

**Clinical  
Laboratory  
Improvement  
Advisory  
Committee**

**Summary Report**

**March 5-6, 2014**

**Atlanta, Georgia**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

# **Clinical Laboratory Improvement Advisory Committee March 5-6, 2014, Summary Report**

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## **RECORD OF ATTENDANCE**

### **Committee Members Present**

Dr. Burton Wilcke, Jr., Chair (Via Telephone)  
Mr. Eugene Augustine, Jr.  
Dr. Robert Baldor  
Dr. Edward Chan  
Dr. Martha Crenshaw  
Dr. Anand Dighe  
Dr. Roger Klein  
Ms. Karen Lacy  
Dr. Elizabeth Marlowe  
Dr. Anthony Okorodudu  
Dr. John Sinard  
Ms. Paula Vagnone  
Dr. Linda Ward  
Dr. Qian-Yun Zhang  
Dr. Richard Press  
Dr. Robert Sautter  
Dr. Hardeep Singh  
Mr. Robert DiTullio, AdvaMed (Liaison Representative)

### **Committee Members Absent**

Dr. Keith Kaplan  
Dr. David Wilkinson

### **Ex Officio Members**

Dr. Alberto Gutierrez, FDA  
Dr. Shambavi Subbarao, CDC  
Ms. Judith Yost, CMS

### **Designated Federal Official**

Dr. Devery Howerton

### **Executive Secretary**

Ms. Nancy Anderson

*Record of Attendance – cont'd*

**Centers for Disease Control and Prevention (CDC)**

Dr. Simon Adebola	Mr. Rick Parry
Dr. Pawan Angra	Ms. Anne Pollock
Dr. J. Rex Astles	Dr. John Ridderhof
Mr. Anthony Barbagallo	Ms. Megan Sawchuk
Ms. Diane Bosse	Mr. Brian Scott
Ms. Cathryn Cambria	Dr. Shahram Shahangian
Dr. Roberta Carey	Mr. Darshan Singh
Dr. Bin Chen	Ms. Theresia Snelling
Dr. May Chu	Ms. Heather Stang
Dr. Nancy Cornish	Ms. Sonya Strider
Dr. Maryam Daneshvar	Dr. Julie Taylor
Ms. Maribeth Gagnon	Mr. H. Eric Thompson
Dr. Amy Gargis	Ms. Pamela Thompson
Ms. Stacy Howard	Ms. Monica Toles
Dr. Michael Iademarco	Ms. Elizabeth Weirich
Dr. Lisa Kalman	Dr. Laurina Williams
Dr. Ira Lubin	Ms. Enjoli Willis
Dr. Duncan MacCannell	Dr. Liu Xin
Ms. Graylin Mitchell	Dr. Barbara Zehnbauer
Ms. Alana McCoy	Mr. Jonathan Zhong

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

Ms. Karen Dyer (CMS)  
Dr. Prakash Rath (FDA)

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 transmission of laboratory information.

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. Devery Howerton, Designated Federal Official (DFO), Clinical Laboratory Improvement Advisory Committee (CLIAC), and Deputy Director, Division of Laboratory Programs, Standards, and Services (DLPSS), 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.

Dr. Howerton introduced Dr. Michael Iademarco, Director of CSELS, and Dr. Shambavi Subbarao, the CDC Ex-Officio representative for CLIAC and Director, DLPSS. Dr. May Chu was recognized for her service to the Committee as previous DFO, and was presented a plaque as a token of appreciation. Dr. Howerton and Ms. Anderson recognized the seven outgoing CLIAC members who also received plaques and letters of appreciation signed by the CDC Director for their service on the Committee. The members included Dr. Martha Crenshaw, Dr. Anand Dighe, Ms. Karen Lacy, Dr. Anthony Okorodudu, Dr. Robert Sautter, and Ms. Lezlee Koch. Dr. Burton Wilcke, Chair, CLIAC, participating via phone, welcomed the new members, Dr. Richard Press and Dr. Hardeep Singh, to the Committee. He thanked Dr. Howerton for acting as Chair in his absence. Dr. Howerton called the meeting to order. All members then made self-introductions and financial disclosure statements.

Dr. Howerton conveyed that the agenda topics included agency 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 Board of Scientific Counselors (BSC). In addition, she explained there would be presentations and discussions on CDC's strategic priority for strengthening public health and health care collaborations and on quality improvement tools for managing laboratory testing in ambulatory settings.

## AGENCY UPDATES AND COMMITTEE DISCUSSION

### Centers for Disease Control and Prevention (CDC) Update

*Addendum 01*

#### **Shambavi Subbarao, PhD**

Director

Division of Laboratory Programs, Standards, and Services (DLPSS)

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

Office of Public Health Scientific Services (OPHSS)

Centers for Disease Control and Prevention

Dr. Subbarao's presentation highlighted the major CLIA program activities underway within DLPSS. She began with an overview of three ongoing cooperative agreements to improve the impact of laboratory practice guidelines (LPGs) in clinical medicine and public health. She also mentioned DLPSS is sponsoring two additional cooperative agreements to evaluate laboratory practice recommendations. Dr. Subbarao announced that a two-year contract had been awarded to the American Society for Cytotechnology

(ASCT) Services, Inc. to conduct operational studies to evaluate the maximum cytology screening workload limits using semi-automated screening instruments. She related that in 2012, CLIAC had made the recommendation to conduct this study and described how the study was being implemented and how the results would be used. She described DLPSS' ongoing educational outreach activities to promote good laboratory practices and the impact these products are having on testing practices. She added DLPSS is now working with CMS to develop an educational workbook for the "individualized quality control plan" being implemented under CLIA. Next, Dr. Subbarao provided updates on the Partial Thromboplastin Time (PTT) Advisor (one of the first Smart Phone apps to be released by CDC), the DLPSS Laboratory Health Information Technology (LabHIT) team activities, and the Genetic Testing Reference Materials Coordination Program (GeT-RM). Dr. Subbarao ended by announcing that historical documents and memorabilia from CLIA '67 through the current era of CLIA '88 are on display in the CDC Library through April 30, 2014. She asked everyone to please visit the exhibit highlighting almost 50 years of CDC's contributions to the CLIA program.

### **Committee Discussion**

- Dr. Wilcke noted that although Dr. Subbarao said that the cytology workload practices survey was to be de-identified, the ASCT Services flyer shown in her presentation did not specify de-identification of survey respondents. He wondered if this would be an impediment to obtaining maximum participation. Dr. Subbarao thanked Dr. Wilcke and said that CDC would talk to ASCT about revising the flyer.
- Dr. Wilcke asked how the effectiveness of the CDC's waived testing educational materials was being measured. He also asked if there were data showing changes in the volume or locations of waived testing, or changes in testing personnel. Ms. Yost replied that her upcoming presentation would answer his questions.
- A member asked for clarification regarding the metrics being used in CDC's project to improve the impact of LPGs. Dr. Howerton replied that the project is a cooperative agreement with three organizations to create metrics to measure and improve how their LPGs are designed, disseminated, and promoted. She explained that the project is just beginning and it is premature to know what the outcome will be. However, the intent is to look at the entire process of guideline development and uptake to ultimately provide information for other organizations that would like to evaluate and improve their guidelines.
- One member asked why reducing blood sample hemolysis in emergency departments was chosen as the focus of the cooperative agreement with the Cleveland Clinic. Dr. Subbarao replied that it was selected because it had been assessed by CDC's Laboratory Medicine Best Practices (LMBP) initiative and it was seen as potentially having a significant impact on test outcomes. She added the LMBP Working Group is always looking for new topics which can be submitted on their website: -- <https://www.futurelabmedicine.org/>
- A member commented that the overuse of laboratory testing deserves more attention, and that tools such as the *Choosing Wisely*<sup>®</sup> or *Safety Assurance Factors for EHR Resilience (SAFER) Guides* could help in the management of laboratory testing.

**Judith Yost, MS, MT (ASCP)**

Director

Division of Laboratory Services

Survey and Certification Group

Centers for Medicare & Medicaid Services

Ms. Yost provided the Committee with the current CLIA statistics and updates; discussed the recent publication of the final rule to provide patients access to their laboratory test reports, and gave an update on the status of the proposed rule to amend the fecal occult blood waived testing criteria. She reviewed the progress of the proposed proficiency testing (PT) rule and the rules to address PT referral. Members were reminded of the Taking Essential Steps for Testing (TEST) Act signed by the President at the end of 2012, which clarified that PT samples are to be tested in the same manner as patient samples except that PT samples may not be sent to another laboratory for analysis.

Ms. Yost provided a brief history of CLIA quality control (QC) and discussed the individualized quality control plan (IQCP) approach to QC, which will be incorporated into the CLIA interpretive guidelines for all specialties except cytology and histopathology. Information on IQCP is now posted on the CMS CLIA website. She discussed CMS's partnerships with the Clinical and Laboratory Standards Institute (CLSI) and their educational collaboration with CDC. She reviewed the current Certificate of Waiver Government Performance Review Act (GPRA) project data and said educational materials like CDC's "Ready? Set? Test!" serve as an excellent means of improving the quality of laboratory testing. Last, she provided resources on where to obtain more information and invited those with questions to contact her at the email address provided.

**Committee Discussion**

- A member requested clarification of the patient access rule. Must the laboratory automatically send the patient their test results? Ms. Yost responded that under this rule, final reports of test results are required to be sent to the patient by request only.
- A member asked if all referral laboratories are listed on the final report. Ms. Yost replied that final reports are issued by the laboratory where testing was ordered and all other laboratories that have any part in the final analysis must be listed.
- A member requested clarification of the one-time exception for PT referral, whether it pertained to the laboratory or the laboratory director. Ms. Yost replied that the one-time exception is for an unintentional confirmatory or reflex test and that the action would be taken against the laboratory. The director is affected if it is determined that the referral was intentional and the certificate is revoked, in which case the director cannot oversee any laboratory for two years.
- A member asked how laboratories' Individualized Quality Control Plans (IQCPs) will be evaluated by surveyors and whether there will be a process for formally addressing subjective disagreements. Ms. Yost replied that surveyors will be looking for the five risk assessment components, whether the entire testing process has been addressed, documentation that supports the process, and the director's signature. If all parts of the IQCP have been addressed, CMS plans to accept what the laboratory director

approves. They will then look at outcomes that result once the IQCP has been implemented before citing a laboratory for IQCP-related deficiencies. If a laboratory is subsequently cited and it disagrees with the survey findings, the issues may be addressed in the wrap-up meeting, on the written response to any deficiencies cited, with the CLIA state agency director, or the CMS regional office.

- A member asked for clarification of the CLIA requirement for laboratory directors to sign procedures. Ms. Yost replied that CLIA requires laboratory directors to sign new procedures and to sign procedure revisions they consider significant changes. She added that the accrediting organizations may have standards that are equal to or more stringent than CLIA.
- Another member asked if waived laboratories were routinely surveyed. Ms. Yost replied that there is no routine oversight of laboratories that perform only waived testing. By law, CMS has no authority to routinely visit waived testing laboratories. However, CMS does visit two percent of the certificate of waiver laboratories each year to provide educational visits and she noted that CDC's educational materials for waived testing sites are helpful.
- Referring to the presentation, a member noted that letters of congratulations were sent to 45% of the waived testing laboratories surveyed. The question that ensued was, "Does that mean that 55% were not performing the tests correctly?" Ms. Yost replied affirmatively that problems were identified in 55% of the surveyed laboratories.

### **Food and Drug Administration (FDA) Update**

*Addendum 03*

**Alberto Gutierrez, PhD**

Director

Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD)

Center for Devices and Radiological Health (CDRH)

Food and Drug Administration

Dr. Gutierrez began his presentation with a brief update on the organizational changes at the FDA. The Division of Program Operations and Management (DPOM) is a new policy group within OIVD established to assist with program management and operations.

Dr. Gutierrez provided a list of DPOM contacts for premarket approval (PMA) applications, 510(k) submissions, and investigational device exemption inquiries.

Dr. Gutierrez explained that the requirement of the Food and Drug Administration's Safety and Innovation Act (FDASIA) to provide a mechanism to track CLIA waiver decisions resulted in the implementation of changes to the FDA information technology tracking software. He reviewed two premarket application approvals, described four de novo down-classifications including the first next-generation sequencer, and noted one emergency use authorization. He described two draft guidance documents developed by the FDA for over-the-counter and point-of-care glucose monitors focusing on the uses and types of testing allowed for each. Dr. Gutierrez highlighted four upcoming workshops and panel meetings noting that the panel meeting on March 27, 2014 will be focused on Exact Sciences' participation in the joint FDA-Medicare pilot parallel review program. He noted the FDA report that describes the FDA's ongoing commitment to the important and emerging area of personalized medicine, which is the tailoring of medical

treatment to the individual characteristics, needs, and preferences of each patient. Dr. Gutierrez concluded his presentation by reviewing two recent warning letters issued by the FDA.

### **Committee Discussion**

- A member asked what is being done about the currently marketed influenza test devices that are incapable of detecting the newest influenza strains. Dr. Gutierrez replied that as influenza strains change, the detection capabilities of the rapid test systems decline. However, there is ongoing work to improve these test devices. He said that the FDA held a panel meeting in 2012 to discuss up-classifying rapid influenza test devices. Under the current system an approved device cannot be removed from the market. Up-classification would require companies to test a panel yearly to verify that their devices are working.
- A member asked whether differences between the FDA and CLSI breakpoints for antimicrobial susceptibility testing had been reconciled. Dr. Gutierrez replied that the issue pertains to whether OIVD can clear a test for use with breakpoints not in the drug label. By law, the FDA is not permitted to do so and the labels cannot contradict each other. He stated that the FDA recognizes that antibiotic resistance is an important topic and they are hopeful for a resolution.
- Another member inquired about the panel meeting for the cobas® HPV Test. Dr. Gutierrez explained that Roche submitted a PMA application for the cobas® HPV Test with the claim that it can be used for cervical cancer primary screening. The FDA will conduct approval panels to determine if the data provided demonstrate the level of safety and effectiveness necessary for the proposed intended use.
- One member commended the FDA on approving the first next-generation sequencer and indicated that the approval alluded to use of the device for laboratory-developed tests (LDTs) that do not use FDA cleared or approved reagents. Dr. Gutierrez explained that the issue is similar to the FDA's regulation of analyte-specific reagents (ASRs) that are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. The FDA provides guidance to the laboratories for the design and development of these reagents. He explained with both the user-developed reagents and the approved instrument under a quality system, any errors occurring should be reported to the FDA ensuring that the tools the laboratories are using are under the control necessary for diagnostic purposes.
- The same member inquired about the FDA's position on LDTs. Dr. Gutierrez responded that the FDA proposed guidance is in administrative clearance.

### **Administrative Changes to FDA's CLIA Categorization Program**

*Addendum 04*

**Prakash Rath, PhD**

Policy Analyst

Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD)

Center for Devices and Radiological Health (CDRH)

Food and Drug Administration

Dr. Rath provided the Committee with an overview of the administrative changes to the FDA’s CLIA test categorization program emphasizing that the changes do not affect the scientific review process for CLIA categorizations. Dr. Rath summarized the information that will be provided in the forthcoming FDA “CLIA Administrative Procedures Guidance” including a description of the tracking nomenclature changes, description of the performance goals outlined in the Medical Device User Fee Act (MDUFA) III commitments, and introduction of a new “dual” application pathway. The dual clearance pathway requires a pre-submission meeting and allows manufacturers to submit a 510(k) clearance and a CLIA waiver application at the same time with both applications on the same decision timeline. Dr. Rath concluded his presentation with an overview of the changes to the FDA’s public CLIA test categorization database and provided a timeline for the implementation of the updates.

### **Committee Discussion**

- The AdvaMed liason asked for clarification on the waiver process for an exempt device. Dr. Rath responded that FDA has not received any CLIA waiver applications for exempt devices, but a process for tracking those applications was developed should it be needed in the future.
- The AdvaMed liason also stated that at a recent pre-submission meeting, some manufacturers said they had been advised not to submit a dual application because end-to-end approvals were preferred. Dr. Rath responded that the dual application path was requested by the manufacturing industry as part of the MDUFA III performance goals. Currently, if a manufacturer has a 510(k) submission in process with the FDA, a CLIA waiver application cannot be submitted until a decision is made on the 510(k) submission. The dual application pathway allows device manufacturers to apply for the 510(k) clearance and the CLIA waiver at the same time after the pre-submission meeting. Dr. Gutierrez added one drawback to the dual pathway results when applications are missing information since they are reviewed concurrently. For example, if the CLIA waiver application is missing information, then the 510(k) approval is delayed.

## **PRESENTATIONS AND COMMITTEE DISCUSSION**

### **Introduction to CDC’s Strategic Priority**

*Addendum 05*

**Michael Iademarco, MD, MPH**

Director

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

Office of Public Health Scientific Services (OPHSS)

Centers for Disease Control and Prevention

Dr. Iademarco highlighted three strategic directions that guide research and programmatic activities at the CDC. He provided a diagram illustrating the coordination efforts of different partners to strengthen public health-healthcare collaborations. He then presented an overview of CDC’s recent reorganization and formation of the Division of Laboratory Programs, Standards, and Services, noting the division’s position in the

Center for Surveillance, Epidemiology, and Laboratory Services within the Office of Public Health Scientific Services. He introduced the first topic for the meeting and concluded by inviting CLIAC to engage in discussions of issues surrounding the rapidly changing healthcare environment and technology, advancement of molecular testing and non-culture based testing, and the balance of the Committee's functions between high-level policy activities and their involvement in scientifically sound technical issues and recommendations.

### **Committee Discussion**

- A member commented on the increasing use of culture-independent microbiology diagnostics and how this change in laboratory practice could lead to the potential termination of bacterial culture for certain organisms. Many public health disease surveillance programs, such as the PulseNet disease surveillance network, rely on information obtained from tests that require bacterial isolates. Dr. Iademarco inquired if the Committee had suggestions that could address these issues in a positive way for public health. The member added that many organizations perform both culture dependent and culture independent tests for certain specimens. This allows the laboratory to have a viable bacterial isolate to send to the public health laboratory to use, if needed, resulting in increased laboratory testing and cost. The member suggested collaboration with the manufacturers to provide a way to obtain samples appropriate for both types of testing. Dr. Iademarco suggested CLIAC address this topic in the future.
- A Committee member proposed that CLIAC address preanalytical variables, including sample preparation, transport, and storage, which account for the majority of laboratory testing errors and result in increased cost and patient safety issues. The member suggested collaboration with other agencies to develop guidelines for the preanalytical phase of testing similar to those produced by the CLSI.
- Several members commented regarding the fact that consumers now have easy access to laboratory testing results. One noted this has caused patient anxiety when abnormal test results are taken out of context. It may also result in unnecessary follow-up testing. The member emphasized that healthcare providers are trained to interpret test results, but now information can be provided to patients who do not have the necessary training. The member suggested CLIAC should address best practices for flagging abnormal test results. Another member added that with the increased use of panels or arrays for multiple tests, the issue becomes even more complex. The consumer not only needs to be educated on test result interpretation but also on how to access their information and use it to their benefit.
- Another member commented there is also an issue with electronic medical records systems sending reports to the patient before they have been reviewed by the healthcare provider. The member agreed that a partnership between public health and clinical healthcare systems to develop best practices for sending results to patients would be beneficial.
- A member noted the CLIA regulations for nonwaived testing require a clinical consultant. The member stated that the position has been under-utilized and suggested exploration and possible expansion of the role of the clinical consultant to advance the public health mission.

## **Board of Scientific Counselors (BSC) Update**

*Addendum 06*

### **Robert Sautter, PhD**

Committee Liaison to CDC Board of Scientific Counselors (BSC)  
Office of Infectious Diseases (OID)  
Director of Microbiology  
Carolinas Pathology Group

Dr. Sautter provided a summary of the December 2013 CDC OID BSC meeting. The meeting included reports from the OID and the three infectious disease National Centers; updates focused on the CDC furlough, antibiotic resistance, and vaccination. The meeting also included reports from the Influenza Coordination Unit, Center for Global Health, BSC Food Safety Modernization Act Surveillance Working Group, the Antimicrobial Resistance Working Group, and the new Infectious Disease Laboratory Working Group. He briefly related several topics important to public health and private health laboratories including state level immunization program changes, the new interagency global health security initiative, polio eradication, and CDC school-based surveillance systems and sexually transmitted disease programs.

## **Advanced Molecular Detection**

*Addendum 07*

### **Duncan MacCannell, PhD**

*Addendum 07a*

Senior Advisor  
Office of Infectious Diseases (OID)  
National Center for Emerging & Zoonotic Infectious Diseases (NCEZID)  
Centers for Disease Control and Prevention

Dr. MacCannell provided the Committee with an update on CDC's Advanced Molecular Detection (AMD) and Response to Infectious Disease Outbreaks initiative. He provided a review of the rapidly growing area of molecular sequencing technology which delivers a greater level of detailed information on infectious pathogens while reducing reliance on more time consuming and costly traditional methods. He emphasized that obtaining a bioinformatics workforce capable of analyzing and interpreting the data is a barrier to meeting the demands of public health and clinical care. Dr. MacCannell reviewed the five goals of the AMD initiative and the strategic investments needed to achieve the goals.

## **Questions for Dr. MacCannell**

- A member asked if the funding for the AMD initiative was granted. Dr. MacCannell responded that the funding was included in the fiscal year 2014 budget.
- Another member wondered if the AMD initiative should focus on the acceleration of research efforts to develop culture independent methods for drug resistance testing. Dr. MacCannell responded that obtaining pure isolates by culture remains an important part of the sample preparation process for sequencing techniques. He noted approaches such as selective enrichment for certain pathogen groups and "clutter

mitigation” to remove human DNA and unwanted organisms before sequencing can aid in detection of drug resistance using culture independent methodologies.

- A member asked Dr. MacCannell to compare and contrast the respective roles of next-generation sequencing (NGS) with mass spectrometry. Dr. MacCannell replied that there are FDA-cleared mass spectrometry platforms for bacterial strain identification, such as matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) platforms. Identification is determined by matching protein profiles of sample organisms generated via MALDI-TOF mass spectrometry to profiles contained in the companies’ proprietary databases. He added there are gaps in the proprietary databases and that CDC laboratories are participating in the effort to bolster these databases with the goal of achieving accurate microbial identification. In comparison, whole genome sequencing is more open-ended and requires a different level of technical complexity involving large data sets, many of which have not been standardized. For whole genome sequencing to become standardized, many of the individual processes would need to be standardized such as the reference sequences, mapping approaches, sequence editing process, and the process used to determine phylogeny. He noted that some platforms are exploring the use of mass spectrometry to identify antimicrobial resistance, and added that best practices for bioinformatics’ approaches need to be developed.
- Dr. Gutierrez inquired if reliable databases for NGS will be developed for laboratories to access. Dr. MacCannell responded that many of the AMD projects promote a commitment to data management and data release with the goal to add to public repositories for use by all laboratories. He referenced MicrobeNet™, which is an internal CDC effort to create a highly curated and searchable reference database that includes standardized isolate data based on phenotypic characteristics, single genes, or even whole genomes. Dr. MacCannell added that CDC has very good reference collections and that disseminating those collections to laboratories will benefit public health, clinical care, diagnostic development, and academic research. Training is also an important piece and the AMD initiative will support curriculum development and webinars in genomics and bioinformatics applications.
- Dr. Gutierrez asked if the AMD initiative would focus on any non-infectious disease areas and Dr. MacCannell responded that currently the AMD initiative is focused on infectious disease.
- A member commented that NGS technology is used for tumor variant and mutation identification in addition to organism identification. The sample preparation and sequencing process are common between both applications, and they diverge in how the data are analyzed and what databases are used for comparison. The member suggested that CDC and the National Cancer Institute (NCI) collaborate to develop database standards for both applications. Dr. MacCannell agreed and added that CDC has an interagency agreement with NCI to address high performance computing and better understand the NCI best practices around system architecture. Dr. MacCannell noted that there is also a collaborative effort between CDC, FDA, the United States Department of Agriculture (USDA), and the National Center for Biotechnology Information (NCBI) on a listeria surveillance initiative. NCBI determines many of the data management standards on microbial genomics since they maintain GenBank, an open access sequence database. Dr. MacCannell emphasized that partnerships are

essential for implementation of NGS technologies across the entire public health system.

- A Committee member commented on the importance of the partnership between the AMD initiative and antibiotic stewardship programs designed to ensure that hospitalized patients receive the right antibiotic, at the right dose, at the right time, and for the right duration. Dr. MacCannell agreed and added that the sequencing technologies provide a genotypic result that may be used to determine a resistance profile, but a functional assay is needed to confirm the phenotype when performing antimicrobial resistance testing.

### **Committee Discussion**

*Addendum 08*

The Acting Chair introduced the four discussion questions related to CDC's strategic priority to strengthen public health-healthcare collaboration.

1. In addition to the examples given in the presentations by Dr. Sautter and Dr. MacCannell, what other examples of collaboration between public health/healthcare are you aware of or can you anticipate with respect to laboratory testing?
  2. What barriers exist that prevent collaboration?
  3. How can the collaborative relationships that exist between these critical laboratory partners be strengthened?
  4. Are there other approaches to consider for strengthening existing public health/healthcare relationships or creating new ones?
- A Committee member commented that the clinical laboratory relies on public health to provide the best information about treatment and changes in antimicrobial resistance.
  - One member commented that clinical laboratories have benefited from collaborating with local public health laboratories through grants that have allowed the clinical laboratories to purchase equipment. For example, through a public health real time disease surveillance program, one laboratory was able to purchase the Luminex<sup>®</sup> technology for detection of multiple respiratory viruses. The most challenging aspect of the collaboration involved the exchange of test data between the clinical and public health laboratories.
  - Another Committee member commented that many clinical laboratories are not culturing for agents of sexually transmitted infections, instead they are collaborating with the public health laboratories that provide culture and susceptibility testing.
  - The Acting Chair noted that interoperability between clinical and public health laboratory information systems is a long-standing issue and becoming more prevalent in the era of electronic health records (EHRs), and that collaboration surrounding EHRs is an important part of the surveillance and informatics work within CSELS.
  - A member stated that CDC is built around collaboration; not only responses to disease outbreaks, but also other efforts such as the GeT-RM project for creating reference materials, quality control measures, and proficiency testing for genetic testing. There is also NCBI's collaborative effort with laboratories across the country to develop curated databases that allow the interpretation of data generated by NGS. These types of efforts are going to be extremely important long term and require

government sponsorship to successfully handle and sustain the enormous amounts of data.

- Another member noted the New Mexico public health department collects private laboratory testing data. However, physicians are not aware of this database. Furthermore, it is difficult to access and extract information from it. These problems act as barriers to collaboration.
- A member noted that standardized testing across laboratories is important. The member provided the example of a patient who was referred to their facility. The data provided by the original testing laboratory was from a test method other than a conventional urine culture and susceptibility testing, which resulted in inaccurate results. Another member commented that a barrier to EHR implementation is nonstandardized test nomenclature.
- A member commented that the recent travel restrictions placed on government employees poses an enormous barrier in terms of the ability of the private and professional community to interact with professional colleagues in government agencies. The member added it is extremely important for people who work in government agencies to be able to go to professional meetings and collaborate with peers. The Acting Chair responded that the government may need to move to virtual meetings and alternative methods of communication.
- Two members commented on the role that manufacturers play in developing databases, which may be proprietary. They suggested the government should encourage collaboration between manufacturers (both manufacturers of test systems and informatics vendors) and public health/healthcare.
- Another member said minimum standards for databases need to be developed.
- A member noted that the data storage process is not as crucial as the tools needed to access the information. The member suggested that database platforms can change as technology evolves, but having fixed standards to submit and query the database encourages collaboration. He also noted that maintaining databases over the long-term will require funding that may need to be provided by the government.
- On the topic of strengthening the existing public health-healthcare relationships, one member commented that data exchange and extraction with a centralized resource was valuable. Other members suggested collaboration with professional organizations such as College of American Pathologists (CAP) or involvement of payers. Another member noted that in academic medicine and health professional education there are strides for inter-professional education, but the laboratory is not involved. The relationships between providers and laboratorians need to be strengthened.
- A member noted that the issue of laboratory test overutilization has been addressed multiple times. The member suggested displaying test costs and recent test orders in the EHR may reduce unnecessary testing. In addition, the creation of a healthcare-public health partnership to disseminate best practices on laboratory test overutilization may be helpful. Another member agreed, citing that tracking of *C. difficile* testing has been added to their EHR to prevent excessive test ordering.
- A member suggested using social media to promote public awareness of issues that may be of interest to public health and clinical care.

## **CDC Laboratory Training Program**

*Addendum 9*

### **Ritchard Parry, MS**

Chief, Laboratory Training Branch

Division of Laboratory Programs, Standards, and Services (DLPSS)

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

Office of Public Health Scientific Services (OPHSS)

Centers for Disease Control and Prevention

Mr. Parry began by presenting statistics related to adult training. He stated that only 30% of what adults learn in a training program is retained, thus the need for references, job aids, and other educational materials. He explained the mission of the Laboratory Training Branch (LTB), its training topics, and collaborative partnerships, highlighting CDC's collaboration with the Association of Public Health Laboratories (APHL) to create the National Laboratory Training Network (NLTN). Mr. Parry explained the five phases of the Analysis, Design, Development, Implementation, and Evaluation (ADDIE) instructional design model used by LTB to create training materials and emphasized the importance of the evaluation process in determining the effectiveness of training and identifying needs for improvement. He shared that the LTB has trained nearly 9,000 individuals and nearly 60% of those have made changes to their laboratory policies or practices as a result of attending a training course. Mr. Parry discussed barriers to meeting laboratory training needs and said training must embrace the advances in communications technology to overcome some of the barriers. He described new training concepts and curricula being developed by the LTB at the basic, intermediate, and advanced levels. He shared one of the existing training videos on basic microscopy and its accompanying job aids, highlighted new courses in development, and described how the barriers to training are being addressed. Finally, Mr. Parry noted that the elimination of barriers via technology has allowed more laboratories to provide training for their staff.

### **Questions for Mr. Parry**

- A member asked who the intended audience is for the LTB's training programs. Mr. Parry explained that the current training programs are focused towards technical laboratory staff or bench scientists. He noted that training programs for managers are offered by other parts of CDC and that APHL offers leadership training for supervisors and managers. However, he added that curricula being developed in areas such as bioinformatics and quality management may target other laboratory personnel. However, these trainings will still be focused on reaching technical staff and not management personnel. The member commented there did not seem to be any training programs for administrators. Mr. Parry indicated that he would make note of that concern.
- A member expressed a need for basic training courses for testing personnel who have had no formal laboratory training, for instance, those performing waived testing. Mr. Parry acknowledged the need for such training. He noted that the LTB works with subject matter experts (SMEs) within CDC and at the public health laboratories and would be interested in recruiting SMEs from clinical laboratories to help with the development of course content and the review of courses.

- A member noted there is value in face-to-face training and asked if the LTB planned to partner with local organizations to provide this type of training. Mr. Parry acknowledged the need for face-to-face training; however, budget cuts and restraints make it more difficult for laboratories to participate in on-site trainings. He noted that face-to-face training is conducted when feasible.

### **APHL CLIA Training Projects**

*Addendum 10*

**Karen Breckenridge, MBA, MT (ASCP)**

Director of Quality Systems

Association of Public Health Laboratories (APHL)

Ms. Breckenridge began with an overview of the APHL CLIA training projects made possible through a CDC /APHL cooperative agreement. The cooperative agreement provides funding to public health laboratories to allow development of training centered on CLIA requirements or quality management systems (QMS). She reviewed the training topics and noted there had been three rounds of project proposals totaling 21 awards to date. She provided an overview of the various projects including the awardee demographics, topics, and public health laboratory partners who also participated in the projects. She discussed how the impact of training was measured and shared some of the participant comments and feedback from state surveyors. Ms. Breckenridge closed with a brief overview of the forthcoming round four of the cooperative agreement, and encouraged anyone who would like to partner with a public health laboratory to contact the laboratory or APHL.

### **Questions for Ms. Breckenridge**

- A member commented that one should prepare for an inspection by concentrating on being compliant to the quality system requirements and suggested that as the future focus of the trainings.

### **Committee Discussion**

*Addendum 11*

The Acting Chair introduced the four discussion questions related to the training presentations presented by Mr. Parry and Ms. Breckenridge.

1. How could the training described in these presentations be useful to your or other laboratory or practice setting? Have you or your staff previously participated in any of these training sessions? If not, why not?
  2. What types of training products are most likely to be helpful in your laboratory or other settings with which you're familiar?
  3. How could training be provided that would facilitate strengthening public health/healthcare collaborations?
  4. What additional topics should be considered for future laboratory training?
- A member commented that each year the Alabama State Public Health Laboratory receives funding from CDC to provide bioterrorism training. The member stated that the trainings have increased staff knowledge and have been very helpful.

- Another member responded that the training discussed in the presentations would be helpful. However, for their laboratory, antimicrobial susceptibility testing (AST) training would be more useful. Dr. Howerton added that there is a new AST online training course available.  
([http://www.cdc.gov/osels/lspppo/Laboratory\\_Training/master/MASTER\\_audio/intro/open.swf](http://www.cdc.gov/osels/lspppo/Laboratory_Training/master/MASTER_audio/intro/open.swf)) Additional modules will be added over time.
- A member commented on the design and flexibility of CAP's training courses and expressed a desire to have the same capacities built into all training websites. Desirable features include the ability to create groups, assign training courses to groups or individuals, track progress, and add courses to those that already exist.
- Another member commented that utilizing advanced technology that allows better communication with the student as part of the training is very valuable.
- A member noted monetary incentives, such as decreases to the CLIA certificate fees paid by small physician office practices, could increase the probability that laboratories will participate in training.
- A member inquired if continuing education credit was available for the training courses presented by Mr. Parry and Ms. Breckenridge. The member noted that offering continuing education credit is a good incentive to get participation as it allows participants to meet requirements for other certifications and accreditations. Mr. Parry commented that a high percentage of both the CDC and APHL training courses offer continuing education credit. Ms. Breckenridge stated that most of the APHL waived testing courses could offer continuing education credits. Dr. Howerton clarified that the CDC *Ready? Set? Test?* online training module offers Continuing Medical Education (CME) and other types of continuing education credits.
- A member stated that engaging physicians' interest by offering CMEs would be a good idea. The member stated that the American Board of Internal Medicine (ABIM) now requires physicians to maintain their certifications requiring them to consistently earn credits. The member suggested that a good resource would be the ABIM.
- A member expressed concern that the LTB quality management training wouldn't be developed until 2016. The member asked Mr. Parry about the possibility of collaborating with other programs in order to work around budget constraints involved in developing training courses. Mr. Parry explained that although additional funding is being explored, there is also a need for additional staff to help develop the training materials. Collaborations are being explored.
- A member suggested that training courses on public health reporting and how to handle public health situations of concern could promote collaborations.
- A member commented that teleconferences, sending out materials, and e-learning are effective ways to deliver training to laboratories. However, they have found the most effective way to build collaborations in their state has been face-to-face meetings.
- A member mentioned the need to train laboratory personnel how to use electronic health records in order to have access and review basic information from the patient medical records. Another member suggested training on validation and verification of new tests, and how to perform both processes. A third member commented there is a trend to move away from long text-based procedure manuals to more streamlined modules and suggested providing training courses on drafting this new style of procedure manual. Training courses on all of these topics would be beneficial.

- Dr. Wilcke recognized the challenges in addressing the training needs of the laboratory community. He expressed concern that there is no requirement for continuing education to maintain laboratory personnel credentialing and identified the lack of this requirement as a hindrance to pursuing training. Without a credentialing requirement, the decision to take training is left up to the desire and willingness of the individual.

### **aLOINC Order Code S&I Framework Initiative**

*Addendum 12*

**Nancy Cornish, MD**

Medical Officer

Laboratory Research and Evaluation Branch (LREB)

Division of Laboratory Programs, Standards, and Services (DLPSS)

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

Office of Public Health Scientific Services (OPHSS)

Centers for Disease Control and Prevention

Dr. Cornish began the presentation by discussing the background of LOINC<sup>®</sup> (Logical Observation Identifiers Names and Codes) as the preferred computer terminology for laboratory test names. She explained that the ability to receive electronic messages using LOINC<sup>®</sup> is required for electronic health records to achieve the objectives of the CMS incentive program referred to as Meaningful Use (MU). She also stated the widespread usage of non-standardized local codes among clinical laboratories across the United States is a significant challenge to interoperability of laboratory data in health information exchange. Dr. Cornish discussed the need to provide standardized terminology for laboratory test names so that computers can “talk” to each other across multiple organizations and platforms without loss of the intended meaning of information being conveyed. She noted several benefits for standardizing laboratory codes, including improved access and ability to compare laboratory test results across the continuum of care, a reduction in the need to repeat laboratory tests, improvements in quality and timeliness of laboratory results and interpretations, and improved local and national surveillance capabilities. Dr. Cornish described the relationship between LOINC<sup>®</sup> and the National Library of Medicine (NLM). She also gave a brief description of the Health Level 7<sup>®</sup> (HL7) code, Office of the National Coordinator for Health Information Technology (ONC), and its current relationship to LOINC<sup>®</sup> through the Standards and Interoperability (S&I) Framework and CDC. She discussed CDC’s involvement in both the S&I Framework’s “aLOINC” initiative to develop a list of the most frequently ordered laboratory tests and corresponding LOINC<sup>®</sup> codes in an ambulatory care setting and an intra-agency workgroup to develop a public health test list of LOINC<sup>®</sup> codes for tests that result in notifiable conditions. Dr. Cornish concluded the presentation by outlining a planned approach and timeline for the intra-agency workgroup activities and identifying potential stakeholders.

## **Committee Discussion**

## ***Addendum 13***

- A member inquired about mapping efforts between Current Procedural Terminology (CPT) codes, Health Insurance Portability and Accountability Act (HIPAA) designated codes and LOINC<sup>®</sup> codes. Dr. Cornish replied there have been attempts to map CPT codes to LOINC<sup>®</sup> codes, but it is not a one-to-one mapping. Another member agreed noting that many LOINC<sup>®</sup> codes map to a single CPT code. Dr. Cornish added there has been discussion on how to decrease the number of different code lists and how to make the process simpler for future coding.
- Another member commented that the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) codes and LOINC<sup>®</sup> codes should be linked. Dr. Cornish replied that personnel from the NLM and Regenstrief Institute for Health Care are working on this endeavor.
- A member asked if there were any regulations or policies, such as MU, that would require laboratories to use LOINC<sup>®</sup> codes. Dr. Cornish responded that achieving MU requires the use of LOINC<sup>®</sup> result codes, although it is being implemented in phases and currently only 30% of test results must be LOINC<sup>®</sup> coded. This percentage will go up as the years go on. She added that some reference laboratories have fully adopted LOINC<sup>®</sup> coding.
- A member asked about the relationship of LOINC<sup>®</sup> coding to patients seeking access to their test results. Will the patients be able to interpret the LOINC<sup>®</sup> codes? Dr. Cornish replied that patients would only be able to see the common name of the test and would not be viewing LOINC<sup>®</sup> codes. She added that in order to have all of a patient's health information in one electronic health record, computers must be able to communicate with each other. Since LOINC<sup>®</sup> is a computer language, having standardized codes facilitates that communication. Another member agreed that LOINC<sup>®</sup> codes are needed for implementation of EHRs in order to assure correct test data for a patient.
- A member commented that patients probably would not want to know the historical values of their test results beyond a few years and wondered how long results needed to be saved in an EHR.
- A member commented that sharing health care information is extremely important and is especially necessary for disease surveillance.
- A member emphasized the need for LOINC<sup>®</sup> codes for waived tests since they are a part of the electronic medical record. Dr. Cornish agreed and said it was a project for the future.
- Dr. Subbarao expressed the concern that waived tests are not captured in EHRs. Also, how are waived tests differentiated from non-waived tests with LOINC<sup>®</sup> coding? Dr. Cornish replied that future plans include having a unique identification code for every test kit and every instrument. She also confirmed that changing the complexity of a test would also change the LOINC<sup>®</sup> code.
- Another member agreed on the need for unique LOINC<sup>®</sup> codes for waived tests so that LOINC<sup>®</sup> coding would be able to differentiate test results for the same test performed by a non-waived laboratory instrument versus a simple waived test performed in a physician's office.

- A member asked if LOINC<sup>®</sup> coding is linked to methodology then why limit this project to ambulatory settings. Dr. Cornish replied that the goal is to, eventually, have all tests LOINC<sup>®</sup> coded.
- A member asked if there was an ongoing effort to standardize the test names associated with LOINC<sup>®</sup> codes. It is difficult for laboratories to know which LOINC<sup>®</sup> code to use because the codes are very specific to the test method, analyte, specimen type, and unit of measurement. Dr. Cornish agreed that test names should be standardized. Another member suggested that a by-product of the LOINC<sup>®</sup> order code initiative should be a naming convention document.
- A member asked how decisions are made regarding how granular to make LOINC<sup>®</sup> codes in terms of test methodologies. Dr. Cornish replied that those decisions are made by the consensus of LOINC<sup>®</sup> experts. Another member added this decision is based upon tests having the same units of measurement and the same method. Because of this there is a need for the test list of LOINC<sup>®</sup> codes for common laboratory tests.
- Dr. Gutierrez commented that with the publishing of the FDA rule on the unique device identifier, there will be a way to link LOINC<sup>®</sup> codes to individual test devices.
- Another member wondered if it was possible to use the World Health Organization (WHO) classification system as an example of how to name tests noting this would result in international agreement of test names. Dr. Cornish replied that the goal is to standardize naming.
- A member stated manufacturers of point-of-care devices need to assist with the creation of software to capture testing information for electronic medical records. Dr. Cornish agreed and said that vendors are a crucial part of the multi-disciplinary team working on the development of the LOINC<sup>®</sup> codes.
- The AdvaMed liaison commented that most vendors are creating a bundling software network that allows for information from different vendors with the same type of devices to be shared within a cloud network.
- The Chair commented that a toolkit or training to help laboratories implement LOINC<sup>®</sup> coding seems to be needed.

## **Quality Improvement Tools for Managing Laboratory Testing in Ambulatory Settings**

### **Laboratory Quality Improvement – Projects and Toolkits (Introduction)**

*Addendum 14*

#### **Barbara Zehnbauer, PhD FACMG FACB**

Chief, Laboratory Research and Evaluation Branch (LREB)

Division of Laboratory Programs, Standards, and Services (DLPSS)

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

Office of Public Health Scientific Services (OPHSS)

Centers for Disease Control and Prevention

Dr. Zehnbauer introduced the speakers for the next session, Dr. Eder and Dr. West, who spoke on quality improvement tools for managing laboratory testing in ambulatory

settings. She presented the Committee with four questions to consider and discuss following the presentations:

1. How can these tools for measurement of quality improvement in physician office laboratories be broadly disseminated and implemented to educate personnel?
2. How can the impact of the tools be evaluated?
3. What additional tools are available or should be developed?
4. Which professional laboratory or healthcare organizations could collaborate with HHS to reach these laboratories or testing sites?

### **Risk Assessment of the Testing Processes**

**Milton Eder, PhD**

Director of Research and Evaluation  
Access Community Health Network

*Addendum 15*  
*Addendum 15a*

Dr. Eder began by providing background on the organization of practice-based research projects and teams. He presented a model of the testing process used in primary care which had been the basis of his research to assess the roles of clinicians and staff and determine where in the process errors are likely to occur. Dr. Eder next presented the findings of an audit of over 2,000 tests at ten sites, which revealed numerous errors including issues with documentation of results and patient follow-up when test results were abnormal. The audit findings indicated the need for simple tools to help physician offices improve how they manage the testing process. Dr. Eder provided an overview of the toolkit: *Starting the Improvement Process in Your Office* (<http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/office-testing-toolkit/officetesting-toolkit3.html>) that can assist primary care practice professionals in their efforts to develop performance/quality communication indicators for clinically important gaps in pre-and post-analytic laboratory medicine. He indicated that the toolkit provides concise, actionable information and recommendations on improvement of the testing process and includes tools, guiding questions, examples, and links to other resources. In conclusion, Dr. Eder noted study limitations including the inability to determine efficacy and effectiveness of the toolkit.

### **Primary Care Laboratory Communication Performance Metrics**

**David West, PhD**

Director, University of Colorado Health Outcomes Program (COHO)  
Associate Chair for Departmental Affairs for the Department of Medicine  
University of Colorado

*Addendum 16*  
*Addendum 16a*

Dr. West presented an update on the Primary Care Laboratory Communication Performance Metrics project supported by the CDC and administered by the State Network of Colorado Ambulatory Practices & Partners (SNOCAP), an affiliation of Practice Based Research Networks affiliated with the University of Colorado in Denver. He described the three phases of the project, which were a literature review, practice survey, and toolkit design. He reported that the key findings from the survey indicated

significant issues and concerns centered around laboratory test tracking and patient notification procedures and the need to identify roles and develop standard operating procedures throughout the pre- and post-analytic laboratory processes. He discussed the development of the toolkit and reviewed the results generated from the toolkit use. Dr. West concluded by proposing a collaborative effort to develop Maintenance of Certification (MOC) programs and certification materials for board certified physicians and capitalizing on CMS incentives for MU modules to allow an opportunity to earn a monetary benefit.

### **Questions for Dr. Eder and Dr. West**

- Noting the differences in accreditation guidelines, a member asked Dr. West if his survey included COLA or CAP accredited physician office laboratories. Dr. West replied that the survey was provided to a range of primary care practices including sites with no laboratory capacity, hospital laboratories, commercial laboratories, and practices that use multiple laboratories based on the patient's form of insurance. Dr. West and Dr. Eder added that the sample size for each primary care practice type was not large enough to analyze each type of arrangement independently.
- A Committee member asked if future laboratory orders, such as cases when the patient needs to return at a later date for additional laboratory work, were addressed in the survey. Dr. Eder replied that their facility does not typically allow future laboratory order requests due to the challenges that result if a test is not directly ordered on the day the patient sees the physician.
- Another member commented that some systems allow the laboratory test order submitters to select the type of reports they want to receive, such as preliminary or final results. He added that when multiple test results for the same patient are reported at different times, it is a challenge for an outpatient office to determine if the physician review should be performed on the preliminary or final results.
- Several members commented on test results with critical values, including how "critical values" are defined. One member asked if the surveys' data included any critical value calls where the patient was not notified or where the physician was unable to be reached. Dr. Eder did not have specific data, but commented that often physicians were frustrated due to the inability to contact patients with critical results. He suggested an important part of quality improvement should be explaining to the patient the importance of the requested laboratory tests and when the test results should be expected. Another member agreed that patient follow-up is an issue with family physicians.
- Dr. West commented that the SNOCAP survey identified a number of instances where medical practices did not agree with what should be considered a critical value and would often ignore result alerts from the laboratories. A member suggested more standardization of critical values to develop a consensus.
- A Committee member commented that an investigation of imaging tests where the radiologist would call the ordering physician directly to convey critical value test results had very few cases of loss of follow-up, which is not the case in the laboratory setting where it is often difficult for the laboratory to contact the ordering physician. The member added that because the ordering physician is identified on the laboratory order entry, the EHR can assist in determining the correct contact for critical value

results. The member suggested that a model of escalation is needed to determine who to contact if the ordering physician cannot be reached.

- A member commented that administrative support is needed to implement the practices and agreed that linking management of testing processes to MOC and MU is needed for laboratory tracking and patient notification improvement. Dr. West agreed and suggested capitalizing on opportunities across a combination of incentives such as MU, MOC, and possibly discounts on insurance premiums. Dr. Eder added that the organizations often manage MU and MOC and impact may not reach the physician level.

### **Committee Discussion**

### ***Addendum 17***

The Acting Chair presented the Committee with four questions to consider.

1. How can these tools for measurement of quality improvement in physician office laboratories be broadly disseminated and implemented to educate personnel?
  2. How can the impact of the tools be evaluated?
  3. What additional tools are available or should be developed?
  4. Which professional laboratory or healthcare organizations could collaborate with HHS to reach these laboratories or testing sites?
- A member commented that the toolkits presented are directed towards physician office laboratories (POLs) where testing is performed in the office or referred to an outside testing site. He noted that accreditation agencies certify many POLs and suggested working with the accreditation organizations to design tools to investigate turnaround times, from identification of critical values to reporting the results to the ordering physician. These tools could then be incorporated into required laboratory inspections. Ms. Yost added that CMS already works with the CLIA-approved accrediting organizations to provide oversight and improve testing in POLs.
  - One member commented that in rural areas single physician practices are prevalent and may require additional assistance to implement the toolkits. Dr. West replied that small offices will need assistance and may be encouraged to use the toolkits by the combination of the opportunity to earn an incentive, avoid a penalty, and achieve certification or accreditation.
  - A member commented on the lack of training of residents in the laboratory discipline. The member suggested that the tools should be provided to family and internal medicine residency programs, to illustrate their importance and encourage incorporation by programs thereby allowing residents to acquire more laboratory experience. Another Committee member commented on their involvement in medical residency programs and the movement towards the patient centered medical home model in residency training.
  - Dr. Eder commented that the medical home model of primary care has become a widely accepted model for how primary care should be organized and delivered throughout the health care system. The medical home encompasses five functions and attributes: comprehensive care, patient-centered, coordinated care, assessable services, quality and safety. He explained that the demands of this model are significant when coordinating with specialists in a patient-centered manner and training is needed to accomplish this collaborative environment. Much of laboratory

testing is structured around physician office mentalities while in the patient centered medical home model the patients' perspective must be addressed. He suggested using MU to encourage patient centeredness and patient engagement with measures that can be evaluated including health outcomes from a patient perspective and financial outcomes from a system perspective.

- A member commented that the focus is often on critical test results, but sub-critical results should also be measured and standardized on a national level and should be a focus from the patient safety perspective.
- In response to the Acting Chair's question as to whether there are potential measures of impact and value from using the toolkits, Dr. West commented that incorporating the critical value concept into the process and outcome indicators and tracking those indicators combined with the ability to provide a process evaluation method that meets MU would be beneficial. He suggested the development of MOC and MU modules to perform a large-scale, multi-state, multi-site, pragmatic comparative effectiveness trial.
- Dr. Eder stated that as an assessment of an organization's system for delivering safe, quality health care, the Joint Commission's on-site survey process includes tracer methodology which is an evaluation method in which surveyors select a patient, resident, or client and use that individual's record as a roadmap to move through an organization to assess and evaluate the organization's compliance with selected standards and the organization's systems of providing care and services. He explained that surveyors retrace the specific care processes that an individual experienced by observing and interviewing staff in the areas where the individual received care to assess the health care organization's compliance with Joint Commission standards.
- Another member inquired about investigation of measured outcomes such as life-threatening critical values and hospital admissions to determine if there is a demonstrable effect on improvement based upon implementation of the processes on those types of patient health measures. Dr. West replied that looking at hospital readmissions and tracking to dysfunctional transitions that include the lack of laboratory information would be very insightful.
- A member provided suggestions for additional tools such as the *SAFER Guides* promoted by the Office of the National Coordinator for Health Information Technology dedicated to test results reporting and follow-up ([http://www.healthit.gov/safer/sites/safer/files/guides/safer\\_testresultsreporting\\_sg008\\_form.pdf](http://www.healthit.gov/safer/sites/safer/files/guides/safer_testresultsreporting_sg008_form.pdf)). The member also suggested performing a self-assessment to determine how to use the EHR as a system to improve test result management. The member stated that working with the Medical Group Management Association (MGMA) Physician Practice Patient Safety Assessment (PPPSA) is important for two reasons; the first is access to other non-primary care physicians' offices since specialists order many tests and often the primary care physicians need to follow-up on the tests the specialists order; and the second involves relieving some of the burden of the primary care physicians on the front lines by making it more suitable for the office managers to assist. Another member commented that as more sophisticated EHRs become available, there needs to be order entry and test tracking systems available.
- Dr. Eder added that smaller organizations are not in a position to develop the kinds of management tools and functions for EHRs that would allow them to share

information with the local hospital and laboratory. He encouraged the EHR industry to recognize the value of these kinds of activities as a patient safety tool.

- The Acting Chair noted that the Committee had suggested COLA, ABIM, and the MGMA as professional laboratory or healthcare organizations that could collaborate with either HHS or others to raise awareness of the available tools.
- A member suggested collaboration with the American Association for Clinical Chemistry (AACC) that is active in physician office testing and the American Society of Microbiology (ASM) that is working with physician offices performing microbiology testing.

### **Future CLIAC Topics Discussion**

### ***Addendum 18***

The Acting Chair opened the discussion on future CLIAC topics.

- Two members suggested addressing the issue of pharmacies that perform testing to assure they have standard procedures for testing and interpretation. Ms. Yost clarified that any site that performs laboratory testing must have the appropriate CLIA certificate. Sites that perform waived testing are only required to obtain a Certificate of Waiver (CW) and follow the manufacturers' instructions for test performance. The CLIA law precludes routine surveys of CW sites. Another member commented that waived testing is a growing issue that CLIAC should address.
- Dr. Wilcke commented on the increasing number of waived tests, not only the number of tests but the number of times they are performed. He suggested a white paper be written examining how well waived tests are being performed and whether the money spent on waived testing is improving population health.
- Another member added that when the CLIA law was enacted there were fewer waived tests than there are now and the methodologies available for waived testing were not as advanced. The member requested that CLIAC continue to advocate for changes to the CLIA law, such as an initial CW site visit subsequent to the application process, followed by inspections every five years.
- A member commented that the major drivers of laboratory test overutilization are availability of prior testing results, procedure reimbursement, and physicians' fear of litigation. There are a number of guidelines available that recommend what testing should be done, but few inform the health care provider what testing is potentially unnecessary or should not be done. The member suggested such guidelines be developed. An additional comment was expressed that although many organizations develop guidelines, the recommendations often differ significantly. Standardizing the guidelines developed by the different professional organizations would be an interesting topic.
- A third member noted that laboratory test underutilization resulting from a lack of reimbursement for emerging technologies may be another topic for future CLIAC consideration.
- A member suggested CLIAC discuss applying *SAFER Guides* to address laboratory health information technology safety, specifically EHR interface challenges between users and laboratories.

- Last, a member reiterated his earlier request that CLIAC discuss pre-analytic variables, noting that approximately 70 percent of laboratory errors occur during the pre-analytic phase of testing.

The Acting Chair summarized the meeting discussion highlights:

- Discussion around the public health-healthcare collaboration topic included:
  - Continuing to look at the issues encompassing culture independent diagnostics and the concerns from the public health community regarding the ever-increasing elimination of culture and isolates needed for surveillance
  - Finding alternatives to laboratory-based surveillance which could replace culture needs while maintaining the capability to track antimicrobial resistance and type outbreaks
  - Improving the comprehension and usability of laboratory test data by patients
  - Using alerts and other features to help guide physicians to improve test utilization and results interpretation
  - The need for standardization around the use of sequencing databases, big data and genetic testing data; and using cloud technology or middleware to develop repositories to help connect public health, clinical laboratories and the CDC
  - Training
    - Suggestions were made to list CDC courses with the ABIM, provide continuing education units for different professional categories, conduct more regional conferences or training events, and explore and maximize the use of new technologies in training delivery
    - Future potential training topics included issues surrounding patient safety, public health reporting, EHR training for laboratory professionals, validation and verification of test systems, and incorporating flow charting or other uncomplicated methods of documentation into laboratory procedures
  - aLOINC project updates and issues
    - Need to determine ownership and who is responsible for providing incentives to drive uptake of standardized test names and LOINC<sup>®</sup> codes
    - Training and toolkits are needed for the laboratories to understand LOINC<sup>®</sup> codes and how to use them
    - There is a need for two-way communication and collaboration between the clinical laboratories and public health on information that is required for public health reporting
- Discussion concerning quality improvement and process management in physician offices or sites performing in-house testing as well as referring testing to external laboratories included:
  - Members suggested that physician offices or other laboratories could be incentivized through MU, MOC programs and organizational drivers
  - There was considerable exchange of ideas concerning patient safety and the necessity for partnerships with professional organizations like MGMA, ABIM, and others. The patient centered medical home model was also discussed.

**PUBLIC COMMENTS - *None Submitted***

**ACRONYMS**

*Addendum 19*

**Useful Links for CLIAC**

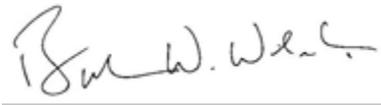
*Addendum 20*

**ADJOURN**

Dr. Wilcke acknowledged the staff that assembled the meeting program and thanked the CLIAC members and partner agencies for their support and participation.

Dr. Wilcke announced the Fall 2014 CLIAC meeting dates as November 5-6, 2014, and adjourned the Committee meeting.

I certify this summary report of the March 5-6, 2014, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.



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Burton Wilcke, Jr., Ph.D., CLIAC Chair

Dated: 6/ 8 /2014