

# Clinical Laboratory Improvement Advisory Committee

## **Summary Report**

**August 31 - September 1, 2011**

**Atlanta, Georgia**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

# **Clinical Laboratory Improvement Advisory Committee August 31 - September 1, 2011 Summary Report**

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***Record of Attendance***

Committee Members Present

Ms. Elissa Passiment, Chair

Dr. Ellen Jo Baron

Dr. Christine Bean

Ms. Susan Cohen

Dr. Martha Crenshaw

Dr. Judy Daly

Dr. Anand Dighe

Dr. John Fontanesi

Ms. Julie Gayken

Dr. Norman Harbaugh, Jr.

Dr. Paul Kimsey

Ms. Karen Lacy

Dr. Anthony Okorodudu

Dr. Stephen Raab

Dr. Linda Sandhaus

Dr. Paula Santrach

Dr. Robert Sautter

Dr. Gail Vance

Dr. Emily Winn-Deen

Dr. Rosemary Zuna

Mr. Robert DiTullio, AdvaMed (Liaison Representative)

Ex Officio Members

Ms. Tremel Faison, FDA

Dr. Devery Howerton, CDC

Ms. Judith Yost, CMS

Designated Federal Official

Dr. May Chu

Executive Secretary

Ms. Nancy Anderson

***Record of Attendance – cont’d***

Centers for Disease Control and Prevention (CDC)

Mr. Ron Alford	Ms. Leslie McDonald
Mr. Todd Alspach	Mr. Monte Martin
Dr. Rex Astles	Ms. Kristi Singletary Meadows
Mr. Anthony Barbagallo	Ms. Andrea Murphy
Dr. Vicki Benard	Dr. Renee Ned
Ms. Diane Bosse	Dr. Jan Nicholson
Ms. Cathy Cambria	Dr. Judith Noble-Wang
Dr. Bin Chen	Ms. Terri Phan
Dr. Nancy Cornish	Ms. Cheri Rice
Dr. Maryam Daneshvar	Dr. John Ridderhof
Ms. Joanne Eissler	Ms. Megan Sawchuk
Mr. James Ellison	Dr. Shahram Shahangian
Dr. Geroncio Fajardo	Dr. Adebola Simon
Ms. Patricia Fields	Mr. Darshan Singh
Dr. Seth Foldy	Ms. Theresia Snelling
Ms. MariBeth Gagnon	Ms. Charlene Smith
Dr. Amy Gargis	Ms. Heather Stang
Dr. Shaw Gargis	Dr. Julie Taylor
Mr. Seth Gazes	Mr. Howard Thompson
Ms. Leta Helsel	Ms. Pam Thompson
Ms. Caroline Henderson	Mr. Ron Van Duyne
Dr. David Holmes	Ms. Irene Williams
Dr. Tara Jones	Dr. Laurina Williams
Dr. Lisa Kalman	Ms. Betsy Weirich
Dr. John Krolak	Dr. Barbara Zehnbauer
Dr. Jun Li	Mr. Jonathan Zhong
Ms. Millie Linville	
Dr. Ira Lubin	

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

Mr. Jitin Asnaani (ONC-HHS)	Ms. Karen Dyer (CMS)
Dr. Elliot Cowan (FDA)	Ms. Ann Snyder (CMS)
Ms. Jodi Daniel (ONC-HHS)	

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.

## **Clinical Laboratory Improvement Advisory Committee**

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 regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

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 – INTRODUCTIONS/FINANCIAL DISCLOSURES**

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 explained the meeting would focus on three main topics that included the laboratory's role in the development and use of electronic health records; electronic laboratory reporting for notifiable diseases and meaningful use; and current practices in gynecologic cytology testing.

Dr. Chu recognized the six CLIAC members and the previous AdvaMed liaison, who were to receive plaques and letters of appreciation for their service on the Committee. They were Dr. Ellen Jo Baron, Ms. Susan Cohen, Dr. Norman Harbaugh, Jr., Ms. Elissa Passiment, Dr. Stephen Raab, Dr. Emily Winn-Deen, and Ms. Luann Ochs. Ms. Passiment received special recognition and appreciation for her exceptional leadership while serving as Chair of the Committee.

Ms. Elissa Passiment, 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 A](#)*

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 the DLSS. She reviewed the CLIAC recommendations made from 1993 through 2010. She discussed the status of the proficiency testing (PT) regulatory revisions in microbiology and said the revision of other specialties will follow a tiered approach. She reported on a recent PT focus group project undertaken in collaboration with APHL; a summary report is under development. Dr. Howerton updated progress on the good laboratory practices for waived testing sites project, noting the enthusiastic reception of postcards, booklets, and posters. The launch of an online training module is scheduled for September 2011

and a booklet to assist those who wish to initiate or direct waived testing is nearing completion. The update on the Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)<sup>TM</sup> projects included a brief review of each workgroup's project. She said an Office of Management and Budget-approved clinician survey and a medical school survey would soon be underway, with results expected early in 2012. Highlights of the Laboratory Medicine Best Practices initiative were described including recent publications/presentations and topics in progress. Finally, Dr. Howerton gave an update on the guidance document for next generation sequencing in clinical practice, intended to inform laboratories of applicable regulatory and professional standards and described the 'Genetics in Clinical Practice' web-based training program developed with Dartmouth Medical School.

### **Committee Discussion**

- One member asked if educational materials could also be developed for consumers/patients, perhaps a laboratory primer for consumers. The member noted physicians don't have the time to explain testing, and written materials are not available for individuals who do not have access to the internet. Dr. Howerton and Ms. Anderson replied CDC has developed information for consumers on molecular genetic testing and development of more consumer oriented materials is under discussion.
- A member asked Dr. Howerton to expand on the PT focus group's recommendations for improving PT. Dr. Howerton explained the report is currently being finalized and more information will be available at a later date. The member also commended the CLIHC<sup>TM</sup> medical school education workgroup for its efforts.
- The Chair asked Dr. Howerton to elaborate on what the PT focus groups were asked to consider related to PT performed by the public health laboratories. Dr. Howerton said the public health laboratories had been asked how they used PT for reasons other than meeting regulatory requirements and if they were realizing additional benefits from PT.
- A member asked if the next-generation sequencing workgroup was working with professional organizations, and mentioned the American College of Medical Genetics was also developing standards. Dr. Howerton replied the workgroup was linked into other professional organizations, including the one mentioned.

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

*Addendum B*

Ms. Tremel Faison, MS, RAC, SCT (ASCP)  
Regulatory Scientist  
Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD)  
Center for Devices and Radiological Health (CDRH)  
Food and Drug Administration

Ms. Tremel reviewed several changes and developments in the Office of In Vitro Diagnostic Devices beginning with several new hires. Center initiatives included evaluation of the 510(k) process; a review by the Institute of Medicine (IOM); public meetings on matters including new technologies, post-market surveillance, and mobile applications; and clinical decision support software. Ms. Tremel listed 12 recently published guidance documents, 15 notable product clearances, and nine devices given pre-market approval. The one notable panel meeting was focused on down-classification (to Class II) of *Mycobacterium tuberculosis* rapid molecular test diagnostics and nucleic acid amplification assays for mutations associated with antibiotic resistance. For post-market compliance, she spoke to a list of six recalls, which included a centrifuge design shown to pose risk of disintegration and contamination. She concluded by noting two warning letters resulting from FDA inspection of manufacturers.

### **Committee Discussion**

- A member was concerned about the Research Use Only (RUO) and Laboratory Developed Tests (LDT) guidance documents, saying laboratories should be given strong consideration for tests they have developed and validated in comparison to using similar FDA-approved test kits that become commercially available. The member suggested it will drive up costs if all laboratories are required to use only the FDA-approved test kits with no guarantee for increased reimbursements from insurance. Another member asked for a timeframe for the release of the RUO and LDT guidance documents. Ms. Faison said the RUO guidance has been released, but she did not know when the LDT guidance would be out.
- A member commented on the RUO guidance impact, relating how test manufacturers used to release new technologies to laboratories under RUO status while they were still being cleared by the FDA; laboratories could validate the test and then release results for clinical care. The member noted the new guidance forbids this practice and wondered how compliance would be policed. Ms. Faison commented this is an example of the regulatory side not keeping pace with technology, but emphasized new improved technologies still need to be evaluated for safety and effectiveness.
- A member commented that endocrinology meetings have encouraged the use of hemoglobin A1C to diagnose diabetes and asked how private practice clinicians can know they are ordering the correct test and using the results appropriately. The member also questioned whether a waived test for hemoglobin A1C could be used to diagnose diabetes. The Chair agreed this is a challenge and explained that currently waived hemoglobin A1C tests have not been cleared for this purpose.
- A member commented that the off-label use of laboratory tests was complicated and confusing for clinicians. Another member wondered whether the manufacturers' sales forces would explain the clinical limitations of different test methodologies to clinicians when trying to sell test devices. The Chair agreed saying that the specifications and performance of point-of-care tests are different from those often used in clinical laboratories. She added there are also the issues of precision, sensitivity, and specificity variations among point-of-care tests and noted the need for useful dialogue between the clinical laboratory and the clinicians. Another member

agreed, noting the challenge laboratory directors have in not always knowing how a test will be used by clinicians.

- One member asked for more information about the IOM's criticisms of the FDA's 510(k) process. The Chair added there are some examples of "substantial equivalence" that have carried over for decades and commented the law needs to be updated. Ms. Faison replied the IOM criticisms were mostly about the process of device approval based on showing substantial equivalence to a predicate, but the 510(k) process does not determine a device is safe and effective for the intended use. She noted the FDA does require clinical data to show safety and effectiveness for *in vitro* devices and added the FDA was seeking new ways to approve innovative devices and would be meeting to discuss this topic.
- A member asked about the FDA's current policy on off-label use of laboratory tests. Ms. Faison replied the FDA has avoided regulating off-label use considering it the practicing of medicine if such use was determined solely by a physician. She added it would be a different matter if the manufacturer was promoting the off-label use of the test. In that case, the FDA would investigate.
- A member asked if the recall of a particular kind of diagnostic glucose strip listed in the presentation was country-specific. Ms. Faison replied it was for France and such information was available on the FDA website.

### **Centers for Medicare and Medicaid Services (CMS) Update**

*Addendum C*

Judith Yost, M.A., MT (ASCP)  
Director, Division of Laboratory Services  
Center for Medicaid and State Operations  
Centers for Medicare & Medicaid Services

Ms. Yost began her presentation with a discussion of CLIA competency evaluation. She noted evaluation of competency is required for all technical, supervisory, and testing personnel and is not the same as a performance evaluation or training. Rather, competency evaluation is the means to confirm training effectiveness. She commented that various related competency requirements are interspersed throughout the CLIA regulations. Ms. Yost discussed the six assessments that must be included in each competency evaluation as well as problems to avoid. She noted flexibility is built into the CLIA competency requirements, and that CMS encourages creativity in meeting these requirements. Ms. Yost continued her presentation with an overview of current CLIA statistics showing that the number of waived laboratories continues to increase and that the number of nonwaived laboratories has ceased to decrease. She briefly related CMS' collaboration with the Center for Biologics Evaluation and Research to investigate transfusion fatalities, the majority of which were not the result of laboratory error. Ms. Yost ended her presentation with a discussion of CLIA deficiencies identified by CMS and those identified by CMS' partners, noting that most of the deficiencies were related to quality control.

## **Committee Discussion**

- A member wanted clarification of the laboratory director's responsibility regarding the approval of procedures and changes in procedures, especially in terms of laboratories with frequent changes. Ms. Yost replied the laboratory director is responsible for the approval and sign off of all procedures, including those specialized technical procedures that may be frequently changed. This responsibility cannot be delegated. However, the technical supervisor may review the procedures and compile a list that the director can sign.
- A member wondered why patients that go to offsite laboratories are not allowed ready access to the laboratory directors, which would encourage consumer feedback. Ms. Yost explained that while CLIA has education, experience, and training requirements for laboratory personnel, the regulations do not address a laboratory director's visibility in the patient areas.
- A member related the scenario of a physician reviewing the test results and adding notes to the laboratory's official record and asked if the laboratory director was required to assess and document the physician's competency. Ms. Yost answered that competency assessment is not required if the notes were not included as part of the laboratory report.

## **PRESENTATIONS AND COMMITTEE DISCUSSION**

### **The Laboratory's Role in the Development and Use of Electronic Health Records (EHRs) and Electronic Laboratory Reporting (ELR) of Public Health Information for Notifiable Diseases and Meaningful Use**

*Addendum D*

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 provided the Committee with a brief overview of the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009 to promote widespread adoption and standardization of Health Information Technology (HIT). Expected benefits of HITECH include easier coordination of patient centered healthcare, reduction of medical errors, and extraction of information for public health surveillance. The Office of the National Coordinator for Health Information Technology (ONC) has been charged to facilitate the implementation of HITECH using two federal advisory committees, the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC), providing recommendations. Dr. Howerton reminded the Committee of prior CLIAC meetings where laboratory issues related to the implementation of EHRs were presented and

discussed. She described the purpose for this segment of the CLIAC meeting, introduced the speakers, and drew the Committee's attention to a series of questions to be used as a discussion guide. In conclusion, Dr. Howerton recognized the complexity of the issues and stressed the importance of assuring the quality of laboratory information and data as well as its accessibility to healthcare providers and patients.

**Overview of Regulations Relevant to Patient Laboratory Testing in the Electronic Health Record** *Addendum E*

Jodi Daniel, JD, MPH  
Director, Office of Policy and Planning  
Office of the National Coordinator for Health Information Technology

Ms. Daniel presented an overview of the HIT regulations, remarking that laboratory information, a critical component of EHRs, is necessary for physicians to provide quality healthcare to patients. She described the regulatory process saying the goal is not only to promote adoption of HIT but also utilization of HIT as a mechanism for improving health outcomes, increasing transparency and efficiency, and improving healthcare delivery. She introduced the three-stage conceptual approach to Meaningful Use (MU) and described the MU Program including who is eligible to participate and EHR incentive programs. She reviewed the MU Stage 1 laboratory-specific objectives and measures and provided the Committee with a status update on the Meaningful Users and Incentive Program. Ms. Daniel went on to explain how standards and certification criteria relate to MU objectives. She provided an overview of temporary and permanent EHR certification programs and indicated that testing and certification is expected to begin under the permanent certification program on January 1, 2012. Ms. Daniels concluded by touching on the focus and importance of laboratory interoperability in the State Health Information Exchange (HIE) Program, and noted the short and long-term objectives associated with this effort.

**S&I Framework Laboratory Results Interface (LRI) Initiative Update** *Addendum F*

Jitin Asnaani, MBA  
Coordinator, S&I Framework  
The Office of the National Coordinator for Health Information Technology

Mr. Asnaani began his presentation by defining the Standards and Interoperability (S&I) Framework and stated it represents one approach adopted by the Office of Standards and Interoperability to fulfill its charge of enabling harmonized interoperability specifications for HIT and implementation of EHRs. The S&I Framework approach creates a collaborative, coordinated process to build incremental standards that can solve real-world issues to enable health information exchange. Mr. Asnaani described the S&I Framework Laboratory Results Interface (LRI) Initiative mission and stated the focus is to establish a nationwide implementation guide for electronic submission of laboratory

results, using an incremental approach that begins with the ambulatory primary care physician and moves outward. He said the initiative objectives are to have EHR and laboratory information systems (LIS) vendors agree that they can use the implementation guide while minimizing intermediaries, customization, and translation, thereby enabling easier implementation for providers who adopt EHRs. Mr. Asnaani concluded his presentation by outlining the outcomes and next steps of the process and stated the implementation guide approach enables flexibility for future harmonization with ELR guides.

### **Committee Discussion:**

- A member asked how the capability to submit electronic data on reportable diseases to public health agencies came to be chosen as an objective under MU Stage 1. It was clarified that MU Stage 1 has two objectives. Objective 1 is to incorporate clinical laboratory test results into EHRs as structured data, while Objective 2 is the capability to electronically submit reportable laboratory results to public health agencies. The HL7 specifications used for reporting results to public health are far more robust than those currently used for reporting to the ambulatory care doctor's EHR. The S&I Initiative is trying to bridge the gap between the HL7 specifications and those used by ambulatory care doctors.
- A member asked how it was determined that EHR incorporation of greater than 40% of certain laboratory results would be the guideline for the MU, Stage 1, Objective 1 measure. Ms. Daniel responded that stakeholders provided input to the MU workgroup focused on suggesting the right measures, metrics, and objectives for MU, who provided input to the HIT Policy Committee. Based on this information, the HIT Policy Committee made the recommendation of greater than 40%. She added this number is just a starting point.
- A member referenced discussion about laboratory interfaces with the EHR and asked if those existing interfaces will change. If this occurs, who will be responsible for bearing the costs? Mr. Asnaani expressed the desire to implement one standard so that the implementation burden of every incremental interface is not high. The interface chosen as the standard is HL7 version 2.5.1 because it is already broadly used and thus reduces the burden on implementation. He noted there will definitely be a cost, but who will pick up the cost is uncertain. Ms. Daniel added MU incentives will help to mitigate costs and encourage adoption of these changes.

### **The Laboratory's Perspective on the Development and Use of Electronic Health Records**

*Addendum G*

David L. Booker, MD  
Chair, Pathology Department  
Trinity Hospital of Augusta, Georgia

Dr. Booker began his presentation with an explanation of why it is important to include the laboratory when planning the development and use of EHRs. He observed that the laboratory supplies the largest volume of clinically actionable data to the EHR and needs data back from the EHR. Therefore, poor integration of EHRs with the laboratory defeats the purpose of EHRs and could lead to increased costs and decreased quality of care. He discussed six problem areas that laboratories are aware of in the development and display of EHRs and emphasized that the display of laboratory and pathology results is especially important as failure to follow best practices for the display of results can affect medical interpretation and patient safety. Dr. Booker concluded his presentation by emphasizing the importance of involving pathologists, laboratory scientists, and laboratory managers in the design, implementation, and use of EHRs.

**Committee Discussion:**

*Addendum H*

The Chair drew the Committee's attention to the first five questions pertaining to EHRs and the LRI and suggested they be used to guide the discussion.

- A member asked if the larger laboratories, as major components of the market, are suggesting their format be adopted for EHRs. Dr. Booker responded he is not aware of that as an issue or of an effort to create proprietary standards. The Chair expressed the likelihood that large laboratories would adapt their interfaces to the EHRs to promote customer satisfaction.
- A member stated the EHR policies and standards committees do not have adequate laboratory representation. Mr. Asnaani replied the S&I Framework Initiative is completely multi-party with work driven primarily by EHR and laboratory representatives. Representatives from large commercial laboratories, hospitals, and smaller laboratories have been involved. He said important issues have come up with respect to the CLIA regulations and also with how the certification of EHRs will affect the day-to-day operation of the laboratories and their laboratory information management systems.
- The Chair voiced concern that the hospital-based portion of the laboratory is not being adequately represented. Mr. Asnaani assured the Committee that, from the beginning, attempts have been made to involve the hospital laboratories. Further, once the standard is confirmed, there will be a public comment period. Ms. Daniel added that beyond the S&I Framework, one of ONC's top six principles is demonstrating openness and transparency. She stressed the need for input and directed the Committee to the ONC website at [www.healthit.hhs.gov](http://www.healthit.hhs.gov), and to [www.siframework.org](http://www.siframework.org) for more information.
- Another member added organizations such as Public Citizen, AARP, and Consumer Federation of America should be included and voiced concern over the potential for the breach of patient confidentiality and associated penalties. Ms. Daniel responded there is consumer representation on the HIT Policy Committee and the workgroups. Also, there is a specific workgroup on privacy and security. She reminded the Committee of the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules, and said there has been increased enforcement of both

through HITECH, enabling HHS to impose larger penalties. Dr. Booker cautioned that patient care could be compromised if the information sharing rules are overly strict and punitive, preventing physicians and others from getting the information needed for patient care.

- One member commented that healthcare has become so complex that good quality care often requires the involvement of professionals across organizations. Errors occur when information crosses boundaries, therefore EHRs must fit into a bidirectional workflow. Errors can also occur when the providers try to locate the relevant information in the EHR and are distracted by the mechanics of the steps in the process. Mr. Asnaani replied the S&I Framework is focused on the boundary, the interface between an EHR and external information. Ms. Daniel, in response to the internal issue of locating the relevant information, discussed the development of an EHR usability protocol focused on patient safety issues. She said ONC is working with the National Institute for Standards and Technology (NIST) towards providing more transparency and increased usability of EHRs. A certification program is under consideration as a way to address usability.
- A member said there seems to be a need for two systems, both an LIS for laboratories to input their particular type of information and another system that will allow clinicians to pull the information they need and view it contextually. That does not seem to be what the EHR is currently being built around. Another member asked why the information in an EHR is still being represented as text and numbers rather than in a more intuitive and easier to interpret graphical manner; a system that would recognize what each team member needs. Mr. Asnaani responded one of the challenges when developing a standard is determining where to create the flexibility that will allow for innovation. This requires public input especially from innovative healthcare providers. Ms. Daniel agreed.
- A member stressed the need for tools to look at outcomes, such as cost of care and better health, which would inform policy going forward. Ms. Daniel responded the goal in MU, after capturing the data, is to measure outcomes. She emphasized the work is currently in Stage 1, but the hope is that by Stage 3 people will be capturing information, reporting information, and making changes to improve outcomes based on the information.
- One member noted there are facilities that are utilizing EHRs effectively. Ms. Daniel agreed, for example ONC has the Beacon Community Program, which is a grant program for communities to build and strengthen their HIT infrastructure and exchange capabilities. The goal of the program is that together the communities will achieve measurable improvements in health-care quality, safety, efficiency, and population health and will demonstrate the vision of a future where hospitals, clinicians, and patients are meaningful users of HIT.
- One member asked if EHRs are limited by the version of HL7 used for the interface system. Mr. Asnaani replied EHRs are not limited by the interface version. While the initial use cases have started with a narrow focus, the implementation guide is not intended to be static and will allow for the addition of other profiles as other use cases evolve over time.
- A member asked about plans related to the management of middleware systems to allow greater EHR functionality. Mr. Asnaani acknowledged the challenges of

connecting between systems that cross multiple boundaries with a custom integration point required for each. He suggested standardization of the systems or components could reduce costs and result in better products.

- One member commented the absence of some of the test report information from the EHR could result in patient safety issues. For example, patient results without reference ranges can result in patient harm. One member commented that they conducted a study looking at results that required the physician to take action and found that 8% of results had no documentation that any action had taken place. The laboratory needs to develop basic metrics to identify actionable results and create a role for result managers to follow-up when action had not been taken. The Chair added that sometimes pertinent text related to result interpretation is not properly linked to the results in EHR.
- A member commented about receiving requests for external laboratory results to be entered into the EHR. Some of this testing comes from facilities that do not have an official laboratory report therefore the result forms may not have all the CLIA-required elements, such as reference ranges. When a healthcare provider sees a result from one of these forms, they may not have the information needed to correctly interpret that result.

The Chair then summarized the key points of the discussion:

- ONC continues to need expertise and additional input from pathology and laboratory science – especially hospital-based. The laboratory community can provide input on usability and the data needs for outcomes.
- Cost and regulations, if not carefully crafted, could be perceived as barriers to implementation of EHRs. The CLIA regulations are not a barrier to the ability to link to an EHR, nor to the exchange of information between healthcare systems.
- Challenges remain because of the lack of understanding of the complexity of laboratory testing and the importance of the successful display of laboratory results in the context of patient care. The EHRs are missing a number of elements that would increase the context and improve the usability of the laboratory results.

### **Overview of CDC's Electronic Laboratory Reporting (ELR) and Meaningful Use (MU) Activities**

*Addendum I*

Seth Foldy, MD, MPH, FAAFP  
Director, Public Health Informatics and Technology Program Office  
Office of Surveillance, Epidemiology and Laboratory Services  
Centers for Disease Control and Prevention

Dr. Foldy introduced the topic of electronic laboratory reporting (ELR) to public health by providing a diagram explaining the different paths laboratory information can take in a person-based case investigation. The goals of ELR were defined and it was noted that over 40 large jurisdictions in the USA receive ELR today. Dr. Foldy explained that MU incentives are paid by CMS to eligible hospitals and providers that adopt a certified EHR

and “meaningfully use” it to improve health care delivery. In Stage 1 of this process, eligible hospitals must test their capability to submit one of three types of public health reports and, when successful, must begin submitting reports. Currently, there are 21 large jurisdictions that report “testing” hospitals and 31 that are “capable” of reporting. Dr. Foldy discussed several ways laboratories can support eligible hospitals and providers in meeting the Stage 1 objectives, such as using ONC-certified information exchange components, adhering to the implementation guide and vocabulary specifications, and collecting needed information. He also stated the usage of correct LOINC and SNOMED-CT codes and machine readable logic were issues related to ELR that were not addressed as part of the HITECH MU regulations and may need to be dealt with in other ways. Dr. Foldy concluded his presentation by discussing the purpose of the HL7 version 2.5.1 Implementation Guide and reviewing several charts detailing the message structure segments.

**Committee Discussion:**

*Addendum J*

The Chair presented a set of three questions pertaining to ELR and MU as a guide for Committee discussion:

- A member said that in addition to reporting data to public health departments, receiving information back, such as causes of outbreaks, is essential and inquired if this is being addressed. Dr. Foldy indicated this is a challenge since some hospitals are unwilling to have their information shared, even if de-identified. He acknowledged the value of sharing public health data and information with clinical laboratories.
- Two members commented that some states are mandating infectious agent reporting but each state differs in what data elements are reported. Dr. Foldy stated the public health reporting S&I Initiative is looking at what the public health case report message standard should be and what other ancillary support is needed to provide public health with the necessary information for case investigation. He said a national reporting standard is the ideal.
- A member commented the United States should be using cloud-based reporting, taking data from every testing site and sending it to a virtual network that parses the data and informs, in real time, those people who need to intervene. Dr. Foldy said CDC is engaging in their first major experiment with syndromic surveillance. All hospitals and clinics could report to a central site that is segregated by and only accessible to the jurisdiction that has the license to see the data. He said this cannot be done with ELR because every state has its own laws and regulations about how things need to be reported; it would take too much time and too many resources to have all facilities provide input into a single system.
- Another member asked Dr. Foldy if the current laboratory report elements are sufficient for the purposes of public health agencies. He responded the HL7 standard is a consensus built tool that takes the data laboratories can provide and transfers it to public health agencies in a way that is usable. However, there is still a lot of clinical

case information that the public health agencies need. Thus, in terms of case reporting, the answer is no.

- Dr. Chu commented a separate module needs to be developed for public health investigations that would include data pertaining to the environmental context of an outbreak and could mitigate risks to humans.
- A member asked whether only finalized results may be transmitted as part of ELR in microbiology. Dr. Foldy replied the HL7 standard includes fields that specify if a result is preliminary and can receive updated and corrected results. Another member added it would be dangerous to report preliminary results on any select agent electronically.
- Dr. Foldy asked Dr. Nikolay Lipskiy for his input on information that should be included in a public health report. Dr. Lipskiy replied most of the necessary laboratory elements are included. However, additional information from the case investigator and epidemiologist as well as details such as antibiotic susceptibility should be added.
- One member noted a case where the data reported to the public health agency did not allow for inclusion of critical clinical information. A second member inquired if it was possible to promote dialog within the ELR, stressing the importance of integrating facts to create the appropriate context. Dr. Foldy replied that although there are new avenues for information exchange, such as syndromic surveillance, there are legal and practice limits to how much of the patients' private information can be reported to the government.
- Dr. Foldy commented that traditionally patient demographic information has not been sent to public health agencies. The Chair stated the reason the public health agency doesn't get that information from the laboratory is because the laboratory doesn't have it. Another member stated when they do have access to this information workload doesn't permit the time to send it. The member stated if the laboratory was incentivized, these extra measures could be undertaken.
- Dr. Foldy asked the Committee what CLIA could do to enhance the interoperability and utility of information exchange between laboratories and public health agencies. The Chair responded CLIA is intended to govern laboratory practice and assure the quality of testing; there is no mention of information exchange in the CLIA law or regulations. Ms. Yost added CLIA just requires a system or a process be in place to ensure the results get to the individual who ordered the test or an agent that is designated by the authorized person, which would be the EHR, accurately, reliably, timely, and confidentially. Though the CLIA regulations include specific reporting elements, they do not include requirements for how this is to be accomplished.

The Chair then summarized the key points of the discussion as being:

- Laboratories can support hospitals and eligible providers in meeting public health objectives by sending whatever reportable results they have within their systems. As far as expanding those systems to meet public health needs, there would have to be a consensus as to what those needs are, followed by changes to ELR systems.
- Current laboratory report elements do not provide the data requested by public health agencies. Public health agencies would like to have clinical context, location of the

patient, and information needed for epidemiological purposes, some of which may be garnered through other systems within the hospital. Again, this would require a change to ELR systems so information can be easily sent to the public health agency.

- It appears that most of the data elements discussed in these proceedings are not addressed in the HITECH MU regulations.

The Chair, on behalf of the committee, thanked the presenters for their excellent explanations and presentations, and their patience and willingness to discuss this important issue.

### **Evaluation of Current Practices in Reporting Gynecologic Results and Cytology PT** *Addendum K*

MariBeth Gagnon, MS, CT (ASCP), HTL  
Health Scientist, Laboratory Practice Standards Branch  
Division of Laboratory Science and Standards  
Laboratory Science, Policy and Practice Program Office  
Office of Surveillance, Epidemiology, and Laboratory Services  
Centers for Disease Control and Prevention

Ms. Gagnon provided an introduction to the cooperative agreements awarded to the College of American Pathologists (CAP) and the Michigan Public Health Institute (MPHI) to develop an inventory of current practices in gynecologic cytology laboratories and to attempt to standardize procedures for quality improvement. She informed the Committee that CAP was tasked to survey all laboratories that participate in gynecologic cytology PT programs while MPHI surveyed the Papanicolaou (Pap) smear providers. While the surveys contained specific questions for laboratorians (CAP survey) or providers (MPHI survey) they also contained overlapping questions; Ms. Gagnon reviewed this compiled data. Based on the results from both surveys, the majority of gynecologic cytology tests were collected by physicians in private practice and Pap tests screened in hospitals. Both CAP and MPHI reported an overwhelming predominance of the ThinPrep Pap test as compared to Surepath and conventional Pap tests. Clinical histories, previous abnormal Pap tests, and abnormal biopsies were factors that most frequently identified patients as high risk in both the CAP and MPHI surveys. A high percentage of the respondents on both surveys reported ordering human papillomavirus (HPV) testing on high risk individuals, while a lower number of respondents also reported testing for HPV on low risk individuals for which there was no clinical indication. The most frequently reported turnaround time for all respondents was two to six days and over half of respondents said HPV results were provided at the same time as Pap test results. Although a majority of laboratories indicated they are actively monitoring unsatisfactory specimens, this information does not seem to be relayed back to providers as often. Ms. Gagnon concluded her presentation with two questions for CLIAC discussion regarding the CAP and MPHI survey results.

## **Good Laboratory Practices in Gynecologic Cytopathology**

*Addendum L*

Joseph A. Tworek, MD  
Author of the CAP-CDC Collaborative Gynecologic Practices Survey  
Anatomic & Clinical Pathologist, Cytopathologist  
Saint Joseph Mercy Saline Hospital  
Ann Arbor, MI

Dr. Tworek discussed the charge, approach, and survey results that were the outcome of the cooperative agreement awarded to CAP by CDC. He related that CAP was charged to develop an inventory of current practices in gynecologic cytology laboratories and to attempt to standardize procedures for quality improvement. CAP's approach involved a multi-step process comprised of sending a survey of QA practices to 1,191 laboratories enrolled in gynecologic PT, forming working groups to analyze specific survey data topics, posting additional questions open to the cytology community on the CAP website, and convening a consensus conference to vet good laboratory practice statements. He said the receipt of 541 useable survey responses was high considering the length of the survey. Dr. Tworek briefly discussed each of the five workgroups' participants, QA topic(s), and results. Each workgroup developed good laboratory practice statements based on the survey data, personal observations, current practice, literature reviews, or expert consensus. The consensus conference, open to the cytology community, was held on June 4, 2011, to vote on the good laboratory practice statements developed by the workgroups. Finally, Dr. Tworek provided the voting results for each good laboratory practice statement.

## **Evaluation of Current Practices in Reporting Gynecologic Cytology**

*Addendum M*

Amy Conners, MS, CT, (ASCP)  
SDL Anatomic Pathology  
St. Joseph Mercy Hospital  
Ann Arbor, MI

Ms. Conners began her presentation with an overview of the cooperative agreement awarded to MPHI by CDC. She related that MPHI's project was to collect data from a national sample of healthcare providers that order gynecologic cytology tests in order to inform improvements in laboratory practice. Ms. Conners detailed the three phases of the project including survey development, data collection, and analysis and reporting. Two advisory workgroups, representing laboratory professionals and healthcare providers, assisted in the development of the survey tool. The survey sampling included physicians and nurses randomly selected from the American Medical Association's master file and a Medical Marketing Service, Inc. nursing practitioner list, with an oversampling of obstetrics and gynecology (OB/GYN) providers in Michigan. Of the 9,164 surveys MPHI distributed, 1,595 completed surveys were returned for a response rate of 17.4%. The clinician respondents were collapsed into four categories: general practice/internal medicine, OB/GYN, nurse practitioners (women's health), and certified nurse midwives,

before the data were analyzed. Adjustments were made to account for the oversampling of providers from Michigan. Ms. Conners presented the MPHI survey results showing the variations in responses within these four categories. In conclusion, she said the analyses are being finalized, a final report is being written, and a manuscript will be completed and submitted for publication this year.

### **Committee Discussion:**

### ***Addendum N***

- A Committee member commented that in terms of outcome, low-risk HPV testing is not warranted and wished to know whether the CAP survey addressed testing performed because of the patients' desire to know their low-risk HPV results or high-risk HPV results based on indicators other than atypical cells of undetermined significance (ASC-US). Dr. Tworek responded that these were not addressed in the CAP survey.
- The Chair requested clarification on the good laboratory practices that were identified by the CAP survey and consensus conference. Dr. Tworek explained that his presentation was a summary of CAP's preliminary findings and the final good laboratory practice statements will be included in manuscripts to be developed by CAP.
- One member commented that the entire field of cervical cancer screening is undergoing tremendous changes and was concerned about mandating time consuming practices that may not be relevant over time. Dr. Tworek explained that the goal of the CAP project is to determine consensus practices that meet regulations for laboratories to use in their QA programs.
- A member noted that there seems to be a lack of standardization on how QA is addressed both across and within laboratories. Therefore, there is a great opportunity to advocate coordination of practices and encourage the standardization of testing across laboratories.
- A member asked whether the CAP or MPHI workgroups addressed management of the healthcare provider follow-up to abnormal Pap test results, many of which are not adequately investigated. The MPHI survey results indicated that the providers do not want additional support from the laboratories. Ms. Conners responded that the MPHI advisory groups, composed of clinicians and laboratorians, discussed the topic at length. She stated that more education is needed on the topic. Dr. Tworek added that many laboratories have policies in place to send out reminders to the clinicians when the laboratories have not received follow-up biopsies on the abnormal Pap tests.
- Two members expressed that together the CAP and MPHI surveys highlight the challenges and gaps between clinicians and laboratorians during the testing process. They agreed there is an opportunity for standardization and added there should be an effort to look at good laboratory practices that mitigate the potential risk to the patient of a missed diagnosis due to lack of follow-up.
- One member suggested the development of a good laboratory practice statement promoting diagnostic reflex algorithms to ensure the proper test is ordered in the appropriate situation. Another member agreed saying there is some uncertainty in the next steps to follow after receiving an abnormal Pap test result.

- A member requested clarification of the results for the MPHI survey question regarding whether laboratories should become more involved in providing recommendations for patient follow-up. The member referred to the fact that 40-60% of responses indicated no changes are needed in the laboratory's level of involvement and asked whether MPHI knew if the laboratories serving those clinicians were already providing patient follow-up. Ms. Conners answered the MPHI survey respondents included a variety of clinician viewpoints, from those not wanting recommendations made on patient follow-up, such as suggested biopsies, to the other end of the spectrum where clinicians look forward to receiving information and recommendations. Dr. Tworek commented that this broad range of responses is due to the lack of the standardization of patient follow-up. He said standardization is the key to improving patient care.
- The Chair noted that the major issue discussed in the MPHI survey is also an issue for all of clinical and anatomical pathology: that is, partnering with the clinician to help choose the appropriate tests for the patient and then helping understand and interpret the results so that the correct actions are followed for the patient and there are no misunderstandings. She added as more tests move to molecular methods, clinicians are not going to know which molecular test is the correct one to use and will require guidance.
- A Committee member requested clarification of the CAP statement that a remedial action should not be taken for a non-perfect PT score if the individual passes the test. Dr. Tworek explained in PT one can pass the test even if a slide is interpreted incorrectly, except in the instances where a high grade squamous intraepithelial lesion (HSIL) is reported as normal. Another member suggested cytology laboratories use missed PT challenges as an educational tool similar to the practices used in microbiology laboratories. Dr. Tworek explained that in cytology the PT pass rate is based on individual performance not the laboratory as a whole. The PT process does not reflect the real life practices of collaboration with other colleagues. Dr. Tworek noted that PT slides are returned to the PT program before they can be used for teaching purposes but encouraged the use of the ASCP and CAP pathology tools and slides of unknowns as learning tools.
- A member inquired if it is possible to link a survey response to the size of the laboratories to determine if the responses differ. Dr. Tworek explained that CAP examined the responses to some of the survey questions based on size of the laboratory, but for a majority of the metrics there was no difference in the analysis, possibly due to the construction of the survey.
- A member found it surprising that only 40-50% of the responses to the MPHI survey question, 'Factors considered when choosing laboratory,' indicated insurance requirements as being a factor. Ms. Conners agreed that the finding was much lower than expected.
- A member wished to know if there has been a decrease in the number of newly trained cytotechnologists similar to that of other laboratory professionals. Ms. Conners said as the Pap smear market decreases there seems to be an increased demand for molecular pathology. Therefore a shortage of cytotechnologists has not been experienced and more cytotechnologists are entering the molecular pathology

field. Dr. Tworek added that the CAP consensus conference commented on recommendations to monitor quality metrics for newly hired cytotechnologists.

- A member commented on the difficulty small laboratories face when they need to consult with other pathologists and wished to know if there were any consultative services offered for those small laboratories. Dr. Tworek acknowledged this challenge as a concern across all of medicine. He noted that in pathology, except for frozen sections or medical emergencies, one can send a slide to another pathologist for a second opinion. He ventured that a service sponsored by a governmental agency, perhaps through existing regulatory mechanisms, to have slides vetted or rescreened for a second opinion might be an option.
- In summary, the Chair said the Committee is looking forward to the publication of the survey results from CAP and MPHI, to include the final list of good laboratory practices, and a future discussion of how they might be promoted. She added one of the major issues to emerge from the surveys and the Committee discussion was identification of the communication challenges between the laboratory and clinician before the actual testing process begins and after it ends, those being knowledge of what tests to order and what to do with the test results.

### **Closing Deliberations**

In closing, the Committee considered the variety of topics discussed at the meeting and provided the following comments regarding communication challenges and possible topics for future CLIAC meetings.

- A member commented that communication throughout the testing process continues to be a major issue and suggested it be a future CLIAC topic. Ms. Yost replied that laboratory communication with staff and clients is addressed in the regulations.
- Another member commented the laboratory is like a ‘black box’ to the clinician and suggested communication might improve with the establishment of laboratory resource liaisons to the various clinical practice societies. The member also encouraged laboratories to call physicians who appear to need assistance with appropriate test ordering. Last, the member commented on the trend toward consumer-driven health care. The physician now needs to be able to tell the patient what the test is, how much it costs, and why it is necessary.
- A member commented communication and points of information transfer provide significant opportunities for errors to occur in the laboratory. The member suggested the Committee focus on how quality could be built into the regulations to handle gaps in pre- and post-testing communications. The Chair said pre- and post-analytic communication issues appeared to be recognized in the CLIA regulations but are not fully considered from an error reduction and quality assurance (QA) standpoint and suggested reviewing how the regulations address this area. Another member concurred with the need to readdress the issue of communication.
- One member said that in the coordination of care, accountable care organizations (ACOs) have opportunities within integrated healthcare delivery systems to promote quality practices among patients, physicians, and laboratories. Another member

agreed, identifying a specific, key need for efficient diagnostic algorithms, but did not want to see their development driven by regulations. Algorithms should be developed through partnership with professional societies. Another member said that practice guidelines are being developed by many organizations which need to be standardized. A member commented that it is important that a pathologist or laboratorian be involved when ACOs are being formed. It is also important for a pathologist or laboratorian to be included on the ACOs' primary care boards.

- Another member noted as their facility was rebuilding all outpatient order entry systems in compliance with Meaningful Use Phase 2, the physicians were asking for the addition of utility, cost, and contact information. The member added now would be a good time for consensus guidelines in this area as well as a repository of information on test utility and alternatives.
- A member noted computerized order entry could make it even more difficult to choose the correct test as the full list of choices is more visible than with paper requisition slips. Another member added a physician does not always have time to call the laboratory when making a decision about the correct test to order. An algorithm could quickly guide the decision process. The Chair commented that the Committee seemed to be expressing the need to review how CLIA applies to ACOs and other patient care models and how the laboratory needs to prepare, within the scope of CLIA, to meet the need to effectively communicate within its working environment. One member described a syndrome-based example, observed in Europe, of a patient testing algorithm where the physician has only to determine a patient's syndrome, on which basis the laboratory sends out the appropriate syndromic package containing all the necessary sample collection tools and containers. The physician does not have to decide which tests need to be ordered, only the syndrome. The system simplifies management of complicated disease diagnostic laboratory requests.
- Another member spoke about the operation of a concierge service in a Boston hospital where persons are assigned to assist and explain appointments and hospital stays to patients and family. A member clarified that an ACO coordinates the care of a patient to minimize the number of visits and tests to only those necessary for the care of the patient. The member suggested laboratories, when approaching ACOs for membership, bring a rationale for overall cost savings.
- A member thought there were could be different pathways toward informing the Committee in matters of communication science relevant to its needs, suggesting formation of a work group and inviting participation by communication experts from outside the laboratory. Another member agreed communication would be a topic worth considering and suggested that a dialogue with clinicians, not a monologue by laboratorians, be part of the process. The Chair said this would be a good topic for the next CLIAC meeting.
- The motion was passed to 'Implement a work group to outline the scope of issues related to communication of laboratory testing information and propose approaches to address these issues for discussion by CLIAC.'

## **REFERENCE MATERIAL**

**Acronyms and Terms Related to Electronic Health Records** *Addendum O*

**Committees and Workgroups of the Office of the National Coordinator (ONC)**  
*Addendum P*

**Regulations and Guidance Areas Related to Electronic Health Records**  
*Addendum Q*

**Standards and Implementation Specifications for Health Information Technology**  
*Addendum R*

**Rules and Regulations Meaningful Use Objectives and Associated Measures Sorted  
by Core and Menu Set** *Addendum S*

**Draft Guidance for Industry and Food and Drug Administration Staff – Mobile  
Medical applications** *Addendum T*

**Issuance of Revised Survey Procedure and Interpretive Guidelines for Laboratories  
and Laboratory Services in Appendix C of the State Operators Manual to facilitate  
the electronic Exchange of Laboratory Information** *Addendum U*

## **ADJOURN**

Ms. Passiment acknowledged the CDC staff that assembled the meeting agenda and provided meeting support, and thanked the CLIAC members and partner agencies for their support and participation.

The following reflects the Committee's recommendations from this meeting:  
Implement a work group to outline the scope of issues related to communication of laboratory testing information and propose approaches to address these issues for discussion by CLIAC.

Ms. Passiment announced the next CLIAC meeting would be February 14-15, 2012, and adjourned the Committee meeting.

I certify this summary report of the August 30 - September 1, 2011 meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Elissa Passiment, EdM, CLS(NCA), CLIAC Chair

Dated 11-22-2011