Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

August 29 - 30, 2012

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
August 29 - 30, 2012 Summary Report

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RECORD OF ATTENDANCE

Committee Members Present
Dr. Paula Santrach, Chair
Mr. Eugene Augustine, Jr.
Dr. Robert Baldor
Dr. Edward Chan
Dr. Martha Crenshaw
Dr. Judy Daly
Dr. Anand Dighe
Dr. John Fontanesi
Dr. Keith Kaplan
Ms. Lezlee Koch
Ms. Karen Lacy
Dr. Anthony Okorodudu
Dr. Robert Sautter
Ms. Paula Vagnone
Dr. Gail Vance
Dr. Linda Ward
Dr. Burton Wilcke, Jr.
Dr. David Wilkinson
Dr. Qian-Yun Zhang
Mr. Robert DiTullio, AdvaMed (Liaison Representative)

Committee Members Absent
Dr. Jeffrey Kant

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

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
Dr. John Besser
Ms. Diane Bosse
Ms. Cathryn Cambria
Dr. Roberta Carey
Dr. Nancy Cornish
Dr. Maryam Daneshvar
Mr. Swapnil Deshpande
Ms. Joanne Eissler
Ms. Maribeth Gagnon
Dr. Amy Gargis
Dr. Tom Hearn
Dr. Lisa Kalman
Dr. John Krolak
Mr. Brian Lee
Mr. Ken Long
Dr. Ira Lubin
Ms. Leslie McDonald
Ms. Anne Pollock
Ms. Megan Sawchuk
Dr. Thomas Savel
Dr. Shahram Shahangian
Mr. Darshan Singh
Ms. Theresia Snelling
Ms. Heather Stang
Ms. Sonya Strider
Dr. Julie Taylor
Mr. H. Eric Thompson
Ms. Pamela Thompson
Ms. Monica Toles
Ms. Glennis Westbrook
Ms. Irene Williams
Ms. Yasmine Zavahir
Dr. Barbara Zehnbauer
Mr. Jonathan Zhong

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

Ms. Karen Dyer (CMS)
Ms. Daralyn Hassan (CMS)
Dr. Reena Philip (FDA)
Mr. Matt Quinn (NIST)
Capt. Cindy Wilkerson (US Navy)

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 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 Director, Laboratory Science, Policy and Practice Program Office (LSPPPO), Office of Surveillance, Epidemiology and Laboratory Services (OSELS), CDC, welcomed the Committee and the members of the public, acknowledging the importance of public participation in the advisory process. She announced this year marks the 20th year since the Committee was formed in 1992. 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) as well as an update from the CDC Office of Infectious Diseases Board of Scientific Counselors. There would be presentations and discussions on the need for educational resources for provider-performed microscopy procedures; communication in informatics; the increased use of culture-independent microbiology diagnostics and the impact on public health; the Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™); and the Laboratory Medicine Best Practices Initiative.

Dr. Chu welcomed new members to the Committee. They are Dr. Keith J. Kaplan, Ms. Lezlee A. Koch, Ms. Paula M. Vagnone, Dr. Burton W. Wilcke, Jr., and Dr. Qian-Yun Zhang.

Dr. Paula Santrach, 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, Ph.D.
Division of Laboratory Science and Standards (DLSS)
Laboratory Science, Policy and Practice Program Office (LSPPPO)
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Centers for Disease Control and Prevention

Dr. Howerton's presentation highlighted the major activities underway within DLSS. She began by recognizing the 20th Anniversary of the Clinical Laboratory Improvement Advisory Committee (CLIAC), whose first meeting was held October 28-29, 1992. With 46 CLIAC meetings, 7 subcommittee meetings, and 15 workgroup meetings having been conducted since 1992, CLIAC has addressed many topics with recommendations making major impacts and contributing to significant changes in CLIA regulations. Next, Dr. Howerton discussed updates being made to the CLIAC website. She then reported that the CDC Workload in Image-Assisted Gynecological Screening Workgroup met on August 15-16, 2012. She discussed the workgroup's charge and provided an overview of the meeting outcomes. She also provided an update on the progress of developing a proposed rule to revise the CLIA proficiency testing (PT) requirements. Earlier this year,

CDC and CMS met with the PT programs to discuss proposed analyte changes, grading changes, and changes to microbiology PT. Currently, proposed acceptance limits are being developed and will be tested and adjusted as necessary, in collaboration with the PT programs. Also pertaining to PT, the planned laboratory survey has been developed and pilot tested, with an estimated Spring 2013 launch date. The Committee was reminded of the release of the April 6, 2012, Morbidity and Mortality Weekly Report: Recommendations and Reports (MMWR R&R) publication "Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders." The web-based training course associated with the MMWR R&R on good laboratory practices for molecular genetic testing has just been released and is available at: https://www.aphlnet.org/eweb/DynamicPage.aspx?Site=APHL&WebCode=CSCEventsSearch-MOL. Additionally, Dr. Howerton informed the Committee that the guidance document on technical aspects of quality management using next generation sequencing is currently in review. Lastly, she updated the Committee on CDC's quality improvement research agenda. Plans are being developed for several new projects.

Committee Discussion

- A Committee member asked if the Institute of Medicine's (IOM) improvement aims listed by Dr. Howerton have been defined in terms of what they mean to the laboratory, especially with respect to patient-centeredness. The member also conveyed the need for standardized definitions for the IOM aims. Dr. Howerton recognized the concern for the standardized definition of IOM's aims; however, she acknowledged the difficulty in addressing some of the specific components. She explained that patient-centeredness is closely related to patient safety, which encompasses a different domain and is becoming more visible with the introduction of electronic health records (EHRs). Difficulty in measuring some of the aspects surrounding patient access to EHRs and the impact on patient care, as related to patient-centeredness, need further investigation in order to develop possible solutions. Dr. Howerton said that suggestions for addressing these issues are welcomed from the Committee.
- One Committee member asked whether the 2012 MMWR R&R "Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders" is being used by laboratories. Dr. Howerton said that studies are being developed to evaluate the utilization of the molecular genetics guidelines published in 2009. Through monitoring of numbers and types of continuing education units awarded, CDC has been able to gauge awareness and interest in the topic; however, this information does not give definitive information on the use and impact of the guidelines. In order to gain more definitive information regarding the impact, CDC plans to conduct a study.

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

Reena Philip, Ph.D.
Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration

Dr. Philip updated the Committee on actions undertaken by FDA to improve pre-market programs and provided an overview of the newly implemented in vitro diagnostics (IVD) pilot program called Triage. The goal of Triage is to improve efficiencies in the 510(k) review process. She also presented proposed organizational changes for OIVD, where they are working to reduce the manager/reviewer ratio and are adding post-market reviews for radiology, mammography, and radiological health. Last, Dr. Philip gave updates on the FDA Safety and Innovation Act including implementation of the Medical Device User Fee and Modernization Act III's implementation on October 1, 2012.

Committee Discussion

- The industry liaison requested clarification about why 85% of PMAs or 510(k) applications submitted to FDA receive a major deficiency letter. Dr. Philip explained that if an application is found to lack necessary information the manufacturer will receive a letter requesting that information. This puts the submission on hold until the additional information is received. She said the percentage is expected to decrease with the implementation of Triage.
- A member asked for clarification of the 30 day approval process that is part of Triage. Dr. Philip explained with Triage there are no letters sent requesting additional information from the manufacturer. It is an interactive review consisting of emails and phone calls. The process takes 27 days from the receipt of the submission until the final decision, including weekends.
- A Committee member asked whether the use of a predicate device was still part of the 510(k) decision making process. Dr. Philip stated the law mandates that 510(k) approval is based on a predicate device.
- A Committee member asked how the FDA eliminates potential conflicts of interest by those reviewing devices for clearance or approval and Dr. Philip explained how the submission is made transparent. For example, the final decision and review memo are posted on OIVD's website allowing a future manufacturer to make a similar submission. Guidances are also published.

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

Judy Yost, M.A., 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 comments to the proposed patient access rule have been analyzed and responses

developed. A plan with milestones has been developed for the proposed PT regulation but at this time, no projection has been made as to when this proposed rule might be published. She noted that regulatory changes, in response to legislative proposals, are expected for PT referral; however, laboratories should read and follow the CMS PT brochure until changes are published and become effective. Last, Ms. Yost provided a brief history of CLIA quality control and discussed the new quality control policy, called the individual quality control plan (IQCP), which will be incorporated into the CLIA Interpretive Guidelines.

Committee Discussion

In response to questions from the Committee, Ms. Yost clarified several points from her presentation.

- Since many physician office laboratories (POLs) and other small laboratories perform nonwaived testing, CMS plans to develop educational materials for IQCP to address their needs.
- Legislation regarding PT referral is in the House and Senate committees. Currently, if a PT sample is mistakenly sent to another laboratory for confirmatory testing, CMS is required to impose serious sanctions on the referring laboratory including revoking the laboratory's certificate for one year, disallowing the laboratory director to direct any laboratory for two years, and losing Medicare and Medicaid payments. The legislation being deliberated in Congress would allow CMS discretion in the enforcement actions under various circumstances. It would place the responsibility of defining the criteria for imposing sanctions for improper activity and determining when an intentional referral has been made on CMS.
- POLs make up the majority of the waived testing certificate holders and their number remains relatively stable. The increase in other types of sites that perform waived testing, such as nursing homes, pharmacies, or other point-of-care sites, has resulted in the greatest increase to the number of waived testing certificates. Laboratory testing is moving further away from central laboratory testing because of convenience, efficiency, and cost.

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 provided a summary on the recent meeting of the CDC Board of Scientific Counselors (BSC). He summarized the BSC Food Safety Modernization Act Surveillance Working Group key updates and priority recommendations. He reported on the BSC Antimicrobial Resistance Working Group and reviewed the two-year agenda focus areas and action list. He provided brief updates on the issues of dual use research and The Affordable Care Act. Dr. Sautter indicated the main focus of the BSC meeting included

overviews of The National Center for Emerging and Zoonotic Infectious Diseases global water, sanitation, and hygiene program; The National Center for Immunization and Respiratory Diseases immunization infrastructure, including discussion on vaccines for children who are Medicaid-eligible, uninsured, or underinsured; and The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention gonococcal antimicriobial resistance working group including CDC's plan to respond to the growing threat resistance with Neisseria gonorrhoeae.

Committee Discussion

- One member asked whether CDC provides any information on the growing movement for philosophical exemptions to immunizations requested by refugees entering the United States. Dr. Sautter answered that immunization requirements are not mandatory therefore voluntary exemptions are permitted.
- The Chair and a member expressed concern about the decreased need for bacterial culture with the advent of molecular techniques and other culture-independent diagnostics and the implications of this on detecting resistance. Dr. Sautter acknowledged the concerns and commented that there are pros and cons for all bacterial identification techniques, especially depending on the organism and the specimen source. He also recognized the importance of maintaining culture-based systems for detecting resistance and noted that laboratory practices may need to change to accommodate this.

PRESENTATIONS AND COMMITTEE DISCUSSION

Resources for Provider-Performed Microscopy Sites ***Addendum 05***

Ms. Nancy Anderson, MMSc.,
Branch Chief, Laboratory Practice Standards Branch (LPSB)
Division of Laboratory Science and Standards (DLSS)
Laboratory Science, Policy and Practice Program Office (LSPPPO)
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Centers for Disease Control and Prevention

Ms. Anderson explained that this topic was raised for CLIAC consideration because comments and inquiries from various laboratory professionals indicated that educational resources were needed for sites that test under a CLIA Certificate of Provider-Performed Microscopy (PPM). As background, she provided a brief overview of the CLIA history of the PPM subcategory of moderate complexity testing, beginning with the establishment of PPM as a CLIA Certificate type in 1993. In 1995, the subcategory was renamed as Provider-Performed Microscopy, thereby including other practitioners as qualified to direct and perform PPM procedures. Also in 1995, the list of PPM tests was expanded and clarified. Ms. Anderson then reviewed the current list of PPM procedures. Next, she stated initial CMS surveys performed in Colorado and Ohio in 1999 as well as a 2001 report published by the HHS Office of Inspector General (OIG) indicated vulnerabilities in sites that perform waived testing and PPM procedures, and data from these led to recommendations by OIG to address the issues. She provided a brief overview of the

additional CMS waived and PPM laboratory surveys from 2000-2001 which included 190 sites performing PPM procedures in eight states. Ms. Anderson discussed the CMS findings pertaining to PPM laboratories and resulting recommendations that included the institution of an educational program and the development of a self-assessment tool for PPM laboratories. She updated the Committee on the current status of PPM Certificate laboratories and recent questions and observations regarding PPM procedures.
Ms. Anderson posed three questions for the Committee:

- Are you aware of knowledge gaps or misperceptions regarding CLIA among providers who perform PPM testing?
- Would educational resources be helpful in filling such gaps?
- If so, what types of materials would be most useful and what content should be included?

Committee Discussion

- There was a comment that during routine inspections by accrediting organizations. PPM procedures are not assessed. The Chair asked whether a complaint made to CMS about a laboratory would trigger an inspection. Ms. Hassan responded that PPM does not have any routine oversight by CMS, but a complaint against a laboratory would result in an inspection.
- The Committee affirmed the need for educational resources for PPM and made the following suggestions for inclusion in potential educational material.
    - A "Tips and Tools" checklist detailing information such as PPM Certificate application, educational resources available, and recordkeeping.
    - A "Cheat Sheet" with a short description and image of PPM procedures. This would be beneficial in POLs.
    - A good laboratory practices booklet similar to *Ready? Set? Test!*
    - Information on:
        - Microscope usage and maintenance.
        - Employee training and competency assessments.
        - How the CLIA IQCP might be applied to PPM procedures.
    - A clear definition of the types of procedures that fall under a CLIA Certificate of PPM.
    - Reference material citing the training available from other sources.
    - The opportunity for continuing education credit.

Communication in Informatics - Introduction

Devery Howerton, Ph.D.
Division of Laboratory Science and Standards (DLSS)
Laboratory Science, Policy and Practice Program Office (LSPPPO)
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Centers for Disease Control and Prevention

Dr. Howerton introduced the topic of laboratory informatics and the implementation of electronic health records (EHRs). She said the continued focus on this topic at recent CLIAC meetings was due to the concern that laboratories need to be included in the

rapidly evolving and widespread use of electronic health information exchange and EHRs. The purpose of bringing this topic repeatedly to CLIAC is to open discussion and raise awareness regarding the issues that need to be addressed.

Update: CDC Clinical Informatics Team Activities *Addendum 06*

Ms. Megan E. Sawchuk, MT (ASCP)
Division of Laboratory Science and Standards (DLSS)
Laboratory Science, Policy and Practice Program Office (LSPPPO)
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Centers for Disease Control and Prevention

Ms. Sawchuk provided the Committee with a brief update on the activities of the CDC Laboratory Healthcare Information Technology (LabHIT) Team. She discussed issues presented during the last CLIAC meeting concerning laboratory test report elements and EHR implementation. She provided an overview of the regulatory agencies involved in EHR implementation and presented the Communication in Informatics logic model which is based on engagement, interoperability, and usability and contextuality. Ms. Sawchuk highlighted team activities since the February 2012 CLIAC meeting and also provided information on future activities. In conclusion, Ms. Sawchuk asked CLIAC to consider the following questions:

1. How can CDC engage laboratory experts with practical HL7 knowledge to support its activities with the Office of the National Coordinator's (ONC) Standards and Interoperability (S&I) Framework and the Laboratory Workgroup Tiger Team?
2. How can EHR vendors and software designers be educated on usability challenges associated with the presentation of laboratory information?
3. Within the existing federal framework, how can laboratory professionals and the CDC support improvements in the usability of laboratory information in the EHR?

Report on Communication in Informatics Workgroup *Addendum 07*

John Fontanesi, Ph.D.
Director, Center for Management Science in Health
University of California, San Diego School of Medicine

Dr. Fontanesi reported on the 2012 Communication in Informatics Workgroup meeting. The Workgroup was convened in response to a CLIAC recommendation made at the September 2011 meeting. He discussed the issues raised by the Workgroup members and the Workgroup's suggestions for multipronged strategies to assure that laboratory interests are represented on the Office of the National Coordinator (ONC) Advisory Committees and workgroups and in the ONC action and surveillance plans for EHR safety. Dr. Fontanesi asked CLIAC to consider the following questions:

1. What issues identified by the workgroup are critical for accurate communication of laboratory testing information, especially with respect to EHRs?
2. What are feasible strategies to address these issues?
3. What strategies would be most effective to facilitate HHS moving forward, to assure patient safety with respect to laboratory testing information in EHRs?

Committee Discussion

The following comments and suggestions were made by the Committee in response to the questions posed by Ms. Sawchuk and Dr. Fontanesi:

- Part of the motivation behind the implementations of EHRs is providing patient access to their medical records. While having access can be helpful, EHRs can be somewhat frightening to patients.
- An EHR system that separates out what is important and puts it in an easy to understand format for patients is desirable. Patients will become increasingly adept at retrieving information, and perhaps even interpreting it with some help from their doctors.
- The essential EHR software components should be standardized. This would improve current software product shortcomings and spur vendors to improve their laboratory data display even after they have achieved EHR incentive program approval.
- Vendors have no reason to develop a smart system if the goal is only to document compliance to gain EHR incentive program approval.
- Pharmacy ordering systems could be used as examples when developing EHR systems. Clinician interface should be improved to promote smarter test selection and result interpretation.
- Laboratory specialties such as anatomic pathology and microbiology, whose reports include textual non-numeric data, present EHR challenges not seen with laboratory specialties whose reports include primarily quantitative or numeric data. These challenges need to be addressed to improve the usability of EHRs.
- The flagging of abnormal results in EHRs needs to be improved. This can be especially problematic for non-numeric results or when individual laboratories have different systems for flagging abnormal results. In some instances, physicians prefer fewer flags to avoid causing confusion, especially for patients.
- Examining adverse events associated with electronic medical records (EMRs) or EHRs can be very effective and can be useful in setting up a system of tracking the entire test order cycle leading to building clinical decision support. The advent of the EHR incentive program and value-based purchasing has given a boost to institutional acceptance of these quality efforts.
- EHR systems that include clinical decision support would be helpful for diseases that are not seen very often. It would also be helpful if the system could help in selecting the best test to order. The simplest solution for physicians may sometimes be to contact the laboratory directly.
- Standardization of laboratory tests would limit and simplify clinicians' choices. However, too much standardization could negatively affect the clinician's decision process. It would be preferable to have laboratorians and clinicians construct protocols that allow probabilities and customization for the patient's care.

- Some EMR or EHR vendors are entering the laboratory information system (LIS) arena. This may be good but it also may be complicated since many LIS products are tailored for a specific application.
- The goal should be one system that integrates all areas of the laboratory and healthcare system. This should include the capability to automatically and immediately contact the physician or person who ordered the test if the result is considered a panic or critical value.
- Investigate how non-medical industries have addressed issues related to safety and standardization, sometimes with help from the National Institute of Standards and Technology (NIST).
- CDC, or others, could survey the laboratory community to gather input and quantify difficulties related to patient safety with respect to laboratory testing information, especially in light of the implementation of EHRs.

ONC's Laboratory Workgroup ***Addendum 08***

- **Direct Project and Laboratory Results Implementation Guide**
- **Addressing Visual Verification**

Karen Dyer
Division of Laboratory Services
Survey and Certification Group
Centers for Medicare & Medicaid Services

Ms. Dyer presented the Committee with an overview of the ONC's Direct Laboratory Workgroup (Direct). She identified the reasons for forming the workgroup, explained the workgroup charge, and defined a Direct project as a project to create the set of standards and services that, with a policy framework, enable simple, directed, routed, scalable transport of laboratory results over the Internet to be used for secure and meaningful exchange between known participants in support of the EHR incentive program. Ms. Dyer explained why current methods of health information exchange are inadequate due to systems now in use to communicate health information among providers and patients. She described how the workgroup could prove to be beneficial in providing a solution with respect to laboratory results with the Direct project, which uses a secure email messaging system to transmit information. She highlighted different aspects of the Direct project and concluded her presentation with a summary of the workgroup efforts.

Mr. Robert Dieterle
Consultant to the Office of the National Coordinator for Health Information Technology
CEO, EnableCare Group, LLC
Leawood, KS

Mr. Dieterle outlined the background, discover phase, and action phase of the ONC's Laboratory Reporting Workgroup and discussed the current verification process of a typical EHR system. He said the main goal of the Laboratory Reporting Workgroup is 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.

Measuring, Evaluating and Improving the Usability of Electronic Health Records

Addendum 09

Mr. Matt Quinn
Computer Scientist
Information Technology Laboratory
Information Access Division
National Institute of Standards and Technology (NIST)

Mr. Quinn presented an overview of how to measure, evaluate, and improve the usability of EHRs. He defined usability as the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use. He explained the importance of usability with EHRs and provided comments from medical professionals and health information technology vendors who are incorporating the concept of usability into EHR software. Mr. Quinn concluded his presentation by explaining how technical guidance provided by NIST would improve the usability of EHRs.

Usability Challenges in Designing EHRs Used for the Care of Children

Addendum 10

David Brick, MD
Pediatric Cardiology
Morgan Stanley Children's Hospital-PDC
New York, NY 10032

Dr. Brick began his presentation with an overview of the challenges faced when designing EHRs for pediatric medical care. He provided examples of the special requirements, human factor solutions, and critical special functions found in pediatric charts and described how the absence, use difficulty, or malfunctioning of these can cause errors. He discussed how the input of different pediatric patient care variables into an EHR may affect how the information is viewed and stored. Dr. Brick concluded by explaining the difference between patient care usability guidelines for adults and newborns.

Committee Discussion

The Chair opened the floor for questions and discussion with presenters Mr. Dieterle, Ms. Dyer, Ms. Sawchuk (for Mr. Quinn), Dr. Fontanesi, and Dr. Brick seated as a panel before the Committee. The following are the comments and clarifications made by the Committee and the panel.

- There is a multi-part problem in microbiology when presumptive organism identifications are not always updated in LIS and EHR systems with final identifications and susceptibility testing results. The first problem can occur because the system must generate the appropriate flags to indicate the report status. The second part of the problem can occur in the transaction and HL7's ability to accommodate the report status. Finally, the EHR must properly consume and display the report. The solution is to get EHR developers to adopt the HL7 standards and to assure the final report status is displayed along with the ability to display all prior reports for a specimen. The developers need to work with laboratories and clinicians when developing new systems.
- The development of LIS and EHR usability guidance requires assessments be performed in a variety of settings to enable the LIS/EHR to be integrated into different physician workflows. Workflow designs are not infinitely variable and systems can be built to accommodate them.
- Because EHR system development requires a substantial upfront investment to adequately assure patient safety once the system is in use, it can be difficult to modify the systems at a later date. However, system-wide corrections are more likely if there are complaints from many institutions. Laboratories need to be sure their comments or complaints reach the EHR vendors and are not filtered out by their institution's information technology department.
- Specific requirements should be made clear before EHR development begins. Currently the monetary incentives rather than laboratory requirements are driving the development. Laboratories also have a vested interest in EHR development which is driven by CLIA. If the correct information is not in the EHR the laboratory will be cited or accreditation could be affected.
- Because of the reimbursements tied to the use of certified software systems, some institutions are considering abandoning the LIS in favor of an EHR that includes a laboratory module. This could affect the laboratory's ability to store data.
- The ONC advisory committees do not seem to have laboratory representation. CLIAC could advocate for the laboratory representation that is currently lacking.
- Currently the ONC workgroup's scope does not seem to include public health because it is focused on the specific goal of minimizing the overall cost and time it will take to implement and interface between the laboratory and an EHR in an ambulatory care environment. However, the EHR incentive program does have requirements for reporting to public health.
- The CDC has complementary interests in clinical and public health with respect to the EHR incentive program and EHR implementation. While the LabHIT Team is focused on patient safety in clinical settings, another CDC Division is focused on public health interests.
- Institutional due diligence is needed prior to purchasing an EHR system to ensure the vendor's product meets the institution's needs. A reporting mechanism to enable sharing information on EHRs with other healthcare systems or a national repository of common problems might make a difference. However, there are problems not solvable by technology, such as physically locating a physician to report a critical laboratory result.

CLIAC Recommendation

CLIAC recognizes that serious patient safety risks can arise from errors in the order entry, transmission, display and interpretation of laboratory data in EHRs. Display and use of non-numerical laboratory information is an under-appreciated critical issue. Interoperability with LIS as well as correct transmission of data across multiple interfaces is also critical. The laboratory community can provide important input and solutions to these challenging problems. CLIAC makes the following recommendations:

1. Laboratory experts with experience in hospital, ambulatory or public health settings should be members of key ONC advisory committees and other agency groups that are setting standards and policies for laboratory information in EHRs.
2. Provider usability is an important strategy for mitigation of these patient safety risks. Further work in this area should be supported.
3. A national system for reporting EHR laboratory related safety events and near misses should be established to clearly define the prevalence, understand the underlying causes and stimulate the design of broad-based solutions.
4. A catalogue of various solutions for laboratory data should be created using work that has already been done and considering areas of expertise [e.g., human factors] that may not have been previously engaged.

Culture-Independent Microbiology Diagnostics: Impact on Public Health

Ms. Nancy Anderson, M.M.Sc.
Branch Chief, Laboratory Practice Standards Branch (LPSB)
Division of Laboratory Science and Standards (DLSS)
Laboratory Science, Policy and Practice Program Office (LSPPPO)
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Centers for Disease Control and Prevention

Ms. Anderson provided a brief introduction to the increasing use of culture-independent microbiology diagnostics and the impact on public health. She stated that in 2006 a CLIAC workgroup looked at this issue from the perspectives of both simple rapid tests done in point-of-care settings and high complexity molecular tests performed in traditional laboratory settings. After hearing that workgroup report, the Committee made a number of points pertaining to how rapid tests were being used, how results were interpreted and reported, regulatory considerations for multiplex testing, the impact of cost and the lack of reimbursement for shipping specimens to public health laboratories, public health reporting mechanisms (especially as related to point-of-care testing), communication challenges between public health laboratories and clinical laboratories, and educational needs. Since that time, six years have passed, and many of the same issues still exist. Ms. Anderson concluded with the introduction of Dr. John Besser.

Culture Independent Diagnostics ***Addendum 11***

John Besser, Ph.D.
Enteric Diseases Laboratory Branch
Division of Foodborne, Waterborne and Environmental Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

Dr. Besser provided the Committee with an overview of the increasing use of culture-independent microbiology diagnostics and the impact of this change in laboratory practice on public health. He began by giving a comparison between bacterial culture tests and rapid culture-independent tests and explained how this could lead to the potential demise of bacterial culture for certain organisms, especially with the advent of nucleic acid amplification tests. He gave several examples that illustrated the flow of medical laboratory information between patient management and public health programs, emphasizing the importance of public health surveillance to limit disease transmission, control underlying problems, and monitor trends. Dr. Besser then provided information on the introduction of the PulseNet disease surveillance network in 1996. He demonstrated how outbreak detection, using PulseNet, leads to prevention measures and disease reduction. Dr. Besser emphasized the major issue with pulsed-field gel electrophoresis techniques is their dependence on bacterial isolates. He explained the development of culture-independent multi-analyte panels for detection of bacterial agents could lead to a decrease or change in the nature of information received by PulseNet laboratories resulting in a loss of PulseNet functionality. Dr. Besser detailed short and long term goals to address the issue including isolate preservation, development of culture-independent pathogen characterization methods, and exploitation of paradigm shifting technologies. He concluded with two questions for Committee consideration:

- How can the public health impact of certain test results be better emphasized as test systems are cleared by FDA?
- Are there ways in which the CLIA program can promote public health recommendations (e.g. supporting CDC guidelines and recommendations)?

Committee Discussion

- One model under discussion to improve the likelihood of having culture isolates available would be to send the specimen to the public health laboratory, though that may be burdensome for the clinical laboratory. Dr. Besser agreed, but noted although forwarding the specimen may be possible, the specimen type would have to be compatible with culture.
- A suggestion was made that laboratories be required to send specimens to the public health laboratory for a mandated list of diseases. Dr. Besser responded that CDC is hoping to collaborate with the FDA to recommend that manufacturers provide language in the product insert related to the importance of sending certain specimens to public health laboratories. He added states have mandatory reportable disease lists while CDC has a voluntary reportable disease list. The states' lists do not always match CDC's.

- A point was made that there are two systems in health; individual patient care and public health. Often the two are not integrated and there are multiple state regulations. Even if regulations required clinical laboratories to forward specimens, the regulations would not necessarily require the state public health laboratories to culture the specimens. In addition, an FDA recommendation to the manufacturers, to add information to the product insert, would not require the clinical laboratories to change their operations. However, it is a CLIA requirement that laboratories follow the manufacturers' instructions.
- The observation was made that diagnostic development and manufacturing companies do not perceive their tests as linked to public health needs thus resulting in a disconnect between the priorities of the clinical healthcare and public health systems. The industry liaison noted the positive impact that point-of-care tests could have on public health by providing rapid results that allow for immediate patient follow-up and treatment.
- It was emphasized that many of the nucleic acid amplification tests are more sensitive than reflex culture. Dr. Besser responded that there are often two reasons for performing bacterial culture, confirmation of organism identity and isolate recovery for public health surveillance, the latter of which is the topic of this discussion.
- The Chair concluded the discussion by stating that the Committee acknowledges the potential impact on surveillance from culture independent diagnostics. A motion was passed that stated: For microbiology culture-independent diagnostic tests, discussion and resolution of issues related to ongoing public health surveillance should be part of the FDA clearance process.

Clinical Laboratory Integration into Healthcare Collaborative ***Addendum 12***

Julie Taylor, Ph.D.
Division of Laboratory Science and Standards (DLSS)
Laboratory Science, Policy and Practice Program Office (LSPPPO)
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Centers for Disease Control and Prevention

Dr. Julie Taylor gave a brief introduction to the Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™). She reviewed the history of the project including past related Institutes held at CDC and stated CLIHC's™ goal is to optimize the utilization of laboratory services for better patient care. Dr. Taylor provided an overview of the Strategy Meeting held on June 19 and 20, 2012, in Atlanta. She displayed the conceptual logic model of the CLIHC ™ strategic plan and discussed the challenges for optimal utilization of laboratory services and the next steps for new projects. She also updated the Committee on two CLIHC™ projects: Clinicians' Challenges in Test Ordering and Interpretation of Test Results, and Diagnostic Algorithms. Dr. Taylor concluded her presentation by introducing Dr. Tom Savel and Mr. Brian Lee, presenters for the CLIHC™ PTT Advisor App Demonstration.

Committee Discussion

- One member asked Dr. Taylor if CLIHC™ has a workgroup focused on graduate medical education. Dr. Taylor replied graduate medical education is being addressed as the second part of a CLIHC™ medical student education project. CLIHC™ also had a project that examined laboratory components of residency programs. Dr. Chu noted that the Office for State, Tribal, Local and Territorial Support, within CDC, is connected with residency programs and is connecting them to laboratories and CLIHC™ endeavors.
- The Chair asked if general internists or specialists were included within the internal medicine physician category in the clinician survey. Dr. Taylor stated the American Medical Association database was used to determine the categories of the survey participants.
- There was a comment that while the goal of CLIHC™ is noble, the public health side of testing is not mentioned and some unintended side effects may come at the expense of public health interests if this is not recognized.

The Committee also made the following suggestions related to improving communication between laboratories and clinicians.

- The laboratory report or order slip should clearly indicate who to contact for help and information.
- EHRs could be populated with an information button that would contain contact information for the laboratory and other pertinent information.
- Post laboratory contact numbers on each floor of the hospital.
- Facilities could establish a laboratory client services group to provide help and information.
- The laboratory manager should visit each hospital floor monthly.
- Medical students should be provided with laboratory experience.
- A pathology resident should act as a clinical liaison on each hospital floor.
- The laboratory could create diagnostic testing algorithms.

App Demo

Thomas Savel, MD and Mr. Brain Lee, BBA
Public Health Informatics and Technology Program Office
Division of Informatics Research and Development
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Centers for Disease Control and Prevention

Dr. Savel gave a demonstration of PTT Advisor, an iPhone/iPad application that gives clinicians step-by-step guidance for follow-up testing when the patient presents with a normal prothrombin time (PT) and an abnormal partial thromboplastin time (PTT). He said application software (apps) must be quick, forgiving, and easy to use. PTT Advisor is the only CDC app that provides guidance and advice. He demonstrated PTT Advisor using a series of screen shots noting there are currently 50 to 100 downloads per month of the app. In conclusion, Dr. Savel stated the app will continue to be refined. PTT

Advisor is a free download from Apple's iTunes store (http://itunes.apple.com/us/app/ptt-advisor/id537989131?mt=8).

Committee Discussion

- One member commented the app functions incredibly well, but since it is specific to a particular laboratory abnormality its use may be limited. The member asked if there are plans to expand the app. Dr. Savel agreed PTT Advisor is specific to one type of abnormality, however, in time it could be made more comprehensive. It could also be used as a model for other algorithms. Technology has a growth patterns and apps, in the future, might be embedded in EMRs. Mr. Lee concurred and added PTT Advisor has open source architecture allowing it to be used for other algorithms as well as becoming a part of a larger, more complex tool.
- A member queried if there was a next generation of the app planned that would allow text-to-speech and direct voice input. Mr. Lee stated that adding voice components or other visual cues is a future goal for many apps.
- Dr. Chu thanked the team that worked on this project, especially recognizing that this was a "first" at CDC that could open up the possibility for many other apps. The Committee agreed and one member expressed enthusiasm for the limitless potential to bring information to physicians and patients using this process.

Update: Laboratory Medicine Best Practices Initiative ***Addendum 13*** ***Addendum 14***

Nancy Cornish, MD
Division of Laboratory Science and Standards (DLSS)
Laboratory Science, Policy and Practice Program Office (LSPPPO)
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
Centers for Disease Control and Prevention

Dr. Cornish began her presentation with a historical overview of Laboratory Medicine Best Practices (LMBP) and noted additional information was available at www.futurelabmedicine.org. She discussed LMBP's accomplishments in 2011-2012, explained the systematic review topic identification and selection process, informed CLIAC of topics being considered for pre-qualification, and reviewed additional lessons learned. She told the Committee that two on-line training modules were available on the LMBP website and additional models were being developed. Dr. Cornish explained the Apply and Assess steps in the A-6 Cycle and revealed that quality improvement study tools were the future focus for LMBP. She concluded the presentation by directing the Committee's attention to the discussion questions that were part of her presentation.

Committee Discussion

- It was suggested that LMBP study whether it is a better practice for remote hospitals to perform blood cultures on-site or send them to an off-site laboratory. Another topic suggested was whether point-of-care INR testing should be performed prior to invasive procedures.

- Webinars could be used to distribute information pertaining to the LMBP process and soliciting topic input.
- A member cautioned that LMBP should not get too restrictive on what is considered evidence. The nature of broad practice has to be understood before asking what works and what doesn't. Questions need to be carefully structured and the methodology used for analysis should fit with those questions.
- In considering the Apply and Assess steps of the LMBP A6 model, the Chair stated that the Institute for Quality Healthcare Improvement uses a collaborative model for quality improvement that is effective because the participants learn from each other. A member added that the Patient-Centered Outcomes Research Institute also has a method for comparative effectiveness research. Dr. Cornish noted that CDC uses a collaborative model called "Communities of Practice."

ACRONYMS

Addendum 15

PUBLIC COMMENTS

- **Microbiologics** ***Addendum 16***
- **George Birdsong, MD, FCAP, for Cytology Proficiency** ***Addendum 17***

ADJOURN

Dr. Santrach 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:

CLIAC recognizes that serious patient safety risks can arise from errors in the order entry, transmission, display and interpretation of laboratory data in electronic health records. Display and use of non-numerical laboratory information is an under-appreciated critical issue. Interoperability with LIS as well as correct transmission of data across multiple interfaces is also critical. The laboratory community can provide important input and solutions to these challenging problems. CLIAC makes the following recommendations:

1. Laboratory experts with experience in hospital, ambulatory or public health settings should be members of key ONC advisory committees and other agency groups that are setting standards and policies for laboratory information in electronic health records.

2. Provider usability is an important strategy for mitigation of these patient safety risks. Further work in this area should be supported.
3. A national system for reporting EHR laboratory related safety events and near misses should be established to clearly define the prevalence, understand the underlying causes and stimulate the design of broad-based solutions.

A catalogue of various solutions using work that has already been done should be created. Areas of expertise that may not have been previously engaged should be considered for inclusion.

Dr. Santrach announced the spring, 2013 CLIAC meeting dates as March 6-7, 2013, and adjourned the Committee meeting.

I certify this summary report of the August 29-30, 2012, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

_____ Dated: 11/14/2012

Paula Santrach, M.D., CLIAC Chair