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

Summary Report

November 6-7, 2019

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
November 6-7, 2019, Summary Report

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CLIAC NOVEMBER 6-7, 2019 MEETING AGENDA *Addendum 1*

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RECORD OF ATTENDANCE

Committee Members Present
Dr. Valerie Ng, Chair
Dr. Birthale Archie
Dr. Marc Couturier
Dr. Keith Davis
Dr. Susan Gross
Dr. Steven Hinrichs (Participation on November 6, 2019 afternoon session only)
Dr. Lee Hilborne
Dr. Bradley Karon
Dr. Thomas Lorey
Dr. Sharon Massingale
Dr. Lavinia Middleton
Ms. Carole Moss
Dr. Katherine Perez
Ms. Jennifer Rhamy
Ms. Bonnie Rubin
Dr. Gregory Sossaman
Ms. Cynthia Wilkerson
Dr. Thomas Williams
Dr. Donna Wolk
Mr. Andy Quintenz, AdvaMed (Liaison Representative)

Committee Members Absent
Dr. Jordan Laser

Ex Officio Members
Ms. Karen Dyer, CMS
Dr. Collette Fitzgerald, CDC
Dr. Peter Tobin, FDA

Designated Federal Official
Dr. Reynolds Salerno, CDC

Executive Secretary
Ms. Nancy Anderson, CDC

Record of In Person Attendance – cont'd

Centers for Disease Control and Prevention (CDC)

Dr. Diego Arambula
Dr. Aufra Araujo
Dr. Gregory Armstrong
Dr. Heba Athar
Mr. Brad Bowzard
Dr. Alicia Branch
Mr. James Bratton
Ms. Jennifer Brooks
Ms. Juley Cetoute
Ms. Jasmine Chaitram
Dr. Bin Chen
Dr. Blanche Collins
Dr. Nancy Cornish
Ms. Sabrina DeBose
Dr. Stephanie Dietz
Dr. Marie Earley
Ms. Sonnet Gaertner
Ms. MariBeth Gagnon
Dr. Manjula Gama Ralalage
Ms. Leona Grant
Ms. Nicole Gregoricus
Ms. Natasha Griffith
Dr. Triona Henderson
Ms. Stacy Howard
Dr. Michael Iademarco
Dr. Jodi Jackson
Ms. Brenda Johnson
Dr. Jeff Johnson
Dr. Uzay Kirbiyik
Dr. Luciana Kohatsu
Dr. William Mac Kenzie
Dr. Rebecca McNall
Dr. Bereneice Madison
Ms. Graylin Mitchell
Dr. Atis Muehlenbachs
Mr. Brandon Paul
Ms. Ami Putman
Dr. Jennifer Salazar
Dr. Paramjit Sandu
Ms. Tara Smith
Ms. Theresia Snelling
Ms. Heather Stang
Ms. Vickie Sullivan
Ms. Sally Thigpen
Ms. Laurina Williams
Ms. Yescenia Wilkins
Ms. Kelly Winter

Department of Health and Human Services (Agencies other than CDC)

Ms. Jelani Sanaa, CMS
Ms. Mary Hasan, CMS
Ms. Regina Van Brakle, CMS

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Approximately 125 public citizens attended one or both days of the meeting. The meeting was also available by webcast.

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 assure 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. In addition, the Committee provides advice and guidance on specific questions related to possible revision 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. Members are selected by the Secretary 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; the Commissioner, Food and Drug Administration; the Administrator, Centers for Medicare & Medicaid Services; and such additional officers of the U.S. Government that the Secretary deems are necessary for the Committee to effectively carry out its functions. CLIAC also includes a non-voting liaison representative who is a member of AdvaMed and such other non-voting liaison representatives that the Secretary deems are necessary for the Committee to effectively carry out its functions.

Due to the diversity of its membership, CLIAC is at times 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 their advice due to other overriding concerns. Thus, while some of the actions recommended by CLIAC may result in changes to the CLIA regulations or may lead to other actions taken by HHS, the reader should not infer that all of the Committee's recommendations will be automatically 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), Office of Public Health Scientific Services (OPHSS), CDC, welcomed the Committee and the members of the

public, acknowledging the importance of public participation in the advisory process, and introduced Dr. Valerie Ng as the new CLIAC Chair. Dr. Valerie Ng welcomed the Committee and took roll call of all the members present. All members then made self-introductions and financial disclosure statements relevant to the meeting topics. Dr. Ng stated that the agenda topics would include updates from the CDC, CMS, and the FDA. In addition, there would be presentations and discussions on the Association of Public Health Opioids Task Force, the clinical laboratory workforce, and improving integration of laboratory information systems with electronic health records. Dr. Ng announced that there will be an extended public comment session focusing on emerging technologies and the clinical laboratory.

AGENCY UPDATES AND COMMITTEE DISCUSSION

Centers for Disease Control and Prevention (CDC) Update ***Addendum 3***

Collette Fitzgerald, PhD
Associate Director for Science
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. Fitzgerald updated CLIAC on DLS's work in four priority goal areas: quality laboratory science, highly competent laboratory workforce, safe and prepared laboratories, and accessible and usable laboratory data. She highlighted the publication of the CLIA proficiency testing (PT) proposed rule, noting that over 100 comment letters were submitted by individuals and organizations. CDC and CMS are now analyzing comments, and gathering data needed to finalize the rule. Dr. Fitzgerald updated members on the Diagnostic Error Scoping Review Project being performed by DLS to look for opportunities for laboratory engagement to improve diagnostic excellence. CDC also plans to pilot a laboratory community of practice on diagnostic excellence using the Project ECHO model. The purpose of this pilot will be to connect laboratory professionals, clinicians, and leaders in laboratory and health care with a goal to engage laboratory expertise to capture innovative use of data and promote data driven processes, and to share best practices. Dr. Fitzgerald highlighted the recent and upcoming Clinical Laboratory Partner Forum meetings. She also described a recent laboratory preparedness tabletop exercise, held in collaboration with the CDC Center for Preparedness, that assessed the CDC's processes for working with commercial laboratories to provide diagnostic surge testing during a public health emergency. She noted a collaboration with the Association of Public Health Laboratories (APHL) to hold a series of biosafety listening sessions and presented the high-level findings from those sessions, including the need for leadership engagement and buy-in and training and resources. She highlighted the CDC's first virtual reality (VR) training course on how to set up a biosafety cabinet, and invited CLIAC meeting attendees to visit the demonstration available in the lobby. She closed with the announcement of the CDC's 16th International Symposium on Biosafety in Atlanta, February 29 through March 4, 2020. She noted that this first time DLS is responsible for leading and coordinating the meeting in partnership with the Eagleton Institute and the American Biological Safety Association.

Centers for Medicare & Medicaid Services (CMS) Update *Addendum 4*

Karen Dyer MT (ASCP), DLM
Director
Division of Clinical Laboratory Improvement and Quality (DCLIQ)
Quality, Safety and Oversight Group (QSOG)
Centers for Medicare & Medicaid Services (CMS)

Ms. Dyer began with the current laboratory enrollment in the CLIA program, including the number of accredited laboratories and certifications among the self-selected laboratory types. She provided an overview of the growth in CLIA-certificate types since 1993 and described the history of CLIA. She described CLIA program activities, including approval of accreditation organizations, exempt states, and proficiency testing programs. She also explained how FDA determines test complexity categorization. She provided a brief description of the five different types of CLIA certificates and the outcome-oriented inspection process for each. Ms. Dyer presented information on the CLIA Communications Listserv, which will allow CMS to disseminate information to laboratories and laboratory professionals, and provided an example bulletin. Ms. Dyer closed with an update on the CLIA Outreach Program – Academic to promote clinical laboratory science as a vital and dynamic career for high school and post-secondary students.

Food and Drug Administration (FDA) Update *Addendum 5*

Peter Tobin, PhD
Chemist
Division of Program Operations and Management
Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH)
U. S. Food and Drug Administration (FDA)

Dr. Tobin began his presentation by describing the CDRH reorganization and staffing changes to support a total product life cycle (TPLC) approach to devices. The reorganization combined offices that were involved in pre- and post-market activities, such as compliance, surveillance, and biometrics, into one office called the Office of Product Evaluation and Quality (OPEQ). The Office of In Vitro Diagnostics and Radiological Health is now called the Office of Health Technology 7 (OHT7) and is one of seven health technology-specific offices within OPEQ, along with two programmatic oversight and support offices. Dr. Tobin introduced the OIR's new Deputy Director for Personalized Medicine, Dr. Wendy Rubinstein, and OIR's new Associate Director for Medical Affairs, Dr. Sara Brenner. Dr. Tobin updated the Committee on FDA's precision medicine accomplishments and shared their vision for regulating next generation sequencing (NGS) based in-vitro devices (IVDs). He noted that Clinical Genome Research (ClinGen) Expert Curated Human Variant Data is FDA's first publicly available genetic variant database to support clinical validity for genetic and genomic-based in vitro diagnostics. Dr. Tobin described the FDA's Clinical Decision Support Software draft guidance (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software) published in September. He announced an update to the 2017 biotin safety communication reminding the public, including health care professionals, patients, laboratory professionals, and test developers, that biotin often found in dietary supplements can

significantly interfere with certain laboratory tests and cause incorrect results that may go undetected. He noted that the new webpage (https://www.fda.gov/medical-devices/vitro-diagnostics/biotin-interference-troponin-lab-tests-assays-subject-biotin-interference) includes a list of troponin IVDs that are subject to biotin interference, and that some test developers have not yet addressed the risk. Dr. Tobin closed with updates on the Systemic Harmonization & Interoperability Enhancement for Lab Data (SHIELD) implementation pilots. He noted the public-private partnership between the Clinical and Laboratory Standards Institute (CLSI) and SHIELD. CLSI is currently developing a report that will provide information on resources for navigating available laboratory data standards and guidelines to promote IVD semantic interoperability.

Committee Discussion

- A member suggested that the CDC ECHO program work collaboratively with HHS evidence-based practice centers to assess the link between laboratory quality and outcomes. Another member stated the Clinical Laboratory 2.0, a Project Sante Fe Foundation initiative, would also be good collaborators.
- One member asked for a clarification on the scope of the CDC's biosafety activities. Dr. Salerno responded that the scope is laboratory biosafety, which includes the prevention of accidental laboratory infections, as well as the prevention of accidental release or dissemination of an organism outside of the laboratory.
- Another member noted that web-based, standardized educational tools related to point-of-care testing are needed. Ms. Nancy Anderson responded that CDC has several well-received educational products available that promote good laboratory practices for waived testing and provider-performed microscopy procedures.
- Another CLIAC member inquired about the proposed CLIA proficiency testing (PT) rule and whether the final PT rule would address the CMS oversight of non-regulated PT, specifically PT for distributive testing models. Ms. Dyer responded that CMS cannot discuss the final PT rule at this time.
- The AdvaMed liaison inquired about the CMS concern about research laboratories and laboratory-developed tests (LDTs). Ms. Dyer commented on the proposal in Congress for oversight of LDTs. Another member commented that it is often difficult to determine when a clinical decision is being made based on results obtained as part of a research project or Institutional Review Board protocol. The member added that educational materials on this topic would be beneficial.
- Several members inquired about the recent biotin safety communication update. Dr. Tobin responded that FDA is working with test developers to mitigate the interference issues and that the website on his slide provides a list of manufacturers who have successfully mitigated the issues and those who are still in process. He stated that there is a coordinated effort to develop a path to work with test developers as new tests come in for pre-submissions as well as when there are tests already in the market that may have potential issues related to biotin interference. One member suggested a centralized resource listing all known drugs and how they may interact with laboratory test including guidance for clinicians ordering tests.

PRESENTATIONS AND COMMITTEE DISCUSSION

Follow up on CLIAC Recommendations

Introduction to Topic *Addendum 6*

Nancy Anderson, MMSc, MT(ASCP)
Senior Advisor for Clinical Laboratories
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

Ms. Anderson began by reminding the committee and audience that a table of all the recommendations and their status are available on the CLIAC website. She provided a refresher of the recommendations made at the April 2019 meeting and briefly reviewed the agenda for the meeting before introducing the next presentation.

The Association of Public Health Laboratories Opioids Task Force *Addendum 7*

Ewa King, PhD
Associate Director of Health
RIDOH State Health Laboratories
President, Association of Public Health Laboratories (APHL)

Dr. King's presentation provided a brief overview on the current multi-substance epidemic and updated the committee on developments of the task force's work since the last meeting, including a Council of State and Territorial Epidemiologists case definition for "non-fatal overdoses." She reviewed some of the challenges and limitations that exist when multiple methodologies, different types of laboratories, and differences in oversight of clinical versus forensic laboratories occur. Dr. King explained how the task force functions, its members, and its focus. She discussed the model surveillance plan that is currently in development and finished by reviewing other task force accomplishments and projects.

Committee Discussion

- Committee members asked about other sources of data, such as the National Center for Health Statistics, the National Hospital Discharge Survey, and hospital emergency room reports, and whether data could be misinterpreted. Dr. King responded that the task force is in the early stages of implementing biosurveillance, and is receiving both screening and confirmatory data; it is difficult to interpret laboratory data in isolation and draw conclusions without considering it in the context of other data sources, such as the medical record, as positive results may be consequent to intentional medical interventions.
- A committee member suggested that the task force reach out to professional organizations to build relationships with people also working on the topic.

Next Generation Sequencing Quality *Addendum 8*

Collette Fitzgerald, PhD
Associate Director for Science
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. Fitzgerald provided a brief overview of past next generation sequencing (NGS) activities, including the April 2018 CLIAC meeting presentation, the NGS workgroup, and the workgroup presentation to CLIAC in April 2019. She updated the committee on the activities of the CDC, CMS, FDA tri-agency NGS group, and discussed how they are related to the eight recommendations made at the April 2019 CLIAC meeting. Dr. Fitzgerald continued by describing the three-year NGS collaborative project among CDC, APHL, and state and local public health laboratories. She addressed the year-one accomplishments and the plans for years two and three.

Committee Discussion

- No questions were asked.

Future CLIAC Topics

Topics suggested by committee members included:

- Key roles for the laboratory to address social determinants of health
    - Creating a social determinants of health profile using validated laboratory data collection instruments to determine gaps in care.
    - Leveraging the laboratory information infrastructure to collect information to identify who is at risk and relay it to clinicians.
    - Strategies to help public health and clinical medicine collaborate and use data from each area to help patients.
- Digital pathology and artificial intelligence (AI), including how CLIA and other regulatory agencies interpret the use of AI.
- Guidance and education needed to differentiate research-based testing and clinical diagnostic testing.
- Issues surrounding the use of for-profit laboratory productivity consultants.
- Empowering patients to self-select laboratory diagnostics and order preventive laboratory tests directly from the laboratory.
- Post-analytical diagnostic error that can occur when laboratory test results are released in an outpatient setting without being reviewed by a physician.
- Best practices for pre- and post-analytical processes, specifically for molecular testing specimen collection.
- Personnel requirements for blood banking specialists to qualify as technical supervisors of immunohematology.
- Test complexity categorizations, particularly for tests categorized in the early years of CLIA - such as categorization of automated blood banking instruments as moderate-complexity except when test results are used for blood transfusions. In this case the testing is categorized as high-complexity.

- Health care/government partnerships to improve communication and provide education for patients, clinicians, and the public regarding:
    - Pre- and post-analytic issues that can influence test results;
    - Assistance with test selection for new and emerging technologies; and
    - Information found in package inserts and quick reference guides.
- The need for quality metric grades for laboratories, such as those made available to consumers for physicians and hospitals.
- The need for FDA approval of software that is considered clinical decision support and is used to make patient care decisions.

Clinical Laboratory Workforce Updates

Health Resources & Services Administration (HRSA) Health Workforce Activities – Health Careers Opportunity Program

Addendum 9

CAPT. Corey Palmer, MS, MPH
Chief, Health Careers Pipeline Branch
Division of Health Careers and Financial Support
Bureau of Health Workforce
Health Resources & Services Administration (HRSA)

Capt. Palmer began with a general description of the National Health Careers Opportunity Program (HCOP) funded through the Public Health Services Act, Title VII, under the Bureau of Health Workforce. The purpose of this grant program is to assist individuals from disadvantaged backgrounds to enter a health profession through the development of academies that will support and guide them through the educational pipeline. Funded training institutions are expected to focus on: 1) promoting the recruitment of qualified individuals from economically or educationally disadvantaged backgrounds into health professions, including allied health programs; 2) improving retention, matriculation and graduation rates by implementing tailored enrichment programs designed to address the academic and social needs of economically or educationally disadvantaged students; and 3) providing opportunities for community-based health professions training in primary care settings, emphasizing experiences in rural and underserved communities. He explained some of the program requirements the grantees must follow and discussed the structured and unstructured activities they provide. Capt. Palmer concluded the presentation by sharing some data on the 21 grantees who have been funded, including demographics, career development areas, and school information.

CDC Division of Laboratory System Updates on Laboratory Workforce Activities

Yescenia Wilkins, MPH ***Addendum 10***
Chief, Training and Workforce Development Branch
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

Ms. Wilkins opened her presentation with a general overview of DLS training courses and training resources. She explained how the trainings can be accessed by learners outside of CDC using the CDC TRAIN system. She continued with an update of the Workforce Assessment for Laboratory Communities project, whose goal is to enable the development of collaborative strategies to address workforce development needs. She described the activities for each year of the three-year project and their accomplishments. Ms. Wilkins updated the Committee with current activities in the branch, specifically a pilot project that incorporates a virtual reality (VR) module. She closed by providing four questions to guide CLIAC discussions on the laboratory workforce topic.

Public Comments

Addendum PC1

Committee Discussion

The committee discussed the following topics related to workforce development:

- Areas of the clinical laboratory competencies or rotations that could benefit from simulation or VR training modules and the financial investment needed for developing and utilizing the training.
- How VR could provide value in areas of the country that lack nearby training programs.
- Studies needed to demonstrate the value of VR courses as compared to traditional learning.
- New opportunities for training, including partnering with larger consolidated health systems, having an independent school within a health system, spreading the clinical rotations throughout state and/or local public health laboratories, and partnering with the Department of Defense to qualify retired military clinical staff for CLIA-certified laboratories.
- Opportunities to increase awareness of CDC laboratory training and other programs such as the HCOP, through the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS), public service announcements, educational organizations, patient safety organizations, state public health laboratory educational coordinators, CLIA surveyors, CMS listserv announcements, CDC communications, accreditation organizations, professional organizations, and elementary, middle, and high schools.
- Standardized curriculum development or awareness of current NAACLS and other educational programs that can be used for on-site workforce training for the post-baccalaureate workers to become clinical laboratory scientists.

Recommendations: Clinical Laboratory Workforce

Recommendation 1: CLIAC recommends that CDC/HHS create a strategy to communicate broadly to the clinical laboratory community the HRSA HCOP program resources currently available.

Recommendation 2: CLIAC recommends that our agency partners collaborate with relevant organizations (e.g. accrediting organizations, manufacturers, professional societies, and academic institutions for higher education bodies) to increase awareness of freely available CDC laboratory training resources.

Recommendation 3: CLIAC recommends that CDC create an online library of clinical laboratory educational resources for use by organizations for their own post-baccalaureate training of clinical laboratory professionals.

Recommendation 4: CLIAC recommends that CDC explore how virtual reality and simulation-based training can be used to achieve competency-based outcomes.

Improving Integration of Laboratory Informatics Systems with Electronic Health Records

Introduction to Topic ***Addendum 11***

Jasmine Chaitram, MPH
Associate Director for Laboratory Preparedness
Chief, Informatics and Data Science Branch
Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Centers for Disease Control and Prevention

Ms. Chaitram provided an update on the two CLIAC recommendations made at the April 2019 meeting pertaining to interoperability. She noted the two questions to guide CLIAC discussions on the topic.

The State of Interoperability of Clinical Laboratories ***Addendum 12***

Talisha Searcy
Branch Chief, Data Analysis Branch
The Office of the National Coordinator for Health Information Technology (ONC)

Ms. Searcy described the current state of interoperability, using the measures that were developed to fulfill ONC's requirements under the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015. Ms. Searcy provided data on how hospitals, physicians, and individuals electronically access laboratory data. She noted that ONC has identified four domains of interoperable exchange of patient health information (send, receive, find, integrate) and commented tha,t in the hospital space, as well as the physician space, providers that report the ability to do all four domains are eight times more likely to report that

they have the information that they need available at the point of care. She explained the surveys ONC uses to collect data and the results of their analysis. Ms. Searcy concluded by discussing the technical, financial, and legal barriers that affect interoperability.

Standardizing Lab Test Names: The TRUU-Lab Initiative ***Addendum 13***

Ila Singh, MD, PhD
Chief of Laboratory Medicine
Texas Children's Hospital
Professor, Baylor College of Medicine

Julia Wang
MD/PhD Student, Baylor College of Medicine

Ms. Wang presented in place of Dr. Ila Singh. Ms. Wang began by stating the three objectives of the presentation and provided data illustrating the problems that have resulted because of the lack of standard laboratory test names. She discussed three scenarios where laboratory test names were confusing, the reasons for the confusion, and multiple solutions. Ms. Wang also detailed how electronic medical records and codes, like Logical Observation Identifiers Names and Codes (LOINC), have contributed to the existing challenges. She provided a description of the Test Renaming for Understanding and Utilization Laboratory (TRUU-Lab) Initiative, its partners, goals, and activities, noting that the initiative lacks representation from clinical professional organizations and instrument manufacturers. She closed by providing information on how to participate in the TRUU-Lab Initiative.

CDC's Digital Bridge Activities: The Importance of Curation of Standard Codes for Laboratory Test Orders and Results ***Addendum 14***

William R. Mac Kenzie, MD
Deputy Director for Science
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Centers for Disease Control and Prevention

Dr. Mac Kenzie began by discussing electronic case reporting as an important part of public health surveillance. He described a multi-partner effort that includes health care, the developers of electronic health records, and public health to automate the generation and transmission of an electronic case report to public health without burden to the clinician. Public health departments can review the electronic case reports and determine actionable steps. Dr. Mac Kenzie described the information that is most useful versus the information that public health receives and how having multiple types of non-standardized laboratory codes causes issues when trying to transmit electronic case reports. He detailed different solutions and barriers to implementation before outlining the SHIELD project and the importance of its pilot projects. Dr. Mac Kenzie concluded by asking the committee how to incentivize laboratories to adopt SHIELD, provided that the pilot projects are successful.

Public Comment

There were no public comments on this topic.

Committee Discussion

The committee discussed the following topics related to interoperability:

- Semantic interoperability and incorporation of data into electronic medical records, including efforts by the ONC standards team to identify priority use cases for standards development and address semantics issues.
- Increased reliance on interoperability and data exchange to assist with laboratory involvement in social determinants of health.
- Obstacles to integration of information in different health systems and harmonization of results, including the use of LOINC instead of other coding and data standards.
- A path to incentivize sharing of laboratory data through the standardization of test codes or other methods as well as electronic medical health records.
- Financial support for an amalgamated compendium of codes for vendors.
- Manufacturer or vendor role to promote interoperability and code standardization.
- Need for buy-in from multiple groups, such as laboratories, information technology department, vendors, and others, to support the standardization of test names.

Public Comment Session on Emerging Technologies and the Clinical Laboratory

Introduction to Topic and Questions *Addendum 15*

Reynolds M. Salerno, PhD
Director
Division of Laboratory Systems (DLS)
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)
Centers for Disease Control and Prevention

Dr. Salerno introduced the public comment session by explaining why the committee decided to dedicate a session to public comments regarding emerging technologies and provided three questions for CLIAC to consider during their discussion.

Public Comments

Addendum PC2
Addendum PC3
Addendum PC4
Addendum PC5
Addendum PC6
Addendum PC7
Addendum PC8
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Addendum PC16
Addendum PC17
Addendum PC18
Addendum PC19
Addendum PC20

Committee Discussion

The committee discussed the following in response to the public comments and the questions posed by Dr. Salerno:

- The terms “bioinformaticists” and “bioinformatician” need to be defined to clarify that there are different roles that can apply to performing and interpreting tests for patient care

or test development. Each role may require different education, experience, and competencies, and should be specified in the CLIA regulations.
- Regulatory oversight and security concerns need to be addressed for laboratory data analysis or test interpretation performed at home or otherwise remotely, including the use of a virtual private network (VPN) to access information technology systems.
- The use of a VPN to perform interpretation and reporting of patient results should be considered as performing those services at the primary CLIA-certified laboratory, where adequate security measures are in place.
- Clarification that working remotely using a VPN connected to a CLIA-certified laboratory is fundamentally different from clinical laboratories obtaining bioinformatics services from a separate establishment.
- Need for inclusion of histotechnicians and histotechnologists as a new personnel category in the CLIA regulations.
- Regulatory oversight of personnel and testing performed in assisted reproductive technology/embryology laboratories under CLIA, FDA, or both, including a request to have a presentation from the FDA Center for Biologics Evaluation and Research at a future CLIAC meeting.

Recommendation: Emerging Technologies and the Clinical Laboratory

Recommendation 5: CLIAC recommends that the CLIA Program consider that, when laboratory professionals are providing patient care through selection, interpretation, and reporting of patient results by accessing data remotely in a secure environment, they shall be deemed as performing those services at the primary site that houses the CLIA Certificate.

The Committee deliberated and proposed the following priorities for the new CLIAC workgroup based on responses to the questions provided as part of the public comments:
- Do CLIA personnel requirements address the role of the bioinformatician?
- How can CLIA be updated to include the responsibilities and competencies of bioinformaticists?
- What areas exist in CLIA where specific requirements or guidance might be needed to ensure the accuracy and reliability of new and emerging laboratory technologies?
- In addition, address other issues related to new emerging technologies (e.g. next generation sequencing, metagenomics, and biomarker testing.)

Though not in direct response to the questions for which comments were solicited, the following topics were raised during the public comment period as considerations for the CLIA program.
- Do the existing CLIA requirements for moderate or high complexity testing personnel encompass activities performed by histotechnologists, histotechnicians, bioinformaticists, and assisted reproductive technology (ART) laboratory testing personnel?
- How can the CLIA program better distinguish testing subject to CLIA that is performed in ART laboratories from other ART laboratory processes, such as in vitro fertilization?
- Should the Doctor of Clinical Laboratory Science (DCLS) degree be considered an acceptable doctoral degree to qualify as a laboratory director under CLIA?

ACRONYMS *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 November 6-7, 2019 CLIAC meeting is an accurate and correct representation of the meeting.

Dr. Valerie Ng, CLIAC Chair Dated: