Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

April 10 - 11, 2018

Silver Springs, Maryland

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
April 10 - 11, 2018, Summary Report

Table of Contents

- **Record of Attendance**
- **Clinical Laboratory Improvement Advisory Committee (CLIAC) Background**
- **Call to Order and Committee Introductions**
- **Agency Updates and Committee Discussion**
  - Centers for Disease Control and Prevention (CDC)
  - Centers for Medicare & Medicaid Services (CMS)
  - Food and Drug Administration (FDA)
  - CDC OID Board of Scientific Counselors Update
  - Laboratory Diagnostics for Future Public Health Infectious Disease Threats
- **Presentations and Committee Discussion**
  - **Implementation of Next Generation Sequencing in Clinical and Public Health Laboratories**
    - Introduction
    - Diagnostic Next Generation Sequencing Challenges: CDC Public Health Laboratory Perspective
    - Clinical Laboratory Perspective: Current State and Challenges for Clinical Labs Implementing and Offering NGS-based Tests
  - **Clinical Laboratory Workforce**
    - CDC's Division of Laboratory Systems: Laboratory Workforce Development Update
    - ASCP Laboratory Workforce Report
    - Laboratory Workforce Shortage: Coordinating Council on the Clinical Laboratory Workforce (CCCLW)
  - **Laboratory Interoperability**
    - Laboratory Semantic Interoperability
    - Information Models to Standardize Access to Lab Data
    - Advancing Lab Data Interoperability with LOINC: An update on current standardization initiatives
    - IICC IVD Instrument Standards for Interoperability and the Harmonization of Laboratory Data

- **Using Clinical Laboratory Data to Improve Quality and Laboratory Medicine Practices**
  - CDC Introduction to Topic
  - Big Data: CMS's Quality Improvement System (QIES) and Proficiency Testing Database
  - Augmenting Administrative Data with Laboratory Data to Improve Quality of Care for Acute Kidney Injury

❖ Acronyms

❖ Background Information

❖ Nomination Information

❖ Public Comments

❖ Adjourn

RECORD OF ATTENDANCE

Committee Members Present
Dr. Ramy Arnaout, Chair
Dr. Sheldon Campbell
Dr. Marc R. Couturier
Dr. Keith E. Davis
Dr. Gwendolyn Delaney
Dr. Steven H. Hinrichs
Dr. Bradley S. Karon
Dr. Jordan S. Laser
Dr. Thomas S. Lorey
Dr. Sharon P. Massingale
Ms. Helen Mills
Dr. Valerie L. Ng
Dr. Elizabeth Palavecino
Ms. Anita Jane Roberson
Ms. Bonnie D. Rubin
Ms. Maureen Rushenberg
Dr. Thomas L. Williams (via conference call)
Mr. Andy Quintenz, AdvaMed (Liaison Representative)

Committee Members Absent
Dr. Monica de Baca
Dr. Katherine K. Perez

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

Designated Federal Official
Dr. Reynolds Salerno, CDC

Executive Secretary
Ms. Nancy Anderson, CDC

Record of Attendance – cont'd

Centers for Disease Control and Prevention (CDC)

Mr. James Bratton
Ms. Diane Bosse
Ms. Jasmine Chaitram
Dr. Marie Earley
Ms. Maribeth Gagnon
Ms. Natasha Griffith
Ms. Stacy Howard
Ms. Rebecca Hutchins
Dr. Michael Iademarco
Dr. Renee Ned-Sykes
Dr. William Mac Kenzie
Ms. Anja Minnick
Ms. Graylin Mitchell
Dr. Toby Merlin
Dr. Atis Muehlenbachs
Dr. Reynolds Salerno
Ms. Heather Stang
Mr. Tom Taylor

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

Julia Appleton, CMS
Stayce Beck, FDA
Sarah Bennett, CMS
Yung Chan, FDA
Kate Donigan, FDA
Lorie Erikson, FDA
Cindy Flacks, CMS
Penny Keller, CMS
Ms. Rachel Jacobs, CMS
Cathy Oliveri, FDA
Ribhi Shawar, FDA
Don St. Pierre, FDA
Debra Sydnor, CMS
Takeesha Taylor-Bell, FDA
Zivana Tezak, FDA
Kathy Todd, CMS
Ms. Felicidad Valcarcel, CMS
Ms. Regina Van Brakle, CMS

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Approximately 30 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 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 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 eventually result in changes to the regulations, 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. Ramy Arnaout, CLIAC Chair, opened the meeting by introducing Dr. Reynolds Salerno, Director of the Division of Laboratory Systems (DLS), Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Office of Public Health Scientific Services (OPHSS), CDC, as the new Designated Federal Official (DFO) for CLIAC and Dr. Collette Fitzgerald, Associate Director for Science, DLS, CSELS, OPHSS, CDC as the new CDC Ex Officio CLIAC member.

Dr. Salerno welcomed the Committee and the members of the public, acknowledging the importance of public participation in the advisory process and took a roll call of the members present. Dr. Arnaout welcomed the Committee and called the meeting to order. All members then made self-introductions and financial disclosure statements relevant to the meeting topics.

Dr. Salerno recognized the five outgoing CLIAC members, who also received letters of appreciation signed by the CDC Director, for their service on the Committee. The members were Dr. Monica de Baca, Dr. Wendy Delaney, Dr. Elizabeth Palavecino, Ms. Janie Roberson, and Ms. Maureen Rushenberg.

Dr. Salerno acknowledged the death of Miss Cindy Johns, a former CLIAC member (2000-2004). He spoke of her work with CLIAC and health care and expressed CLIAC's gratitude for her contributions.

Dr. Arnaout reminded the Committee that CLIAC seeks suggestions for candidates to the Committee at any time. Suggestions for consideration can be provided by emailing CLIAC@cdc.gov. Each slate of nominees is carefully selected in an effort to assure that the Committee meets the required balance of stakeholders with respect to laboratory medicine, pathology, public health, clinical practice and consumers. The HHS policy stipulates that Committee membership be balanced in terms of professional training and background, points of view represented, and the Committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government.

Dr. Salerno stated that the agenda topics would include updates from the CDC, CMS, and the FDA, an update from the CLIAC liaison to the CDC Office of Infectious Diseases (OID) Board of Scientific Counselors (BSC), and a CDC update on laboratory diagnostics for future public health disease threats. In addition, there would be presentations and discussions on next generation sequencing in clinical and public health laboratories, on the clinical laboratory workforce, on laboratory interoperability, and on using clinical laboratory data to improve quality and laboratory medicine practices.

AGENCY UPDATES AND COMMITTEE DISCUSSION

Centers for Disease Control and Prevention (CDC) Update ***Addendum 01***

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 focused her talk on the DLS domains related to quality and safety systems and laboratory preparedness. In the area of quality and safety systems, she noted the *Ready? Set? Test!* online course had recently been updated, reviewed the Clinical Laboratory Integration into Healthcare Collaborative (CLIHC) achievements, mentioned upcoming diagnostic safety and improvement activities, discussed next generation sequencing (NGS), announced the culture independent diagnostic test (CIDT) forum to take place in May 2018, and discussed the new DLS initiative in laboratory biosafety. Moving to the area of laboratory preparedness, she touched on the Clinical Laboratory Partnership Forum and reviewed the Laboratory Outreach Communication System (LOCS) activities. She ended her presentation by observing that April 22-28, 2018 would be Medical Laboratory Professionals week.

Committee Discussion

- Several members asked how the effectiveness of the various activities is evaluated. Dr. Fitzgerald replied evaluation is important to DLS and is currently being explored. She hoped to be able to share updates on metrics at a future meeting.
- Members asked if CLIA state surveyors knew which laboratories had utilized the waived testing resources and if making the *Ready? Set? Test!* course mandatory had been considered. Ms. Anderson replied that the number of people who have taken the course is tracked and that information is periodically provided to CLIAC. Ms. Karen Dyer added that it would require a regulatory change to make the course mandatory.
- A member asked how the *Ready? Set? Test!* booklets are distributed. Ms. Anderson replied the booklets are distributed at professional meetings and can be freely obtained by contacting CDC. She added, it has been suggested that laboratories applying for a Certificate of Waiver (CW) be provided with booklets when they apply.
- A member requested that some consideration be given to reflex testing and assuring that results can be entered in laboratory information systems (LIS) for new emergency use authorization tests.

Centers for Medicare & Medicaid Services (CMS) Update ***Addendum 02***

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 a brief overview of the current CLIA statistics. She provided an overview of the comments received to the Request for Information (RFI CMS-3326-NC) and an update of the CLIA Outreach Program - Academic (COPA) that went live in February, 2017. Ms. Dyer finished with an overview and examples of nontraditional testing models and asked that the Committee discuss recommending forming a workgroup to discuss this issue.

Committee Discussion

- A member asked whether the FDA requested input from CMS before approving the Sysmex complete blood count analyzer as a waived test. Ms. Dyer replied CMS provided comments on the overall operation of the analyzer but did not provide a recommendation for its categorization.
- A member noted that CW laboratories are not required to perform proficiency testing (PT). However, if a CW laboratory enrolls in PT, CMS requires the laboratory to meet CLIA PT regulations. The member asked if CMS had considered reversing this stance. Ms. Dyer replied the issue is under discussion.
- The Chair commented that frequently PT referral involves two laboratories within the same organization.
- The Chair noted the large increase in CW Laboratories and asked about the cause for this growth. Ms. Dyer replied there are more waived tests available and facilities are embracing waived testing to realize a faster turn-around time. Also, there has been a massive increase in laboratories that perform waived toxicology tests. The Chair said a finer breakdown of the types of waived testing would be useful. He also commented the public seems to expect greater access to testing. Ms. Dyer agreed.
- A member asked how COPA is funded. Ms. Dyer responded it is funded through limited existing CLIA resources.
- One member suggested CMS provide educational materials for use by colleges and universities in order to further their COPA goals. The member noted professors could be given a certificate for providing training.
- A member commented efforts occurring at the state and local levels should not be duplicated in the COPA program. The member suggested more interaction with the state public health laboratories, high schools, and grade schools.
- A member expressed appreciation to CMS for reaching out to CLIAC for input on nontraditional, distributive testing models. The member voiced concern with bioinformatics companies that initially identified themselves as performing as part of the laboratory test process but now market themselves as software providers.

The Committee having discussed the proposed workgroup made the following recommendation:

❖ **Recommendation: Nontraditional Testing Workgroup**

CLIAC recommends the development of a workgroup to address non-traditional testing models. The workgroup will provide input to CLIAC for consideration in making recommendations to HHS regarding the need for optimal oversight by CLIA and best methods for such oversight in non-traditional testing models such as:

- Telemedicine (i.e. remote review/interpretation/reporting of laboratory results, pathology etc.)
- Bioinformatics facilities (ex. Cloud based programming)
- NGS testing, sequencing
- Toxicology

Food and Drug Administration (FDA) Update ***Addendum 03***

Peter Tobin, PhD
Director
Office of In-Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)

Dr. Tobin began his presentation by noting the FDA has issued two CLIA waiver draft guidances. One pertains to accuracy requirements for waived test systems. The other is a draft guidance on dual 510(k) and CLIA waiver applications. He emphasized FDA is actively engaging with stakeholders for feedback on these documents. He then discussed the pilot to publicly release CLIA waiver decision summaries and the Sysmex XW-100 CLIA waiver decision. Dr. Tobin finished his talk with an overview of Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) project.

Committee Discussion

- A member asked if companies perform their waiver studies in the test's intended setting. Dr. Tobin replied the FDA encourages manufacturers to include a variety of personnel in their studies, to include some of the least trained or experienced users.
- Another member asked if the FDA could provide greater transparency regarding studies performed related to transport media approved for use with a waived test. Dr. Tobin responded he would relay the suggestion back to the FDA's microbiology division.
- A member asked for clarification regarding PT and waived testing. Dr. Tobin responded PT is not required for waived tests. The member asked if CLIA required CW laboratories to be inspected for proper use of the test system. Ms. Dyer responded CW laboratories are not required to be routinely inspected. Dr. Tobin added CW laboratories are required to follow the manufacturer's test instructions.

CDC OID Board of Scientific Counselors (BSC) Update ***Addendum 04***

Sheldon Campbell, MD, PhD, FCAP
Committee Liaison to CDC Board of Scientific Counselors
Office of Infectious Diseases (OID)
Clinical Pathologist
Pathology and Laboratory Medicine Service
VA Connecticut Healthcare System

Dr. Campbell stated that his summary would focus on the OID reports that had a laboratory component. He began with information from the National Center for Emerging and Zoonotic Infectious Diseases that included discussion pertaining to a brochure about *Candida auris*, funding initiatives, and an update on the Presidential Advisory Council on Combatting Antibiotic-Resistant Bacteria. He said other BCS working groups also gave updates at the meeting, including CLIAC information he had presented. Dr. Campbell concluded by summarizing updates from the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention and the National Center for Immunization and Respiratory Disease.

Committee Discussion

- One Committee member asked if there was broader communication of these reports to the public and Dr. Campbell replied there have not been any discussions regarding broader public engagement outside of those groups at risk from the specified diseases.
- Another member asked if the BSC recognized that the implementation of reverse syphilis algorithms has increased the incidence of syphilis. Dr. Campbell replied that the BSC did not discuss this.
- A member asked if the current molecular test for hepatitis C virus (HCV) is approved for testing samples in infants due to the challenges of performing reflex testing when HCV antibody tests are positive. Dr. Campbell referred the question to Dr. Tobin who offered to get the information for CLIAC. Another Committee member responded that it was possible to collect two different types of tubes for reflex testing but it took time and effort reprogramming their laboratory information system.
- A member asked if there was any discussion of the need for HCV rapid tests based on the recommendation for universal HCV testing of all pregnant women. Dr. Campbell stated there had not been any discussion of that.

Laboratory Diagnostics for Future Public Health Infectious Disease Threats

Toby Merlin, MD ***Addendum 05***
Director
Division of Preparedness and Emerging Infections
National Center for Emerging & Zoonotic Infectious Diseases
Office of Infectious Diseases
Centers for Disease Control and Prevention (CDC)

Dr. Merlin began by informing the Committee that his presentation was a response to their request during the November 2017 meeting for more information about how CDC anticipates the need for assays for new or emerging pathogens or analytes. He provided background on the laboratory response network (LRN) and reviewed CDC's role in the LRN, which includes the development, manufacture, distribution, regulatory approval, and quality assurance of assays. He addressed the question of how CDC prioritizes assays for the LRN and described the working group that was formed to handle this. Dr. Merlin reviewed considerations for agent prioritization and noted the focus is on domestic testing. He reviewed the World Health Organization research and development blueprint priority agents for 2018 and discussed the considerations for assay prioritization and the LRN assays currently under development. He described the process for developing assays and getting a CDC laboratory-developed test approved by FDA for LRN distribution. He enumerated the challenges of assay development and discussed the design control process, noting the greatest difficulty is getting a final locked-down assay. He reviewed emergency use authorization (EUA) and said for new and emerging infectious diseases and biological threat agents CDC relies on the EUA process. He noted LRN assays have special controls and reviewed other considerations.

Committee Discussion

- A member requested information regarding intellectual property ownership for CDC-developed assays. Dr. Merlin replied CDC shares the methods for assays other than those for biological threat agents. He added there can sometimes be intellectual property issues when some countries claim they have residual rights to the products developed using their specimens or organisms.
- The Chair requested more information on CDC's role in developing testing to support clinical care. Dr. Merlin responded most of the tests CDC develops are not for the instrumentation found in clinical laboratories. Most are for select agents being tested at biosafety level 3. He noted that as the BioFire instruments become more available, more laboratories will be able to test for unusual pathogens.
- A member asked what the timeline was for an EUA assay to become available for use in clinical laboratories. Dr. Merlin replied that the timeline varies.
- One member asked if there is a plan to facilitate the EUA process and move high consequence pathogen tests into clinical laboratories. Dr. Merlin replied that part of the limitation for moving many of these tests to the clinical laboratories is the lack of a commercial market. He noted that much of the drive for the BioFire development has come from the Department of Defense, which has been trying to develop instruments that can be deployed for use by the military.

PRESENTATIONS AND COMMITTEE DISCUSSION

Implementation of Next Generation Sequencing in Clinical and Public Health Laboratories

Background/Introduction *Addendum 06*

Ira Lubin, PhD, FACMG
Geneticist
Quality and Safety Systems Branch (QSSB)
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 (CDC)

Dr. Lubin gave a brief synopsis of what the session would cover. He explained the types of applications that use Next Generation Sequencing (NGS), a rough estimate of the number of laboratories using the method, and an overview of the typical workflow, particularly the laboratory portion. He pointed out that with the broader uptake of the technology by laboratories, a quality framework becomes especially important. He discussed the challenges of applying CLIA regulations to NGS including contracting out the bioinformatics portion of the method and handling secondary findings. Dr. Lubin explained that there are many different NGS standards and guidelines from federal and state agencies and professional organizations. Dr. Lubin closed with a proposal for a CLIAC workgroup to inform the Committee how CMS, CDC, and FDA can assist in assuring the quality of NGS in clinical laboratories.

Diagnostic Next Generation Sequencing Challenges: CDC Public Health Laboratory Perspective *Addendum 07*

Ms. Rebecca Hutchins, MS
Clinical Research Associate
Office of Infectious Diseases
Centers for Disease Control and Prevention (CDC)

Ms. Hutchins covered challenges in public health laboratories using NGS. She began by describing the CDC NGS workgroups and the issues they are addressing. She continued by discussing five areas of challenges CDC laboratories have faced as they have begun to implement NGS, how they addressed the challenges, and where gaps remain. The five challenge areas include personnel (training), process controls, distributive testing (portions of the testing process occurring in different physical locations), validation and re-validation of the methods, and analysis and reporting of results. She concluded with possible approaches to fill in the remaining gaps.

Clinical Laboratory Perspective: Current State and Challenges for Clinical Labs Implementing and Offering NGS-based Tests ***Addendum 08***

John D. Pfeifer, MD, PhD
Vice Chairman for Clinical Affairs,
Department of Pathology and Immunology
Chief (Interim), Division of Anatomic and Molecular Pathology
Professor of Pathology and Immunology
Professor of Obstetrics and Gynecology
Washington University School of Medicine

Dr. Pfeifer explained that he would discuss the pressure points seen in the Washington University School of Medicine NGS laboratory. He listed the different types of NGS-based sequencing they do, both somatic (cancer) and hereditary disease, to illustrate that NGS is a method, not a test. He detailed the challenges currently in the field, including the lack of standardization for NGS tests with the same intended use, their interpretation, and the bioinformatics portion of the test process. Additionally, he indicated no standards-based criteria exist for evaluating the performance of NGS tests. He explained the difference between process-based laboratory accreditation versus standards-based laboratory accreditation. He discussed why, for NGS, the standards-based paradigm is more applicable but that it takes time for standards aimed at novel methods to be developed. Dr. Pfiefer explained the uncertainties of the regulatory approach, test validation, and outside reference materials. He gave an example of a quality assurance pilot for one type of NGS testing and explained emerging NGS-based testing issues, along with their implications.

Committee Discussion

- Multiple members commented on NGS and standardization.
  - One member stated that not all clinical chemistry methods have traceable standards or definitive methods. Because specimen matrix effects can affect testing, the member suggested using peer grouping as they do with chemistry analytes.
  - Another member suggested that the focus could be on harmonization and traceability of the result and a third member commented that for some chemistry tests, clinical need drove standardization.
  - A member stated that database issues resulting in poor quality data can affect results and the Committee needs to think about how database issues can be standardized into a CLIA framework.
  - A member suggested that NGS is such a large and complex area that no standard can cover all of it and that any discussion should focus on one area at a time (oncology, heritable, infectious disease).
- Multiple members discussed result reporting obligations.
  - A member asked about reporting of incidental findings. The member also asked if physicians use the data later to compare with other patients' findings. Another member responded that reference laboratories usually report variants of unknown significance (VUS) and any references regarding the VUS. Companies that sequence DNA for genealogical purposes cannot legally discuss any disease

information. The research community struggles with incidental findings and the member noted their laboratory included the disclosure of results policy they as part of the patient consent.
    - Another member commented that decisions need to be made about how long to keep sequence data and if it can be re-analyzed for research years later. A member stated that this type of situation brings up medicolegal issues as the data need to be tracked and constantly re-evaluated based on clinical outcomes. Result reporting from NGS testing incurs ethical, legal, and psychological issues.
    - Dr. Pfeifer commented there is not necessarily a precedent for going back to old samples for re-analysis as this is not done in other laboratory specialties such as surgical pathology. He also noted the bioinformatics pipelines change over time and re-analysis may be clinically inappropriate at a later point in time.
    - No members voiced analogies or precedents that apply to the use of bioinformatics to interpret NGS results. The Chair compared NGS to other tests, such as identification of microorganisms from culture, where an instrument analyzes the results based on a database or dictionary that constantly changes and returns a probability of the answer.
    - A member voiced concern about the clinical relevance of a result even if a standard for sensitivity and specificity exists.
    - A member commented that analytical questions remain such as the limit of detection for the specific target(s) and that experts in the field have a better understanding of the issues.
- Multiple Committee members discussed precedents and possible regulatory solutions.
    - Members noted that because NGS is a rapidly emerging technology, it is challenging to apply the CLIA regulations. NGS was compared to polymerase chain reaction (PCR) in terms of regulation of a rapidly changing method. A member stated that the scientific community is still developing and modifying checklists to conform to current practices with respect to PCR and other emerging technologies. It was also expressed that regulation and guidance tend to lag behind emerging practices, but having flexible guidance helps overcome the time it takes to draft and implement federal national regulations. Another member said the accreditation and professional organizations have provided voluntary guidance/standards, which leads to disparity in laboratory practices since guidance is voluntary.
    - A member stated that NGS does not have traditional analytes as most chemistry tests do. He suggested that, like bacterial culture which is regulated in a process fashion, NGS might be regulated using this type of framework.
    - A member suggested regulating NGS based on its use (oncology, infectious disease, and inherited disorders) as the College of American Pathologists did when they split molecular microbiology from other molecular tests. The issues of molecular microbiology tests were distinctly different from other molecular tests.
    - A member warned that if the Committee implies that there is no oversight of NGS testing, the response could be to shut it down until issues can be resolved. Currently, the benefits outweigh the risks and peer review allows the scientific community to police itself.
    - One member commented that the laboratory community has not adapted beyond

the concept of regulated and non-regulated analytes as specified for proficiency testing.

The Committee having discussed the topic made the following recommendation:

Recommendation: Next-Generation Sequencing (NGS) Workgroup
CLIAC recommends the formation of a next-generation sequencing workgroup to provide input to CLIAC for consideration in developing recommendations to CDC, CMS, and FDA and to prioritize regulatory gaps for assuring the quality of next generation sequencing in clinical laboratory settings.
Proposed Workgroup Tasks:

- Identify challenges in applying the existing regulatory framework
- Identify challenges and gaps in guidance
- Consider and suggest strategies to address the identified gaps and challenges
- Consider and suggest strategies for assuring workforce competency

Clinical Laboratory Workforce

Background/Introduction: DLS Laboratory Workforce Development Update
Renee Ned-Sykes, MMSc, PhD ***Addendum 09***
Health Scientist ***Addendum 09a***
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 (CDC)

Dr. Ned-Sykes spoke about DLS projects related to training and workforce development, including the development of online training and in-person workshops. She discussed how DLS promotes trainings and highlighted courses designed for CDC staff that are subsequently released to the broader laboratory community. She listed the courses DLS expects to release in 2018. For workforce development activities, she pointed to the DLS website for information about competencies, resources, and tools. Dr. Ned-Sykes closed by summarizing a new project, the Workforce Assessment of Laboratory Communities, intended to determine what published workforce data are already available and identify current gaps and challenges. DLS plans to use the information to help guide future projects.

Clinical Laboratory Workforce Initiatives ***Addendum 10***

Barbara Caldwell, MS, MASCP, MLS (ASCP)^{CM}, SH^{CM}
Administrative Director
Clinical Laboratory Services
MedStar Montgomery Medical Center

Ms. Caldwell began by providing background on the ASCP Wage and Vacancy surveys. She described information from the U.S. Bureau of Labor Statistics (BLS) for all occupations versus information specific to health occupations and for Medical and Clinical Laboratory Technologists/Technicians and Phlebotomists. She noted the extensive occupational position titles and departments used in the ASCP workforce surveys as compared to those used by the BLS. Ms. Caldwell described the ASCP Wage Survey methodology, summarized the data, and compared it to previous survey results. She followed with the ASCP Vacancy Survey methodology, summarized the data, and reviewed challenges to staffing, including new technologies' certification requirements. Overall, both surveys illustrated the ongoing laboratory workforce challenges.

Coordinating Council on the Clinical Laboratory Workforce (CCCLW) Initiatives

Susan Morris, MPH, MLS (ASCP)^{CM}, CPPS ***Addendum 11***
Patient Safety Specialist
St. Luke's Health System
Coordinating Council on the Clinical Laboratory Workforce (CCCLW) Chair

Ms. Morris explained that CCCLW is concerned with recruitment and retention of laboratory workers and listed the member organizations. She also provided BLS information. The CCCLW sees retirement numbers as the most concerning challenge to the laboratory workforce. She presented data from the National Association of Accreditation of Clinical Laboratory Science showing that the number of clinical laboratory science students is increasing and the number of programs has remained stable; however, there are not enough students to cover all the vacancies. Ms. Morris discussed potential solutions to help with the shortage of workers. She covered four CCCLW activities and a project to help laboratory professionals demonstrate their value. She concluded with a list of opportunities where government could affect the laboratory workforce shortage.

Committee Discussion

- Money was a key issue discussed by the Committee. The Chair and multiple members noted that even though there is a shortage of workers, salaries have not been increasing and offered possible reasons:
  - Salaries are higher for certified or otherwise credentialed laboratory professionals. There are costs associated with the education needed prior to obtaining certification or other credentials.
  - Funding in the form of grants and scholarships for clinical laboratory scientist education is not always readily available.
  - Rising healthcare costs and changes to reimbursement rates have an impact on

salaries for laboratory professionals.
    - There is a lack of promotion potential within laboratories or more generally in healthcare institutions. Laboratory professionals are often overlooked for higher administrative positions.
    - Competition from industry where salaries are higher impacts the workforce shortages in healthcare settings.
- Other points made by multiple members was that the value of laboratories and laboratory professionals offer is not recognized because:
    - Laboratories are not generally a patient-facing part of the healthcare setting.
    - A shortage of laboratory staff is not recognized as having the same consequences as a shortage of nurses.
    - The laboratory tends not to be mentioned specifically in legislative discussions concerning healthcare shortages.
    - Laboratory careers are not well known or promoted among high school and college science majors.
- A Committee member responded that the Association of Public Health Laboratories has a campaign to show the value of laboratory professionals and the clinical laboratory science field.
- A speaker commented that there is often a lack of training sites due to shortages of staff to oversee the training.
- Multiple Committee members offered possible solutions:
    - There should be a laboratory system similar to nurses' acuity scale.
    - Laboratories should seek out opportunities to become more involved in direct patient care so that they are more visible and seen as more patient-facing.
    - Changes to hospital staffing models should be pursued.
    - A tax incentive could be offered to hospital systems or institutions that set aside money to help entry level staff receive more ongoing training or education so that there is more potential for career advancement within the laboratory or healthcare setting.
    - Laboratories might consider how highlighting instances of diagnostic error might validate the need for more resources. Perhaps reports about diagnostic error might be used to better quantify the value of the laboratory.
- One member suggested that CLIAC request the Government Accountability Office to prepare a report that brings the value of the laboratory into focus for the public.

The Committee having discussed the topic made the following recommendations:

Recommendation 1: Clinical Laboratory Workforce

CLIAC recommends that CDC, CMS, and FDA prioritize approaches to address the 20-year shortfall of trained laboratory professionals and report back to CLIAC, including but not limited to:

- Create incentives for clinical affiliate sites to allow more mentoring and training of lab students (similar to the Graduate Medical Education model).
- Develop a crosswalk for trained Veterans to accelerate entry into the laboratory professional field and qualify under CLIA regulations.

- Create or evaluate existing career ladder models developed by laboratory organizations and developing strategies to implement them.
- Develop methods to demonstrate the economic impact of laboratory testing, possibly using return on investment (ROI) and/or cost-savings and avoidance.
- Create strategies for increasing public awareness of clinical laboratory science as a career.

Recommendation 2: Clinical Laboratory Workforce

CLIAC recommends that HHS:

- Issue a recommendation to the U.S. Department of Education to include laboratory science professions in science, technology, engineering, and mathematics (STEM) programming.
- Issue a recommendation to request that Health Resources and Services Administration include Title VII funding to authorize resources to educational programs for laboratory professions experiencing a workforce shortage crisis.
- Create a plan and appropriate funding for a program within the Public Health Service Act to ensure training for citizens seeking to enter the clinical laboratories workforce.

Recommendation 3: Clinical Laboratory Workforce

CLIAC strongly recommends that HHS and/or its agencies fund a study of the opportunity costs of the two decades of reduction in the laboratory workforce.

We suggest proceeding along the lines of past government funded/sponsored/written reports such as the number of deaths due to medical error, to provide data, context, and guidance to the public and the healthcare establishment regarding the likely effect of continued pressure on the laboratory workforce (in terms of numbers, training, and compensation).

We specifically recommend:

1) a careful analysis of the role of technology and other efficiencies (perhaps reminiscent of changes to the U.S. agriculture workforce over the past century) vs. contraction of purview and provision of care (for example, resources insufficient to provide the best test with the best turnaround time, or to make improvements that would otherwise have been possible to the full laboratory cycle, as opposed to just the pre-to-post-analytical phases).

2) calculations and analysis of the return-on-investment on laboratory personnel, in useful units (e.g. dollars, quality-adjusted life years, or errors avoided), that can be used as a landmark reference for the public, healthcare industry, and potential future members of the laboratory workforce.

3) that HHS create a workgroup or fund the process to develop a simple quantitative method, considering current laboratory methodologies and utilization patterns, that any clinical laboratory can use to demonstrate the impact of the laboratory on the healthcare system. This method needs to be able to demonstrate the economic impact of laboratory testing, possibly using ROI and/or cost-savings and avoidance. It should also address the impact on quality of care and timeliness of results.

Laboratory Interoperability

Laboratory Semantic Interoperability *Addendum 12*
MariBeth Gagnon, MS, CT(ASCP) HTL *Addendum 12a*
Health Scientist *Addendum 12b*
Informatics and Data Science Branch (IDSB)
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 (CDC)

Ms. Gagnon began her introduction by defining semantic interoperability. She provided examples of why this has been and continues to be an important topic for CLIAC to discuss and provided an overview of CLIAC's engagement on this topic. Ms. Gagnon briefly discussed the SHIELD project, as previously mentioned by Dr. Tobin from the FDA. She emphasized that SHIELD has 50 supporting partners including five government agencies (FDA, CDC, CMS, the National Library of Medicine, and the Office of the National Coordinator for Health Information Technology) and has realized two accomplishments thus far. Finally, Ms. Gagnon presented four questions for CLIAC to consider and introduced the three speakers noting all are involved in the SHIELD project.

Information Models to Standardize Access to Lab Data *Addendum 13*
Stanley M. Huff, MD
Chief Medical Informatics Officer
Intermountain Healthcare
Professor, University of Utah

Dr. Huff began his presentation with a discussion of how healthcare data currently flows. He noted that every system has unique codes, which creates a burden when data move. He remarked that one of the great innovations currently taking place is Fast Healthcare Interoperability Resources, an interoperability standard for the electronic exchange of healthcare data developed by Health Level Seven (HL7) International. He said the challenge in developing an interoperability standard is coordination and development of common standardized codes. Dr. Huff discussed interoperability strategy stating there is no single model that is best for all situations but there should be one preferred style for a given situation. He presented an example of a laboratory equivalence spreadsheet and noted there is a clinical information modeling initiative repository available online where mapping between the different variations in codes can be found. Dr. Huff finished with a discussion of the value of detailed information models.

Regenstrief Harmonization Efforts *Addendum 14*

Daniel J. Vreeman, PT, DPT, MS, FACMI
Director
LOINC and Health Data Standards
Regenstrief Center for Biomedical Informatics
Regenstrief-McDonald Scholar in Data Standards
Indiana University School of Medicine

Mr. Vreeman began with a brief overview of the Regenstrief Institute noting it is the creator and steward for two key interoperability standards: Logical Observation Identifiers Names and Codes (LOINC) and Unified Code for Units of Measure (UCUM). He said LOINC is designed to be a universal standard for identifying health measurements, observations, and documents and is utilized by a global community with many kinds of technologies. He reviewed the key interoperability pieces and the user-driven growth of LOINC and highlighted federal initiatives using LOINC as well as other key efforts. He discussed "LOINC groups," a process to develop a mechanism for rolling up groups of codes that might be considered for a particular purpose and noted that Regenstrief has defined a way that users can share and comment on the groups they find useful. He discussed the ongoing effort to improve display names or LOINC concepts and announced that a beta release of new display names is scheduled for June 2018. Mr. Vreeman concluded his talk with a discussion of the projects being worked on with the FDA including a microbiology guidance document related to LOINC codes.

IVD Instrument Standards for Interoperability and the Harmonization of Laboratory Data *Addendum 15*

Edwin O. Heierman, Ph.D. *Addendum 15a*
Product Cybersecurity Architect *Addendum 15b*
Information Security and Risk Management
Abbott

Dr. Heierman provided an overview of the in vitro diagnostic (IVD) Industry Connectivity Consortium (IICC), emphasizing that the IICC's role has been that of facilitator to the standards organizations. He disclosed the IICC has been working on two initiatives – Laboratory Analytical Workflow (LAW) and LOINC for IVD (LIVD). He related LAW has focused on standardizing the flow of information related to the testing process and said a consensus standard on this topic being developed by the Clinical and Laboratory Standards Institute. He noted one of the most important aspects of LAW is that it is intended to improve the integrity of patient test data, including test results. Dr. Heierman described the LIVD initiative and ended his talk with a list of the IICC's next steps.

Committee Discussion

- The Chair asked for clarification of the metrics being used to evaluate interoperability. Dr. Huff replied there are two ways it could be measured. After standards have been defined, software could be developed to measure adherence to

the standards. Second, a study could be designed to determine whether interoperability is being achieved and accomplishing the goals for which it was intended. Dr. Vreeman added that ONC had published a document in 2017, Proposed Interoperability Standards Measurement Framework that was open for public comment. Dr. Heierman commented that metrics starts at the instrument level. Therefore, the first step is to establish the standards laboratories should meet while also continuing with the harmonization efforts related to LOINC codes.

- A member noted that Dr. Heierman's presentation indicated that few laboratory information system (LIS) companies are participating in the IICC and asked if that was true. Dr. Heierman concurred and added IVD vendors and manufacturers have been much more receptive to collaborating on these initiatives. It appears the LIS vendors are waiting to see how the manufacturers respond. Currently, a manufacturer develops an instrument and establishes an interface for it then the LIS and middleware vendors create the drivers and their interfaces.
- A member asked why the LOINC code is not included in the manufacturer's package insert. Dr. Heierman replied the dynamic nature of LOINC coding, plus other coding that may be added later, makes placing the LOINC coding information in a separate on-line mapping table preferable.
- One member asked what the greatest obstacle was to interoperability. Dr. Huff answered he believed it was creating awareness of the issue and getting people invested in finding a solution.
- A member asked what percentage of the FDA cleared or approved commercial laboratory tests could be manipulated in a LIVD database. Dr. Heierman replied very few at this point in time, since LIVD was newly launched in 2017.
- A member observed there are multiple barriers to interoperability such as regulatory, resource, conflicting values or incentives, and silos. Dr. Heierman replied that in terms of LAW and LIVD the biggest barrier is adoption and the promotion of adoption.
- Another member noted the system adopted for coding and to achieve interoperability must be made easy and standardized for the end user.

The Committee having discussed the topic made the following recommendations:

Recommendation 1: Laboratory Interoperability

CLIAC recommends that FDA and CMS create and implement guidelines for in vitro diagnostic device and laboratory information system manufacturers which describe specifications for interoperability, and require use of emerging standards such as Laboratory Analytical Workflow (LAW) Profile and Logical Observation Identifiers Names and Codes for In Vitro Diagnostics (LIVD).

Recommendation 2: Laboratory Interoperability

The Committee recommends that the CDC consult with the Office of the National Coordinator for Health Information Technology (ONC) to identify the appropriate agency to develop a report to

1. quantitatively define "interoperability" at each of the following levels: device, department, institution, health-care system, and nationally (e.g. "the U.S. is 12% interoperable"),
2. Determine the yearly dollar spend on interoperability is, and who pays for it (manufacturers, hospitals, insurers),
3. Determine the costs in terms of adverse outcomes of a lack of interoperability, which is presumably related to the appreciable cost of diagnostic error,
4. Determine the ROI on (degrees of) interoperability; e.g., how much in terms of health, lives, and/or money is saved by a device/department/institution/system/the country achieving a certain level of interoperability,
5. Delineate the barriers to achieving interoperability (in terms of regulation, financial resources, human capital, conflicting values/incentives among stakeholders, access to data, and adoption)

Using Clinical Laboratory Data to Improve Quality and Laboratory Medicine Practices

Introduction ***Addendum 16***

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 introduced the two speakers and reviewed the discussions questions.

Big Data: CMS's Quality Improvement System (QIES) plus Proficiency Testing Data ***Addendum 17***

Tomas Taylor, Jr., PE, MS
Mathematical Statistician
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

Mr. Taylor's presentation focused on the CMS Quality Improvement Evaluation System (QIES) data set and the CLIA proficiency testing database. He discussed the methods of examining these data sets and provided examples of the information that can be obtained. He reviewed the challenges of using big data sets and data science axioms, and then discussed QIES data quality and how challenges are met. Mr. Taylor finished his talk with a recap of his perspective on data analytics.

Augmenting Administrative Data with Laboratory Data to Improve Quality of Care for Acute Kidney Injury ***Addendum 18***

Tarush Kothari, MD, MPH
Physician Informaticist, Northwell Health Laboratories
Assistant Professor in Pathology and Laboratory Medicine
Donald and Barbara Zucker School of Medicine

Dr. Kothari began by discussing the clinical and economic significance of acute kidney injury (AKI). He discussed why AKI is under-diagnosed and the implementation of a laboratory AKI alert as a solution. He described the implementation of a laboratory AKI alert and the diffusion of laboratory AKI alerting to other hospitals in his healthcare organization. He recounted the lessons learned including the limitations of administrative data and how augmenting administrative data with laboratory data adds significant granularity by providing vital information. Finally, Dr. Kothari reviewed the barriers to enhancing administrative data and the value of laboratory data to the healthcare system.

Committee Discussion

- A member commented that the point of the AKI study seemed to be decreasing the number of hospital days by diagnosing AKI earlier, yet there were no outcome measures to show this. Dr. Kothari concurred and said the initial goal was to reduce the length of stay and mortality but it is difficult to attribute a reduction in length of stay to just one condition alone. He added they are in the process of creating a prospective study which will look at this.
- One member asked if the LIS used in the AKI study required customization. Dr. Kothari replied the LIS group customized the system and designed the algorithm.
- Another member asked if CDC had run data to determine whether decreased PT success correlates with laboratories that have declining numbers of staff. Mr. Taylor replied that study has not been done.
- The Chair asked whether the QIES database is publicly available. Ms. Dyer replied much of the data is associated with older systems that don't necessarily communicate and are internal to CMS. CMS is currently converting QIES to a new system called iQIES which will be a cloud format and will be publicly available.
- The Chair commented it seemed institutional culture was blocking the use of big data. A member commented changing institutional culture requires expertise in change management. Another member added that administrators and leaders of organizations need to have evidence that use of data will result in financial savings. Another member stated many projects result in cost avoidance but not cost savings.

ACRONYMS *Addendum* **19**

NOMINATION INFORMATION *Addendum* **20**

BACKGROUND INFORMATION *Addendum* **21**

PUBLIC COMMENTS *Addendum 22*
Addendum 23
Addendum 24
Addendum 25

ADJOURN

Drs. Arnaout and Salerno acknowledged the staff that assembled the meeting agenda and thanked the CLIAC members and partner agencies for their support and participation. The following are the seven Committee recommendations passed at this meeting:

Nontraditional Testing Workgroup

CLIAC recommends the development of a workgroup to address non-traditional testing models. The workgroup will provide input to CLIAC for consideration in making recommendations to HHS regarding the need for optimal oversight by CLIA and best methods for such oversight in non-traditional testing models such as:

- Telemedicine (i.e. remote review/interpretation/reporting of laboratory results, pathology etc.)
- Bioinformatics facilities (ex. Cloud based programming)
- NGS testing, sequencing
- Toxicology

Next-Generation Sequencing (NGS) Workgroup

CLIAC recommends the formation of a next-generation sequencing workgroup to provide input to CLIAC for consideration in developing recommendations to CDC, CMS, and FDA and to prioritize regulatory gaps for assuring the quality of next generation sequencing in clinical laboratory settings.

Proposed Workgroup Tasks:

- Identify challenges in applying the existing regulatory framework
- Identify challenges and gaps in guidance
- Consider and suggest strategies to address the identified gaps and challenges
- Consider and suggest strategies for assuring workforce competency

Laboratory Workforce

Recommendation 1:

CLIAC recommends that CDC, CMS, and FDA prioritize approaches to address the 20-year shortfall of trained laboratory professionals and report back to CLIAC, including but not limited to:

- Create incentives for clinical affiliate sites to allow more mentoring and training of laboratory students (similar to the Graduate Medical Education model).

- Develop a crosswalk for trained Veterans to accelerate entry into the laboratory professional field and qualify under CLIA regulations.
- Create or evaluate existing career ladder models developed by laboratory organizations and developing strategies to implement them.
- Develop methods to demonstrate the economic impact of laboratory testing, possibly using return on investment (ROI) and/or cost-savings and avoidance.
- Create strategies for increasing public awareness of clinical laboratory science as a career.

Recommendation 2:
CLIAC recommends that HHS:

- Issue a recommendation to the U.S. Department of Education to include laboratory science professions in the science, technology, engineering, and mathematics (STEM) programming.
- Issue a recommendation to request that Health Resources and Services Administration include Title VII funding to authorize resources to educational programs for laboratory professions experiencing a workforce shortage crisis.
- Create a plan and appropriate funding for a program within the Public Health Service Act to ensure training for citizens seeking to enter the clinical laboratories workforce.

Recommendation 3:
CLIAC strongly recommends that HHS and/or its agencies fund a study of the opportunity costs of the two decades of reduction in the laboratory workforce.

We suggest proceeding along the lines of past government funded/sponsored/written reports such as the number of deaths due to medical error, to provide data, context, and guidance to the public and the healthcare establishment regarding the likely effect of continued pressure on the laboratory workforce (in terms of numbers, training, and compensation).

We specifically recommend:
1) a careful analysis of the role of technology and other efficiencies (perhaps reminiscent of changes to the U.S. agriculture workforce over the past century) vs. contraction of purview and provision of care (for example, resources insufficient to provide the best test with the best turnaround time, or to make improvements that would otherwise have been possible to the full laboratory cycle, as opposed to just the pre-to-post-analytical phases).
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testing, possibly using ROI and/or cost-savings and avoidance. It should also address the impact on quality of care and timeliness of results.

Laboratory Interoperability

Recommendation 1:

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7. Determine the yearly dollar spend on interoperability is, and who pays for it (manufacturers, hospitals, insurers),
8. Determine the costs in terms of adverse outcomes of a lack of interoperability, which is presumably related to the appreciable cost of diagnostic error,
9. Determine the ROI on (degrees of) interoperability; e.g., how much in terms of health, lives, and/or money is saved by a device/department/institution/system/the country achieving a certain level of interoperability,
10. Delineate the barriers to achieving interoperability (in terms of regulation, financial resources, human capital, conflicting values/incentives among stakeholders, access to data, and adoption)

Dr. Arnaout announced the fall 2018 CLIAC meeting would be held on November 7-8, 2018, at the CDC in Atlanta and adjourned the Committee meeting.

I certify this summary report of the *April 10-11, 2018,* meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Dated:_____

Dr. Ramy Arnaout, CLIAC Chair