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

Summary Report

April 13-14, 2022

Atlanta, Georgia (Virtual)

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee (CLIAC) April 13-14, 2022, Summary Report

Table of Contents

RECORD OF ATTENDANCE

Committee Members Present

Dr. Valerie Ng, Chair
Dr. Birthale Archie
Mr. Michael Black
Dr. Kimberle Chapin
Dr. James Crawford
Ms. Heather Duncan
Dr. Mary Edgerton
Dr. Susan Gross
Dr. Lee Hilborne
Dr. Ewa King
Dr. David Koch
Dr. Lavinia Middleton
Ms. Carole Moss
Dr. Nirali Patel
Dr. Michael Pentella
Ms. Jennifer Rhamy
Dr. Gregory Sossaman
Dr. Mark Tuthill
Dr. R.W. (Chip) Watkins
Dr. Donna Wolk
Mr. Andy Quintenz, AdvaMed (Liaison Representative)

Committee Members Absent

Dr. David Koch

Ex Officio Members

Dr. Collette Fitzgerald, CDC
Ms. Sarah Bennett, CMS
Dr. Timothy Stenzel, FDA

Designated Federal Official

Dr. Reynolds Salerno, CDC

Executive Secretary

Ms. Nancy Anderson, CDC

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. The meeting was a full virtual Zoom webcast, and approximately 283 public citizens attended one or both days of the meeting.

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC) BACKGROUND

The Secretary of Health and Human Services (HHS) is authorized under Section 353 of the Public Health Service Act, as amended, to establish standards to ensure consistent, accurate, and reliable test results by all clinical laboratories in the United States. The Secretary is authorized under Section 222 to establish advisory committees.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) was chartered in February 1992 to provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health pertaining to improvement in clinical laboratory quality and laboratory medicine practice. In addition, the Committee provides advice and guidance on specific questions related to possible revisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic submission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

The Committee consists of 20 members, including the Chair. The Secretary selects members from authorities knowledgeable in the fields of microbiology, immunology, chemistry, hematology, pathology, and representatives of medical technology, public health, clinical practice, and consumers. In addition, CLIAC includes three ex officio members, or designees: the Director, Centers for Disease Control and Prevention (CDC); the Commissioner, Food and Drug Administration (FDA); the Administrator, Centers for Medicare & Medicaid Services (CMS); and such additional officers of the U.S. Government that the Secretary deems are necessary for the Committee to carry out its functions effectively. CLIAC also includes a non-voting liaison representative who is a member of AdvaMed and other non-voting liaison representatives that the Secretary deems necessary for the Committee to carry out its functions effectively.

As a result of the different perspectives among its members, CLIAC is sometimes divided in the guidance and advice it offers to the Secretary. Even when all CLIAC members agree on a specific recommendation, the Secretary may not follow the Committee’s advice because of other overriding concerns. Thus, while some of the actions recommended by CLIAC may result in changes to the CLIA regulations or may lead to different actions taken by HHS, all of the Committee’s recommendations may not be accepted and acted upon by the Secretary.

CALL TO ORDER AND COMMITTEE INTRODUCTIONS

Dr. Reynolds Salerno, Designated Federal Official (DFO), Clinical Laboratory Improvement Advisory Committee (CLIAC), and Director of the Division of Laboratory Systems (DLS), Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Deputy Director for Public Health Science and Surveillance, CDC, welcomed the Committee and the members of the public. Dr. Salerno expressed gratitude to the CLIAC members and laboratory community for their ongoing efforts in responding to the COVID-19 pandemic. On both meeting days, Dr. Valerie Ng, CLIAC Chairperson, welcomed the Committee and reviewed the process for public comments, quorum requirements, and official CLIAC recommendations. On April 13, 2022, Dr. Salerno recognized and thanked Ms. Monique Spruill for her service as CMS ex officio and introduced Ms. Sarah Bennett, who served as the CMS ex officio for the meeting. All members made self-introductions and financial disclosure statements relevant to the meeting topics. Dr. Ng stated that the agenda topics would include agency updates from CDC, CMS, and FDA. In addition, the meeting would consist of presentations and discussions on the future of laboratory medicine, especially testing in non-traditional sites. During the second meeting day, there would be an extended public comment session focusing on anticipated changes in testing practices, personnel issues, and emerging technologies used in non-traditional testing sites.

AGENCY UPDATES AND COMMITTEE DISCUSSION

Centers for Disease Control and Prevention (CDC) Update ***Addendum 1***

Collette Fitzgerald, PhD
Deputy Director for Science
Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Deputy Director for Public Health Science and Surveillance (DDPHSS)
Centers for Disease Control and Prevention (CDC)

Dr. Fitzgerald updated CLIAC on CDC's DLS activities in five areas: laboratory preparedness and response, health equity, laboratory quality and safety, laboratory training, and partnership communication and outreach. She explained that CDC launched the Increasing Community Access to Testing (ICATT) for COVID-19 website to help connect consumers in under-resourced communities with free COVID-19 laboratory testing. DLS collaborated with the CDC COVID-19 Expansion for Screening and Diagnostics Task Force to create the ICATT website. Dr. Fitzgerald further explained that CDC provides online information and resources to educate the public, including clinical and public health laboratory professionals, as well as those who perform at-home tests or perform tests at the point of care, about testing for COVID-19 and how to interpret test results. She also recognized the CDC Laboratory Outreach Communication System (LOCS), one of the CDC's top ten most subscribed e-newsletters, and the DLS Clinical Laboratory COVID-19 Response calls, which provide timely outreach to facilities that perform COVID-19 testing. Dr. Fitzgerald then highlighted the work DLS is doing to improve health equity in collaboration with the CDC's Division of Heart Disease and Stroke Prevention and the Million Hearts® program. She continued her update by discussing the manuscript in development by DLS that identifies gaps and challenges associated with providing linguistically appropriate test results to non-English speaking populations. She shared that CDC is a co-host of the 17th International Biosafety Symposium in August 2022.

The meeting will provide in-depth, engaging sessions to help laboratory staff develop biosafety plans that build on lessons learned from the COVID-19 pandemic. Dr. Fitzgerald informed the members about the collaboration between DLS and CDC's Division of Healthcare Quality Promotion on the development of a National Quality Forum measure to establish a standard for evaluating and reporting blood culture contamination rates. She shared that DLS will host a virtual Town Hall on Medical Device Design - Incorporating Safety and Biosafety in collaboration with clinical and public health laboratory partners and instrument manufacturers on June 24, 2022. Dr. Fitzgerald informed the members about the CDC and the Association of Public Health Laboratories (APHL) Next Generation Sequencing Quality Initiative effort to harmonize quality standards for next generation sequencing (NGS). She described the OneLab initiative to bridge, train, and sustain a capacity-building community among public health and clinical laboratory communities and she highlighted the OneLab Virtual Summit 2022. Dr. Fitzgerald closed with the recognition of the DLS Medical Laboratory Professionals Week 2022 digital tool kit.

Centers for Medicare & Medicaid Services (CMS) Update ***Addendum 2***

Sarah F. Bennett, MT(ASCP)
Acting Director
Division of Clinical Laboratory Improvement and Quality (DCLIQ)
Center for Medicaid and State Operations (CMSO)
Centers for Medicare & Medicaid Services (CMS)

Ms. Bennett began by giving an overview of the CMS DCLIQ organizational structure. She continued by outlining the division's priorities and CLIA statistics compiled during the pandemic. Ms. Bennett noted that two priorities include survey consistency and stakeholder engagement. She continued by providing the current laboratory enrollment in the CLIA program, including the increased number of Certificate of Waiver sites, accounting for 79% of all CLIA-certified laboratories. Ms. Bennett discussed the flexibilities and enforcement discretions CLIA allowed during the public health emergency available on the CMS Current Emergencies site. Ms. Bennett informed CLIAC that CMS had extended the timeline for publication of the final proficiency testing rule and announced the approval of COLA as an accreditation organization under the specialty of pathology. Ms. Bennett announced the posting of the updated surveyor guidance related to SARS-CoV-2 test result reporting. She provided an overview of the COVID-19 inquiries received at CMS and the process to triage the over 4,900 emails received since January 2020. Ms. Bennett discussed the survey prioritization process and reviewed the tools CMS put out during the public health emergency to help the public understand CLIA requirements. Ms. Bennett concluded with CMS efforts to disseminate information to laboratories and laboratory professionals through the CLIA Communications Listserv.

Food and Drug Administration (FDA) Update ***Addendum 3***

Timothy Stenzel, MD, PhD
Director
Office of In Vitro Diagnostics and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)
U. S. Food and Drug Administration (FDA)

Dr. Stenzel began his presentation by providing updates on the proposed recommendations for the Medical Device User Fee Amendments for fiscal years 2023 through 2027 (MDUFA V). He noted the FDA received requests for more than 5,000 emergency use authorizations (EUAs) since the pandemic, which significantly impacted CDRH's workload, particularly the ability to review in vitro diagnostic (IVD) product submissions unrelated to COVID-19. Dr. Stenzel next updated the Committee on the CDRH participation in Collaborative Communities created to bring together private- and public-sector members, including FDA, to work together to solve shared challenges, and leverage collaborative opportunities. He then returned to the topic of EUAs and provided an overview of the more than 400 tests authorized as of April 11, 2022, including home collection, point-of-care, and at-home tests. Dr. Stenzel highlighted recent policies, including the November 2021 HHS Secretary statement on the laboratory-developed test policy and the policy for COVID-19 tests. Next, Dr. Stenzel discussed the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics (RADx) Independent Test Assessment Program (ITAP), established to accelerate regulatory review and availability of high-quality, accurate, and reliable over-the-counter COVID-19 tests to the public. He highlighted five tests authorized after an ITAP evaluation by this collaboration between the FDA and the NIH RADx program. Dr. Stenzel described the outreach FDA did during the pandemic, including safety communications, virtual town meetings, and webinars to assist test developers and labs with questions. He concluded by discussing FDA's new FAQ addressing what will happen to EUA tests after the public health emergency expires and draft guidance on transition for EUA IVDs.

Report: CDC Board of Scientific Counselors, Deputy Director for Infectious Diseases

Donna Wolk, PhD, D(ABMM)
System Director, Clinical and Molecular Microbiology
Geisinger Health System
Department of Laboratory Medicine
Danville, PA

Addendum 4

Ms. Wolk summarized the information given at the January 2022 Board of Scientific Counselors, Deputy Director for Infectious Diseases meeting. She mentioned the new Advisory Committee to the Director formed to advise the Secretary, HHS, and the Director, CDC, on policy and broad strategies that will enable the CDC to fulfill its mission of protecting health through health promotion, prevention, and preparedness. She continued by discussing the report on the COVID-19 surveillance response, the Omicron prevalence dashboards, and the seven-day average risks. Ms. Wolk updated CLIAC on the data analysis for the pandemic and the goals to improve the systems and develop new capabilities, new modeling, predictive modeling, and analytics with a particular focus on underserved communities and health equity. She presented information on CDC's work in the Real-Time Epidemic Preparedness and the Advanced Molecular Detection program. Ms. Wolk briefly touched on the data modernization initiative at the CDC and the plans to modernize the data infrastructure. She ended by giving an overview of the future of the public health workforce and announced that AmeriCorps and the CDC joined forces to launch Public Health AmeriCorps and support the recruitment, training, and development of the next generation of public health leaders who will be ready to respond to the nation's public health needs.

Committee Discussion

- A Committee member inquired if all Certificate of Waiver (CoW) sites are aware of the OneLab initiative. Dr. Fitzgerald indicated that CDC would coordinate with CMS on strategies to reach sites performing waived testing.
- One member asked if the NGS Quality Initiative engages with CMS inspectors. Dr. Fitzgerald added that CDC is working with CMS to determine a pathway to share NGS resources or develop new resources for surveyors.
- A Committee member noted that pharmacies are now involved in performing point-of-care testing for COVID-19 and asked if biosafety is addressed in these sites. Dr. Salerno pointed out that biosafety has been included for the pharmacies contracted with the ICATT program, but other engagement with pharmacy partners may be needed.
- Another member asked about the timeline to achieve a CoW and the current landscape of these waived testing sites. Ms. Bennett provided an overview of the CLIA certificate process. She noted that the increase in CoW applications could be attributed to the need for increased COVID-19 testing. Still, the future of these testing sites beyond the pandemic is uncertain.
- A member commented on the need for an online self-evaluation process for newly waived testing sites. Ms. Bennett promoted the use of the CDC's resources for waived testing. These resources include a self-assessment checklist that can be downloaded.
- A member inquired about supply chain issues beyond those related to SARS-CoV-2 testing. Ms. Bennett noted that CMS would consider each independently.
- One CLIAC member commented on the need to be ready for the next pandemic, including the ability to provide at-home testing solutions rapidly. Dr. Stenzel noted the need for a well-designed public health response that may include a partnership with manufacturers and testing sites ahead of any pandemic.
- A Committee member inquired about how the infrastructure and workforce programs are funded. Dr. Wolk commented that a large portion of the funding for the programs she described is part of the American Recovery and Reinvestment Act. Dr. Salerno added that many of the programs described in the Board of Scientific Counselors update had received temporary funding through the American Rescue Plan and CARES Act.

PRESENTATIONS AND COMMITTEE DISCUSSION

The Future of Laboratory Medicine in Non-Traditional Testing Sites

Introduction to the Topic ***Addendum 5***

Collette Fitzgerald, PhD
Deputy Director for Science
Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Deputy Director for Public Health Science and Surveillance (DDPHSS)
Centers for Disease Control and Prevention (CDC)

Dr. Fitzgerald provided an overview of CLIAC presentations from 2006 and 2007 on the future of laboratory medicine and highlighted some changes since those discussions. She then reviewed the CLIAC workgroups that will provide insight on long-standing topics, including the CLIA Regulatory Assessment Workgroup, the CLIA Certificate of Waiver and Certificate for

Provider-performed Microscopy Procedures, and a new NGS Workgroup. She introduced the session's speakers and their presentation topics and provided general questions for the Committee to consider.

Current and Future Applications of Point-of-Care Testing – The Industry Perspective
Michael Palm, PhD — ***Addendum 6***
Director of Commercial Strategy & Innovation, Rapid Diagnostics
Abbott Diagnostics Business

Dr. Palm began his presentation by discussing the clinical diagnostics environment before and after COVID-19 and highlighted some of the significant challenges and lessons learned from the pandemic response. He explained how different parts of the healthcare and diagnostics systems should interact to have an efficient system and discussed the importance of access to care and health equity. Dr. Palm provided examples of centralized and decentralized diagnostics and the importance of having the infrastructure to utilize both. He explained how point-of-care testing could provide more access and fit into algorithms that will provide clinical impact.

Current and Future Applications of Point-of-Care Testing – The Laboratory Perspective
Sheldon Campbell, MD, PhD, FCAP — ***Addendum 7***
Professor of Laboratory Medicine
Yale School of Medicine
Director for Clinical Laboratories
VA Connecticut Healthcare

Dr. Campbell described the evolution of modern practices in point-of-care testing (POCT) with an overview of the history of urine analysis leading to the first rapid antigen test for Group A *Streptococcus* and the expansion of POCT during the COVID-19 pandemic. He provided a list of constraints for POCTs, including when testing is beneficial for inpatient and outpatient situations. Then, Dr. Campbell expanded upon the future of POCT, including an analysis of the strengths, weaknesses, opportunities, and threats and the importance of the environment where the test is performed. He discussed POCTs in the context of future information technology and concluded with thoughts on how testing and care models may change in the distant future.

Culture Independent Diagnostic Testing Impact on Enteric Disease Surveillance
Heather Carleton, PhD, MPH — ***Addendum 8*** ***Addendum 8a***
Branch Chief
Enteric Diseases Laboratory Branch (EDLB)
Division of Foodborne, Waterborne, and Environmental Diseases (DFWED)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Deputy Director for Infectious Diseases (DDID)
Centers for Disease Control and Prevention (CDC)

Dr. Carleton presented an overview of culture-independent diagnostic tests (CIDTs). She showed the contrast between the pre-CIDT gastrointestinal illness testing that relied on bacterial isolates for public health surveillance, outbreak detection, and antimicrobial resistance monitoring, and gastrointestinal illness testing in the CIDT era where diagnosis no longer relies on an isolate. Public health laboratories have the added burden of culturing an

isolate from specimen sources when CIDTs are used for testing. Dr. Carleton reviewed the benefits and challenges of CIDTs, including test performance considerations when using CIDTs. She provided an overview of PulseNet, the national network for molecular surveillance of bacterial enteric infections that relies on isolates for whole-genome sequencing, highlighting the impact of CIDT usage. Dr. Carleton discussed CDC's plan to address short-term and long-term needs to preserve the ability of PulseNet to improve food safety systems through the early identification of outbreaks. She concluded by reiterating that CIDTs have been a challenge, but DFWED has developed a multi-step action plan to address the effect of CIDTs on foodborne disease surveillance.

Digital Pathology: The Past, Present, and Future ***Addendum 9***

Keith J. Kaplan, MD
Pathologist
Chief Medical Officer
Corista

Dr. Kaplan discussed the emergence of telepathology within the Armed Forces Institute of Pathology in the early 2000's and noted the successes of creating a system for intraoperative consultation. One of the earliest advantages of telepathology was the ability for multiple pathologists to review the specimens and microscopic images to provide consultations within hours, instead of days, regardless of location. He described the differentiated service model in histology as consisting of shared expertise, improved consultation and turnaround time, elimination of slide shipping issues, better connectivity to patients, colleagues, and more extensive image analysis applications and searchable image databases. Dr. Kaplan explained how digital pathology could help with patient diagnoses, especially in combination with artificial intelligence and other new technologies. He concluded with a review of the pathologist's role in the past, how it differs today, and opportunities in the future.

Committee Discussion

- Committee members asked if there are solutions for the disconnect between physicians and patients experienced during the pandemic as more people were using non-traditional testing sites or at-home testing and the risk for widening disparities based on access to the rapid tests and health literacy. Dr. Palm answered that his company had explored solutions, including a companion application and digitizing results, but other solutions should be investigated. He stated that infrastructure, such as telehealth, is needed to provide better access to resources for a correct understanding of the test results and acknowledged that more needs to be done to realize health equity.
- A Committee member asked how to aggregate all the data available from a distributed model and, if digitizing is the answer, how can it be standardized among multiple vendors. Dr. Palm agreed that an automated system to collect data is needed and suggested that the data owners push for standardization among the vendors.
- A member commented that sometimes physicians will not perform a particular test even when asked by the patient and that affordable and readily available single tests that can distinguish between different infections with similar symptoms are essential. Dr. Campbell explained that physicians struggle to determine which patients would benefit from a broad range test for many respiratory pathogens as there are only a small number of these tests available, and they are expensive.

- A CLIAC member remarked that the COVID-19 pandemic and the need for a large portion of the population to be tested differ from past epidemics where the non-symptomatic population was not tested. The focus should be on what other types of testing could be helpful for the next pandemic. Dr. Campbell replied that flexibility and building adaptable systems are needed to prepare for the next epidemic.
- A Committee member commented on the increasing types of POCTs available and asked if additional guidance should be available to those sites performing all types of waived tests, not just those for COVID-19. Dr. Campbell added that the current CLIA complexity model may be too simple and outdated and should be revisited, especially in light of the increase in CoW sites.
- One member asked if research is being done to determine the reliability and validity of at-home and rapid tests. Dr. Campbell answered that some tests do work better than others and that there are sometimes concerns about testing performed by individuals who do not have training or experience with performing laboratory testing. He further explained the COVID-19 modeling study he discussed during his presentation. Other committee members commented on numerous considerations for POCTs, especially those for infectious diseases, including the prevalence of the organism being tested, the design of the tests, automatic communication of test results, training of those performing the test to assure they understand the results, and patient counseling regarding a negative or a positive result.
- A CLIAC member asked how contamination of transport media or culture media with non-viable organisms that can be amplified and detected using CIDTs impacts the plan for the use of CIDTs in public health surveillance. Dr. Carleton responded that CDC is aware of these issues and is considering how best to address them in surveillance systems.
- A member asked if there is a way to keep tests from being used on patients after being recalled. Dr. Campbell acknowledged the challenges that have occurred as a result of the fast-moving, emerging environment that laboratories have experienced during the COVID-19 pandemic.
- A Committee member asked, based on their recent experiences, what else could be done to help laboratories or testing sites improve their processes, improve training, and address other challenges that CLIAC has discussed.

Personnel Challenges in Non-traditional Testing Sites ***Addendum 10***

Matt Kossman
Senior Vice President Operations
WellStreet Urgent Care

Mr. Kossman provided an overview of WellStreet Urgent Care, including over 70 urgent care centers across Georgia and Michigan that work on a provider-based model with each patient seen by a physician, nurse practitioner, or physician assistant as part of the delivery of care. He illustrated the growth in patient volumes since 2020 compared with what they had estimated the pre-pandemic volumes to be. Mr. Kossman described the staffing and training challenges that WellStreet experienced as a result of the need to rapidly change workflow processes and offer new types of testing. He also noted the seriousness of the increase in violence against healthcare workers as patient frustrations have risen during the COVID-19 pandemic. Mr. Kossman concluded by emphasizing that staffing at all levels continues to be a

challenge for urgent care centers, but urgent care continues to provide a much-needed community service.

American Association for Clinical Chemistry Point-of-Care Testing Certification Program ***Addendum 11***

T. Scott Isbell, PhD, DABDD, FAAC
Director, Laboratory Medicine
SSM Health St. Louis University Hospital
Associate Professor of Pathology and Pediatrics
Louis and Marguerite Privat and Marguerite Hard Memorial Professor
Saint Louis University School of Medicine

Dr. Isbell provided a brief overview of the point-of-care (POC) market, expected to increase to $50.6 billion by 2025. He noted that most people who perform POCT are not trained explicitly as clinical laboratory scientists, but are healthcare providers such as medical assistants, nurses, respiratory therapists, radiology technicians, and community pharmacists. Dr. Isbell commented on the increased use of POCT in community pharmacies that have collaborative practice agreements. He noted the need for a standardized curriculum in clinical laboratory science for these types of individuals led to the 2008 launch of the American Association for Clinical Chemistry (AACC) POC Specialist Certificate Program, consisting of an online course of eight modules followed by an assessment and certificate of completion. Dr. Isbell explained the difference between a certificate program and a professional certification program. He stated that in 2017, AACC established a professional certification in POCT. He described the process of establishing the program, including forming the AACC POCT Professional Certification Board, curriculum design, and development of exam questions. Dr. Isbell concluded with testimonials from recent participants and the desire for Federal recognition of this professional certification.

Committee Discussion

- A Committee member commented that individuals without laboratory degrees but with various educational credentials can be recruited to fill some laboratory staffing needs. The member suggested consideration of the need for a new classification for these types of positions in the CLIA personnel regulations.
- Committee members inquired about the educational requirements to enroll in the AACC POCT assessment-based certificate and professional certification programs. Dr. Isbell clarified that there is not an academic requirement to complete the AACC POCT certificate online course module. Still, the best audience is somebody with some medical or laboratory science background. He acknowledged there might be an educational gap and a specific course needed for those individuals who perform waived testing in non-hospital, non-clinic sites where support from a core laboratory may not be in place. He added that the AACC professional certification in POCT requires passing a competency-based certification exam and previous experience in laboratory testing may also be needed to pass that exam.
- Multiple CLIAC members commented on the need for educational resources for personnel performing waived testing who have no medical or laboratory training, as there are no CLIA personnel requirements for sites that perform CLIA-waived testing.
- A member commented that the AACC POCT certificate and certification programs seem focused more on individuals that already have experience in the medical field and

expressed a concern that laboratory personnel who complete these programs may choose to move into the POCT field resulting in more staffing shortages in laboratories. The member suggested directing educational opportunities towards individuals who do not have a science background and could be led towards the laboratory profession, noting that the program may be more accessible and easier to complete than lengthy studying required for board certification. Dr. Isbell agreed with the staffing shortage issue and noted the need for fundamental POCT training.

- One Committee member asked if a licensed practical nurse (LPN) would have the pre-requisite competency to sit for the AACC POCT certification exam since LPNs work in nursing homes or other settings outside of the acute care areas. Dr. Isbell responded that the eligibility requirements for the AACC POCT certification would need to be reviewed to determine if LPNs would meet the eligibility requirements.

Recognition of Outgoing CLIAC Members ***Addendum 12***

Reynolds Salerno, PhD
Director
Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Office of Public Health Scientific Services (OPHSS)
Centers for Disease Control and Prevention

Dr. Salerno recognized CLIAC outgoing members, Dr. Susan Gross, Dr. Lee Hilborne, Dr. Lavinia Middleton, Dr. Valerie Ng, Dr. Gregory Sossaman, and Dr. Donna Wolk. Dr. Salerno recognized Dr. Ng for her outstanding contributions as the CLIAC Chair.

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

Public Comments

Addendum PC1
Addendum PC2
Addendum PC3
Addendum PC4
Addendum PC5
Addendum PC6
Addendum PC7
Addendum PC8
Addendum PC9
Addendum PC10
Addendum PC11
Addendum PC12

Committee Discussion

- Multiple members noted three areas emerging in the public comments: personnel, quality, and the role of remote activities, including the need for continuation of enforcement discretion related to remote pathology.
- One member noted with the significant increase in CoW testing sites during the pandemic, it is challenging to assess the quality of the testing being performed in these sites. The member suggested the expansion of the medical laboratory science pipeline to address future staffing needs, beginning at the junior high, high school, university, and post-graduate level. The member also suggested creating a certificate program for staff such as a medical laboratory assistant that could fill some of the POCT gaps.

- One member suggested the need for training for nurses and clinicians performing waived testing who may not completely understand the impact of the results, such as the false-negative rates and the need for reflex testing.
- One member commented that laboratory testing should be kept under the umbrella of the laboratory since healthcare providers who do not have laboratory training have additional and different responsibilities. More laboratory oversight and collaboration are needed at the local, community, and academic levels to support testing and healthcare needs.
- Multiple members suggested developing a program to train and certify a new category of testing personnel to support the advancement and rapid growth of POCT. The POC tester would not be required to have had formal laboratory training, but certification and training could be required ongoing. Another member noted that creating a new job category or certificate program for non-college-based employees could support the POCT expansion and may be an option for certification in high school vocational or traditional high-school settings.
- A member suggested that CMS and CDC synergize their expertise to create a medical laboratory assistant option for certification at the high-school level, formalizing a medical laboratory continuum and outreach program for high schools and universities across the U.S. in diverse communities. The goal would be to create a roadmap into medical laboratory science and public health careers, with communication of workplace needs at the high school, university, and post-graduate level.
- Another member emphasized the critical need to fund medical technology schools and develop a laboratory-based AmeriCorps program to support the next generation of laboratory personnel recruitment, training, and development.
- A member commented on establishing minimum education and training standards for laboratory directors of facilities (testing sites) that perform waived testing before issuing a CoW. Examples of acceptable training may include, at a minimum, completing CDC elearning courses such as Ready? Set? Test!
- One Committee member commented that there might be a need for another category of tests or subcategorization of moderate complexity testing to ensure appropriate oversight of POCT, including personnel qualifications under this new subcategory of moderate complexity testing.
- A Committee member commented that newly emerging waived testing that incorporates molecular methods brings challenges in template controls, biohazard issues, cleaning, and the need for adherence to quality standards, which may not be relevant to other CLIA-waived tests.
- Multiple members emphasized the need for the HHS to make permanent the current enforcement discretion for delivery of digital pathology and digital laboratory medicine services in remote analysis sites. The members suggested that CMS and HHS work actively to update CLIA regulations leverage this critical technology and improve access to care.
- A member commented that the terminology of “traditional” and “non-traditional” settings should be modified. Several members suggested the use of “non-laboratory” settings.

The Committee deliberated, voted, and approved the following recommendation on the topic of remote analysis and interpretation of digital data:

Recommendation 1: Laboratory practice over the last two years has demonstrated the success of remote analysis and interpretation of digital data securely. CLIAC augments its 2019 recommendation that CMS and the U.S. Department of Health and Human Services permanently codify that a laboratory's CLIA certificate covers employees of that laboratory who are performing data analysis and interpretation of digital information under the quality oversight from a primary site when working remotely under the home laboratory's CLIA certificate.

CLIA Regulations Assessment Workgroup

Introduction *Addendum 13*

Heather L. Stang, MS, MT
Deputy, Quality and Safety Systems Branch (QSSB)
Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Deputy Director for Public Health Science and Surveillance (DDPHSS)
Centers for Disease Control and Prevention (CDC)

Ms. Stang presented updates on the CLIA Regulations Assessment Workgroup. The workgroup was developed to address the CLIAC recommendation that HHS update the CLIA regulations to address new technology. She outlined the efforts of CDC, CMS, and FDA to organize topics, develop questions, and identify the members, including the CLIAC members who are serving as Co-Chairs, the agency ex officio members, and the workgroup members. Ms. Stang presented an updated diagram of the total testing process that describes the workflow that's associated with a clinical laboratory test, and this representation emphasizes a broad integration of laboratory practice into health care delivery while also integrating the concepts that are described in multiple publications since this diagram was first described in 1981 by George Lundberg. She concluded with a list of topics discussed at the first workgroup meeting.

Report from the CLIA Regulations Assessment Workgroup Meeting *Addendum 14* *Addendum 14a*

Gregory N. Sossaman, MD
System Chairman, Ochsner Health System
Department of Pathology and Laboratory Medicine
Ochsner Medical Center

Dr. Sossaman thanked the workgroup members and presented a report from the first CLIA Regulations Assessment Workgroup Meeting. He provided an overview of the discussions related to when the CLIA regulations should begin to apply to the total testing process and when CLIA coverage should end. Dr. Sossaman next discussed the workgroup's interpretation of several definitions in the CLIA law and regulations, including "materials," "derived," and "clinical laboratory." He suggested the possible need for an allowance for extensions of laboratories to encompass remote analysis sites. The workgroup suggested that if a laboratory employee is working out of their home or at another remote location, data analysis and interpretation would be covered by extending the primary site's CLIA certificate. Under a distributive model where laboratory A does the wet laboratory work, and laboratory B interprets

the test results, those two sites should have separate and distinct CLIA certificates. The workgroup also noted that there should be more stringent requirements for stability studies for at-home specimen collection devices both by the vendor and by the laboratory. Dr. Sossaman concluded with a discussion on the use of non-CLIA-certified laboratories or companies for informatic analysis of laboratory data.

Committee Discussion

- A member inquired if biosafety practices would be part of the workgroup discussions. Dr. Sossaman noted that a future workgroup topic is analytical testing specifications, which may include biosafety.
- One Committee member inquired about where programs such as the AACC POCT certification program fit into the current CLIA personnel regulations. Another member commented that these programs could be part of the "deemed" status designation.
- Several members noted that given the current workforce shortages of trained and competent laboratory personnel, including regional/local shortages in sufficient personnel to safely operate clinical laboratories, HHS funding and public-private partnerships are urgently needed to expand the clinical laboratory workforce. The funding would create and oversee clinical laboratory science training programs and partnerships with the laboratory science community to increase interest in laboratory careers, creating a roadmap beginning with middle or high schools and vocational schools and extending to university and fellowship settings. The programs would focus on broadly representing and addressing the needs of a full continuum of laboratory professionals, particularly the recruitment, incentive, and retention of personnel in underserved communities.
- One member commented that there needs to be minimum education and training requirements for laboratory directors of facilities (testing sites) with a CLIA CoW. Directors of waived testing sites should receive basic training in the regulatory, ethical, and scientific aspects of CLIA-waived laboratory testing.
- Another member stressed the need for safeguards against testing fraud and lack of quality and asked if CMS imposes fines to dissuade fraudulent CoW sites. Ms. Bennett responded that CMS could levy civil money penalties, but there is a process that must be followed before CMS can impose those monetary sanctions.

The Committee deliberated, voted, and approved the following recommendation on the topic of competent laboratory personnel:

Recommendation 2: Given the current crisis in trained and competent laboratory personnel, including regional/local shortages in sufficient personnel to safely operate clinical laboratories to serve their patients as required by law, CLIAC recommends that CDC:

- Raise the recognition of laboratory professionals in health care through its outreach, communication, training, and guidance (partnerships with the laboratory science community to increase interest in laboratory careers)
- Work with partners to create and expand access to educational content and resources and identify other opportunities to reduce the burden on individual training programs (create and oversee programs for clinical laboratory sciences training programs)
- Conduct a workplace survey of laboratory professionals to support and guide critical recruitment and retention activities.

Future CLIAC Topics

Topics suggested by Committee members included:

- A session at the next meeting to continue discussions on career pathways in medical laboratory sciences and hear what professional organizations are doing to address training and workforce issues.
- The role of the clinical laboratory productivity consultants and the need to examine the transparency of this consulting practice.
- Additional discussions on ensuring that educational literature and methods to access health information are prepared in various languages.
- A discussion of the 21st Century Cures Act's mandate for interoperability and what information blocking means when speaking about large reference laboratories competing with hospital-based testing.
- A Committee discussion focused on finding ways to apply lessons learned during the COVID-19 pandemic related to remote access to testing, to testing for other types of diseases, especially in this area of opioid addiction.
- The emergence of biomarkers for testing for different types of diseases and their role in clinical care.

CLIAC APRIL 13-14, 2022 MEETING AGENDA *Addendum 15*

CLIAC MEETING TRANSCRIPT *Addendum 16*

NOMINATION INFORMATION *Addendum 17*

ADJOURN

Drs. Ng and Salerno acknowledged the staff that assembled the meeting agenda and thanked the CLIAC members and partner agencies for their support and participation.

I certify this summary report of the April 13-14, 2022, CLIAC meeting is an accurate and correct representation of the meeting.

Dr. Valerie Ng, CLIAC Chair Date