# **C**linical **L**aboratory **I**mprovement **A**dvisory **C**ommittee


## Summary Report

**November 8-9, 2023**

**Atlanta, Georgia**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

# Clinical Laboratory Improvement Advisory Committee (CLIAC) November 8-9, 2023, Summary Report

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## RECORD OF ATTENDANCE

**Committee Members Present**

Dr. Jordan Laser (Chair)
Dr. Esther Babady
Mr. Michael Black
Dr. Chester Brown
Dr. Kimberle Chapin
Dr. James Crawford
Ms. Heather Duncan
Dr. Mary Edgerton
Dr. Tanner Hagelstrom
Dr. Yael Heher
Dr. David Koch
Dr. Hung Luu
Dr. Nirali Patel
Dr. Michael Pentella
Dr. Mark Tuthill
Dr. R.W. (Chip) Watkins
Ms. April Veoukas, AdvaMed (Liaison Representative)

**Ex Officio Members**

Dr. Collette Fitzgerald, CDC
Mr. Gregg Brandush, CMS
Dr. Timothy Stenzel, FDA

**Designated Federal Officer**

Dr. Reynolds Salerno, CDC

**Executive Secretary**

Ms. Heather Stang, CDC

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. The meeting was attended in person and via virtual Zoom webcast, and approximately 319 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 Officer (DFO), Clinical Laboratory Improvement Advisory Committee (CLIAC), and Director of the Division of Laboratory Systems (DLS), Office of Laboratory Science and Safety (OLSS), CDC, welcomed the Committee and the members of the public. On both meeting days, Dr. Jordan Laser, CLIAC Chairperson, welcomed the Committee and reviewed the process for public comments, quorum requirements, and official CLIAC recommendations. All members made self-introductions and financial disclosure statements relevant to the meeting topics. Dr. Laser stated that the agenda topics would include CDC, CMS, and FDA agency updates. In addition, the meeting would include presentations and discussions on the final report from the CLIAC CLIA Regulations Assessment Workgroup and deliberation of the efforts to address the CLIA top 10 laboratory deficiencies, standardization of test result communication, and the role of the laboratory in antibiotic stewardship.

## 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 Laboratory Systems and Response (CLSR)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control and Prevention (CDC)

Dr. Fitzgerald updated CLIAC with information about the new CDC organizational structure, including the new Center for Laboratory Systems and Response (CLSR). Dr. Reynolds Salerno will serve as Acting Director of CLSR. DLS and the Division of Scientific Resources will now be part of this new Center. She announced that CDC welcomed Dr. Mandy K. Cohen as the new CDC Director in July and highlighted Dr. Cohen's priority focus areas for the agency to address as she started her tenure at CDC. Dr. Fitzgerald then highlighted DLS activities in five areas: laboratory preparedness and response, laboratory quality and safety, laboratory informatics, laboratory training and workforce development, partnership, communication, and outreach. She provided information about two published request for information (RFI) documents. The first focuses on improving the efficiency of large-volume testing before and during emergency testing events. The second RFI is focused on improving the efficiency of rapid test development, technology transfer, and validation before a public health emergency (PHE) and enabling rapid test manufacture during a response. She described how information gathered from both RFIs will improve efficiency and enhance efforts before and during a PHE. Dr. Fitzgerald announced that The Extension for Community Healthcare Outcomes (ECHO) Biosafety Project was launched in January 2023 with ten sessions conducted to date. She announced that the 18th CDC International Symposium on Biosafety will be held in March 2024. The agenda will include a series of engaging sessions about modernizing biosafety operations and practices focused on clinical care, public health, research, and animal care, as well as topics about modern laboratory design, artificial intelligence (AI), and biosafety in space. Dr. Fitzgerald then informed the members about the collaborative efforts of CDC, the Association of Public Health Laboratories (APHL), and state public health laboratory partners to develop a strategy, provide guidance, and support the implementation and use of a biorisk management system in accordance with ISO 35001:2019. Next, Dr. Fitzgerald highlighted the work DLS is doing in collaboration with

CDC's Division of Heart Disease and Stroke Prevention and the Million Hearts program initiative to implement a process that leverages clinical laboratory expertise to contextualize laboratory results for health care providers and patients through laboratory notes, patient portals, and public service announcements. Related to laboratory informatics, Dr. Fitzgerald shared updates on the Public Health Laboratory Electronic Test Orders and Results (ETOR) resources to public health laboratories to ensure they implement an electronic system for ordering, testing, and results reporting, the CDC's Enterprise Laboratory Information Management System (ELIMS), which has electronic laboratory functionality to send test results directly to state partners using HL7 messages, and the collaboration of DLS and CDC programs to submit laboratory data elements to the United States Core Data for Interoperability (USCDI). She continued her updates by highlighting several laboratory training and workforce development activities, including another major milestone in OneLab™ membership. As of October 2023, there were over 12,000 unique members across all OneLab™ elements. She also discussed a major update to OneLab™ VR on Meta's app lab. Next, Dr. Fitzgerald discussed the OneLab Summit, scheduled for April 2024. The meeting theme will be Thrive, People, Planning, and Preparedness. She closed the presentation by discussing several activities related to partnerships, communication, and outreach, including the most recent CDC Clinical Laboratory Partners Forum, which focused on the role of the laboratory when addressing health equity challenges. Dr. Fitzgerald thanked all DLS partners and the clinical and public health laboratory and testing community for their hard work, collaboration, and support.

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

Gregg S. Brandush, RN, JD
Director
Division of Clinical Laboratory Improvement and Quality (DCLIQ)
Quality, Safety, and Oversight Group (QSOG)
Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services (CMS)

Mr. Brandush began by providing an update on the CMS DCLIQ leadership team, including new Technical Advisors and a new Northeastern Operations Branch Manager. He provided the current laboratory enrollment in the CLIA program, including the increased number of Certificate of Waiver (CoW) sites, accounting for 81% of all CLIA-certified laboratories. Mr. Brandush described CMS' accomplishments for 2023 in three areas: improved processes, modernizing CLIA, and continued stakeholder engagement efforts. He emphasized the improvements made to the state oversight activities, including the centralization of enforcement decisions. Mr. Brandush provided examples of how CMS is working to improve consistency in the survey process by revising the state agency survey process and collecting data to determine the effectiveness of the CLIA program. He discussed CMS's enhancements to the State Agency Performance Review (SAPR) evaluation and data collection processes. The improved data collection process enables CMS to identify the required activities for administering the CLIA program and determine how effectively states perform. Related to modernizing CLIA, Mr. Brandush highlighted the collaborative work of CMS and CDC on the proficiency testing (PT) final rule. He also discussed CMS' continued stakeholder engagement efforts. Mr. Brandush concluded his presentation with an overview of several new policy and administrative memos released since the last CLIA meeting.

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

Timothy Stenzel, MD, PhD
Director
Office of In Vitro Diagnostics
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 with an update on the FDA's response efforts to COVID-19 and MPOX PHEs. Dr. Stenzel noted that test developers were more active during these PHEs compared to any other prior public health emergency. He highlighted that over 6,000 submissions were received during the last four years for COVID-19 and over 200 submissions since September 2022 for MPOX. Dr. Stenzel gave an update on the number and description of currently available tests for COVID-19 and MPOX. He then noted several COVID-19 assays that are now fully authorized and no longer considered under the Emergency Use Authorization (EUA). He mentioned that over 30 over-the-counter (OTC) COVID-19 diagnostic tests were authorized and noted that the FDA web page provides information about Authorized At-Home OTC COVID-19 Diagnostic Tests, including links to home use instructions for each test and information about updated expiration dates. Dr. Stenzel then discussed the status of premarket submissions, highlighting CDRH's recent accomplishments in reviewing all backlogged premarket and Medical Device User Fee Amendments (MDUFA V) submissions. Dr. Stenzel stated that CDRH met the FDA's review performance goals established in the MDUFA V Commitment Letter, with a decrease in the overall number of submissions received. Next, Dr. Stenzel discussed two final COVID-19 transition guidances to assist with transition plans for medical devices that were issued EUAs or those that fall within specific enforcement policies issued to support the response to the COVID-19 PHE. He described the process for COVID-19 transition, including that for each PHE declaration, the FDA will publish advance notice in the Federal Register 180 days before termination of the PHE and provide guidance related to developing a transition implementation plan for in vitro diagnostics with an EUA. Dr. Stenzel then gave a brief overview of multiple marketing authorizations that have recently been granted using the De Novo review pathway. He added that the dual pathway for a 510(k) CLIA-waiver application continues to be available, as Congress gave the FDA authority to perform a dual de novo and CLIA-waived review for COVID diagnostic tests. He continued his presentation with key FDA highlights for 2023, including several first de novo authorizations. Dr. Stenzel shared that the FDA cleared the first OTC test to detect fentanyl in urine in October 2023. He also shared that the FDA recently authorized a DNA test to assess predisposition for numerous cancer types. Dr. Stenzel discussed the Medical Devices; Laboratory Developed Tests proposed rule aimed at helping to ensure the safety and effectiveness of laboratory developed tests (LDTs). He concluded his presentation by describing the Oncology Diagnostics Pilot Program, a new approach to provide greater transparency regarding minimum performance characteristics that specific tests for certain oncology drugs should meet to reduce the risk of using LDTs for oncology drug treatment decisions.

## PRESENTATIONS AND COMMITTEE DISCUSSION

## CLIAC Workgroup Reports

**CLIA Regulations Assessment Workgroup Report** *Addendum 4* *Addendum 4a*

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

Kimberle C. Chapin, MD, ABMM, FCAP
Chief Medical Officer
Deepull

Dr. Chapin thanked the workgroup members and presented the final report from the CLIA Regulations Assessment Workgroup. She provided an overview of the workgroup charge, membership, scope, and discussion topics. Dr. Chapin then provided an overview of the workgroup discussion and agreements regarding histopathology.

**Public Comments**
*Addendum PC1* *Addendum PC2* *Addendum PC3* *Addendum PC4*

**Committee Discussion**
The Committee discussed the histopathology workgroup agreements summarized in the CLIA Regulations Assessment Workgroup presentation and report. Relevant CLIAC member comments follow.

- A member noted that New York State recently passed a statutory law to establish the profession of histotechnology. The member agreed with the National Society of Histotechnology's public comment and stressed the need for a pipeline with appropriate educational requirements, relevant training, and experience to build a solid anatomic pathology laboratory workforce.
- Another member agreed that workforce competency is a priority and noted that at the 2023 Digital Pathology Association Pathology Visions Meeting, several presentations focused on the quality of histopathology and how histopathology impacts both AI and patient care. The member added that any changes to update the CLIA regulations should consider testing modalities, such as digital pathology and AI.
- Another member commented that histotechnicians, histotechnologists, and pathologist assistants play an essential role in the preanalytic phase of laboratory testing and should be recognized as part of the anatomic pathology total testing process.
- Several members suggested that resources from professional organizations, such as the American Society for Clinical Pathology and the National Society of Histotechnology, should be used to inform educational requirements.
- Many members agreed that if CLIA is modified to recognize histotechnicians, histotechnologists, and pathology assistants as testing personnel, there should be a phased implementation to mitigate workforce issues.

The Committee deliberated, voted, and approved the following recommendations based on the topic of *The CLIA Regulations Assessment Workgroup Report*.

**Recommendation 1:** CLIAC recommends that CMS update CLIA to recognize histotechnicians, histotechnologists, and pathology assistants as testing personnel and define educational requirements for each personnel category.

## Efforts to Address the CLIA Top 10 Laboratory Deficiencies

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

Gregg S. Brandush, RN, JD
Director
Division of Clinical Laboratory Improvement and Quality (DCLIQ)
Quality, Safety, and Oversight Group (QSOG)
Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services (CMS)

Mr. Brandush introduced the topic of the top 10 deficiencies found during CLIA surveys. He discussed CMS activities aimed at reducing the deficiencies, especially those that continue to occur. He concluded his presentation by providing an overview of the questions for CLIAC deliberation.

**Overview of the CMS CLIA Top 10 Deficiencies** ***Addendum 6***

Karen Sutterer, MT(ASCP)
Survey Technical Advisor
Division of Clinical Laboratory Improvement and Quality (DCLIQ)
Quality, Safety, and Oversight Group (QSOG)
Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services (CMS)

Ms. Sutterer began by displaying the top 10 deficiencies in 2009 and highlighted that four continue to recur and are included in the top 10 for 2023. She described the top 10 deficiencies as of September 2023, including their frequencies and examples of when a laboratory may be cited for each. She provided a table that categorized each of the deficiencies and frequencies cited according to the CMS survey region. Ms. Sutterer explained that the most common deficiency cited by surveyors was D5413, based on the regulation 42 C F R § 493 1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies. She explained that two common reasons for citing D5413 include when laboratories fail to document room temperature and humidity and when laboratories fail to store reagents at the correct refrigerator or freezer temperature ranges as required by the manufacturer. Ms. Sutterer acknowledged that D5413 is cited frequently because documentation of temperatures is easily checked during the survey process. In most cases, correction of this deficiency is easily addressed by the laboratory. Next, she discussed a poll sent to both CMS and State Agency surveyors to rank deficiency citations that would impact patient testing outcomes. She noted that D5421, failure to verify the reference interval (normal values), ranked the highest. She concluded by discussing rankings and why differences in rankings may occur between CMS and State Agency surveyors.

**The American Association for Laboratory Accreditation (A2LA): Advancing Laboratory Quality through Continuous Improvement** ***Addendum 7***

Carlyn Mathews
Program Manager
A2LA

Ms. Matthews began with a short description of The American Association for Laboratory Accreditation (A2LA) and presented the top 10 deficiencies identified by their inspectors. She stated that they primarily see deficiencies that involve quality and, often, it is because the laboratory does not have a policy or procedure required by the regulations or the policies and procedures are not followed. She described how A2LA works with laboratories to determine the cause of deficiencies. Ms. Matthews concluded by describing the A2LA corrective action process and the steps they use to help the laboratories address deficiencies.

**The Association for the Advancement of Blood and Biotherapies (AABB): The AABB Experience with Addressing Common Nonconformances and How to Prevent Them**

Melanie Sloan ***Addendum 8***
Senior Director, Accreditation and Quality
AABB

Ms. Sloan began her presentation by showing the top five deficiencies that The Association for the Advancement of Blood and Biotherapies (AABB) cited during their assessments and explained how their standards align with the CLIA regulations. She described that personnel competency assessment is the most frequent citation and provided an in-depth look at AABB's standards associated with competency assessments. Ms. Sloan described AABB's best practices library and educational material to assist laboratories in achieving CLIA compliance and to provide member facilities with examples of successful and unsuccessful implementation of a standard. She described an AABB partnership with COLA to address identified workforce challenges and provide educational offerings on their three most common nonconformances. Ms. Sloan concluded by describing several venues where AABB provides information to their members on laboratory regulations and quality.

**COLA: A New Look at the Most Frequent Citations** ***Addendum 9***

Kathy Nucifora, MPH, MLS(ASCP)
Chief Operating Officer
COLA

Ms. Nucifora began by reiterating how deficiencies only appear to change a little yearly and are very similar between the different accrediting organizations. She explained that the top deficiencies from COLA-accredited laboratories fall under personnel responsibilities, proficiency testing, and competency assessment. She indicated a lack of competency assessment performed as required accounted for 33% of repeated citations in COLA's previous two survey cycles. Ms. Nucifora described the targeted support and education that COLA provides to laboratories to address deficiencies. She stated that while it is essential to report the top deficiencies, data need to be collected to determine the impact of the specific interventions. In coordination with other organizations, Ms. Nucifora stated that The Workforce Action Alliance aims to implement meaningful solutions to address the workforce shortage over the long term. She stressed that engagement is needed in similar efforts to help laboratories achieve compliance, meet regulatory expectations, and be recognized for their role in patients' and communities' health and wellness.

**The College of American Pathologists (CAP): Most common deficiencies - CAP Accreditation** ***Addendum 10***

Michael Datto, MD, PhD
CAP Complaints and Investigations Committee
Medical Director and Associate Vice President,
Duke Health Clinical Laboratories
Associate Professor and Vice Chair, Department of Pathology
Duke University Medical Center

Dr. Datto began by reporting the top 10 deficiencies from CAP-accredited laboratories and stating how they are similar to the other organizations. He discussed how the commonalities of the deficiencies can be grouped into four categories: missing records, not following the manufacturer's defined requirements, inadequate records of supervisory oversight, and a lack of understanding of the complex requirements. Dr. Datto continued by describing the root causes behind these common deficiencies, including the complexity of the regulations, workforce shortages, and manual processes. Next, he provided a deeper look into each of the root causes. Using the CLIA regulations for competency assessment, he stressed the need for clear regulatory language. Dr. Datto provided data on the workforce shortage and noted that a limited laboratory workforce means that personnel and supervisors must focus their time on patient-facing work at the expense of record-keeping and administration. He described how many laboratories are still using paper-based documentation and how transitioning to an electronic documentation system can be cost-prohibitive for many laboratories. Dr. Datto concluded his presentation by discussing several CAP initiatives to help laboratories become compliant and offered several recommendations for the CLIA program to consider.

**The Joint Commission: Assessing the Most Common Standards Findings**

Amy Null, MBA, MLS(ASCP), SBB ***Addendum 11***
Associate Director, Standards Interpretation Group
The Joint Commission

Ms. Null started her presentation with an overview of their Comprehensive Accreditation Manual for Laboratory and Point of Care Testing (CAMLAB), how it is organized, what the standards encompass, and how the elements of performance are used. She listed the top 10 deficiencies found and stated that they typically stay the same year to year. She concluded by providing an overview of the different resources that The Joint Commission has available to their laboratories, including an electronic copy of the accreditation manual, a crosswalk of their standards to CLIA regulations, an educational conference, and a survey readiness document.

**New York's Clinical Laboratory Evaluation Program** ***Addendum 12***

Available online only

**Public Comments**
***Addendum PC5***

**Committee Discussion**

- Multiple Committee members commented on the need for laboratory personnel, hospital administrators, and executives to be aware and educated on CLIA laboratory

regulations. One member added that information on the CLIA top 10 deficiencies should be disseminated to the laboratory community and administrators.

- Multiple members agreed that educational tools and resources should be available to address reoccurring deficiencies, with one member suggesting that the training be required for all CLIA personnel.
- Several CLIAC members commented on the advantage of instituting a regularly scheduled self-assessment of their laboratories to identify areas for quality improvement. Members commented that any regulatory change to require interim self-assessments should consider the burden to laboratories before becoming final. A member commented that it is valuable for laboratories to partner with other laboratories in assessment activities.
- A few Committee members provided examples of situations that made remaining in compliance with CLIA a challenge. Most notable was the staffing shortage and the high turnover seen in laboratories. Two Committee members mentioned the large number of trainings their institution currently requires and suggested that if additional training was required, the training should be directly applicable to the function of the laboratory.
- Many Committee members described specific solutions that have been implemented in laboratories or that have the potential to help decrease the common deficiencies seen by CMS and all of the accreditation organizations. These included having administrators, executives, and laboratory directors take training on CLIA regulations, identifying additional methods to communicate CLIA regulations with laboratory testing staff, and conducting laboratory self-audits to be prepared for official surveys and assessments.
- A CLIAC member commented that while much of the discussion focused on issues in larger hospitals and hospital systems, challenges are also seen in smaller laboratories, especially when the laboratory director is disengaged. The member stated that a culture of quality flows down from leadership to the bench workers.
- One Committee member suggested, and others agreed, that highlighting laboratories with few or no deficiencies or partnering laboratories would help illustrate that compliance is possible and give examples of improvements that could be implemented.
- Multiple Committee members commented that the process and number of data points that need to be documented for competency assessments are complex and confusing.
- Members discussed the formation of a CMS workgroup to address competency requirements. One Committee member suggested that laboratories utilize digital tools to help manage tasks required for compliance with the CLIA competency requirements. Other suggestions ranged from simplifying the regulations to having templates covering all the elements necessary for an electronic documentation system.
- Committee members commented on the data needed to determine barriers contributing to the top 10 deficiencies and discussed the data types collected by CMS and Accreditation Organizations. Members suggested that CMS and Accreditation Organizations collect more granular data related to deficiencies and report back to CLIAC periodically.
- The DFO also reiterated the Committee’s role, encouraging CLIAC to direct recommendations to one or more government agencies rather than making a general recommendation to HHS. He included examples of DLS's educational efforts, such as CLIA-related training modules and the Next Generation Sequencing Quality Improvement initiative.

The Committee deliberated, voted, and approved the following recommendations based on the topic of *The Efforts to Address the CLIA Top 10 Laboratory Deficiencies*.

**Recommendation 2:** CLIAC recommends that CMS engage Accrediting Organizations to increase the granularity of data related to the CLIA top 10 deficiencies.

**Recommendation 3:** CLIAC recommends that CDC and CMS engage with professional organizations and hospital and facility agencies to incorporate CLIA regulation requirements into the required training programs for hospital and laboratory quality organizational leaders.

**Recommendation 4:** CLIAC recommends that CMS evaluate and consider modifications to the CLIA regulations for competency assessment to simplify the regulations and clarify the procedures while ensuring the competency of laboratory personnel.

**Recommendation 5:** CLIAC recommends that CMS consider requiring interim CLIA self-assessment and documentation of correction of self-identified deficiencies.

## The Role of the Laboratory in Diagnostic and Antibiotic Stewardship

**Introduction to Topic** ***Addendum 13***

Nancy E. Cornish, MD
Senior Advisor for Quality and Safety
Division of Laboratory Systems (DLS)
Center for Laboratory Systems and Response (CLSR)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control and Prevention (CDC)

Dr. Cornish introduced the topic of diagnostic stewardship, which promotes ordering the right tests for the right patient at the right time to inform optimal clinical care. She explained that diagnostic stewardship aims to improve the entire diagnostic process, from test ordering to test performance to reporting the test results. Dr. Cornish shared that diagnostic stewardship principles can be used throughout all areas of the clinical laboratory. She noted that an example of diagnostic stewardship in blood banking is the use of blood utilization committees that many institutions have adopted. Dr. Cornish emphasized that diagnostic stewardship relies on creating multidisciplinary partnerships, including clinicians, hospital administration, laboratory professionals, and patients, to ensure that tests are ordered appropriately and collected correctly, clinicians and patients understand results, and treatment is instituted as necessary. She next explained that diagnostic stewardship is now considered essential to antibiotic stewardship. Proper diagnosis and treatment of infectious diseases are often used as an example of how diagnostic stewardship can improve timely and accurate diagnosis and treatment. Dr. Cornish concluded the presentation by introducing the session speakers and providing questions for the Committee to consider during their deliberations.

**Diagnostic Stewardship to Improve Antimicrobial Stewardship** ***Addendum 14***

Daniel J. Diekema, MD, D(ABMM)
Director, Division of Infectious Diseases
Department of Medicine
Maine Medical Center
Professor of Internal Medicine (Emeritus)
University of Iowa College of Medicine

Dr. Diekema opened his presentation by defining diagnostic stewardship and providing an overview of the diagnostic testing process. He shared many examples and publications of diagnostic stewardship activities covering the preanalytic, analytic, and postanalytic phases of testing. Dr. Diekema explained how diagnostic stewardship has been embedded in antimicrobial stewardship programs for a long time, but it is possible to identify and delineate differences in some of the immediate goals, values, targets, and interventions each team does. He explained that an ideal diagnostic stewardship intervention would be minimally disruptive but not bypassed by clinicians and could be built into the testing workflow to improve the selection and interpretation of tests. Dr. Diekema shared that there is a need for improved education and methods to allow clinicians to accurately estimate the pretest probability of disease and adjust those probabilities when they receive test results. In closing, Dr. Diekema shared future directions in medical education intended to improve diagnostic reasoning. He stated that creating and supporting diagnostic stewardship teams with expansion beyond infectious diseases is important. Dr. Diekema explained the need for more funding for research and innovation.

**The Adult Blood Culture Contamination National Patient Safety Measure**

Jake D. Bunn, MBA, MLS(ASCP)$^{CM}$
Clinical Laboratory Scientist
Division of Laboratory Systems (DLS)
Center for Laboratory Systems and Response (CLSR)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control and Prevention (CDC)

***Addendum 15***

Mr. Bunn started the presentation by briefly describing the blood culture total testing process. He shared the significant diagnostic challenges one may encounter, such as false negative blood cultures due to an inadequate blood volume, which can result in misdiagnosis, delay therapy, and put patients at heightened risk for morbidity and mortality from bacteremia. Likewise, commonly occurring commensal bacteria or fungi on the human skin can increase the risk of false positives, compromising care by leading to unnecessary antibiotic therapy and prolonged hospitalization. He noted a publication by the American Society for Microbiology that summarized problems with blood culture contamination and potential patient safety events and recommended that CDC address the issue. Mr. Bunn indicated that CAP is the only accreditation organization providing standards for blood culture contamination. He added that only 25% of hospital laboratories with inpatient settings are accredited by CAP and would have standards for blood culture contamination. He noted that the CLIA regulations for specimen submission, handling, and referral and the standard for preanalytic systems quality assessment apply to blood culture quality monitoring. Mr. Bunn explained that clinical laboratories can use laboratory information system data to generate and report the blood culture contamination rate, and this monitoring can serve as a proxy measurement of the effectiveness of the blood culture collection procedures. He explained that to help reduce blood culture contamination and improve the collection of blood cultures,

CDC recently leveraged the CMS consensus-based entity measure process to establish the blood culture contamination rate as a national patient safety measure. In describing the process, Mr. Bunn reviewed the primary and secondary national measures and provided an overview of the measure evaluation criterion. Mr. Bunn shared that preanalytic errors account for most blood culture contamination events. He suggested that clinical laboratories work with institutional antibiotic stewardship teams to evaluate contamination rates and take a collaborative approach to improve blood culture collection. He highlighted several tools published by CDC to support stewardship and promote the blood culture contamination measure. Mr. Bunn concluded by sharing the next steps for the measure, explaining promotional efforts, defining the target audiences, and exploring the development of training materials and data collection activities through CDC's National Healthcare Safety Network.

**Public Comments**

*No public comments were received on this topic.*

**Committee Discussion**

- One CLIAC member commented that healthcare is different now than when CLIA was implemented, and patients receive care through multiple institutions. The commenter added that diagnostic stewardship plays a role in reducing repeat testing by collecting and analyzing data to provide clinical decision support.
- A member commented on the importance of looking at postanalytic and preanalytic issues when considering diagnostic stewardship.
- One member suggested that the FDA has a role when authorizing a new test to ensure that a method comparison is performed against tests already on the market. Dr. Stenzel responded that the FDA encourages harmonization and stressed the importance of international standards and qualified reference materials. He added that the 510(k) clearance process does require a method comparison to an authorized comparator or well-qualified reference method. He noted that challenges exist to achieve harmonization when multiple tests are on the market. Dr. Stenzel added that the FDA is always willing to work with organizations and stakeholders.
- Several CLIAC members suggested encouraging the development of diagnostic stewardship programs or committees in hospitals, similar to how antibiotic stewardship programs began, which led to them being required by CMS. One member added that non-hospital-based organizations should be considered before making any additional requirements, emphasizing the need to focus on the availability of test result data across different organizations and electronic medical record platforms regardless of whether the physician is part of a sizeable hospital-based network or rural practice.
- One CLIAC member commented on the need for prioritization of diagnostic stewardship activities and suggested that input from a broad range of providers would be beneficial to determine national and local healthcare needs and have the most significant impact on improving patient safety and outcomes.
- Several members suggested raising awareness of the benefits of a diagnostic stewardship program, noting the need for publications that provide evidence of the diagnostic utility and clinical impact of these programs.
- A CLIAC member commented on partnering with electronic health record (EHR) and laboratory information system (LIS) vendors to harmonize test orders and result requirements.
- Members agreed that in the context of diagnostic stewardship, there is a need to reduce duplicate testing. A fundamental step to achieve that is determining whether testing from another institution is the same. One member added that results can vary

significantly depending upon the testing platform, and knowing the instrument and manufacturer would be helpful.
- Members expressed the need for guidelines to improve the quality of blood culture samples. One member suggested that a laboratory's quality improvement program should include the blood culture contamination measure.

The Committee deliberated, voted, and approved the following recommendations based on the topic of *The Role of the Laboratory in Diagnostic and Antibiotic Stewardship*.

**Recommendation 6:** To expand the influence of the CLIA quality program and strengthen clinical laboratory quality, CLIAC recommends that CMS and CDC develop an educational campaign promoting diagnostic stewardship programs targeting clinical laboratories.

**Recommendation 7:** CLIAC recommends that CDC and FDA encourage in vitro diagnostics (IVD) manufacturers to harmonize results across different platforms, when possible, to allow for safe aggregation of patient results from other institutions to trend results and reduce duplicate testing.

**Recommendation 8:** CLIAC recommends updating the CLIA regulations to include blood culture contamination rate monitoring within the laboratory quality management system.

## Standardization of Test Result Communication

**Introduction to Topic** ***Addendum 16***

Jasmine Chaitram, MPH, MT(ASCP)
Chief, National Laboratory Response Systems Branch
Division of Laboratory Systems (DLS)
Center for Laboratory Systems and Response (CLSR)
Office of Laboratory Science and Safety (OLSS)
Centers for Disease Control and Prevention (CDC)

Ms. Chaitram provided a brief overview of past Committee discussions on the communication of test results, including the formation of a workgroup that resulted in two recommendations during the November 2016 CLIAC meeting. Ms. Chaitram clarified that there are no specific requirements in the CLIA laboratory test communication regulations. She noted that there is a CLIA requirement for the laboratory to have procedures for entering results in the patient record, and there is a CLIA requirement that the laboratory must have a system in place to ensure test results and other patient data are accurately and reliably sent from the point of entry to the final point of destination. To conclude, Ms. Chaitram introduced the presenters for the session and reviewed questions for the Committee to consider during their deliberations.

**Communicating Test Results to Providers and Patients: An Overview of the VHA Directive 1088 and Electronic Test Result Communication in the Era of the 21st Century Cures Act** ***Addendum 17*** ***Addendum 17a***

Hardeep Singh, MD, MPH
Center for Innovations in Quality, Effectiveness & Safety (IQuESt)
Michael E. DeBakey VA Medical Center
Baylor College of Medicine

David R. Hunt, MD, FACS
Medical Director,
Patient Safety and Health IT Adoption,
Office of Clinical Quality and Safety
Office of the National Coordinator for Health Information Technology

Dr. Singh discussed the challenges in communicating subcritical abnormal test results in the era of electronic health records and patient portals. He highlighted issues such as ambiguous responsibility and information overload in clinicians' inboxes. Dr. Singh emphasized the need for a sociotechnical approach, addressing not only technology but also rules, regulations, communication, workflow, and organizational policies. He introduced The Office of the National Coordinator for Health Information Technology (ONC) SAFER Guides, which consists of nine guides organized into three broad groups. He noted that these guides enable healthcare organizations to address EHR safety in various areas and include national best practice recommendations for implementing electronic health records safely, focusing on test results communication. Dr. Sigh highlighted the three SAFER Guides that are directly of interest to CLIA, focused on test order entry, test results communication, and follow-up and clinician communication. He noted that as of 2022, CMS requires attestation to the SAFER Guides for Medicare Promoting Interoperability Program participants. Dr. Singh also provided an overview of the Veterans Health Administration (VHA) Directive 1088 to ensure timely and standardized communication of test results to both clinicians and patients. He explained specific timelines for communicating results requiring action and those that do not, along with documentation requirements and backup procedures outlined in the Directive. Dr. Singh touched on the challenges posed by the 21st Century Cures Act, which has led to patients sometimes receiving results before clinicians, causing confusion and distress. He discussed ongoing efforts with the Agency for Healthcare Research and Quality (AHRQ) to explore best practices for providing patients with immediate access to test results through portals. Dr. Singh noted the need for national standards, laboratory involvement in institutional policies, and engagement with SAFER Guides to address these challenges. His presentation concluded with a call for CLIAC to recommend establishing national standards, engaging laboratories in developing institution-specific policies, and focusing on SAFER Guides to ensure effective test results communication.

Dr. Hunt emphasized the importance of transparency and empowerment within the healthcare system. He highlighted ONC's policy framework and the importance of shared responsibility and teamwork. He acknowledged the value of SAFER Guides in providing a systematic framework for addressing challenges in test results communication. Dr. Hunt discussed the need for ongoing dialogue and communication with various healthcare communities, including the laboratory community, and noted the continuous review of federal policies, such as information blocking under the 21st Century Cures Act and the adjustments made based on feedback from clinicians and patients. He emphasized the importance of revisiting and reviewing policies to ensure their relevance to current circumstances. He

suggested engaging in an expanded discussion with the laboratory community around SAFER Guides' recommendations to inform communication and to identify opportunities, best practices, and concerns. Dr. Hunt concluded by highlighting the HHS Secretary's initiative around patient safety and the Patient Safety Alliance as additional avenues for communication with HHS and CMS.

**Public Comments**
*No public comments were received on this topic.*

**Committee Discussion**

- A member requested clarification on the definition of results requiring reported action within seven days. Dr. Singh responded that the VHA Directive 1088 focuses on non-life-threatening results that should be called within 30 minutes to an hour. He added that the Directive includes a section for definitions and noted that results requiring action are defined as those where there needs to be a therapeutic or management change.
- Another member asked to clarify the laboratory's responsibility for reporting subacute or subcritical results. Dr. Singh explained that the VHA system is a closed-loop electronic system, and the laboratory communicates results electronically to the physician. He added that no additional laboratory responsibility is specified other than ensuring that results are effectively and immediately communicated electronically unless they're life-threatening, in which case the laboratory would follow the policies and procedures of the institution.
- A member asked how communication happens for reflex testing. Dr. Singh responded that the VHA Directive focuses on electronic communication and that all VA medical centers should develop local policies to determine which results rise to the need for a telephone call to the physician versus electronic communication. Another member added that the onus seems to be on the laboratory, which takes time away from testing. Dr. Hunt added that the SAFER Guides provide a framework for the test communication process.
- Several members asked how to encourage communication between professionals in the coordinated care process and if there is a way within the VA system to allow the laboratory to know when results are communicated proactively. Dr. Singh clarified that the VHA is a closed system, and they are working to define responsibility for test result follow-up questions. Dr. Hunt added that ONC is working to advance the social and cultural changes needed to promote all local communication within a health system.
- A member commented on the challenges with safe communication within the electronic medical record system, mainly when reporting results, noting that the limited space for comments makes it difficult to provide valuable insights for result interpretation. The member added that constraints on the number of figures for test names can lead to ambiguity in orders and results.
- Several members commended Dr. Singh for the VA policy that designates responsibility for communicating test results to the ordering physician unless a specific designee is appointed. The member emphasized the need for a national policy to clarify responsibility for result communication.
- Several members discussed the process of communicating abnormal laboratory test results and the need for providers to define what those results would be in their organization. Many members agree that the ordering provider is responsible for reviewing and following up on test results. One member expressed concern about the

overwhelming nature of primary care physicians' inboxes and the limited time they have to review results
- One CLIAC member also discussed challenges related to releasing results to patients and suggested promoting standards to address issues arising from the CARES Act.
- Members discussed the formation of a workgroup to understand and develop processes for communicating laboratory test results. Members noted that a workgroup should include laboratory staff, healthcare providers, and EHR vendors. The members also discussed that the workgroup should focus on discussing the abnormal laboratory results that should be actionable, working with EHR vendors to identify processes that facilitate laboratory awareness when transitions in care occur, and monitoring the impact of the SAFER Guides on patient outcomes.

The Committee deliberated, voted, and approved the following recommendations based on the topic of *Standardization of Test Result Communication*.

**Recommendation 9:** CLIAC recommends that HHS require that all transmission of laboratory results throughout the healthcare ecosystem, at a minimum, adhere to the required discrete results defined in laboratory result reports in CLIA.

**Recommendation 10:** CLIAC recommends a CLIAC workgroup be formed, including key stakeholders, organizations/agencies from the provider, and health IT communities, to understand the opportunities for enhanced communication of laboratory results and to verify action upon those results.

## Future CLIAC Topics

Topics suggested by Committee members included:
- Continued discussions on the laboratory workforce to stay current with the workforce shortage crisis.
- AI and machine learning and how these advances relate to the laboratory industry.
- Certification processes for pathology laboratory information management systems.

## CLIAC NOVEMBER 8-9, 2023 MEETING AGENDA *Addendum 18*

## CLIAC MEETING TRANSCRIPT *Addendum 19*

## ADJOURN

Drs. Laser and Salerno acknowledged the staff who assembled the meeting agenda and organized the meeting. They also thanked the CLIAC members and partner agencies for their support and participation.

I certify that this summary report of the November 8-9, 2023, CLIAC meeting accurately and correctly represents the meeting.

Dr. Jordan Laser, CLIAC Chair Date