Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

August 21-22, 2013

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
August 21-22, 2013, Summary Report

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RECORD OF ATTENDANCE

Committee Members Present
Dr. Burton Wilcke Jr., Chair
Mr. Eugene Augustine Jr.
Dr. Robert Baldor
Dr. Edward Chan
Dr. Martha Crenshaw
Dr. Anand Dighe
Dr. Keith Kaplan
Dr. Roger Klein
Ms. Lezlee Koch
Ms. Karen Lacy
Dr. Elizabeth Marlowe
Dr. Anthony Okorodudu
Dr. John Sinard
Ms. Paula Vagnone
Dr. Linda Ward
Dr. David Wilkinson
Dr. Qian-Yun Zhang

Committee Members Absent
Dr. Richard Press
Dr. Robert Sautter
Dr. Hardeep Singh
Mr. Robert DiTullio, AdvaMed (Liaison Representative)

Ex Officio Members
Dr. Alberto Gutierrez, FDA
Dr. Devery Howerton, CDC
Ms. Judith Yost, CMS (remote)

Designated Federal Official
Dr. May Chu

Executive Secretary
Ms. Nancy Anderson

Record of Attendance – cont'd

Centers for Disease Control and Prevention (CDC)

Mr. Todd Alspach
Dr. J. Rex Astles
Mr. Henry Bishop
Ms. Diane Bosse
Ms. Cathryn Cambria
Dr. Roberta Carey
Dr. Bin Chen
Ms. Laura Conn
Dr. Nancy Cornish
Dr. Maryam Daneshvar
Mr. Steven Ethridge
Dr. Geroncio Fajardo
Ms. Maribeth Gagnon
Dr. Kathleen Gallagher
Dr. Sundak Ganesan
Dr. David Holmes
Dr. Lisa Kalman
Dr. Robert Kobelski
Mr. Austin Kreisler
Ms. Debra Kuehl
Dr. Ira Lubin
Ms. Alana McCoy
Ms. Leslie McDonald
Dr. Janet Nicholson
Ms. Anne Pollock
Dr. Daniel Pollock
Ms. Cathy Ramadei
Dr. Chesley Richards
Dr. John Saindon Jr.
Ms. Megan Sawchuk
Dr. Shahram Shahangian
Ms. Charlene Smith
Ms. Theresia Snelling
Ms. Heather Stang
Ms. Sonya Strider
Dr. Shambavi Subbarao
Ms. Vickie Sullivan
Dr. Julie Taylor
Mr. H. Eric Thompson
Ms. Pamela Thompson
Ms. Monica Toles
Ms. Elizabeth Weirich
Dr. Laurina Williams
Ms. Yasmine Zavahir
Mr. Jonathan Zhong

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

Dr. Aldo Badano (FDA)
Dr. Doug Fridsma (ONC)
Mr. Bailey Mapp (DoD)
Ms. Jessica Reinhardt (DoD)
Ms. Ann Snyder (CMS) (remote)
Ms. Cindy Wilkerson (DoD)

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 to the public via webcast and all CDC and FDA staff on intranet protocol television (IPTV).

CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE (CLIAC) -BACKGROUND

The Secretary of Health and Human Services is authorized under Section 353 of the Public Health Service Act, as amended, to establish standards to assure consistent, accurate, and reliable test results by all clinical laboratories in the United States. The Secretary is authorized under Section 222 to establish advisory Committees.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) was chartered in February 1992 to provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health pertaining to improvement in clinical laboratory quality and laboratory medicine. In addition, the Committee provides advice and guidance on specific questions related to possible revision of the CLIA standards. Examples include providing guidance on studies designed to improve safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods and the electronic submission of laboratory information.

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. May Chu, Designated Federal Official (DFO), Clinical Laboratory Improvement Advisory Committee (CLIAC), and Senior Advisor, 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. She 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). In addition, there would be presentations and discussions on improving laboratory quality in diverse settings; digital pathology; and advancing laboratory interoperability in health IT.

Dr. Wilcke introduced Dr. Chesley Richards, the newly appointed Director for the CDC OPHSS and welcomed him to the CLIAC meeting. Dr. Richards thanked Dr. Wilcke and the Committee for allowing him time to introduce himself and to let CLIAC know that he considers their work very important for the CLIA program and for CDC. He said CDC and OPHSS are committed to advances in information technology, quality standards, laboratory programs, laboratory integration, and many activities that are at the nexus of the issues CLIAC considers. He added that he was a practicing internist before joining public health and as such had ordered laboratory tests, interpreted their results, and used the information for clinical decision making. He noted he had ten years of other relevant experience at CDC in various roles centered on patient safety, healthcare improvement, immunization systems, concepts of healthcare quality, and disease prevention. He also mentioned he had worked directly with the CMS Center for Clinical Standards and Quality and more recently with the CMS information technology innovation program. He said CMS and CDC had worked very collaboratively over the years to advance priorities for both agencies. In conclusion, he noted the CLIA program was one of the first examples of how CDC and CMS had successfully worked together.

Dr. Burton Wilcke, 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.

AGENCY UPDATES AND COMMITTEE DISCUSSION

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

Devery Howerton, PhD
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
Centers for Disease Control and Prevention

Dr. Howerton highlighted the major activities underway within DLPSS (Proposed). She began by reviewing the proposed restructuring of the CDC Office of Surveillance, Epidemiology and Laboratory Services and introducing the Division's new leadership

team. She noted the new CDC CLIA website is now live. She announced that the CDC/Association of Public Health Laboratories (APHL) national survey of proficiency testing (PT) practices was currently in progress. She said the solicitation for a contract to assess cytology workload for laboratories that use one of two FDA-approved image-assisted slide-screening systems closed on August 21. She provided an update on two online trainings developed by the Division: "Good Laboratory Practices for Molecular Genetic Testing" and "Strategies for Improving Rapid Influenza Diagnostic Testing in Ambulatory Settings." Post-test scores and reviews from participants have indicated an increase in their knowledge on these topics after completing the trainings. In addition, she mentioned the Laboratory Medicine Best Practices (LMBP™) team has developed a new online tutorial to assist laboratories in the design of quality improvement studies and she discussed the four current LMBP™ systematic reviews. Dr. Howerton stated this process is also a means to acquire unpublished data and information; therefore, she encouraged individuals and laboratories to submit relevant information to https://www.futurelabmedicine.org/get_involved/data_submission/. Dr. Howerton next said the Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™) has developed new strategic goals to define more effective communication strategies between laboratories and clinicians, improve utilization of clinical laboratory services by integrating electronic tools into the electronic health record (EHR), and enhance collaboration in development of CLIHC™ products. She mentioned the recent genetics publications by Division staff and discussed the collaborative effort to produce the online GeT-RM and Next-Generation Sequencing Virtual Reference Material tool, a government funded tool available to all laboratories. She reviewed a new initiative to evaluate the effectiveness and impact of CDC recommendations and other laboratory guidelines and described three ongoing studies. Dr. Howerton concluded her update by sharing information about the CDC/APHL Informatics Self- Assessment Tool developed to assist state and local public health laboratories in assessing their informatics capabilities and gaps. It is freely available to the public and covers 19 capability areas.

Committee Discussion

- The Chair asked whether the post-tests were taken immediately upon completion of the "Good Laboratory Practice for Molecular Genetics Testing" tutorial. Dr. Howerton explained the post-test assessment had to be taken immediately upon course completion in order to receive course credit.
- The Chair asked if the evaluation of the effectiveness of guidelines and recommendations would include a review of past guidelines. Dr. Howerton responded the evaluation would be focused on a recent *Morbidity and Mortality Weekly Report: Recommendations and Reports* (MMWR R&R) publication on biochemical genetic testing and newborn screening.

Food and Drug Administration (FDA) Update *Addendum 02*

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 update by recapping the Medical Device User Fee Act (MDUFA) III that was implemented in October 2012. He reminded CLIAC of the previous user fee negotiations and discussed the FDA review times and MDUFA performance goals. He noted the appearance of delays in the review process and said that some lag times resulted when companies delayed responding to requests from FDA, causing an increase in the time from submission to review completion. This resulted in a re-evaluation of the submission process. Dr. Gutierrez reported that the agency has now devised a simple one-tier system. FDA publishes quarterly MDUFA status reports and posts them on their website. He pointed out that it is still too early to determine if goals are being met, based on the data. He also said changes to the information technology structure were made so requests and times for completion of those requests could be tracked more effectively. Dr. Gutierrez next reviewed the number of CLIA waivers by application and the number of devices categorized in each CLIA category. He listed recent FDA pre-market approvals, highlighting the increase in companion diagnostics. He described four *de novo* down-classifications and concluded his update with information on newly released guidances and notable panel meetings and workshops.

Committee Discussion

- A member commented there seems to be confusion about the difference between over-the-counter tests and waived tests. The member emphasized the importance of helping those in the field understand the difference and added that on occasion, vendors may give incorrect information to small facilities that purchase their devices. Dr. Gutierrez responded that, by law, tests cleared for over-the-counter (home) use are automatically waived. However, over-the-counter tests designed for single patient use are often less robust than tests categorized by the FDA as waived. Problems can result when devices designed for single patient use are utilized to test multiple patients. He said that the FDA should be notified if manufacturers misrepresent the intended use of their devices.
- Another member inquired about test clearance or approval by the FDA through conducting a literature review. Dr. Gutierrez stated that this option has been communicated to the vendors. Vendors need only show, through extensive literature review, that their instrument can meet the analytical performance requirements for a specific intended use.
- A member asked whether manufacturers have the responsibility of informing the FDA of modifications, including updates to the instructions, to an FDA-categorized test. Could this cause a test to be re-categorized? Dr. Gutierrez responded that manufacturers are responsible for bringing changes to a test to the FDA's attention. Typical relabeling would not result in a need for re-categorization; however, if a

manufacturer has made modifications that change the test's complexity, then the manufacturer should apply for a re-categorization.

Centers for Medicare & Medicaid Services (CMS) Update *Addendum 03*

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 on the future of the proposed patient access rule, PT regulation revision, and PT referral. She said the final patient access rule is currently undergoing HHS clearance with a tentative publication date of October 2013. Once the rule is published, the CLIA guidelines for laboratories and surveyors will be updated. She reviewed the progress of the proposed PT regulations and the PT burden rule. Members were reminded of the Taking Essential Steps for Testing 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. Rulemaking will follow to detail the adverse actions for PT referrals. Ms. Yost provided a brief history of CLIA quality control and discussed the new quality control policy, called the individualized quality control plan (IQCP), which will be incorporated into the CLIA interpretive guidelines for all specialties except cytology and histopathology and will be posted on the CMS CLIA website. She reviewed the current Certificate of Waiver project data and said educational materials like "Ready? Set? Test!" serve as an excellent means of improving the quality of laboratory testing. Last, she provided information on competency assessments and invited those with questions to contact her at the email address provided.

Committee Discussion

A member asked about oversight by CMS of laboratories in the exempt states of New York and Washington. Ms. Yost said the regional offices annually perform validation surveys of a percentage of laboratories in those states. Additionally, CMS collects performance measure data on a regular basis from all the approved accrediting organizations and exempt states.

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

Robert Sautter, Ph.D.
Committee Liaison to CDC Board of Scientific Counselors,
Office of Infectious Diseases (OID)
Director of Microbiology
Carolinas Pathology Group
Charlotte, NC

Dr. Sautter was unable to attend the meeting; however, his presentation is provided.

PRESENTATIONS AND COMMITTEE DISCUSSION

Improving Laboratory Quality in Diverse Settings – Introduction and Background

Devery Howerton, PhD
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
Centers for Disease Control and Prevention

Dr. Howerton introduced the topics for the meeting. First, she said the Committee would hear about improving laboratory quality in diverse settings, including Certificate of Waiver (CW) sites and laboratories performing high complexity testing that are beginning to implement digital pathology. She stated that between 2005 and 2007 CLIAC discussed similar topics focused on the future of laboratory testing in various settings and some of the challenges raised at that time are still present today. As a result of CLIAC recommendations, in November 2005 CDC published "Good Laboratory Practices for Waived Testing Sites" as an MMWR R&R. This document has been referenced repeatedly and CDC subsequently developed several related educational products to provide resources to improve testing in waived testing sites. Progress has been made but new issues continue to surface as the number of waived testing sites and waived tests continue to increase. She said the Committee would be asked to consider additional ways to help assure the quality of waived testing and provide assistance to those who perform waived testing.

With respect to digital pathology, Dr. Howerton stated that the first attempt to transmit a pathology image took place in 1960, but capturing a virtual slide image did not become widely accepted until the 1990s. She said digital pathology continues to grow and is being utilized in anatomical pathology, microbiology, and hematology. In 2011, the FDA announced that it would regulate whole slide imaging (WSI) systems as Class 3 Medical Devices. She said CLIAC's input on whether additional guidance is needed from HHS regarding the requirements for implementing and using digital pathology, as well as ideas on how to align validation guidance with the FDA's performance review and labeling would be welcomed.

Finally, Thursday's topic would be "Advancing Laboratory Interoperability and Health Information Technology." Dr. Howerton said the informatics topic had been brought before the Committee repeatedly over the last several meetings with discussion centered on the increasing use of health information technology (HIT), electronic test ordering, standardization of test reports, and issues concerning clinicians and information technology.

Government Performance and Results Act (GPRA) *Addendum 05*

Ann Snyder, MT (ASCP)
Division of Laboratory Services
Survey and Certification Group
Centers for Medicare & Medicaid Services

Ms. Snyder began by providing some background on the Government Performance and Results Act (GPRA) and the Government Performance and Results Modernization Act of 2010 (GPRMA). She discussed the HHS strategic plan for 2010-2015 as well as the CMS strategic goals for 2014/2015. Ms. Snyder related that the CMS GPRA goal she would be discussing focuses on educating testing personnel in CW sites in 20 states by providing them with the "Ready? Set? Test!" booklet developed by CDC and subsequently conducting educational surveys in those CW sites and measuring the outcomes of the surveys. The GPRA goal is to increase the percentage of surveyed CW sites that are in full compliance with the CLIA requirements for waived testing. This is indicated by CMS issuing a "Letter of Congratulations" to those sites. Ms. Snyder stated the GPRA goal is to show at least a 2% increase in the "Letters of Congratulations" issued to CW sites in the states participating in the project and said there had been a 29% increase from 2011 to 2012. Finally, Ms. Snyder said CMS will continue with the GPRA goal using the same 20 states and is considering expanding the project to all CW laboratories or testing sites.

Educational Resources to Improve Waived Testing Practices *Addendum 06*

Heather Stang, MS, MT
Health Scientist
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

Ms. Stang reminded the Committee that over the last 20 years, there has been a significant increase in waived tests and in laboratories or testing sites with a CW. She related that CMS surveys of CW and provider-performed microscopy procedures laboratories from 2002 to 2004 revealed quality problems as published in the 2005 MMWR R&R on "Good Laboratory Practices for Waived Testing Sites." She provided an overview of the CDC's related educational outreach materials that include booklets, poster/postcards, and online training. Ms. Stang described the distribution data for the educational material and participation data for the online training. She reviewed the "Ready? Set? Test!" online course evaluation data emphasizing the high approval ratings for the course and noting that 87% of participants indicated they will implement some of the ideas learned during the training. Ms. Stang concluded her presentation by announcing the Kentucky Department of Health now requires that all waived testing personnel in their public health laboratories take the online training and that Illinois is recommending personnel in new CW sites take the training before applying for a CLIA CW.

Waived Testing: Current Observations and COLA Solutions *Addendum 07*

Verlin K. Janzen, MD, FAAFP
Member, COLA Board of Directors
Chair, Accreditation and Acceptance Committee

Dr. Janzen began his presentation by defining what COLA promotes and whom they accredit. He reviewed the history of waived testing and discussed the broad usage of waived tests. He reviewed the common quality challenges encountered and stated the two most common quality challenges are high staff turnover and the failure to adequately train personnel and determine if competency is maintained. Dr. Janzen described the waived testing program and supporting material that COLA has developed to provide assistance and resources for physicians who perform waived testing in their office laboratories.

The Joint Commission and Waived Testing *Addendum 08*

Jennifer F. Rhamy, MBA, MA, MT (ASCP), SBB, HP
Executive Director
Laboratory Accreditation Program
The Joint Commission

Ms. Rhamy shared the mission of the Joint Commission and data from their 2012 surveys of healthcare organizations that perform waived testing. The surveys covered a variety of settings and in these, 25 waived testing performance elements were reviewed. She showed the rates of noncompliance with Joint Commission standards by organizational setting and said the data from the laboratory surveys showed that long-term care facilities have the highest rate of noncompliance with the waived testing requirements, followed by laboratories. She also reviewed the most frequently cited finding for each type of organization. Ms. Rhamy concluded by stating even with well-defined standards, clinical staff struggle with the framework for performing waived tests, especially verifying staff performance; all organizations that perform waived testing may benefit from periodic on-site review; and laboratory surveyors should be used to support and train clinical program surveyors.

Committee Discussion

- A member asked if the Joint Commission's requirements for competency assessment were too high since it appeared there were a high number of failures in that area and yet the tests were still being performed correctly. Ms. Rhamy stated the Joint Commission standards have four methods for assessing competency and two of these four should be performed. The Joint Commission does not believe the requirement is too stringent. The high number of failures is due to failure to perform assessments and/or failure to document competency assessments.
- Another member noted that the Joint Commission's standards for waived testing exceed the CLIA requirements and commented there may be confusion about what is actually required. Ms. Rhamy agreed and added that one of the goals of accreditation is to meet evidence-based standards that are higher than minimal regulatory

requirements. In addition, the waived testing sites that are inspected by the Joint Commission have the manuals containing the accreditation standards to serve as resources.

- One member suggested that the Joint Commission surveys of the hospital and the laboratory be combined. This would allow the laboratory surveyor to provide guidance to the hospital surveyor. Ms. Rhamy agreed this would be helpful.

CAP Programs for Waived Testing *Addendum 09*

Paul Bachner, MD, FCAP
Professor
Pathology and Laboratory Medicine
University of Kentucky

Dr. Bachner began his presentation by reviewing the definition of a waived test as stated in the CLIA law. He cited CAP's credos about waived testing and noted CAP's accreditation requirements for waived testing are similar to nonwaived testing with a few exceptions. Dr. Bachner stated that CAP accreditation requires PT for most waived tests and described CAP's PT program for waived testing. He informed the Committee of the educational products available from CAP. In conclusion, Dr. Bachner said that CAP believes that waived testing should have oversight commensurate to the level of harm the test poses to patients.

Questions for Dr. Bachner

- Dr. Gutierrez asked Dr. Bachner to relate his view of appropriate training and qualifications for a laboratory director of waived testing. Dr. Bachner said the lack of statutory training requirements for directors of waived testing is problematic. Some CW laboratory directors may not have the appropriate background and training to recognize and address issues related to testing or may choose to ignore them. However, similar situations also exist in some laboratories that perform nonwaived testing.
- Dr. Gutierrez asked whether CAP's accredited waived testing laboratories understood how the intended use of a test relates to its waiver status. He continued, saying the FDA would not have considered the use of a glucose meter in an intensive care unit as being within the intended use of meters that are waived or cleared for point-of-care use. Furthermore, the FDA did not evaluate specimens from critical care patients when determining if an instrument should be given waived status. Dr. Bachner agreed with Dr. Gutierrez and stated that reliable results are especially needed in clinical settings such as critical or intensive care units.
- A Committee member asked for Dr. Bachner's views on the use of waived tests in a screening environment versus a diagnostic environment. Dr. Bachner stated that screening tests have different performance specifications from diagnostic tests, therefore waived tests should not be used in the same way in both test settings.
- A member asked, since Dr. Bachner said CAP believes that oversight of waived testing should be commensurate with the level of risk, whether CAP had determined how to assess levels of risk. Dr. Bachner answered CAP has studied the issue of risk

for laboratory developed tests and proposed a three tier model for risk assessment based on the affect a test result will have on a patient's care. However, a similar assessment has not been attempted for waived testing.

Committee Discussion ***Addendum 10***

The Chair introduced three discussion questions related to waived testing for the Committee to consider.

1. What additional efforts would be helpful to assure the quality of waived testing in the variety of sites that perform this testing?
2. How can HHS work with accrediting organizations to provide assistance or educational resources to waived testing sites?
3. With what other professional laboratory or healthcare organizations should HHS collaborate to reach the target audience with respect to waived testing? What mechanisms are most useful to educate and inform this audience?

- A member suggested that level of risk should be considered before using a waived test and that the setting where the waived test is used should be strongly considered when deciding how much oversight needs to be in place. He noted that the increasing ability to perform waived testing in point-of-care settings provides a tremendous service for patients. Another member commented that using the test setting to determine the level of regulation had merit. However, some accrediting organizations, such as the Joint Commission, have standards that say a test must be offered with the same level of oversight across the whole continuum of care.
- A member stated all patients should receive the same quality of testing therefore the setting that a waived test is used in should not be the deciding factor in oversight of that test. There should be quality oversight for all waived testing laboratories bolstered with educational efforts and resources.
- A second member agreed the goal is to have quality care in every setting and suggested that training or education, such as provided by CDC's "Ready? Set? Test!" resources, be required as part of the application process for a CLIA CW.
- A member commented that a laboratory director for a CW testing site does not have to meet educational requirements or any specific qualifications.
- Dr. Howerton emphasized there are no personnel requirements for waived testing. She clarified the only requirements for the CLIA CW are that the laboratory or testing site must have a CLIA certificate and must follow the manufacturers' instructions. In addition, one of the principles behind the passage of CLIA was that the regulatory requirements would be site neutral. This was a new paradigm in that the level of oversight was intended to be based on the complexity of the testing not the location where the testing was performed.
- A member asked whether the CMS plan to implement a risk-based approach to quality control (QC) could be used to drive CW laboratories into performing QC or PT. Dr. Gutierrez responded that labeling determines the amount or type of QC testing that must be performed and PT is voluntary for waived testing. Dr. Howerton again stated there are no QC requirements for waived testing other than those specified in the manufacturer's instructions, so CW laboratories are not required to follow a QC plan. Laboratories that choose to become accredited may be subject to

additional requirements. Dr. Gutierrez clarified that much of the expansion in waived testing resulted when devices were cleared for over-the-counter use and thus automatically waived. He stated it is difficult to require QC for over-the-counter devices.

- A member questioned the value of the waived testing category in light of the expressed need for QC or PT to assure the quality of testing.
- A member commented that in certain settings there is an expectation by the patient that test results are accurate when performed in a medical environment.
- The Chair asked what market drivers would encourage waived testing facilities to improve performance and quality. Two members said increased reimbursement would be a market driver with one of the members adding that accreditation of waived testing sites could be used to qualify the sites for increased reimbursement. Another member suggested a national approach rather than each state addressing the issue. Another stressed that insurance companies are looking for partners to improve care and indicated that improving quality could decrease repeat or duplicate testing as well as costs.
- A member asked if there was a way to regulate the intended use of a waived test. Also, if a waived test is performed for a different intended use than stated in the manufacturer's instructions (i.e. off-label use), would it then be categorized as high complexity? Dr. Gutierrez stated that manufacturers design their tests for a specific intended use and any use of that test in a different population would be considered off-label and the test would be high complexity.
- A member stated the FDA should make sure the intended use is clearly specified for every test they clear or approve. The member added that FDA should review waiver approvals after a period of time to verify the tests continue to meet the most current performance standards and that their intended use has not changed. Dr. Gutierrez acknowledged that over time testing practices and the need for better performance standards can change. He agreed with the member and said FDA is looking into this.
- In summary, the Chair said there is ample documentation that quality is an issue within the waived testing category. On behalf of the Committee, he collectively acknowledged that guidelines and educational endeavors are valuable and stated that waived testing performance may differ depending on whether the laboratory decides to be voluntarily accredited. Absent any formal recommendation from the Committee, he concluded the discussion.

Introduction of Digital Pathology ***Addendum 11***

MariBeth Gagnon, MS, CT (ASCP), HTL
Senior Health Scientist
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

Ms. Gagnon briefly recounted CLIAC's past discussions of digital pathology before introducing the three speakers, Dr. Schwartz, Dr. Parwani, and Dr. Badano. She reviewed

the definitions of the terms telepathology, telemedicine, digital pathology, virtual microscopy, WSI, and image analysis. She presented the Committee with four questions to consider and discuss following the presentations:

- What HHS guidance is needed for validation of whole slide imaging?
  - Can the CAP guidance serve as a model?
  - Are other sources of guidance available that should be considered?
- What practices discussed at the International Color Consortium (ICC) Color Summit should be considered during implementation or validation of whole slide imaging by a laboratory?

Tele-pathology Evolution and Usage ***Addendum 12***

Jared Schwartz, MD, PhD
Chief Medical Officer
Leica BioSystems
Consulting Professor of Pathology
Stanford University Medical Center

After disclosing he was representing only himself, Dr. Schwartz illustrated that tele-pathology, digitization, and WSI do not represent new medical devices. He explained the process and benefits of WSI and digital pathology, especially in settings where there is a shortage of pathologists or a lack of access to medical care. He described how the use of e-slides enables pathologists to read more slides without traveling or waiting and explored the question of whether variations in color make a difference in routine stained tissue diagnosis. Dr. Schwartz discussed why he thought the FDA should classify WSI as a Class 2 rather than a Class 3 device and made three recommendations:

- WSI for primary diagnosis should have a fast track for clearance so US patients can having access to same levels of pathology services as those available to patients anywhere else in the world.
- The medical director should continue to use standard methods for validation and determine when and how to introduce WSI technology in the laboratory, as is the practice for other laboratory specialties under CLIA.
- WSI should be treated as no more than a Class 2 device.

He concluded by stating WSI for primary diagnosis has been used worldwide for many years with no evidence of risk or harm to patients or users.

Committee Discussion

Dr. Gutierrez commended the presentation and noted it argued for technology that could have a positive impact on pathology but he cautioned the new technology should be introduced with some care. Based on FDA's experience regulating radiology/mammography, he emphasized it is sometimes difficult to know when to allow the use of new technology as an aid to healthcare without the risk of patient harm. He said standards do need to be set for imaging.

Recommendations for Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology ***Addendum 13***

Anil Parwani, MD, FCAP ***Addendum 13A***
Associate Professor of Pathology
Director of Division of Pathology Informatics
Department of Pathology
University of Pittsburgh

On behalf of the CAP's WSI Validation Expert Panel, Dr. Parwani listed ten uses for digital pathology, suggesting computerized pathology slides may result in faster, more accurate diagnoses. He reviewed the imaging process and imaging modes, and said current technologies can create a digital image that is sometimes better than the glass slide image. After citing four WSI regulatory issues, he listed the CAP Expert Panel members and reviewed the steps used to answer the key question: What needs to be done to validate a WSI system for diagnostic purposes before it is placed in clinical service? Following a description and definition of parameters, quality assessment and grading evidence, recommendations, and guidance used by the Panel, he discussed the twelve guideline statements, revealing the Panel's guidance and grade of each. Dr. Parwani concluded with three statements:

- Validation of WSI is necessary to ensure that a pathologist using this technique to view digitized glass slides can consistently make the same clinical interpretation as they would from viewing the glass slides using a traditional bright field microscope.
- Validation should address both technical and interpretative components and must be specific for the intended clinical use.
- Ongoing future updates on this topic are planned.

Addendum 13A contains the recently released CAP guideline for validating WSI for diagnostic purposes in pathology.

Committee Discussion

- A member asked for an explanation of why it appeared glass slide specimens were diagnosed more accurately than WSI specimens. Dr. Parwani replied the studies reviewed ranged over the last decade, and there was variability in the number and types of cases chosen.
- Another member asked if there was a recommendation about the order of review of glass and digital image cases. Dr. Parwani replied studies on this question were indeterminate, but that a good approach may be to randomize the order of review to reduce possible bias.
- A member commented the two previous presentations segued nicely. Past studies are limited in nature since they are often limited to a single sub-specialty and by datasets that are enriched with difficult or unusual cases. The member cited newer and broader-based studies now available that show equal if not higher concordance than what was established.

Recommendations from the Summit on Color in Medical Imaging and Implications for Laboratory Practices ***Addendum 14***

Aldo Badano, PhD, ME
Division of Imaging and Applied Mathematics
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health
Food and Drug Administration

Dr. Badano presented a summary of the FDA-convened public workshop "Summit on Color in Medical Imaging." He said its purpose was to bring together key stakeholders to clearly identify areas of need, investigate solutions, and propose best-practice approaches in the handling of color in medical imaging. He described the significance of two key words, "consistency" and "interpretability," as they related to the key question of the summit "What one step, if any, would you suggest we take in order to improve the handling of color in medical imaging systems within your area of expertise?" He illustrated and described color image comparisons in light of several variables that could affect colors: stains, scanners, software, and monitors. He said the Summit resulted in agreement that improved color handling results in a documented improvement in the workflow. However, no hard evidence was found to indicate that poor handling of color significantly affects diagnostic performance. The Summit also identified major consensus points, roadblocks, and next steps. Dr. Badano reviewed the ten initiatives drafted to forward color standards in medical diagnosis and emphasized that calibration slides were thought to be key to the standards. Concluding, he remarked the need was clear to advance interpretability and consistency of color handling in medicine, particularly in WSI devices being reviewed by FDA.

Committee Discussion ***Addendum 15***

The Chair opened the floor for discussion. The following comments and suggestions were made by the Committee in response to the discussion questions posed by Ms. Gagnon and the presentations by Dr. Schwartz, Dr. Parwani, and Dr. Badano.

- One member commented it has been argued that using digital images is a problem because they are surrogates to a glass slide, but the slide is actually surrogate to the patient specimen and it is the specimen that is being diagnosed, not the slide nor the image. A pathologist's evaluation of any slide by any modality, be it digital or using a traditional microscope, is whether the quality of the slide is good enough to make a diagnosis. Depending on the particular diagnosis needed, the need for quality may vary. The member added that considering the staining and examination of glass slides, there have never been standards with respect to staining qualities, number of bubbles, number of tissue folds, chatters, or the microscope requirements. He also said that regulatory issues should focus on elements within the system where pathologists may not be aware of problems. For example, it is critical that the specimen on a slide or in an image contains the right tissue to enable the correct diagnosis. Last, the member said color is not a major factor for pathologists when they make diagnoses, as colors can vary within a laboratory and pathologists adapt to color differences.

- Another member commented that microbiology laboratories are moving towards total automation and the use of digital images. For example, in some cases young technologists who may not have experience reading conventional microbiology cultures are using technology that produces images of microbial growth on agar plates. Color may be a bigger issue in microbiology, with chromogenic agars, than in pathology, and the discussion should be broadened to encompass other laboratory specialties.
- A member stated short of complete computer diagnosis, there is still some human intervention to determine whether the slide, image, or system is faulty. As was demonstrated, we all perceive color differently. Usually this does not affect the production of a high fidelity image or a clinically accurate diagnosis. The member concurred that color calibration may be more important than color standardization in terms of being able to make a clinically accurate diagnosis using either an image or a glass slide and light microscope.
- One member asked whether blind studies have been conducted that compare diagnoses made from glass slides to those made from WSI. Another member responded there are a number of cases where every pathologist will make the same diagnosis and often those cases are chosen for the validation studies. However, imaging technology is generally used for the borderline cases where the inter-expert agreement rate is low. Determining a baseline error rate for validation studies will vary tremendously based on the individuals involved, the cases selected, and the organ systems represented on the slides. To eliminate that set of variables, the Panel that worked on the CAP consensus guidelines recommended studying intra-observer variability to try to separate the subjective nature of surgical pathology from the variability contributed by the technology.
- Another member concurred it is very difficult to perform studies in terms of outcome versus diagnostic concordance and suggested it should be asked if there are applications within WSI that are better at predicting outcomes or quantifying disease than can be achieved by glass slide analysis.
- Dr. Gutierrez asked whether the CAP Panel took into account the effect of prior experience with WSI. A member answered that the Panel discussed the effect of prior experience with WSI and accuracy. A number of studies have shown that the viewing time is substantially altered by familiarity with the technology. Some of the higher error rates seen among inexperienced users may occur because they eventually give up and make an educated guess. A certain amount of training with the technology is necessary to assure someone is able to use it effectively in practice.
- One member asked if the CAP Panel made any recommendations about the number of samples that must be tested to validate a WSI procedure. In addition, did the Panel determine who was responsible for approving the test's validation? Another member replied the Panel's recommendations were for validation of the equipment not for validation of the users. The Panel concluded that it should be up to the laboratory director to decide what the criteria should be and to determine the training necessary for an individual before that individual is allowed to practice using this technology.
- Dr. Badano clarified that one approach being used to understand the performance of digital systems is that of studying each variable independently and then determining a performance metric that represents the sum of the individual variables.

- One member commented that the advantages of WSI center on accessibility and ease of storage. Another member concurred and said that with WSI the right slide on the right patient is sent to the right pathologist at the right time, which is a tremendous value proposition because there is a near real time diagnosis compared to delayed diagnosis with glass slide testing.
- The Committee passed the recommendation that the "Clinical Laboratory Improvement Advisory Committee (CLIAC) endorses use of College of American Pathologists (CAP) Guidelines as a model for validation of whole slide imaging systems for clinical use."
- The Chair concluded the discussion and enumerated the identified issues:
    - The quality of WSI is dependent on the quality of the slide.
    - The pathologist is responsible for determining slide quality.
    - The Committee disagreed about the importance of color variability on diagnosis with WSI or when reading glass slides.
    - The topic of digital imaging affects more laboratory specialties than just surgical and histopathology.
    - A distinct advantage of digital technologies is increased accessibility and ease of storage.

Introduction and CDC LabHIT Update ***Addendum 16***

Megan E. Sawchuk, MT (ASCP) ***Addendum 16A***
Health Scientist
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

Ms. Sawchuk provided the Committee with a brief background of the Health Information Technology for Economic and Clinical Health (HITECH) Act, noting this Act and the implementation of electronic health records (EHRs) were first discussed by CLIAC in 2010. In 2012, CLIAC sent a letter to the Secretary of the Department of Health and Human Services that included a four-part recommendation for ways to help assure that laboratory information in the EHR can be safely and effectively used by healthcare professionals, public health, and individuals. She described the two "bookend" regulations designed to ensure the quality of EHRs: one concerning EHR certification and the other the EHR Incentive Program. Ms. Sawchuk gave an overview of laboratory data-related Meaningful Use objectives and EHR certification criteria, several of which are the focus of activities being performed by CDC's LabHIT Team. She described "semantic interoperability" and "syntactic interoperability" and provided detail on the Meaningful Use objectives that include laboratory data. Ms. Sawchuk conceptualized the LabHIT Team's vision and highlighted their work related to the Office of the National Coordinator (ONC) Laboratory Report Workgroup Tiger Team, content standards development, and vocabulary standards development. She concluded the presentation by providing contact information for the LabHIT Team and introducing the next several speakers on the agenda.

ONC presentation to CLIAC *Addendum 17*

Doug Fridsma, MD, PhD, FACP, FACMI
Chief Science Officer and Director
Office of Science and Technology
Office of the National Coordinator for Health Information Technology (ONC)

Addendum 17A
Addendum 17B

Dr. Fridsma began his presentation by explaining the Office of Science and Technology's four working concepts and describing ONC's interoperability strategy. He then defined the Standards and Interoperability (S&I) framework and conceptualized framework coordination among the various stakeholders. Dr. Fridsma detailed the S&I framework lifecycle, operating metrics, and initiative list, then provided a snapshot of the initiative's portfolio and pilot sites. He recounted the recommendation made by CLIAC in the 2012 letter to the HHS Secretary and provided a comprehensive response to each of the four parts. Dr. Fridsma concluded by thanking the Committee for their thoughtful recommendations and encouraged future involvement.

Committee Discussion

- One member asked about patient access to their healthcare information. Dr. Fridsma replied the Blue Button activity is a campaign to engage patients in getting structured access to their electronic healthcare information. It enables patients to download information and is a key tenet of the direction the agency wants to go. Laboratory results could be inserted into this initiative. He also stated, due to differing regulations in each state, there are patient access policy issues that are currently being addressed. In addition, the ONC Office of Consumer Engagement is striving to get patients engaged in their health care.
- Another member inquired about the feedback received from the pilot sites. Dr. Fridsma answered the purpose of the pilot sites is to be certain ONC is on the right track with the standards they are working on and to assist in refining the standards. The pilot participants can test the standards to be sure they are appropriate and work. If the pilot sites indicate the ONC standards cannot be implemented, then ONC will re-evaluate the standards.
- A member asked Dr. Fridsma to elaborate on the involvement of the large healthcare providers and manufacturers of laboratory information systems in the ONC initiatives. Dr. Fridsma stated some large commercial laboratories are engaged. ONC is also attempting to engage academic and regional hospitals that have their own systems in place. He emphasized this initiative is open to anybody. Dr. Fridsma went on to say the laboratory ordering and laboratory results initiatives have been good due to their very broad participation.

Laboratory Reporting Tiger Team Presentation to CLIAC *Addendum 18*

Robert Dieterle
Consultant to the Office of the National Coordinator for
Health Information Technology (ONC)
CEO, EnableCare Group, LLC

Mr. Dieterle outlined the background, discovery phase, and action phase of the ONC's Laboratory Reporting Workgroup. He discussed the CLIA guidance issued March 1, 2010, and the current verification process of a typical EHR system. He provided a diagram explaining the components of the Laboratory Reporting Tiger Team. He stated the overall goal of the Workgroup was to reduce the time and cost to implement and verify laboratory result reporting interfaces in the ambulatory environment while maintaining the accuracy, completeness, and usability of laboratory test result information viewed by the authorized person for safe and effective interpretation. Mr. Dieterle outlined each sub-workgroup along with their participants and purpose. He described the successes of the Tiger Team and provided a description of a laboratory test report for EHR certification. He discussed the preliminary recommendations of the Workgroup and next steps, which include completing and presenting the recommendations to ONC, CMS, and CDC. Mr. Dieterle completed the presentation by briefly summarizing the teams' activities and introducing the new Logical Observation Identifiers Names and Codes (LOINC) orders efforts.

Committee Discussion *Addendum 19*

- Dr. Gutierrez commented there are FDA regulations with specific language requirements for reporting laboratory results that apply only to laboratory-developed tests that use analyte specific reagents. He asked whether the Tiger Team had addressed this issue. Mr. Dieterle deferred to CDC and Dr. Howerton replied it would be necessary to connect with the FDA to make certain the issue was adequately addressed.
- A member inquired how EHR vendors assure the valid transmission of laboratory information when multiple views of the laboratory data are possible. The member noted that certain views may have missing elements and said this could result in quality and safety issues. Mr. Dieterle stated he is hoping to build off the public health reporting transaction requirements. It would not appear to be difficult for the vendors but like any new development, it is meeting with some resistance. ONC is working with EHR vendors to discuss the potential benefits of having a standardized system. Mr. Dieterle commented the savings resulting from the improvement in patient safety would seem to justify the initial cost.

Clinician Experience in Health IT Policy and Standards Development ***Addendum 25***

Alexis B Carter, MD
Director of Pathology Informatics and Assistant Professor
Emory University School of Medicine

Dr. Carter provided her professional credentials and stated she was a member of the ONC Laboratory Reporting Tiger Team. She lauded CLIAC's recommendations and ONC's acknowledgement that laboratory experts, especially pathologists, have a grasp of the potential for mismanaged laboratory data to cause patient harm. Dr. Carter said by setting and using appropriate standards, medical errors can be prevented thereby ensuring patient safety. She hoped CLIAC would consider the need for laboratory experts to be involved in the display of laboratory data in patient portals as required under Meaningful Use. She relayed her concerns about the potential for psychological harm when patients read laboratory results that they do not fully understand. Dr. Carter concluded her presentation by discussing what she believed patients should be able to see in their patient portal.

Committee Discussion

- One member asked for further clarification about the information patients should be able acquire from the portal. Dr. Carter answered it should be easy for patients to understand which laboratory results are abnormal. Doctors should have the opportunity to annotate the data in the patient portal to explain when abnormal results are of true concern. She agreed patients should have access to all of their laboratory data; however, the timing of the release of data is a question for consideration, since there could be some psychological harm to patients when results they may not understand are released. These issues are being worked on and input from patients is critical to this discussion.
- Two members concurred that granting patient access to un-annotated data could lead to misinterpretation of results and cause anxiety, and agreed this issue needs attention. Another member added some doctors request that the abnormal flags be changed in reports going to patients. This is a concern because the original report should not be different from the report the patient receives. Members suggested:
    - A summary report from the physician be provided to the patient rather than the raw data.
    - Filtering the data through the clinicians prior to releasing results to patients would eliminate some patient anxiety but create a burden for the physicians who would need to review and determine when to release results.
    - Patient centered education could help but it is difficult and could be expensive.
    - Standardizing the physicians' final interpretative comments would be an excellent solution, if possible.
    - Obtaining feedback from the organizations that currently have patient portals.
- One member remarked the job done so far is very good concerning EHR certification. A member stated there are significant costs associated with laboratory interoperability that laboratories are expected to bear and there is the threat of loss of business if they cannot bear the costs. This issue needs to be considered.

PHIN VADS - Application & Content Overview *Addendum 20*

Sundak Ganesan, MD
Ms. Roochi Sharma
Division of Health Informatics and Surveillance DHIS
Center for Surveillance, Epidemiology, and Laboratory Services CSELS
Office of Public Health Scientific Services OPHSS
Centers for Disease Control and Prevention

Dr. Ganesan and Ms. Sharma provided the Committee with an overview of the Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS), a public web-based enterprise vocabulary system for accessing, searching, and distributing Health Level 7 (HL7) messaging value sets (sets of related codes) used within the Public Health Information Network (PHIN) and the Nationwide Health Information Network (NHIN). PHIN VADS provides the vocabulary metadata needed to facilitate public health reporting. It allows users both within and external to CDC to have access to all versions of value set collections and detailed code system metadata to facilitate the implementation of such code sets and their associated vocabularies.
Dr. Ganesan described the laboratory content available in PHIN VADS, such as the Reportable Condition Mapping Table (RCMT), which associate reportable conditions with laboratory tests and results that are indicative of those conditions. The RCMT can be used to filter clinical laboratory test results to select for a list of codes associated with each notifiable condition that is of interest to public health. Ms. Sharma provided a brief overview of the CDC Public Health Vocabulary Community of Practice and provided a list of contacts and support available for PHIN VADS. Dr. Ganesan concluded the presentation with a demonstration of the PHIN VADS website.

DLSS LabHIT Team and Specimen Test Vocabulary LabMCoP *Addendum 21*

Nancy Cornish, MD
Medical Officer
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 with an overview of the specimen cross mapping table project started in 2009 by a working group that included CDC and APHL representatives in the Laboratory Messaging Community of Practice (LabMCoP). As part of the Public Health Laboratory Interoperability Project (PHLIP), the table is designed to optimize computer communications between clinical and public health laboratories. The CDC LabHIT Team joined the LabMCoP group to represent the perspectives of the clinical laboratory. They also recruited relevant clinical laboratory professional organizations (i.e. the American Society for Microbiology and the Association of Molecular Pathology) to review terms related to those laboratory specialties. Dr. Cornish explained that development of the table started with a comprehensive list of laboratory-test computer codes, which were

harmonized for use in HL7, LOINC, and Systematized Nomenclature of Medicine (SNOMED) systems. When developing the specimen cross mapping tables, the group identified a number of issues such as ambiguous terminology and limited specimen description fields. Dr. Cornish discussed the solutions developed to address these issues, including the use of SNOMED codes for medical terminology mapping and the use of multiple HL7 specimen fields to fully characterize specimens along with the development of a preferred term that included a clear and complete definition of the term. She concluded with the LabMCoP specimen cross-mapping table working group's list of future goals.

Committee Discussion ***Addendum 22***

- A member inquired about the progress of developing a unified list for tests such as a complete blood count with differential. Dr. Cornish responded that the specimen cross-mapping for microbiology has been completed and molecular tests are next with the goal to work section by section until a table is complete for all clinical laboratory specialties.
- One member clarified that HL7 is a syntactic standard not a semantic standard and noted that multiple sets of standards are not useful unless everyone uses the same standard set. The member asked whether PHIN VADS has penetrated the standards network for both state public health reporting and use outside the public health network. Dr. Ganesan responded that challenges exist because many hospitals use local codes in their systems and without the use of standard vocabulary the systems cannot communicate to exchange data. Dr. Ganesan said that ONC as well as standards organizations like the Regenstrief Institute are making efforts to assist the mapping of local codes to vocabulary standards such as LOINC. The Regenstrief LOINC Mapping Assistant (RELMA) utility is available to facilitate searches through the LOINC database and to assist efforts to map local codes to LOINC codes, which would result in a standardized vocabulary. However, specialized assistance is often needed to facilitate the adoption of this utility.
- The member questioned why people should use PHIN VADS standards. Dr. Ganesan responded that while standards development organizations manage the standards, such as LOINC and SNOMED, PHIN VADS supports the implementation of those standards for public health reporting.
- A member commented that Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, used to report services and procedures in outpatient and office settings, and the International Classification of Diseases (ICD), used to report hospital inpatient procedures, should be addressed since those are the code sets used for reimbursement. Dr. Cornish acknowledged the multiple code sets and responded that there are discussions underway on how to streamline terminology. She added these are international efforts so decisions will have an international impact.
- One member stated that having national standards would help achieve interoperability and that there are two components needed to make this happen. The first is to develop the tools needed to facilitate the use of standard vocabulary, such as an electronically downloadable list of standard vocabulary codes. The second component involves provision of appropriate incentives, such as reimbursement, to encourage the use of

the standard vocabulary sets. The member explained that currently there are too many standards and vocabularies with overlap between them. The member suggested having a specific set designated as the recommended official vocabulary standard set. The member provided as an example that SNOMED and ICD are two different vocabularies that serve the same purpose, to identify diagnoses, and they are both recommended standards. CPT codes, a third vocabulary with a different purpose to identify procedures performed, stands alone and has been largely protected, not only because it is copyrighted, but also because it is the code used for reimbursement. The member suggested the reconciliation of the different groups advocating for different vocabularies and ultimately deciding upon an official vocabulary set that would be used long term and would be internationally compatible.

- Dr. Ganesan clarified that there are basically two types of standards, the administrative billing standards such as ICD and CPT and the clinical vocabulary standards such as LOINC and SNOMED. He agreed that ICD and CPT have been adopted because of reimbursement and there is an effort from standards organizations to provide the guidance needed to map a CPT code to a corresponding LOINC code.
- Another member asked about the feasibility of drafting an overview diagram showing the relationships of all informatics activities and indicating redundant activity, such as multiple standards. Ms. Sawchuck responded that such a chart, called a "star map," has been developed and it is very complex. She agreed there is some duplication of efforts, which are being evaluated. The member suggested the diagram be simplified, for ease of understanding.
- The Chair summarized the morning discussion. He expressed appreciation that the previous CLIAC recommendations were addressed in the report given by ONC and applauded the work of the Tiger Team. He said the Committee acknowledges that there is a need to simplify health informatics activities by addressing redundancy and moving towards standardization with the help of incentives to address the issues that were discussed.

PUBLIC COMMENTS

- **Dennis J. Ernst MT(ASCP) Executive Director of the Center for Phlebotomy Education** ***Addendum 23***

- **JEAN PUBLIC** ***Addendum 24***

ACRONYMS ***Addendum 26***

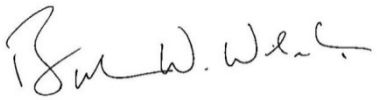
ADJOURN

Dr. Wilcke acknowledged the staff that assembled the meeting program and thanked the CLIAC members and partner agencies for their support and participation. The following is the Committee recommendation passed at this meeting:

Clinical Laboratory Improvement Advisory Committee (CLIAC) endorses use of College of American Pathologists (CAP) Guidelines as a model for validation of whole slide imaging systems for clinical use.

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

I certify this summary report of the August 21-22, 2013, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.



_____ Dated: 10/24/2013

Burton Wilcke, Jr., PhD, CLIAC Chair