICIO] about whether there was opportunity to reassess the existing interpretive guidelines to see if there was options to address some of the current NGS gaps that we've been discussing all morning--

CLIAC MEMBER: Hm.

CDC EX OFFICIO: --whether the committee thinks that's something that should be considered. I mean, it's part of the process anyway, right, [CMS EX OFFICIO]?

CMS EX OFFICIO: Yeah.

CDC EX OFFICIO: Yeah.

ADVAMED LIAISON: How much quicker does that actually come if you were to go--

CMS EX OFFICIO: If it's to the guidelines, it would be-- it starts to go through a clearance process and everything. But it would be additions to what was already there probably. Depending on how quickly it would go through, it'd be about six to eight months.

CLIAC MEMBER: That's fast.

CMS EX OFFICIO: Anything we add, again, goes through our OGC as well. So we could think that something to add is, like, really, really great. And then they can say, no, it's got to be rule making, which then brings it to a halt. But we would run any of that by them. And if they were OK with it, we would draft it and go forward.

CDC EX OFFICIO: But it's not years.

CLIAC MEMBER: So for clarification, do we need changes to the interpretive guidelines that CMS uses on their inspections, versus most of what we've been talking about is, I guess, more rule making. Is that the--

CMS EX OFFICIO: The interpretive guidelines or surveyor guidelines when they go into the labs as far as some extra interpretation--

CLIAC MEMBER: Right.

CMS EX OFFICIO: --of the regulatory requirements. But labs can use that as well.

CLIAC MEMBER: And that's what you were--

CDC EX OFFICIO: Yes.

CMS EX OFFICIO: Yes.

CDC EX OFFICIO: Correct.

CLIAC MEMBER: I wasn't sure if we're using guidelines here and--

CMS EX OFFICIO: Lots of guidelines.

CLIAC MEMBER: Right.

ADVAMED LIAISON: And do those roll down to accrediting organizations as well?

CMS EX OFFICIO: Yeah.

CLIAC DFO: They're public.

ADVAMED LIAISON: Well, I realize they're public. I just didn't realize-- I didn't know if the interpretive guidelines were only for CLIA surveyors or the accrediting-- the AEOs also--

CMS EX OFFICIO: They can use them.

ADVAMED LIAISON: --look at those--

CMS EX OFFICIO: They can all use them.

ADVAMED LIAISON: --and incorporate those into their changes.

CMS EX OFFICIO: And that when we would make those changes, we would send out notices, so they would be aware of them anyway.

CLIAC EXECUTIVE SECRETARY: And just following up on what [CMS EX OFFICIO] already said, so the guidelines can't include any new requirements. But they can clarify or provide additional information that's helpful to surveyors for the existing requirements.

CLIAC CHAIR: So I suppose at this point having had a chance to consider these first several recommendations that we look at them again with an eye toward a vote. So if you are prepared to vote them up, I propose that you propose a motion to vote. And if not, then I would focus your discussion as to why you think that they should not be voted in favor in the current form. So starting with recommendation one.

CDC EX OFFICIO: Could we just have a reconsideration of number two?

CLIAC CHAIR: Yes. How so, [CDC EX OFFICIO]?

CDC EX OFFICIO: Well, I just-- I mean, I can't--

[INTERPOSING VOICES]

CLIAC DFO: Yeah. So I mean, maybe I'll be a little more blunt than [CDC EX OFFICIO]. You know, CDC can't publicly endorse a specific organization's position. And so I think I'll speak for CDC. CDC can publish and post CDC guidance and CDC recommendations. But we can't get into the practice of deciding to advertise for CAP or some other organization.

CMS EX OFFICIO: No, we can't, either.

CLIAC DFO: So we can't, as much as we recognize the importance of a repository on this issue that extends beyond government resources, we can't host that repository.

CLIAC CHAIR: So we have to change to something like that. I'm not saying that we want to do that. But I'm saying that that's what we could do.

CLIAC DFO: Yeah.

CLIAC CHAIR: OK.

CDC EX OFFICIO: Maybe in partnership with others.

CLIAC CHAIR: Right.

ADVAMED LIAISON: So I would ask that would this recommend that they create guidelines and best practices while we're asking HHS to revise and update CLIA so that when they may be done with creating best practices and then the regs change, and then we have to read that again. Is that what we're recommending?

CLIAC CHAIR: That's a good point. What do people think about that? I mean, I think it's an excellent point. I think that what might be a prudent approach right now is to not recommend-- yes, CDC EX OFFICIO.

CDC EX OFFICIO: Well, maybe it could be interim. I mean, I think there's a need for something sooner than later. And you know, we've heard it's going to take some time to get a change to the regulations, which are needed. So maybe an interim is the compromise so I’m just proposing that to the committee.

CLIAC MEMBER: Yes, I heard. Basically, we needed any changes six years, so I agree with that interim is needed.

CLIAC CHAIR: Fantastic. Need we put that word in, or will that just be the effect of these guidelines will be interim? I mean, our lives are all interim, right? I mean, everything comes to an end.

CLIAC CHAIR: Happy thoughts at the end of my tenure here, right?

CLIAC MEMBER: I think maybe we ought to throw it out because it's tied to another recommendation that may or may not go anywhere. What do you say?

CLIAC CHAIR: That's a good point, too,

CLIAC EXECUTIVE SECRETARY: When I read that first sentence it's so general to me that I don't really know what it's saying-- best practices related to lab clinical diagnostics. I mean, that's anything in the realm of laboratory testing.

CLIAC CHAIR: [CLIAC MEMBER] you penned that. Might I change it back to clinical NGS in the spirit of the workgroup?

CLIAC MEMBER: Correct, yeah. So originally, we weren't asking the institutes to create guidelines. We were asking them to house guidelines from other organizations. So then leaving it general, I think is more appropriate. Now we're asking the committee to create guidelines for NGS.

CLIAC CHAIR: Fantastic. All right. So thank you, [CDC EX OFFICIO], and [CLIAC DFO] for bringing those issues to attention. So now we have a revised two.

CLIAC MEMBER So Remy, I heard [CDC EX OFFICIO] say that some of the concerns were coming out of the public health.

CLIAC CHAIR: I'm sorry. It's the fan here. I can't hear anything anybody says.

CLIAC MEMBER: I thought I heard some of the concerns that need to be addressed are coming out of the public health laboratory sector. So when we say clinical NGS, would that be broad enough? Or should we instead say related to tests methodologies employing or testing employing NGS.

CLIAC MEMBER: How about clinical and public health NGS.

CLIAC MEMBER: Could do that.

CMS EX OFFICIO: Yeah.

CLIAC MEMBER: Yeah.

CDC EX OFFICIO: Yeah. That would be great.

ADVAMED LIAISON: And I might say that this might actually be quicker than later because there was a 2012 MMWR report that was good laboratory practices for genetic testing. And that might just need a dust-up, refresh, and letting other standards and guidelines organizations create something more lasting.

CLIAC CHAIR: How's that for two? And I should say, by the way, as soon as-- you know, don't let me be pulling teeth here-- as soon as people are satisfied enough with something to move it to a vote, time is of the

essence. So I'm happy to entertain those motions. And I'm also happy if somebody moves to a vote and somebody else raises her hand and says, nope, we ought to change this. Great, let that come out. And so if you want two before one or three before [INAUDIBLE], it's all fine. Valerie.

CLIAC MEMBER: I move approval of number two.

CLIAC CHAIR: Do we have a second? We have a second. OK, all those in favor for number two. On the phone.

CLIAC MEMBER: second

CLIAC CHAIR: Fantastic. All opposed. Abstentions, none. All right, number two is passed. I'm going to do this, I think. That leaves us with, and here in fact, I will do-- whoops. I'm going to move that to the top and out of the way so that we can focus on one, three, and four and five. And I should point out there's now a bunch of others that I just kind of added while people were talking. But we don't have to get to all of those.

[LAUGHTER]

Again, we're not trying to break any records here. And to give credit where credit is due, those were basically the notes that I was taking while [CLIAC MEMBER] was delivering the report of the workgroup. So it's pretty much the workgroup's words as far as I could tell. But let's get one through five out of the way first.

CLIAC MEMBER: Yeah, I would like to nominate or recommend number four to be approved. And that's not just to support your goal of becoming the Michael Jordan of recommendations out of the CLIAC committee.

[LAUGHTER]

CLIAC CHAIR: Do we have a second for number four? We have a second? All in favor? All opposed? Any abstentions? Sorry, on the phone-- I think I heard at least one approval.

CLIAC MEMBER: [CLIAC MEMBER] approves.

CLIAC CHAIR: Fantastic. OK, it's unanimous on the phone. So number four is passed. So that leaves the odd numbers. For numerologists following along, I think we will--

CLIAC MEMBER: I have a suggestion for some wordsmithing on number one.

CLIAC CHAIR: Yes, please.

CLIAC MEMBER: Just that first sentence.

CLIAC CHAIR: Yes.

CLIAC MEMBER: "CLIAC recommends the CMS" [INAUDIBLE] to be "that CMS, CDC, and FDA." You can get rid of "to." Thank you.

CLIAC MEMBER: Good.

CLIAC CHAIR: Yes.

CLIAC MEMBER: So is number one now-- is it subsumed by [INAUDIBLE] is number two [INAUDIBLE]

CLIAC CHAIR: I would have the same question. Again, we are under no obligation to pass everything that's up here or even to edit it into shape.

ADVAMED LIAISON: With the new number one we used for the proposed new workgroup to make recommendations.

CLIAC CHAIR: If so, the new workgroup would presumably be getting those guidelines itself without us having to ask an agency to do so. It's my guess. But again, I defer to the authors of number one. So with that question, I mean, let me push hard here then. So shall we delete number one?

CDC EX OFFICIO: Yeah. I mean, I was just thinking about number two. We were going to do an outreach to partners before any writing will be done. We're not trying to reinvent the wheel. We want to just fill the gaps. So I think it's sort of assumed that we do number one.

CLIAC CHAIR: So number one and number two go together, you're saying, basically, [CDC EX OFFICIO]?

CLIAC MEMBER: Sorry, I missed that. What's happening with that one?

CLIAC CHAIR: I'm sorry. And again, I apologize to people. You have to be standing here to appreciate it. So you're saying nix-- thumbs down, number one? OK, we have a vote-- we have a couple of votes for a thumbs down on number one. Other thoughts? Anybody want to stand in defense of poor, lonely number one?

CLIAC MEMBER: Yes, I would.

CLIAC CHAIR: All right.

CLIAC MEMBER: Correct. Again, I think it'd be worthwhile for the professional societies and other organizations to hear the government say, hey, we're asking you to help fill the gaps of need for guidelines. And then I didn't want to overcomplicate it, it's just a call-out-- a call to arms for the professional societies to help meet community need. I don't know what that venue would be. But whatever that venue is, once that's communicated, I would say suggest number one is complete and like I said, it could result in a single organization development of a single guideline, it would validate these questions.

CLIAC CHAIR: So that complements our past number two how then?

CLIAC MEMBER: I don't-- well, I think they're separate. I think one is a call to the community and one is a call to the government, recognizing that the government can't inform community guidelines. This is not an endorsement of community guidelines. It's just a call to make more of them.

CLIAC CHAIR: Is that call then best directed at the community and not at the government agencies? Sorry, we have a comment.

CLIAC MEMBER: Well, how does this compare to the CDC best practices that we heard?

CDC EX OFFICIO: I mean, so as I said, I mean, we would do a call-out to all of the professional organizations before they develop.

CLIAC CHAIR: So it sounds, [CLIAC MEMBER], that CDC EX OFFICIO--

CLIAC MEMBER: That was excellent.

CDC EX OFFICIO: I mean, that's sort of part of the process.

CLIAC MEMBER: I think it's a good idea.

CLIAC CHAIR: So it sounds, [CLIAC MEMBER], that [CDC EX OFFICIO] is saying that in order to accomplish our past number two, CDC will do number one without needing to be told.

CLIAC DFO: So what I hear [CLIAC MEMBER] saying is that this call to professional societies is to encourage professional societies to also develop or update their guidelines. It's not just a--

[INTERPOSING VOICES]

CLIAC MEMBER: we're sitting on information from experts in the field that are calling for guidance. And assuming we have a responsibility to share that request from the experts with all those stakeholders. Otherwise, we're holding up that information-

CLIAC CHAIR: So I've tried to revise the first sentence in response to what I heard from the past three commenters. Does this now better or more accurately capture what is being proposed?

CLIAC MEMBER: How does this relate to the second sentence of number two that we approved?

CLIAC MEMBER: So I guess maybe I misheard it or misunderstood. But I heard that the government cannot endorse or be perceived as endorsing any particular society guidelines. So the effectiveness of number two, to me-- actually says this-- in partnership with guidelines. So that means the only guidelines that are going to come out of part two is guidelines that are either wholly created by the government or in partnership with a professional society. Recommendation number one excludes the government altogether. It just says, hey, community, put out guidelines. They're needed.

CLIAC CHAIR: So I hear and understand that it's just who the call is to. One is saying, hey, CDC make some guidelines-- others saying, hey, government, please ask everybody to make some guidelines. I'm on board with that.

CDC EX OFFICIO: And we can coordinate one and two.

CLIAC CHAIR: And we can coordinate. So I've changed that first sentence with that in mind to CLIAC recommends that CMS, CDC, and FDA encourage professional societies and others, for example, CLSI, to develop and/or update NGS guidelines. And then the rest of the recommendation is unchanged from how we've put it together.

CLIAC MEMBER: But isn't that different than CDC coming up with best practices?

CLIAC CHAIR: It is different. So again, summarizing, I think [CDC EX OFFICIO] point is that CDC, of course, is going to ask people for their current guidelines ahead of making their best practices. [CLIAC MEMBER] point is yes, but we need more of such guidelines anyway coming from those other places. And so

it's so recommendation one is to encourage those other places to make their guidelines. So that's how they fit together.

CLIAC MEMBER: OK, thank you.

CLIAC CHAIR: OK, Maybe just one or two more comments,

CLIAC MEMBER: I motion to pass.

CLIAC CHAIR: OK, we have a motion to-- OK, and we've got a second. I'm assuming those are seconds and not other comments. OK. All in favor--

CLIAC MEMBER: Do we need to add that generic clause where it says, "recommended topics for guidelines include but are not limited to--"

CLIAC CHAIR: I'm fine with that. I don't suppose anybody's not fine with that. All right, well, we have a motion on the floor to vote. And we have it seconded. So all in favor of adopting one, and how about on the phone?

CLIAC MEMBER: I think we're good.

CLIAC CHAIR: OK. All opposed? OK, none. Any abstentions? None. All right, recommendation one is approved.

CLIAC MEMBER: When it gets written up, maybe sort of group together because it's kind of the way that two will be operationalized in part is by getting the information from one.

CLIAC CHAIR: Yeah. I think that's fair. And I'll try to keep them in that order. And now the transcript will reflect that desire. So that leaves three and five. And like I said, we have a whole fun slew of bonus ones. I want to emphasize we are not looking for-- I mean, it says this is about quality, not quantity. And not notwithstanding the number of recommendations passed while I've been chair, that's not the primary purpose here.

So please feel free, if there's something that we want to turn down and have a major problem with, again, we can just say now let's not talk about it. And as we started off this segment of the meeting saying there's plenty here to talk about next meeting as well. So don't feel like this is our last chance to ever talk about anything related to NGS. We have the strategic umbrella recommendation or those first few recommendations are exactly reflecting that fact. So I talk fast. And I'm trying to fit in as much as we can to today, but only in order to fulfill our charge, not to kind of get the numbers up in the fourth quarter here.

CLIAC MEMBER: I think that number three is succinct and obvious. So I move to take a vote on that.

CLIAC MEMBER: I second.

CLIAC CHAIR: We have a second. All in favor-- so vote on number three. All in favor? Any opposed? Abstentions? Oh, sorry, on the phone?

CLIAC CHAIR: Great. OK, so now we have number five.

CLIAC CHAIR: OK, no further discussion. Do we have a second? We have a second. All right. All in favor of number five? Any opposed? Sorry-- on the phone?

CLIAC MEMBER: Approved.

CLIAC CHAIR: OK, and no abstentions. OK, so five is also passed. Well, thank you, [CLIAC MEMBER], for taking the lead in summarizing those low-lying fruit issues. Hopefully, this will lead to some good progress.

CLIAC MEMBER: Thank you. And I apologize. I do have to drop off. I have something that I have to get to. But I just wanted to thank everyone for the conversation and the privilege of being able to lead this workgroup and report out. And I'm really happy that the recommendations we have from CLIAC approved for the workgroups. So thank you.

CLIAC CHAIR: Fantastic. Thank you very much. All right, so deep breath and momentary pause. Like I said, there's a number of other potential recommendations. I don't feel especially strongly or not especially strongly about any of them. Again, these were mostly written down as the presentation of the workgroup report was going on. So just kind of like things I heard include these things. Maybe I'll give people a minute or two to read through them. And then depending on what people think, just a quick time check. We've got plenty of time. We're on track for discussion of at least one or two of these, unless there are other more pressing issues, including, by the way, topics for future meetings, which I'm happy to defer discussion of any of these in favor of. I propose we just go ahead and discuss whatever ones of these the committee feels piques their interest. That sound good? Everybody's reading already. OK, so it sounds good.

CLIAC MEMBER:. I thought it might be helpful if we put numbers or letters on them. But I'm very interested in discussing the fourth one, which is the long term storage.

CLIAC MEMBER: I also have a question about pharmacogenomics and how we have outcomes in drug therapy. And I don't know if CLIAC has ever made a recommendation on utilization of pharmacogenomic data. But if they have, I'm just wondering if this is a place for it.

CLIAC CHAIR: That is a great idea. Not to my knowledge is the answer. Although, I defer to Nancy and staff. I'm sorry, you guys, as I give you all epilepsy trying to zoom in and out here. But I'm trying to fit everything on screen. So Katherine, do you have a specific place where that might--

CLIAC MEMBER: There's a whole issue going on with FDA now, the pharmacogenetics. So it might be worthwhile to hear, at some point, from the FDA. But that's like new as of this week.

CLIAC CHAIR: Would that be useful then to maybe ask if [FDA EX OFFICIO] could mention a few words about pharmacogenomics reporting for the fall or right now if he can. I mean, it's up to you.

CLIAC MEMBER: [INAUDIBLE] any policy [INAUDIBLE]

FDA EX OFFICIO: Yeah, I think we probably can come back in the fall with more information. I mean, you know, we did have a warning letter that went out on April 4th that was related to your prior safety communication in the area of pharmacogenetics. And as probably as many of you are aware that safety notification was related to that basically there isn't sufficient scientific evidence yet to support many of the claims that are out there for certain tests that are including some of those that are directly marketed to consumers. There are other pharmacogenetic tests that have information in the drug labeling or information in a [INAUDIBLE] approved test labeling. But that's not the case across all tests in this area. And so we're

continuing to monitor the landscape in this area to make sure that there is safe and effective use of these products.

CLIAC MEMBER: Right. And I know there's lot of concern around the commercial use. And we have patients that come to the hospital. But we do also use that data in-house [INAUDIBLE]. We have a pharmacogenomic department. We have a pharmacist who that's what she does. That's just her niche area of specialty. And there are certain drugs that we use this information for. So it is worth adding to number six up there, in terms of studies or just studying drug therapeutic outcomes as well.

CLIAC MEMBER: Is this where? Like that?

CLIAC MEMBER: And maybe companion diagnostics in there because it's a link. Related to number six as well, I serve on the evidence-based laboratory medicine practice guidelines collaboration of ASM and CDC. And when you're talking about funding long term outcome studies, there is a mechanism in place for meta analysis of published documentation. And what we run into is the fact that you need at least three high-quality publications to perform the outcome studies. And it's very difficult to find three on certain topics.

So I mean, even as a precursor to this, one of my topics for future consideration, and I don't know if it's in scope or not, is that I believe we have the responsibility to teach the laboratory community how to establish guidelines similar to the starred criteria for accuracy studies of what guidelines we can or what minimum requirements for an outcome document there is to support the longer term assessment of the impact of these outcome studies because it's not a subspecialty that clinical laboratorians teach. It needs to be incorporated into training documents. And so if we want to say we're going to fund these studies, we first have to say what the expectations are for these studies. So they can be conglomerated. And there is a pretty good CDC system in place with the lab medicine best practice group. And maybe we could make some recommendations around that as a step before the outcome studies.

CLIAC CHAIR: Oh, I misunderstood that. I first thought you were talking about providing more grist for that mill in that the proposal-- the stuff proposed in six would help fund that. But you're saying something different.

CLIAC MEMBER: Well, I'm saying that they could put all the funding in the world out there. But if people don't know how to do the publications that would lead to inclusion in a systematic review and meta analysis, that it may be premature to fund it until we have some standards around-- and there are quality ratings. There's a whole CDC manual for that. And I'm suggesting that maybe we put that out to the-- we make a recommendation, and that gets put out to the community. Here's the stringent requirements that are included to properly document outcome studies. CDC has a whole manual on this, and that we circulate it to the larger complete clinical laboratory community in such a way that we could raise the bar on the types of publications that we're doing.

CLIAC CHAIR: So I'm thinking that we could say something like that. And then the question is, is XXX like-- I mean, for meta analysis there's like MOOSE and Prisma for-- that you're saying the CDC has guidelines as well. Is there some-- first of all, would that capture the idea that you propose, in which case, it's just a matter of figuring out what X is? OK. So the poor man's way out is something like that. I think there are two O's in MOOSE for the MOOSE meta analysis studies.

CLIAC MEMBER: Then it's LMBP, Lab Medicine Practice Guidelines for the CDC version.

CLIAC CHAIR: So is that how it is?

CLIAC DFO: B-- BP, as in best practices.

CDC EX OFFICIO: Mm-hm. Yeah, and the methods manual is close to going into clearance, so it should be available shortly.

CLIAC CHAIR: Sorry, [CDC EX OFFICIO], CDC methods manual, like that?

CDC EX OFFICIO: Laboratory medicine best practices.

CLIAC DFO: LMBP med.

CDC EX OFFICIO: LMBP.

CLIAC CHAIR: Oh, that is the CDC.

CDC EX OFFICIO: Mm-hm. Yeah.

CLIAC CHAIR: Shows what I know. So we've had discussion so far about item six. And then [CLIAC MEMBER] expressed interest in item nine. Shall we see if we can get through those or other thoughts. Again, it's your committee. It's your choice to discuss what you like.

CLIAC MEMBER: I do think we should talk about future topics. I heard one real interesting. I've got one.

CLIAC CHAIR: OK. Well, in that case, how about we do the following, unless, let's say, six or nine is at this point, so uncontroversial that somebody wants to move it to a vote and we vote it through. I propose we table all of these and talk about future topics. And these will still be waiting for us in the fall.

CLIAC MEMBER: So I move approval of number nine.

CLIAC CHAIR: So we have a vote for approval of number nine. Do we have a second? Number nine about long term storage-- a survey of clinical laboratories. And I guess, here, does it also have to be CDC, CDC EX OFFICIO, or is--

CLIAC MEMBER: Yeah.

CLIAC CHAIR: Yeah.

CLIAC MEMBER: I will second this to support the incoming chair.

[LAUGHTER]

CLIAC MEMBER: I don't do return favors. I'm sorry.

[LAUGHTER]

But now that it's been seconded, I would like an explanation of that sentence that you've highlighted. I don't understand that sentence.

CLIAC CHAIR: I was actually just going to delete that sentence. That was mostly a note to myself as to why I wanted to put it down.

CLIAC MEMBER: Then I have no other discussion, obviously.

CLIAC CHAIR: So let me ask you about the new second sentence, also keeping archival versions or software. So for me, that was a recommendation that labs be required to keep that. So that's different from the survey part. Should I strike that and make that its own recommendation which we don't talk about right now or what?

CLIAC MEMBER: a survey both use cases for long term storage of data and for keeping archival.

CLIAC CHAIR: I see. Whoops.

CLIAC MEMBER: And I think it's bigger than the archival version. It's the archival environment in which that version lives.

CLIAC MEMBER: But if you're using a different platform and a different operating system, will that archive version work?

CLIAC CHAIR: So let me give everybody a couple of seconds to read that new sentence or second half of the sentence now. So is this now accurate, [CLIAC MEMBER] to the point made?

CLIAC MEMBER: Yeah. I can actually simplify it. Where it goes, of NGS data and for keeping archival versions and-- I'm sorry-- archival versions of software and environment.

CLIAC MEMBER: How about just archival software and the environment?

CLIAC MEMBER: Yeah.

CLIAC CHAIR: I'd like to keep the word version in there, though, because you might have changed your software.

CLIAC MEMBER: That clarifies it.

CLIAC MEMBER: So the platform is kind of like I found a whole bunch of floppy disks when I was cleaning out my garage. And I have no way to know what's on them, right?

CLIAC MEMBER: No, it's more like you have the original Mac, and now you're using a PC.

CLIAC MEMBER: Yeah, OK. It's all-- and for how long?

CLIAC MEMBER: That's what that's supposed to figure out. So for example, if you did that study two years ago, and then Katherine comes around and says I need the pharmacogenomics for this drug, can you yank out that sequence and run it and tell me whether or not it has X, Y, or Z.

CLIAC CHAIR: OK.

CLIAC MEMBER: So with all that inclusion, then 10 is sort of encompassed in 9 now about the versioning, or am I missing something there?

CLIAC CHAIR: One is a requirement for a demonstration. Number 10 is a requirement for a demonstration. Number nine is a survey to figure out what people do. Let's focus in on number nine. And if there is no further

discussion, I will re-entertain the motion to bring it to a vote. Any further discussion? OK, any motion to bring it to a vote? Second? Do we have a second? OK, all in favor of number nine, and Sue on the phone? Maybe no longer on the phone. Any opposed? Any abstentions? All right, nine is passed.

And then in the interest of time, I propose that we defer the rest of these until the fall or whenever, since I will no longer be chair, and discuss future topics. And we've got about, I don't know, five or seven minutes or so to write them down. I'm, again, grateful that we have a transcript system, so I will not have to write down the future topics. But we should say them. And then if we feel good at the end of that time, maybe convene for a quick photograph. And if not, well, we have the last photograph. But without further--

CLIAC MEMBER: Yeah, so I don't know which agency would consider this. I believe it's CDC. But the review of the blood culture contaminants that is currently adopted for infection prevention, monitoring, and lab monitoring by NHSN is outdated and includes organisms that are considered true pathogens in microbiology now. And so there's a disjunct between what we count as a contaminant and what is now in the world of immunocompromised and certain patient populations considered true pathogens most of the time. An example of that would be staph lugdunensis.

So it can go either way. But there are interpretive models, I think, that should go into place to not just the organism name but the type of background of the patient that's included for a more accurate assessment of blood culture contamination. And this is especially important in today's age where we're going to decide to use a $250- or a $500-dollar test on something that may be thrown away as a contaminant if we're not proactively considering the patient background in that assessment. And there's nothing for the background. And the organism list probably was devised in the '70s or '80s, maybe, from the look of it. So I don't know where that goes. But that's a potential topic I'd like to propose.

CLIAC CHAIR: Fantastic. Yeah, the role of traditionally quote, unquote, "exclusively contaminant organisms," which are no longer that. That's a great topic. [CLIAC MEMBER], you had a topic, I think.

CLIAC MEMBER: Yeah. In my daily life as a lab director, my biggest pain point is I've got all these great tests. And I can't frigging find anybody to do them. So I'm back to laboratory workforce. And I feel like we've only nibbled around the edges of laboratory workforce. I went hunting on the HHS website for health workforce stuff. And HRSA has a whole thing on health careers and funding health careers.

And I wonder if CLIAC could get a presentation from HRSA about funding of health careers and health career development that we could hear and give our feedback to programs that might improve the supply of clinical laboratory workers. Because there's a lot of stuff there, some of it specifically pointed at physicians and at nurses. And then all of the rest of us are sort of lumped in in other piles. And I think that might be something that we could have some input on.

CLIAC CHAIR: I think that's a great idea. And you remind me of a presentation two meetings ago or at least part of a presentation. I think it was one of yours, [CMS EX OFFICIO], where you had presented work-- you had given us a nice list of numbers of the number of presentations that had been done to, I think as young as high schoolers-- maybe even younger.

CMS EX OFFICIO: High school and we've done the Allied Health programs.

CLIAC CHAIR: And there was an interest expressed by the committee in analysis or a follow-up to say, well, you know, what is sort of-- almost like-- from a mathematical perspective-- forgive me-- the expected value of one of those presentations for somebody joining the workforce? So kind of an ROI-- a return on investment type analysis might fit in with what [CLIAC MEMBER] describes. Others?

CLIAC MEMBER: I just wanted to add on to [CLIAC MEMBER], we've discussed this issue for the last decade in California with the Health Laboratory Workforce Initiative. And we've identified the block, at least in California, is we lack adequate clinical training sites. It's not the training school. We can't train them in the laboratories because we don't have enough people to do it. There is no monetary incentive because the administrators are cutting budgets because there's no productivity linked to that.

So our requests through our California thing was go over to HRSA and see if they would fund hospital laboratories independent of hospital budgets to further the education program. The ROI we've conducted is like an eight-month payback. It's almost instantaneous. So I don't know if we can push that funding issue because it interfaces with hospital budgets.

CLIAC MEMBER: I have another issue. This might be the one we discussed last night--

CLIAC CHAIR: Yeah.

CLIAC MEMBER: I mentioned it briefly last time, but I was on the phone. I think that it will be important for us to look at the role of the laboratory in addressing issues of social determinants of health. It's certainly a big issue. It's becoming important across the whole spectrum of medicine. If our goal is to improve quality, only 10% of health is related to delivery of medical care. But the social determinants are about 50%.

So it's not exactly how we can take over that area, but how can we be a better player. And CDC has a whole division now focusing on social determinants. So I would strongly recommend that we hear from them and then have a discussion about how can the laboratory play a role. And I've got some ideas. But I'd like to sort of socialize that social determinants of health.

CLIAC CHAIR: That's fantastic. So I guess [CMS EX OFFICIO] and then [CLIAC MEMBER].

CMS EX OFFICIO: I don't think anybody needs me to talk into the microphone. But I've had this idea kind of tying in with the workforce. And I know all too well that it's hard to train people in the lab because they're busy. They don't have time. And I wonder if like you said, it's just an idea. And you can look at me like I'm crazy. That's OK. What would be the feasibility of creating-- so many labs may be regional labs that are just geared to training students. They would be a real lab. But that's all they would do.

And I mean, you're not going to get an influx of 500 students for it. You could have a limited number of people that would go. You would still need to get people that could educate-- you know, retirement techs or whatever. But that would give them the reality of a lab-- the total environment of it. And we, again, would not be endangering patients or taking the care away from patients.

I don't know how much it would cost. Like I said, it's just something that I've been thinking about in relation to our outreach. So I just wanted to throw that out there as something maybe to consider. I don't know. It would be a lot of work involved to do it. But it would kind of solve one of the problems.

CLIAC CHAIR: We call it a lab learning lab.

CMS EX OFFICIO: A lab learning lab. Yes.

[INTERPOSING VOICES]

CLIAC MEMBER: Isn't one of the training requirements that the clinical training has to be in a CLIA certified lab? And so how would this be CLIA certified?

CMS EX OFFICIO: It would be a real lab.

CLIAC MEMBER: Oh, like a--

CMS EX OFFICIO: It would have to be a real lab.

CLIAC CHAIR: I want to make sure-- so it's clearly a fascinating topic for discussion--

CMS EX OFFICIO: I mean, it's just something that kind of throw out there.

CLIAC CHAIR: I want to make sure we get to everybody who had ideas for topics before--

CLIAC MEMBER: So an idea we may or may not want to tackle a line with-- the lab workforce. And first, I agree with [CLIAC MEMBER]. It's critical we focus on that. And there's more to do. There are projections of shortages of laboratory medical professionals. I'm a residency program director.

I'm quite honestly a little skeptical about some of the projections. They need pathologists-- other professional organizations. There's been a huge expansion in the number of ComACC accredited clinical chemistry fellowships in projection over this shortage of laboratory professionals. I kind of wonder where all these pathologists and chemists and other professionals are going to go, and what is the need, and are we producing the right skill sets, and are there needs that aren't met that we're not matching the programs-- the graduates-- to the needs. So we could consider looking at the medical professionals training in addition to lab workforce or as part of lab workforce.

CLIAC CHAIR: Great. Others? Well, I'll insert one, then. And I believe this is something that most of the people present have heard me mention in passing at least once, which is this idea of aligning budgets at health care institutions to reflect the value of the laboratory. This is not sort of like a me, too, come on. We ought to get some money. This is wherever the chips may fall, let us understand the true marginal benefit or marginal cost of, and I'll say this carefully, every activity performed by the laboratory for every outcome that those activities or that activity bears on. So I want to know categorically whether a serum sodium for an outpatient who comes in with you name it, I want to know what fraction of that patient's future health care costs were saved or were increased based on us having run that test.

Obviously, that's not something humans can do. That's something you need machines to do. But I would argue that only by doing that-- and frankly, there's no reason to limit it to the lab, other than the purview of the committee-- only by doing that do you have a full understanding of the value that is provided by health interventions. I would love to see such a system. And I would love to hear-- I guess, remotely in the future for me-- but hear discussion of what it would take and what would be the drawbacks of requiring such a system at some point in the future for places that receive federal money. It's the right thing to do in my mind. And I would love to hear a discussion about people about it.

CLIAC MEMBER: I'll add to that, but slightly different focus in terms of a future discussion, and that is laboratory test utilization and cost. I think there is a lot more that we could say and do in that realm and there are now a number of organizations who are putting good data out there. But test utilization is a major issue. And it should be engaged in some sort of a national way.

CLIAC CHAIR: You know, I would put in appropriate utilization, add to that.

CLIAC MEMBER: Right. And related to that, productivity consultants are comparing our worth across America without any transparency or disclosure and setting metrics based on cost savings alone, coming up with recommendations that we should do in some cases against what the medical standards would recommend. And so not only the impact of those things, but this is a pressing issue in terms of what's happening as they're just going around from big lab to big lab saying, well, we got these four labs to cut so much, so now you should. But now you cut so much so that lab one, two, and three need to, and there's no quality metrics involved in their assessment.

I mean, we have just gone through this. And we insisted that there would be. But we're being barred against people who didn't include quality metrics. So I would like to see some-- it's a free for all in the laboratory productivity consultant world right now. I would like to see some best practices or guidelines just as we have for our for-profit reagent manufacturers, instrument manufacturers, and we have nothing for these huge consulting firms just basically driving everything through our finance-- the CFO of an organization-- to your point, [CLIAC MEMBER].

CLIAC CHAIR: Well, these are--

CLIAC MEMBER: First of all, you mention, when you're talking about the return on investment laboratories. ABHL has started a study and has created an ROI system for laboratories because those of you in clinical labs, think about public health laboratories and the problems we have in justifying our existence in trying to make sure we have the funding to exist. So that might be a group that could come and present so that we have that already.

CLIAC CHAIR: That would be fantastic. Well, it sounds like the committee and staff and the ex-officios-- and Valerie, I'm looking at you-- have your hands full of plenty of things to discuss and usefully contribute to in upcoming meetings. I want to thank you all collectively. And I thank each of you individually. If I've had a chance to talk with you, I'm grateful for that. And if not, I'm sort of doing so now to express, again, my gratitude for having kind of shared the floor with you all for the past couple of years.

And you know I pride myself on trying to run a tight ship and keep things on time. I think we'll forego the picture in favor of our picture that we had last time, seeing as it's 1:02. I promised to get us out at 1:00. Hopefully, you'll give me that two minutes leeway. And with that, I would entertain a motion to adjourn.

CLIAC MEMBER: So moved with the acknowledgment and grateful appreciation to you for the work you've done over the last years.

CLIAC MEMBERS: Hear, hear.

[APPLAUSE]