Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

November 1 - 2, 2017

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
November 1 - 2, 2017, Summary Report

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RECORD OF ATTENDANCE

Committee Members Present
Dr. Ramy Arnaout, Chair
Dr. Sheldon Campbell
Dr. Keith E. Davis
Dr. Monica de Baca
Dr. Gwendolyn Delaney
Dr. Steven H. Hinrichs
Dr. Bradley S. Karon
Dr. Elizabeth Marlowe
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. Hardeep Singh
Mr. Andy Quintenz, AdvaMed (Liaison Representative)

Committee Members Absent
None

Ex Officio Members
Ms. Karen Dyer, CMS
Dr. Peter Tobin, FDA
Dr. Reynolds Salerno, CDC

Designated Federal Official
Dr. William (Bill) Mac Kenzie, CDC

Executive Secretary
Ms. Nancy Anderson, CDC

Record of Attendance – cont'd

Centers for Disease Control and Prevention (CDC)

Mr. Ronny Alford
Dr. Rex Astles
Dr. John Besser
Ms. Diane Bosse
Ms. Juley Ann Cetoute
Ms. Jasmine Chaitram
Dr. Bin Chen
Dr. Nancy Cornish
Ms. Evelyn M Dunn
Dr. Marie Earley
Ms. Ethel Edwards
Dr. Lin Fan
Ms. Maribeth Gagnon
Dr. Natasha Griffith
Ms. Stacy Howard
Dr. Michael Iademarco
Dr. Lisa Kalman
Dr. Maja Kodani
Dr. Ira Lubin
Dr. Bereneice M. Madison
Ms. Leslie McDonald
Ms. Anja Minnick
Ms. Graylin Mitchell
Dr. Atis Muehlenbachs
Mr. Linh Nguyen
Dr. Jean Patel
Ms. Ami Putman
Mr. Manjula Gama Ralalage
Dr. John Ridderhof
Dr. Diana Riner
Mr. Matthew Rubinstein
Dr. Paramjit Sandhu
Dr. Shahram Shahangian
Ms. Theresia Snelling
Ms. Heather Stang
Dr. Sonya Strider
Ms. Vickie Sullivan
Ms. Monica Toles
Mr. Jordan Chun Wah Wong
Dr. Yang Xia
Mr. Xin Yin
Mr. Jonathan Zhong

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

Dr. Steven Gitterman, FDA
Ms. Rachel Jacobs, 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, 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 considerations. 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. William Mac Kenzie, Designated Federal Official (DFO), Clinical Laboratory Improvement Advisory Committee (CLIAC), and Deputy Director for Science, 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 took a roll call of the members present. Dr. Ramy Arnaout, Chair, CLIAC, 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. Mac Kenzie recognized the six outgoing CLIAC members who also received letters of appreciation signed by the CDC Director for their service on the Committee. The members were Dr. Roger Klein, Dr. Elizabeth Marlow, Dr. Richard Press, Ms. Susan Sheridan, Dr. John Sinard, and Dr. Hardeep Singh.

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. Mac Kenzie conveyed that the agenda topics included updates from the CDC, the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA) as well as an update from the CLIAC liaison to the CDC Office of Infectious Diseases (OID) Board of Scientific Counselors (BSC). In addition, there would be presentations and discussions on laboratory testing in the era of telemedicine, on antibiotic resistance-testing issues, Institute of Medicine (IOM) workgroup updates on pathologists as integral care team members and on interoperability, and on culture independent diagnostic tests.

Dr. Mac Kenzie, on behalf of himself and the Committee, acknowledged Dr. Alberto Gutierrez who had recently retired from the position of Director of the Office of In Vitro Diagnostics and Radiologic Health at the Food and Drug Administration. Dr. Mac Kenzie noted that Dr. Gutierrez had a distinguished career at the FDA. He was a tremendous public servant, a thoughtful leader, he worked to protect and improve diagnostics, and always endeavored to make things better for the American public. Dr. Mac Kenzie added we owe him a debt of gratitude and wish to thank him as he begins this new chapter in his life. Dr. Gutierrez acknowledged the tribute and responded that he felt he was being

honored for having done what he loved doing. He noted he spent about ten years as an ex officio member of CLIAC and enjoyed every minute of the experience.

AGENCY UPDATES AND COMMITTEE DISCUSSION

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

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

Dr. Salerno reviewed the accomplishments and ongoing projects in each of the four areas of focus within the division, those being laboratory quality and safety systems, informatics and data science, training and workforce development, and preparedness. He began by noting a new website (http://www.cola.org/education-resources/clia-waived-tests) has been launched in collaboration with COLA Resources, Inc., to provide waived testing resources. He also reviewed the Clinical Laboratory Integration into Healthcare Collaborative (CLIHC) achievements, discussed the tri-agency next generation sequencing initiative and conveyed DLS is writing a new chapter for the Biosafety in Microbiological and Biomedical Laboratories (BMBL) document. He reviewed the semantic interoperability taskforce and noted that two new modules have been developed for laboratory informatics. Next Dr. Salerno recounted the laboratory training that had taken place in the last year and discussed the new initiative focused on the future of the laboratory workforce. He disclosed that the division is embarking on an initiative to strengthen the public-private laboratory partnerships and related that DLS has activated the Laboratory Outreach Communication System (LOCS) to enhance communication with the clinical laboratories. He finished with a discussion of the CLIA tri-agency work towards improving deployment and implementation of assays via emergency use authorization (EUA).

Committee Discussion

- A member asked for clarification regarding EUAs and expediting the CLIA process. Dr. Salerno responded the issue is validation of the tests. For example, when the CDC-developed Zika tests were deployed under an EUA, there was not an adequate supply of material that laboratories could use to establish performance characteristics (validate) for those tests as required by the CLIA regulations. Another challenge was that the tests that were developed relied on technologies and platforms that many of the public health laboratories were not using and could not access. DLS realized that the process was primarily an engagement between CDC and FDA. In addition, the CDC DLS and the CMS Division of Laboratory Services were not actively involved in the development of the protocol for the EUAs. Therefore, CMS was not in a position to provide adequate information to their surveyors about the EUAs.

- Another member asked if the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) was a component of the division's work towards semantic interoperability. Dr. Salerno responded yes, but the current focus is on the Logical Observation Identifiers Names and Codes (LOINC).
- A member asked for clarification regarding who could send a message to CDC on a clinical laboratory issue via the LOCS email box. Dr. Salerno responded anyone may send a message to the LOCS email on a clinical laboratory issue. He added that DLS uses LOCS to send out messages that are important and timely. Those messages, however, only go to the professional associations. The professional associations are asked to forward the messages to their members.
- A member asked whether CDC has considered dialogue with the United Kingdom regarding how they are handling next generation sequencing (NGS). Dr. Salerno responded CDC has not yet specifically engaged them on this question. At the moment, the new tri-agency work group is trying to understand the issues from the point of view of the role of CDC, FDA, and CMS, and how that impacts the CLIA program.

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

Karen Dyer MT (ASCP), DLM
Director
Division of Laboratory Services
Survey and Certification Group
Centers for Medicare & Medicaid Services (CMS)

Ms. Dyer began with a brief overview of the current CLIA statistics. She presented the 2016 Individualized Quality Control Plan (IQCP) survey findings, discussed the CLIA Outreach Program – Academic (COPA) which went live in February of 2017, and reviewed the CLIA virtual basic training required of all surveyors. She briefly discussed interagency coordination in which CMS, CDC, and FDA have formed a tri-agency response team to keep each agency informed of potential issues involving CLIA laboratories. Ms. Dyer finished with an overview of non-traditional testing models and posed questions for the Committee to consider.

Committee Discussion

- A member noted that the goal of the IQCP approach was to prevent errors that could lead to mismanagement of patients and asked how CMS will evaluate whether the goal has been reached. Ms. Dyer responded that the first year's evaluation of the data collected had been broken down into categories. Laboratories with major issues received a follow-up survey. CMS is now collecting year-two data at which point CMS will be in a better position to evaluate IQCP.
- A member noted that CDC and CMS have initiatives regarding the laboratory workforce. However, the role of the laboratory in health care seems to be missing in the outreach that CMS has begun. The lack of visibility and the lack of understanding of how the laboratory fits into the scheme of health care makes it hard to attract people to laboratory careers. The member asked what the agency's long-term plan is

for the laboratory workforce. Ms. Dyer replied, historically, laboratories have not been a visible part of the health care system and laboratory professionals have not been proactive in promoting their roles. She added that this can be addressed as part of the CMS outreach.

- Another member expressed the hope that cytology and histology were being included in CMS outreach, as there is an approaching crisis in that particular workforce. Ms. Dyer responded these specialties are included.
- A member noted that many state public-health laboratories are involved with developing their workforce and are partnering with the various science, technology, engineering, and math (STEM) education programs. The member asked how CMS will be partnering with the work that is already going on in the states. Ms. Dyer replied that this is the first year of the outreach effort; more will be accomplished as CMS gets further into the process. The member asked if high schools will be incorporated into the program. Ms. Dyer said CMS has met some resistance going into high schools. The member suggested one way to incorporate high schools may be to sponsor high-school science teacher externships during the summer. This might encourage the teachers to incorporate public health and laboratory medicine into their curricula and to take the idea back to their teacher associations. Ms. Dyer expressed appreciation for the suggestion.

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

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)
Food and Drug Administration

Dr. Tobin began his presentation by noting the retirement of Dr. Gutierrez. He then discussed the 21st Century Cures Act commenting that an update to the CLIA waiver guidance was required as part of the legislation and a draft guidance would be published in 2017. He reviewed the CLIA waiver process as addressed in the Medical Device User Fee Amendments (MDUFA) and reviewed MDUFA II and III. He noted the FDA was beginning a pilot to release CLIA waiver by application decision surveys. Dr. Tobin presented updates in the area of semantic interoperability. He touched on de novo classifications, premarket approvals (PMAs), and EUAs. He noted the FDA 2018 guidance priorities and upcoming meetings and workshops.

Committee Discussion

- A member commented that FDA's classification of antigen-based rapid influenza virus antigen detection test systems had been changed and many of the rapid tests currently available are obsolete in light of the new FDA classification. The member suggested that the FDA provide a table on their website that clearly shows which influenza tests are class II rapid tests. Dr. Tobin replied he would relay the request.

- A member commented that in point-of-care testing, reimbursement for many of the new rapid tests is less than the cost to perform the test which makes it difficult to implement the testing. Dr. Tobin acknowledged that is a significant concern; reimbursement for testing, in general, is an issue and certainly for point-of-care testing.
- A member requested clarification of the MDUFA process, especially with regard to application turnaround time and fee payment by manufacturers. Dr. Tobin responded that application turnaround time and fee payments are two different processes. Part of MDUFA is to provide additional resources for FDA, which allows hiring additional staff, enabling faster turnaround times. As part of that, the performance goal is for a certain number of FDA days for reviewing a particular submission type, such as a CLIA waiver. These are negotiated goals. The member asked if FDA would reduce the turnaround time in reviewing applications if the manufacturer agreed to an increase in the fee paid. Dr. Tobin responded affirmatively.

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

Elizabeth M. Marlowe, PhD, D(ABMM)
Committee Liaison (past) to CDC Board of Scientific Counselors
Office of Infectious Diseases (OID)
Assistant Director
Microbiology-Molecular Testing
Southern California Permanente Medical Group
Regional Reference Laboratories

Dr. Marlowe provided updates for the January 2017 meeting of the CDC Board of Scientific Counselors. She discussed the Food Safety Modernization Act Surveillance Working Group (FSMA) charge and summarized their discussions surrounding Culture Independent Diagnostic Tests (CIDT) and the importance of culture based testing. She briefly discussed the Interagency Food Safety Analytics Collaboration (CDC, FDA, and USDA) 2017-2021 strategic plan. Dr. Marlowe summarized the change in the PulseNet program from Pulse Field Gel Electrophoresis to Whole Genome Sequencing, the reasons behind the change, and the challenges. She finished her overview by listing the key topics in the 2016 annual report and providing an overview of the Office of Advanced Molecular Detection's external review.

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

Dr. Campbell provided updates for the May 2017 meeting of the CDC Board of Scientific Counselors. He related the continuing discussion around CIDTs and listed the FSMA themes for FY2018. He summarized key updates from the National Center for

Immunization and Respiratory Disease and reviewed the H7N9 influenza focused discussion that took place at the meeting. He provided updates from the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, and from the National Center for Emerging and Zoonotic Infectious Diseases. Dr. Campbell ended his presentation with a summary of the acting CDC Director's comments.

Committee Discussion

- The Chair asked if there was a formal way to relay CLIAC input back to the BSC/OID. Dr. Marlowe suggested the CLIAC liaison to the BSC bring it to the attention of the BSC and noted there is an overwhelming amount of information provided at the meetings. Dr. Campbell agreed the liaison could relate CLIAC's thoughts to the BSC but said he would prefer to work through CDC DLS staff. He said interaction with the BSC on topics such as workforce development, next generation sequencing, diagnostics with public health impact, and a developmental diagnostics pipeline in anticipation of future threats would be valuable topics to consider.
- A Committee member commented that the Department of Defense generates solicitations for the development of devices and therapeutics in targeted areas and suggested CLIAC advocate for CDC to be funded to undertake a similar program for areas of public health importance. The member also suggested there should be a Public Health Threat Reduction Agency similar to the Department of Defense's Defense Threat Reduction Agency.
- Dr. Marlowe commented on challenges that can result from the BSC's recommendations for testing that do not consider the perspective of the clinical laboratory, and thus emphasized the role that the CLIAC liaison plays in BSC discussions. Dr. Salerno agreed with the importance of the CLIAC liaison in bringing the clinical laboratory perspective to the BSC.
- A member commented on several topics within the purview of the BSC related to laboratory testing for infectious diseases. As one example, the member asked that the CLIAC liaison to the BSC request the various governmental agencies to harmonize the definition of carbapenem-resistant Enterobacteriaceae, since currently, several different definitions may be used within the health care setting.
- Two Committee members expressed their reliance on public health laboratories for providing technical assistance. One of the members commented that the role of CDC laboratories does not appear to be considered a core function of the CDC and would like to see that changed based on its importance to the country. Dr. Salerno agreed and added that DLS is working to promote the status of laboratories at CDC and to emphasize the importance of clinical laboratories and how they intersect with public health laboratories.

PRESENTATIONS AND COMMITTEE DISCUSSION

Laboratory Testing in the Era of Telemedicine

Introduction ***Addendum 05***

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

Dr. Salerno began by reiterating the challenges that clinical laboratories experience when implementing new technologies, such as NGS, that had been mentioned during the agency updates. He reminded the Committee of the questions related to CLIA applicability that are pertinent to these technologies. Many of the challenges relate to the fact that data analysis and/or result interpretation may be conducted remotely or even outsourced to another non-laboratory facility. Telemedicine is another of these nontraditional diagnostic models that utilizes remote data analysis and/or result interpretation. He observed that in spite of the challenges, there are many benefits and opportunities afforded by the availability of telemedicine, especially with respect to increased access to information, data sharing, and expertise that may not otherwise be readily available in all health care settings. Dr. Salerno asked the Committee to keep in mind six questions while listening to Dr. Allen's talk.

Considering telemedicine, next generation sequencing, and other new or nontraditional technologies that remotely conduct data analysis and/or test result interpretation:

1. Which laboratory specialties, subspecialties, and tests are being impacted by this change in practice?
2. What types of non-traditional business models between the laboratory and an outsource facility need to be considered?
3. What challenges do laboratories encounter when implementing this type of testing and working with a nontraditional facility that remotely performs part of the testing process?
4. What steps can HHS take to facilitate implementation and assure the quality of the testing?
5. Are there gaps in CLIA that need to be addressed?
6. What guidance do laboratories need to address critical steps in the testing process and ensure that they are meeting CLIA requirements?

The Anatomic Pathology Diagnostic Management Team Conference ***Addendum06***

Timothy Craig Allen, MD, JD, FCAP, FASCP
Professor, Department of Pathology
The University of Texas Medical Branch (UTMB)
Galveston, Texas

Dr. Allen began by stating that it is striking that clinical and anatomic pathology laboratories have the same concerns about being visible to the public and in taking on different roles outside the traditional laboratory space. He noted that the online presence

of medical information has fundamentally altered the patient's view of their healthcare and that e-patients are coincident with a fundamental change in cancer care. He stated that now is an excellent time for pathologists to provide expert consultation that can directly affect patients' treatment and lives, noting that diagnostic and therapeutic delays have significant impact on the outcome of lung cancer and other cancers. Dr. Allen described the concept of the real-time online tumor board as envisioned by himself and another physician, Dr. Byron Liang. He noted that in such a scenario, a team should be assembled as soon as cancer is diagnosed and went on to describe who might be on the team and issues that could be addressed. He discussed resistance to as well as opportunities afforded by such teams. He emphasized that significant information technology participation is necessary and that both a dedicated team and dedicated institution are necessary. The Committee was shown a video of a tumor board in action. Dr. Allen ended his talk with a discussion of areas, other than cancer, where such teams would be useful.

Committee Discussion

- A member remarked interfacing with patients via real-time boards would make the laboratory visible to the care team. The member asked what Dr. Allen's experience was with a patient that was not as articulate and well informed as the one in the video clip. Dr. Allen confirmed that the patient in the video was a retired physician and an engaged patient and verified that not all patients are that articulate. He conveyed that he had dealt with patients of various levels of understanding and various levels of education. He added, although they may not understand the laboratory results most do appreciate that a team is involved in their health care and gain a better sense of how the team is working for them. Also, the team approach better utilizes time.
- Another member stated the limits on telemedicine should also be clearly conveyed. Dr. Allen agreed that boundaries should be defined when using the technology.
- A member asked how UTMB will sustain the program described by Dr. Allen. He responded such a program requires institutional engagement and support however, at this time reimbursement isn't available. Therefore UTMB is building the program, will demonstrate the value, and then will pursue reimbursement. The member asked whether Dr. Allen had evaluated the program, looking at outcomes from the patient, provider, and health system perspectives, to demonstrate the value of this intervention. Dr. Allen replied that a plan for evaluation of the program is being developed and is critical.
- A member observed that there are many opportunities for telemedicine in microbiology as well as in anatomic pathology and in some areas, pathology is ahead of other areas of health care. The member also noted that in the current climate of consumer driven health care, the costs are being shifted to the patient, and health care delivery systems will need to adapt.
- A member voiced the concern that we may end up separating our society into people who have no access to technology and those who do have access to technology. The member asked how this would be addressed. Dr. Allen replied there are various solutions for this such as the patient traveling to the local clinic or the library. It would also be possible to send the information to the patient and have them connect

with the team by phone. The Chair remarked that a cell phone could be sent to a patient. Dr. Allen agreed that utilization of cell phone technology is a possibility.

- A member opined although some types of care are great for telemedicine, telemedicine is adding to the depersonalization of medicine and the relationship between the care provider and the patient. Dr. Allen agreed that telemedicine did not fit every situation. However telemedicine allows everyone to be more involved with the patient.
- A member remarked that the costs and benefits of telemedicine need to be regarded within the broad scope of the health care system and not restricted to a single department. The member also noted that as health care becomes more digital, the implications of that and how to reduce potential hurdles or restrictions, such as requiring multiple CLIA certificates for office and home for those signing out cases, must be addressed. Dr. Allen agreed and added it goes beyond signing out cases from home but also includes the potential for using one's phone anywhere to review and sign out cases.
- Another member noted that CLIA certificates are based on addresses and asked how CMS might address that issue. Ms. Dyer responded CMS is aware of this issue and is working to address it. She said it ties into who considered as ultimately responsible for testing.
- A member asked if Dr. Allen envisioned including not only the academic team on the virtual tumor board but also the community provider who manages the whole patient. Another member commented that a patient's caregiver does not always have the time available to join multiple care team meetings each day. The member suggested providing a webinar that could be viewed any time after the meeting. Dr. Allen commented that the reduction in confusion engendered by the use of a tumor board develops a sense that the patient is being better cared for may reduce medical malpractice risk.
- A member asked how the Health Insurance Portability and Accountability Act (HIPAA) issues and confidentiality are handled. Dr. Allen replied as part of a diagnostic management team conference, each patient signs an institutional document regarding HIPAA. The technology UTMB uses is HIPAA-compliant web-based technology, which is absolutely critical.
- A member commented their state has a lot of small town, critical access hospitals. A weekly tumor board consisting of a pathologist, radiologist, oncologist, surgeon, and the attending physician convenes at their hospital. The family is also invited. However, to link the critical access facilities with the parent institution, a tumor board telemedicine approach is being utilized. The attending physician and the family participate from the critical access facility.
- The Chair asked about possible processes that could be established at institutions to encourage building tumor boards and to route attention toward things which provide value. He also wondered what could be done, given the important requirements and constraints of having evidence before reimbursement, to foster these kinds of innovations. Dr. Allen responded if this is instituted, a physician's day would not be structured as it is now. A series of 10-minute conferences could be scheduled with the team throughout the day, and the patient would not need to schedule multiple appointments, which would improve efficiency for all.

- A member expressed appreciation that the tumor board system is patient focused and patient centered. However, patient confusion could occur during tumor board discussions that involve life altering decisions. The member asked, in terms of the payment, would the oncologist's payment be taken from the reimbursement and given to the diagnostic management team? It would seem that the health care system would be financing this. Dr. Allen expressed the expectation that the oncologist's role should be enhanced with the diagnostic management team conferences. He stated to keep this sustainable, it is important that the accrediting agencies for cancer diagnosis and treatment recognize these diagnostic management team conferences as parts of the tumor board. Finally, the patient should receive the diagnosis from their physician before the team-based educational meeting takes place.
- A member asked if there are clear guidelines that should be addressed in terms of telemedicine and noted that Dr. Salerno's initial questions should be addressed. The Chair noted conversations thus far had encompassed the patient, the patient's immediate care team, economics, evaluation, oversight, and efficiency advantages. He asked the Committee to consider the laboratory perspective in addressing Dr. Salerno's questions.
- A member observed that the new distributive model of telemedicine is challenging for the laboratory. One barrier for implementation is that the pathologist's role is tied to an address. The member noted the line between a laboratory, a software provider, and a service provider is blurring and each may contribute key aspects of the testing process and should therefore follow best practices and be subject to regulations.
- The AdvaMed liaison agreed that was a very interesting point. He provided the example of a laboratory that was performing sequencing then sending the data files to an informatics company to be processed and returned. The data company did not perceive themselves to be a laboratory as they do not make diagnoses. The question is how the laboratory would assure the quality of the test results. A member concurred and added that laboratories and other institutions must put the processes in place to assure the quality of the testing. Ms. Dyer agreed that is a concern.
- Ms. Dyer remarked that most laboratory professionals would welcome the opportunity to be part of a care team and suggested that facilities be proactive and include laboratory representation as part of the care teams.

Antibiotic Resistance Testing Issues

Diagnostics for Antibiotic Resistance ***Addendum 07***

Jean Patel, PhD, D(ABMM)
National Center for Emerging Zoonotic and Infectious Diseases
Office of Infectious Disease
Centers for Disease Control and Prevention

Dr. Mac Kenzie briefly introduced the topic of antibiotic resistance testing issues. He noted that the development and release of antibiotic susceptibility tests may lag behind

the development and release of new antibiotics, and this impacts clinical care and the ability to monitor and track resistance.

Dr. Patel related her talk would be on CDC's work to expand the national capacity for detecting and characterizing antimicrobial-resistant pathogens and noted this testing also helps in deciding when enhanced infection control measures are needed in a health care facility for an individual patient. She disclosed that in 2016 CDC received new funding that was used to create the Antibiotic Resistance Laboratory Network (ARLN) to increase the public health laboratories' capacity for detecting and characterizing antimicrobial resistance. She related the purpose of the testing is to collect carbapenem-resistant Enterobacteriaceae (CRE) isolates, confirm they are resistant and producing a carbapenemase, and identify which carbapenemase is present. She described other projects CDC has funded using this money and other types of antibiotic resistance that CDC considers urgent. Dr. Patel gave examples of what the ARLN has accomplished. She summarized the challenges when a new drug is approved for use but there is no corresponding antimicrobial susceptibility test and explained why that happens. She described a pilot program for the next round of funding and new technology that will be implemented as part of the program. Dr. Patel ended the presentation with a description of the CDC and FDA antibiotic resistance isolate bank and said more information about CDC's work in antibiotic resistance could be found at https://wwwn.cdc.gov/arinvestments.

Diagnostic (AMR) Update ***Addendum 08***

Steve Gitterman, MD
Office of In-Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiological Health (CDRH)
Division of Microbiology Devices
Food and Drug Administration

Dr. Mac Kenzie began by introducing Dr. Gitterman and stating that his presentation would be about diagnostic antimicrobial resistance tests and the antimicrobial resistance susceptibility testing device development process.

Dr. Gitterman began by showing a timeline of antimicrobial resistance (AMR) tests. He discussed a few of the tests the FDA has evaluated, noting that multiplex devices that include antimicrobial resistance markers are in development, and explained some of the challenges addressed during a recent FDA workshop held to discuss the process for developing antimicrobial susceptibility and resistance diagnostic devices. He mentioned recommendations from the Presidential Advisory Council on Combating Antibiotic-Resistance Bacteria and he briefly discussed semantic interoperability standards. Dr. Gitterman described the FDA's new "breakthrough pathway" for devices and compared it to a previous process. He finished the presentation by listing ongoing issues for antimicrobial susceptibility device development.

Committee Discussion

- The Chair asked about the AMR diagnostic challenge prize. Dr. Gitterman explained the AMR diagnostic challenge is a $20 million federal prize competition seeking innovative, rapid point-of-care diagnostic tests to combat the development and spread of drug resistant bacteria. He stated that multiple prizes would be awarded. He added that moving from a prize to a product being used in a laboratory takes a long time from the FDA's perspective. The products may not be ready to commercialize and implement at the time the prize-winners are announced.
- A member asked about the level of international collaboration and coordination of regulations regarding antibiotic susceptibility and antimicrobial resistance and test approval. Dr. Gitterman stated that there is coordination. The FDA is increasingly standardizing the specific recommendations and formats to make it as least burdensome as possible to European nations.
- A member asked for clarification of the "breakthrough pathway" that Dr. Gitterman had described. He briefly explained this classification and referred the member to the FDA website (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf).
- One member expressed frustration when "Research Use Only" tests are the only ones available and stated this makes it almost impossible to perform the test and report results. The member asked how a manufacturer is going to have a test approved by the FDA if there are no breakpoints available. Dr. Gitterman answered that the 21st Century Cures Act takes breakpoints out of the drug label and puts them on a website. Concomitantly, the FDA may now recognize standards development organizations (SDOs) so if the breakpoints provided by an SDO are listed on the website, then FDA will accept them. Comments are now being received on this proposal.
- Another member asked what tests are available for two new antibiotics and asked about the developmental pathway for two high volume analyzers. Dr. Gitterman answered disk tests are available for the antibiotics mentioned and explained there are several issues being addressed as part of the development process for the analyzers.
- A member observed that minimum inhibitory concentration testing is complicated and asked if every laboratory provides the same testing quality. Committee members commented that the testing quality is not all the same, it depends on who operates the laboratory and the characteristics of the test being used. One member expressed frustration because often the insurance companies will determine which laboratory can be used or what testing can be done, and the results may not lead to the best choice for the patient. Committee members suggested talking to the antimicrobial stewardship committee in an institution or calling the laboratory if the clinician has questions or concerns about the testing.

Institute of Medicine (IOM) Workgroup Updates

Introduction

William Mac Kenzie, MD
Deputy Director
Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

Office of Public Health Scientific Services (OPHSS)
Centers for Disease Control and Prevention

Dr. Mac Kenzie stated the purpose of the CLIAC workgroup was to gather information on the laboratory-related issues included in the 2015 Institute of Medicine (IOM) report on reducing diagnostic errors, frame the Committee's discussion, and propose language for potential CLIAC recommendations. He introduced the workgroup topics to be discussed at this meeting and explained why these are important topics for patient care.

Pathologists as Integral Care Team Members ***Addendum 09***

Roger Klein, MD, JD
Attending Pathologist
Department of Molecular Pathology
Cleveland Clinic Foundation

Dr. Klein began by citing the IOM report's definition of a diagnostic error and stated these errors are a huge problem. He noted that Goal 1 of the IOM report is to facilitate more effective teamwork in the diagnostic process and related his talk would focus on issues surrounding the use of clinical laboratory tests and clinical pathology. He provided an example of a clinical laboratory error and explained why the pathologist's integration into the diagnostic team is important. He indicated there are three areas where a pathologist is particularly important: test ordering including selection, result interpretation, and communication to caregivers and patients. He presented evidence that pathologist input and involvement improves patient outcomes but added one reason for lack of pathologist integration into the diagnostic team is the lack of Medicare reimbursement for clinical pathology consultation. Dr. Klein finished by discussing specific recommendations from the IOM and potential recommendations from CLIAC to address them.

Committee Discussion

- A Committee member commented that the reimbursement-related discussion should not be limited to pathologists but that board-certified PhDs consult in other laboratory specialties and should also be considered. Related to clinical decision support, the member added that one problem is assuring the correct test is ordered. A possible solution would be to encourage manufacturers to incorporate decision support systems within electronic health records. Another member stated that building decision support into an electronic health record is a slow process. One member responded they had implemented a decision support system and related that it had saved money and improved patient care. The member said CMS now requires someone representing the laboratory to be on an institution's antimicrobial stewardship committee and suggested that diagnostic stewardship or test utilization could be included to the topics within the purview of the committee. Another member commented that order sets in the electronic health record are built by the facility so going directly to the manufacturers of electronic health record systems may not solve the problem. A member noted there are systems that ask specific questions when a

test is ordered which encourages the physician to think through what they are ordering. A second member commented that a system that asks specific questions about a test order is difficult to produce unless an institution has a pathology informatician to collaborate with the informatics expert in their health care system. The member also noted the installed system must be curated, kept up to date, accessible by the informatician, and would need to avoid the usual ticketing process when changing something in the electronic health record.

- A member commented on the three proposed CLIAC recommendations noting the third was more global and the first and second were embedded in the current fee for service model. He suggested that the fee for service model may be obsolete before the two proposed recommendations could be implemented. Dr. Klein responded that there is pushback and lack of interest in changing the current payment model. It may take more time to change than expected. However, Dr. Klein suggested there is interest in Washington to allow for experimentation and innovation.
- A member commented there are many American Society of Clinical Pathologist-certified professionals who could perform consultations which would allow the pathologists to handle more complex questions.

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

❖ **Recommendation 1**

HHS encourages the development and evaluation of team-based care innovations that include CLIA covered specialties (and engage patients) in reducing diagnostic error

- Areas of special interest could include consultations by laboratory professionals e.g. pathologists' work in advising ordering clinicians on the selection, use, and interpretation of diagnostic testing for specific patients
- Evaluation should include patient and provider outcomes (including satisfaction) and health system outcomes (e.g. costs) including innovation's implementation related challenges and opportunities

<u>The Quest for Interoperability</u> ***Addendum 10***

Monica de Baca, MD
Director of Hematopathology
HematoLogics, Inc.

Dr. de Baca began with an overview of Health Information Technology (HIT) including the national priorities noting that the 2004 HIT plan was updated in 2015, although the core priorities remain similar. She reviewed the Office of the National Coordinator for Health Information Technology's (ONC) definition of interoperability along with goal 3 of the Institute of Medicine 2015 report and ONC's recommendations intended to further this goal. She noted that before systems can work together there has to be a structured transfer. Dr. de Baca discussed data coding via Health Level-7 (HL7), LOINC, International Statistical Classification of Diseases and Related Health Problems (ICD),

and SNOMED CT emphasizing the strengths and weaknesses of each noting that no single standard meets all coding needs to achieve the IOM's objective. She noted the IOM paper determined that without seamless interoperability the implementation of HIT will not achieve the goal of improving the quality of healthcare. She said the issue is what interoperability encompasses. She stated there are currently efforts to align the different standards however, more of these endeavors are necessary. It is important that the standards are used adequately and appropriately. She ended her talk by commenting we should not jump to solutions before the problems are defined and then proposed a recommendation for the Committee to consider.

Committee Discussion

- The Chair commented that the HIT goal of interoperability in healthcare is a very important issue that currently affords opportunity for improvement. He added currently there is a lot of exciting work going on in this area.
- A member commented on CDC's work in the area of interoperability noting that, in cooperation with the Association of Public Health Laboratories (APHL), CDC undertook pre-coordination rather that post-coordination of codes. This required that the manufacturers of a test agree on the LOINC and the SNOMED CT codes prior to the release of a new test. The member asked Dr. de Baca to comment on work being done on an international level towards interoperability. Dr. de Baca replied that in a recent conference in Bulgaria, a large number of countries indicated that the utilization of LOINC is not within their countries' interests. SNOMED CT does have some international translations, and those are being used in quite a few of the countries who have shown less acceptance of LOINC.
- A member noted CLIAC made three previous recommendations regarding interoperability and asked Dr. de Baca if she had built her recommendation on those. The member said the Committee should refer to the previous recommendations if a new recommendation was to be made.
- A member said although today's discussion is focused on interoperability among laboratories the same problems extend outside of the laboratory to include insurance payers and drug manufacturers.
- The Chair asked what percentage of the clinician's work could be handled by a well-run electronic heath record system so that the physician would not need to spend so much time collecting, inputting, and analyzing data. A member responded that would be the idealized version. The problem is that there are so many treatment choices. The Chair asked whether these were issues for the practitioner, or issues that need to be handled on the back end. The member responded the issues could be handled on the back end. There is also the value of having that information in making public health decisions.
- A member commented that a laboratory professional can sometimes spend 25% of the day trying to determine appropriate coding for testing and medications. The member added that erroneous conversions between formats for result displays in electronic health records have resulted in serious unintended consequences.
- Dr. Gitterman conveyed there are tremendous efforts being made related to laboratory interoperability. He said a lot of the issues have been discussed at a number of workshops and at previous CLIAC meetings. The HL7 standard will allow

manufacturers to put in the recommended coding for their devices and transmit that seamlessly to laboratories. So, for a given device, the FDA is hoping that laboratories will not have to do a lot of the thinking about codes. It will be hard baked into the device and into their information system. The FDA anticipates that the laboratorians are going to have a large role, because they are legally responsible for the machine's output. So the FDA is anticipating a very quick turnaround to correct errors. The FDA also anticipates that the manufacturers will standardize codes among themselves. There have been concerns with this because if a company publishes this, and there are questions about them using the correct code is it off-label use. The FDA is working to resolve this. Many of the issues that Dr. de Baca addressed will hopefully be resolved soon. Dr. Gitterman used DailyMed (https://dailymed.nlm.nih.gov/dailymed/), a website operated by the U.S. National Library of Medicine (NLM) to publish up-to-date and accurate drug labels, to demonstrate interoperability.

- A member asked Dr. Gitterman if this is also about laboratory results display or just about standards at the back end. The member noted there have been many problems, with studies showing that only 90% of laboratory results are being displayed correctly. Dr. Gitterman responded that the FDA is only supporting the infrastructure at this point.
- A member related there are multiple display issues such as numeric display, labeling results, critical information jammed together causing results to go unnoticed. The vendors are not responsive to the complaints. The member opined that display is a very important aspect of interoperability. The display of data is a large issue that needs to be addressed.
- Another member remarked that the Committee was discussing two separate topics; interoperability and patient safety as related to the electronic health record. The member suggested the patient safety discussion be tabled for another meeting.
- Dr. Alberto Gutierrez commented that as a result of the 21st Century Cures Act, laboratory information systems are no longer under FDA purview.
- The Chair asked for input from the AdvaMed liaison about how to focus the discussion as related to the manufacturer's perspective. The liaison said that some of the Committee's questions focus on whether instrument manufacturers support the initiatives and could do more to enable them. He said the AdvaMed organization, as a representative of multiple manufacturers, has worked closely with FDA, CDC, and committees on these issues and, in general, is very supportive of being able to provide correct LOINC codes. One of the challenges is the number of older instruments still in use. The instrument manufacturers have some of the same challenges as the laboratories, there are many different codes and not every manufacturer agrees with every other manufacturer as to which is the most appropriate. This is why AdvaMed recommended a third party organization be involved to help with the mapping and recommendations of the codes, so that industry can provide that information to laboratories in a non-biased and supportive way. However, laboratories often use tests in different ways than manufacturers envisioned, therefore the manufacturers must be careful about the information they provide to laboratories. He said there are other issues such as if they advise on what a LOINC code would be for something that's not indicated in our usage, is that providing guidance for off-label usage? The Chair asked if, setting aside the issue of the legacy machines, going forward the chief

obstacle is the threat of litigation or off-label use. Or is there a sense in industry that, irrespective of legislation and policy, that there is a competitive advantage, a marketplace advantage, to harmonization? The liaison responded that industry agrees it is in the interest of better health to provide the codes in a supportive, non-regulated way. He added, by and large, all the major manufacturers in the United States or elsewhere are working towards providing the information that's being requested in terms of LOINC and working through AdvaMed to support these initiatives. The challenge is that it is impossible to predict all scenarios.

- Ms. Dyer said she was disappointed to hear about the interface and reporting issue because CMS worked very hard with the standards and interoperability groups to craft the interface guides for ordering and reporting including what CLIA required.
- A member remarked that one challenge that has been addressed very little is standardization of anatomic pathology reporting. The next big challenge after that is molecular diagnostics. Those are challenges that the Committee also needs to consider in the future.
- Another member noted the Committee has discussed this topic multiple times before and made recommendations. The member asked if the Committee could take some of the general language from past recommendations and add that into the specific recommendation of the larger proposal.
- A member stated HHS should be encouraged to set the standards. An effort to create universal coding has already begun but the standards must be set.
- Dr. de Baca said her intent was to find a way to create a process to standardize their standards. She added there seems to be no published information indicating how robust these systems are. For example, LOINC is especially used in laboratories, it is now also being used for other medical reasons such as ordering and results. The challenges that we are going to see in molecular diagnostics are overwhelming. She said her intent was to create a process by which there could be some testing of how the software is performing in the gray areas. When we know what we can expect by implementing standards and we know that the output is correct then we know we can use the standards effectively.

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

❖ **Recommendation 2**

CLIAC recommends that HHS create a process for standards utilization field studies across a wide range of clinical laboratories (varying size and complexity) to:

1. Better understand the nuances, specificity and compatibility of sharing LOINC or other standard codes
    a. on both order-and result-side implementation
    b. in special cases (radiology, clinical findings, anatomic pathology, molecular diagnostics, etc.)
2. Identify areas in which a combination(s) of standards is needed to realize the level of granularity and semantic interoperability necessary to achieve the IOM goals

Culture Independent Diagnostic Tests

Culture Independent Diagnostic Test (CIDT) Issues ***Addendum 11***

John Besser, PhD
Deputy Chief
Enteric Diseases Laboratory Branch
Division of Foodborne, Waterborne and Environmental Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Besser began with an overview of the increase in and benefits of CIDTs and discussed the challenges of using CIDTs for diagnosis. He recounted the CIDT impacts on public health including difficulty in monitoring trends with the discontinuation of maintaining culture isolates. He provided an overview of PulseNet including its importance and long range plans to transition to the use of metagenomics as the solution to pathogen characterization. Dr. Besser discussed the Regulatory Work Group (an ad hoc Association of Public Health Laboratories group with CDC members) activities towards assuring the continued flow of specimens and isolates to public health laboratories in light of increasing CIDTs. He reviewed the questions asked of CLIAC about CIDTs in 2012 and provided an update on what has changed over the past five years. He expressed his opinion of where diagnostics and public health are heading including major trends, changes in clinical microbiology, and diagnosis using whole genome sequencing and ended by presenting current needs and questions for CLIAC.

Committee Discussion

- A member commented on the challenges of sustaining culture-based reflex testing in the clinical laboratory without reimbursement. The member asked how to convey to administrators and medical technologists the importance of sending samples to the state public health laboratory. Dr. Besser responded that he did not have an answer for the communication issue and added that state laboratories are rapidly being overwhelmed and are not usually funded to perform reflex culture. He mentioned that CDC is working to identify ways to screen specimens so only those with a high probability of having isolates will be used.
- The same member asked if all positive cases should be followed up, especially because molecular testing is more sensitive and results in more positives than the culture tests. Dr. Besser commented that with new technologies, it is expected to have unanswered questions and that is why CDC is asking for help.
- One member commented there is a problem with the balance between regulations/guidelines and actual testing when newer technologies come along and do not fit with the guidelines. The member suggested partnering with manufacturers to discover what they are hearing from their customers. Dr. Besser responded that the epidemiologists need information about the performance characteristics of CIDTs, as well as knowing how many and which tests are being performed, to develop models in order to adjust the trends appropriately and be able to advise where resources need to be applied for control measures.

- A member commented that a larger discussion is needed, especially because there are also benefits to performing CIDTs at the point of care. However, a bigger question is what to do if neither a clinical laboratory nor public health laboratory can receive or culture an isolate. Another member commented that as laboratories stop using culture, they lose the expertise and capability. A member replied that with the loss of expertise and capability, laboratories may not have people who can identify reemerging infectious diseases.
- A Committee member asked where CLIAC could contribute and how to help as more point of care tests are available and can be used by employees with little experience in microbiology. The member commented that proficiency testing (PT) has not kept up with how the work is being done. Another member commented that PT programs typically will not change their PT unless required to by CLIA. Ms. Dyer responded that CMS is working toward updating PT regulations.
- A member asked if insurers or HHS could suggest how to pay for public health surveillance as CIDTs are increasingly used instead of cultures. Dr. Besser responded that he found that private payers understood the situation but this is not a priority for them. Ms. Dyer responded that reimbursement is handled by another part of CMS and she could not answer. A member also commented that some point of care tests in an office setting may not be covered by insurance. If the practice had the test available and offered it, insurers would not pay for it. Multiple Committee members commented on the need to increase reimbursement for culture.
- A member asked about the Regulatory Work Group and asked if CDC leadership is fully aware of the problem of not receiving isolates. Dr. Besser replied that there has been steadily increasing awareness and many groups are working on this problem.
- A member asked if it was possible for the FDA to require diagnostics manufacturers to monitor and update sensitivity and specificity to assure the diagnostic test is able to detect organisms that may have mutated or changed. Dr. Gitterman responded that yes, in the case of influenza tests, manufacturers must demonstrate performance against active or anticipated strains.
- Multiple Committee members commented on the cost of testing, funding, reimbursements, and who should pay. Cost is a major driver of healthcare at this time. They stated that often the administrators use cost to determine productivity but that comparison often does not show the entire picture.

The Committee concluded the discussion on CIDTs and made the following recommendation:

❖ **Recommendation 3**

In clinical microbiology, culture-independent diagnostic tests (CIDTs) are rapidly supplanting culture-based tests, but cultures are indispensable for surveillance and outbreak prevention, which are both cost-effective and vital to public health and national security.

CLIAC recommends that CDC urgently convene a cross-agency coordinating group to assess the impact of CIDT on public health surveillance and to recommend impactful solutions that are brought to the attention of agency and government leaders.

ACRONYMS *Addendum* 12

NOMINATION INFORMATION *Addendum* 13

PUBLIC COMMENTS *Addendum* 14

ADJOURN

Dr. Arnaout and Dr. Mac Kenzie acknowledged the staff that assembled the meeting agenda and thanked the CLIAC members and partner agencies for their support and participation. Dr. Arnaout also reminded meeting attendees about how to nominate potential candidates for CLIAC membership. The following are the three Committee recommendations passed at this meeting:

❖ **Recommendation on Pathologists as an Integral Team Members:**
HHS encourages the development and evaluation of team-based care innovations that include CLIA covered specialties (and engage patients) in reducing diagnostic error

- Areas of special interest could include consultations by laboratory professionals e.g. pathologists' work in advising ordering clinicians on the selection, use, and interpretation of diagnostic testing for specific patients
- Evaluation should include patient and provider outcomes (including satisfaction) and health system outcomes (e.g. costs) including innovation's implementation related challenges and opportunities

❖ **Recommendation on Interoperability:**
CLIAC recommends that HHS create a process for standards utilization field studies across a wide range of clinical laboratories (varying size and complexity) to:

2. Better understand the nuances, specificity and compatibility of sharing LOINC or other standard codes
   c. on both order-and result-side implementation
   d. in special cases (radiology, clinical findings, anatomic pathology, molecular diagnostics, etc.)
3. Identify areas in which a combination(s) of standards is needed to realize the level of granularity and semantic interoperability necessary to achieve the IOM goals

❖ **Recommendation on CIDT:**
In clinical microbiology, culture-independent diagnostic tests (CIDTs) are rapidly supplanting culture-based tests, but cultures are indispensable for surveillance and outbreak prevention, which are both cost-effective and vital to public health and national security.
CLIAC recommends that CDC urgently convene a cross-agency coordinating group to assess the impact of CIDT on public health surveillance and to recommend impactful solutions that are brought to the attention of agency and government leaders.

Dr. Ramy Arnaout announced the spring 2018 CLIAC meeting dates as:
April 10-11, 2018, and adjourned the Committee meeting.

I certify this summary report of the November 1-2, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Dated:

Dr. Ramy Arnaout, CLIAC Chair