Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

February 14 - 15, 2012

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
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RECORD OF ATTENDANCE

Designated Federal Official
Dr. May Chu

Committee Members Present
Dr. Paula Santrach, Chair
Rev. Eugene R. Augustine, Jr.
Dr. Robert A. Baldor
Dr. Christine Bean
Dr. Edward L. Chan
Dr. Martha Crenshaw
Dr. Judy Daly
Dr. Anand Dighe
Dr. John Fontanesi
Ms. Julie Gayken
Dr. Paul Kimsey
Ms. Karen Lacy
Dr. Anthony Okorodudu
Dr. Linda Sandhaus
Dr. Robert Sautter
Dr. Linda D. Ward
Dr. David S. Wilkinson
Dr. Rosemary Zuna

Liaison Representative
Mr. Robert Di Tullio, AdvaMed

Committee Members Absent
Dr. Jeffrey A. Kant
Dr. Gail Vance

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

Executive Secretary
Ms. Nancy Anderson

Record of Attendance – cont'd

Centers for Disease Control and Prevention (CDC)

Dr. Simon M. Adebova
Mr. Todd Alspach
Dr. J. Rex Astles
Ms. Diane Bosse
Ms. Cathryn Cambria
Dr. Roberta Carey
Dr. Nancy Cornish
Dr. Maryam Daneshvar
Mr. Swapnil Deshpande
Ms. Sheila Dooley-Edwards
Dr. W. David Dotson
Ms. Joanne Eissler
Dr. Seth Foldy
Ms. Maribeth Gagnon
Dr. Amy Gargis
Ms. Patricia Haskell
Mr. Matthew Hough
Mr. Richard Jones
Dr. Lisa Kalman
Dr. John Krolak
Dr. Elizabeth Leibach
Ms. Millie Linville
Mr. Ken Long
Dr. Ira Lubin
Ms. Isabel McAuliffe
Ms. Alana McCoy
Ms. Leslie McDonald
Mr. Kevin Malone
Dr. Joanne Mei
Dr. Ninad Mishra
Mr. James Nowicki
Ms. Anne Pollock
Mr. John Ready
Dr. John Ridderhof
Ms. Megan Sawchuk
Ms. Andrea Scott-Murphy
Dr. Shahram Shahangian
Mr. Darshan Singh
Ms. Theresia Snelling
Ms. Heather Stang
Dr. Julie Taylor
Mr. H. Eric Thompson
Ms. Pamela Thompson
Mr. Ron Van Duyne
Ms. Betsy Weirich
Ms. Glennis Westbrook
Ms. Irene Williams
Dr. Laurina Williams
Dr. Yang Xia
Ms. Yasmine Zavahir
Dr. Barbara Zehnbauer
Mr. Jonathan Zhong

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

Dr. Aldo Badano (FDA)
Mr. Daniel Cajigas (CMS)
Mr. Ramil Codina (DoD)
Dr. Elliot Cowan (FDA)
Ms. Karen Dyer (CMS)
Ms. Tremel Faison (FDA)
Ms. Elizabeth November (CMS)
Ms. Debra Sydnor (CMS)
Ms. Harriet Walsh (CMS)
Ms. Cheryl Wiseman (CMS)

In accordance with the provisions of Public Law 92-463, the meeting was open to the public. Approximately 30 public citizens attended one or both days of the meeting.

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 said the meeting would begin with a legal update from Kevin Malone followed by updates from the CDC, FDA, Board of Scientific Counselors, and the Coordinating Council on the Clinical Laboratory Workforce. The Committee would then hear a presentation from CMS on the CLIA individualized quality control plan and a presentation on CLSI EP23-A. The remainder of the day would be spent on the topics of semi-automated cytology workload and emerging issues in digital pathology. She said Wednesday would begin with a presentation and discussion on communication and electronic health records. The remainder of Wednesday would be spent on the topic of integrating laboratory services into evolving healthcare models.

Dr. Chu recognized the five CLIAC members who were to receive plaques and letters of appreciation for their service on the Committee. They were Dr. Christine Bean, Ms. Julie Gayken, Dr. Paul Kimsey, Dr. Linda Sandhaus, and Dr. Rosemary Zuna.

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 A*** ***Addendum B*** ***Addendum C***

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 began by updating the Committee on the progress being made in the area of standards, guidelines, and reference material development. The Genetic Testing Reference Materials (GeT-RM) program group is involved in the development of reference materials for cytogenetic microarray analysis. The current program goal is to characterize 95 reference materials with common cytogenetic abnormalities for use by laboratories and manufacturers. She described the efforts of the Next-generation Sequencing: Standardization of Clinical Testing (Nex-StoCT) working group that are

culminating with the development of a guidance document for next generation sequencing in clinical practice. She reviewed the historical timeline of the *Morbidity and Mortality Weekly Reports Recommendations and Reports: Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Inherited Metabolic Disorders*, announcing an expected publication date of April 2012. With regard to laboratory proficiency testing (PT) she apprised the Committee of the status of the CLIA PT regulatory revisions and mentioned the CDC-Association of Public Health Laboratories collaborative survey to evaluate how laboratories use PT for quality improvement. Dr. Howerton discussed the Division's educational outreach activities reminding the Committee of the materials and online training available for good laboratory practices in waived testing, "*Ready? Set? Test!*" and introduced the forthcoming companion product, "*To Test or Not to Test?*" for use by those interested in initiating a waived test or adding one to their test menu. She noted the Laboratory Medicine Best Practices Initiative is developing online training modules designed to educate laboratory professionals about the evidence-based systematic review method. A second module will provide information for laboratories developing quality improvement studies to assure that data collected meets robustness criteria required for evidence-based systematic review. The last educational outreach project that Dr. Howerton mentioned was the provision of grants to state agencies to develop training on CLIA-related topics targeted toward clinical and physician office laboratories. Before concluding, Dr. Howerton briefly introduced the Public Health Laboratory Efficiency Initiative (LEI), a project aimed to address the current realities faced by public health laboratories and the services potentially impaired by budget cuts and decreased staffing. The goal of this collaborative LEI effort is to conceive enhanced approaches to efficiency in order to reduce costs and share or consolidate services.

Committee Discussion

- One member asked if the content of the "*Ready? Set? Test!*" online training module could be made available to hospitals and healthcare organizations performing point-of-care testing so they might adapt the training for use on their own intranet systems. Ms. Nancy Anderson replied that in order to award continuing education credits, training must be performed through the online system. Dr. Howerton replied CDC will evaluate the options and report to the Committee.
- A member asked Dr. Howerton if proposed PT scoring criteria will be open for comments and whether historical data will be used to determine the new scoring scheme. Dr. Howerton replied the proposed rule will be open for comments once it is published in the Federal Register. These comments will be analyzed and influence the requirements that become part of the final rule. She added PT programs would provide data to help make scoring decisions for the analytes that are under consideration for the revised rule. CMS and CDC will be working with them and other experts to derive the new scoring schemes.

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

Alberto Gutierrez, Ph.D.

Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD)
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration

Dr. Gutierrez began by outlining the OIVD 2012 pre-market program priorities geared at improving transparency, consistency, efficiency, communication and benefit-risk balance. To address these issues, the Office is working towards better engagement with industry, greater use of external experts, establishment of a Center Science Council, proposed guidances on benefit-risk determinations and the 510(k) process, new communication tools, and implementation of efficient processes. Dr. Gutierrez updated the Committee on organizational changes to support reducing the manager/reviewer ratio and the addition of post-market duties in the area of radiology. He briefly mentioned the development of down-classification guidance entitled *Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices* and other guidances being developed or issued. He concluded his presentation by reporting on notable waivers based on the 2008 waiver guidance (Binax Strep A and OraQuick HCV) and the justification for granting waiver to rapid influenza tests based on evaluating the public health benefits and risks of test use rather than based on waiver guidance.

Committee Discussion

- One member applauded the FDA for having utilized the benefit/risk ratio clause of the waiver guidance document. Another member asked if the FDA uses a formal method to determine benefit/risk and the consequences of erroneous results. Dr. Gutierrez replied a benefit/risk determination is made in an informal way similar to the determination of safety and effectiveness for diagnostics. He added that challenging determinations are taken to a panel of experts. Last, he noted the forthcoming benefit/risk guidance will have more formalized steps included so people can understand how the FDA makes the determinations.
- A member asked about the classification of digital imaging devices in radiology. Dr. Gutierrez replied classification of imaging devices tends to be regulated based on intended use. He added the FDA's radiology group has joined OIVD. This has benefited forward progress in digital pathology because there are many similar issues that need to be addressed.
- A member inquired about how FDA is addressing inconsistencies between Clinical and Laboratory Standards Institute (CLSI) testing guidelines and the FDA-approved device breakpoints for antimicrobial susceptibility testing. Dr. Gutierrez indicated the FDA is exploring methods to assure consistency between labels for the drugs and breakpoints for susceptibility testing.

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

Robert Sautter, Ph.D.
Committee Liaison to CDC Board of Scientific Counselors, Office of Infectious Diseases (OID)

Director of Microbiology
Carolinas Pathology Group

Dr. Sautter provided a summary on the recent meeting of the CDC Board of Scientific Counselors. He indicated the main focus of the meeting was to generate ideas on how CDC laboratories can maintain core capacities and provide leadership and support to state and local laboratories despite funding challenges and limited resources. He summarized OID and National Center key updates including the establishment of a working group to advise CDC on implementation of *A Public Health Action Plan to Combat Antimicrobial Resistance*, an overview of the 2011 Food Safety Modernization Act, and the recently released *CDC Infectious Disease Framework* (www.cdc.gov/oid/framework.html). He briefly related several topics important to public health and private health laboratories including the precipitous decrease in the use of viral and microbial cultures, the impact of workforce shortages, the value of data streams, and the impact of funding shortages on disease surveillance.

Committee Discussion

- One member supported Dr. Sautters' comment pertaining to the impact funding constraints are imposing on collaborations between state public health networks and private entities.

Coordinating Council on the Clinical Laboratory Workforce (CCCLW) Update

Christine Bean, Ph.D.
Laboratory Director
Public Health Laboratories
New Hampshire Department of Health and Human Services
Concord, NH

Dr. Bean provided an update on the quarterly CCCLW meeting held on December 12, 2011, in Chicago, Illinois. She began her presentation by discussing the current and potential constituency of the CCCLW. The CCCLW continues its mission of being the united voice of clinical laboratory organizations and stakeholders, focusing efforts to increase the number of qualified clinical laboratory professionals, increase awareness of the laboratory's value in achieving positive patient outcomes, and enhance the image of clinical laboratory professionals. Dr. Bean noted the National Accrediting Agency for Clinical Laboratory Sciences provides information on the number of training programs and graduates, and CCCLW intends to put these data on their website as they are not currently readily accessible. Also, the American Society for Clinical Pathology's January 2012 issue of *Critical Values* documents wage and vacancy trends for the past 22 years. Placement of students in clinical rotations as a limiting factor in laboratory workforce training was a significant topic of discussion for CCCLW at their recent meeting. Dr. Bean commented that many laboratories and hospitals do not have the staff available to perform needed training and public health laboratories are currently helping to train students. CCCLW also intends to encourage industry partners and large commercial

laboratories to join them in an effort to increase their awareness and encourage their support of the laboratory. A representative from Becton, Dickinson and Company attended the December meeting to evaluate how they could assist in improving communication through marketing and public relations campaigns as well as education via simulation laboratories. Dr. Bean concluded by discussing CCCLW's involvement with the Labs are Vital™ (www.labsarevital.com) and Lab Science Careers (www.labsciencecareers.com) websites to engage healthcare administrators, pathologists, and clinicians and create an awareness of the laboratory's role in the healthcare community. She noted the next meeting of the CCCLW will include a discussion on website content strategy and that they welcome any topic ideas.

Committee Discussion

- One member suggested in order to make the workforce training more cost effective for laboratories, they should find students who are at the right phase of their training and are committed to moving to their particular location. Then when the laboratory makes the commitment to train the student, it may ultimately lead to potential employees who are already trained to work at that facility.
- Another member inquired if CCCLW has thought about connecting with children to encourage an interest in the sciences and several members suggested involvement in various other outreach strategies such as science fairs, connections with area health education centers, and development of videos for posting online. Dr. Bean responded that CCCLW has made efforts to partner with member organizations to develop products that could be used to attract young children, middle and high school students into the clinical science field.
- A member asked if CCCLW is attempting to address laboratory salaries and commented that some two-year program graduates can earn a larger salary than a four-year program graduate. Dr. Bean commented that the two-year programs are at 100 percent capacity because of the high number of jobs available. She stated that the salary issue is being addressed by other groups and is beyond the reach of the CCCLW.
- A member commented on the hiring of graduates with bachelor degrees in biology and chemistry versus the hiring of medical laboratory science (MLS) technologists in clinical laboratories and noted the non-MLS workforce is not acquiring the necessary introduction to the clinical laboratory in school. Dr. Bean added that in her experience with teaching in an MLS program at a university level she found that the general science students were unaware of opportunities in clinical laboratory science. Outreach to college freshmen biology majors may encourage more students to choose clinical laboratory science as a career path.
- A member inquired if the CCCLW was addressing employee retention and career development. Dr. Bean responded that CCCLW needs to focus more on this issue. There have been surveys aimed at determining what incentives are needed to encourage young employees to remain in the clinical laboratory. These surveys indicate that they want upward mobility in their careers and opportunities for continuing education.
- The Chair was intrigued by the concept of incorporating a simulation laboratory into training programs and encouraged CCCLW to consider those that exist in their future

discussions. She stated that development of a curriculum where the laboratory is integrated with the total healthcare of the patient would prove powerful in showing the value of the laboratory and the role it plays in medical decision-making and healthcare.

PRESENTATIONS AND COMMITTEE DISCUSSION

CLIA Individualized Quality Control Plan (IQCP)

Addendum F
Addendum G
Addendum H

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

Ms. Yost provided the Committee with a brief overview of the upcoming CLIA IQCP. The final CLIA regulations, published in 1992, defined minimum quality control (QC) requirements and allowed previously unregulated laboratories to become familiar with QC requirements through a phase-in of the provisions. In April 2003, the CLIA Quality System Regulations were published and included a new voluntary provision for alternative QC, termed equivalent QC (EQC), clarified in the CLIA Interpretive Guidelines. EQC was an option to reduce the amount of external QC and laboratory costs when the laboratory could demonstrate alternative control procedures that would detect immediate errors and monitor performance over time. Due to concerns expressed by industry, laboratories, and experts following the implementation of EQC, CMS partnered with CLSI to facilitate development of a consensus-based QC guideline. This CLSI guideline, *EP23-A: Laboratory Quality Control Based on Risk Management*, was published in October 2011. CMS will be incorporating key EP23-A concepts into the CLIA Interpretive Guidelines as a QC alternative called IQCP which will supersede the current EQC. IQCP will allow laboratories to develop their own plan for QC using many of their existing quality practices. Ms. Yost explained training, information, and guidance will be available for surveyors and laboratories prior to IQCP's effective date allowing laboratories to make an informed choice between IQCP and traditional QC.

CLSI EP23-A Laboratory Quality Control Based on Risk Management; Approved Guideline

Addendum I

Ms. Luann Ochs, M.S.
Vice President, Standards Development
Clinical and Laboratory Standards Institute (CLSI)

Ms. Ochs provided an overview of EP23-A emphasizing that the document is not designed to reduce QC but is rather about understanding where errors can occur and establishing the right controls to reduce the risk of errors throughout the entire testing process. EP23-A expands the current concept of QC from the use of two external controls

to including everything that a laboratory can do to ensure quality testing and results. She described the steps required to create a quality control plan (QCP) and the benefits of developing an appropriate QCP including improvement of laboratory efficiency and true customization of QC for each laboratory situation. EP23-A introduces the concept of risk assessment by encouraging users to create process maps for every test performed, identify key process steps, and examine those steps to identify the potential hazards and their causes. Once these hazards are identified, an element can be added in the QCP to reduce the severity of harm, making residual risk acceptable. The QCP will need to be reviewed on a regular basis to determine whether any changes need to be made. Ms. Ochs concluded her presentation by providing a list of EP23-A companion products including an EP23-A Implementation Workbook, EP23-A Risk Assessment Worksheet, QCP Examples, and CLSI-sponsored webinars.

Committee Discussion

- One member complimented the speakers on the EP23-A presentation stating that the upcoming development of the molecular test QCP example is needed to provide guidance and clarification due to the different platforms for molecular testing and advances in the molecular field.
- A member commented that there will be some subjectivity with respect to adoption of EP23-A and IQCP, which could lead to different interpretations by laboratories and surveyors. Ms. Ochs agreed adding that laboratories will need to think critically about the tests they perform so they put processes in place to help mitigate risks that have been identified. Ms. Yost agreed that there is a risk due to the potential flexibility that exists with EP23-A, but CMS surveyors will still be using an outcome oriented type of survey in which they review the laboratory's results and how they impact patients. If problems are found, the surveyors will ask for the additional details.
- Dr. Gutierrez commented EP23-A provides a nice understanding of what a quality system entails. He expressed concern about the FDA's ability to monitor the information provided by manufacturers to laboratories in order to perform the assessment. He specifically asked whether examples would be provided to assist users of research use only (RUO) instruments and reagents. Ms. Ochs responded that the molecular QCP example in development will use test systems that are already on the market and will be made as generic as possible. However, she added that if a laboratory implements an EP23-A based QCP for an RUO system, they might better assure the quality of results when using that system.
- One Committee member asked whether calibration samples or standards will be developed to allow the laboratory to monitor the performance of the device manufacturer's internal QC. Ms. Ochs responded that is out of the purview of CLSI and suggested that the questions might be addressed to organizations such as the National Institute of Standards and Technology.
- Another member commented that FDA 21 CFR Part 820, also known as the Quality System Regulation, outlines Current Good Manufacturing Practice regulations that include a risk management element for manufacturers. Ms. Ochs added that if there are QC measures built into a system, the laboratory will need to obtain information from the manufacturer regarding the specifics of those controls. She explained how

CLSI is reaching out to manufacturers to ensure their understanding of EP23-A and the information that they will need to provide to their users.

- One member expressed concern that the CMS rollout and associated timelines for implementation of IQCP may place a burden on the laboratories trying to create a QCP for each individual test. Others members asked if there would be a phase-in period for IQCP and whether accreditation organizations would be included. Ms. Yost responded there are a large number of CMS resources dedicated to the education and transition period for laboratories. She noted that CMS has not set an implementation date thereby allowing laboratories the time needed to implement IQCP if they desire. When a date is set, there will be a phase-in and laboratories will have opportunities to correct issues that are identified before any enforcement would be taken. She reminded the Committee that QC must still be performed on the test systems not covered by an IQCP. Last, she added that CMS will work with each of accrediting organizations and those who wish to adopt IQCP will be included in the education and implementation periods.
- A member noted there was no discussion on post-analytic QC in the EP23-A presentation. Ms. Ochs responded that EP23-A covers all phases of testing, and laboratories may need to address events after results reporting if errors are known to occur at that point in the process. Ms. Yost added CLIA regulations cover all phases of testing so one should consider all events as the QCP is developed.

Semi-Automated Cytology Workload

Introduction to Semi-Automated Cytology Workload ***Addendum J*** ***Addendum K***

Ms. Maribeth Gagnon, M.S., CT (ASCP) HTL
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. Gagnon reviewed the CLIA workload requirements for individuals who screen Papanicolaou (Pap) tests manually and using semi-automated screening devices. She stressed that the workload limits in CLIA are not performance targets and that the technical supervisor must determine each individual's maximum workload number. She recounted the significant events occurring from 1999 to 2011 related to cytology workload using semi-automated screening devices beginning with the 1999 CLIAC workgroup convened to gather information on utilization of semi-automated screening devices and the September 1999 CLIAC comment that standards need to be developed for manual and automated methods. In 2003 the Cytotechnology Education and Technology Consortium task force published *Daily Workload Guidelines for Cytotechnologists Utilizing Automated Assisted-Screening Technologies*. FDA approved the first assisted screening device (Hologic ThinPrep® Imaging System) in 2003 followed by approval of the BD FocalPoint™ GS Imaging System in 2008. At the September 2010 CLIAC meeting, problems identified by CMS survey teams were

described regarding the two FDA-approved cytology semi-automated screening devices and FDA and CMS announced the method used for the calculation of workload when using semi-automated screening devices was being revised. In October 2010, FDA issued an alert, *How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automated Gynecologic Cytology Screening Devices.* Ms. Gagnon wrapped up her review by noting that in November 2011 an American Society of Cytopathology (ASC) task force published a recommendation that the average laboratory cytotechnologist's productivity not exceed 70 slides/day using the guidelines published by the FDA for calculating workload. The recommendation received support from all of the cytology professional organizations. Ms. Gagnon then related the purpose for this portion of the CLIAC meeting was to inform CLIAC of the revised FDA method for counting workload for cytology semi-automated screening devices, to ask the CLIAC members to provide input on the best approach to keep laboratories informed of product labeling changes, and to consider an ASC task force recommendation to lower the workload maximum when using cytology semi-automated screening devices. She concluded by introducing the three speakers who would present on aspects of the workload issues and requested the Committee keep two questions in mind during the presentations and subsequent discussions.

- How can HHS determine if the maximum workload limit using semi-automated screening instruments is appropriate?
- What are the potential impacts to lowering the workload limits for screening using a semi-automated device?

Committee Discussion

- A Committee member asked Ms. Gagnon for some clarification of current workload calculations. Ms. Gagnon responded that the maximum manual workload limit was 100 slides in an eight hour day. Semi-automated screening devices were approved for screening a maximum number of slides where only the "fields-of-view" are screened. This maximum number, 200 or 180, was included in the device labeling. She said current labeling does not describe how to calculate workloads for the various ways of looking at slides.

Workload Issues for Computer-Aided Cytology Devices ***Addendum L*** ***Addendum M***

Ms. Tremel Faison, M.S., 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. Faison reviewed the background of the FDA's experience with setting the cytology workload limits for semi-automated screening devices for the two imaging systems currently on the market, Hologic ThinPrep® Imaging System and BD FocalPoint™ GS Imaging System. She described the clinical trials for pre-market approval that determined the workload limits included in the initial package inserts for these devices and explained

the workload calculation challenges that led to confusion in the package inserts. Next Ms. Faison said that because of the unclear labeling, CMS and FDA decided to collaborate on a project to standardize and clarify the method used for workload calculation. Ms. Faison closed her presentation with a slide that showed the newly derived formula for calculating workload that was published as an FDA laboratory safety tip.

A Career That Has Eternal Significance!?! ***Addendum N***

William N. Crabtree, Ph.D., SCT (ASCP)
Director and Associate Professor
Cytotechnology Program
Indiana University School of Medicine
Indiana University Health Pathology Laboratory

Dr. Crabtree's presentation began with a description of a patient's close-call experience with cervical cancer because a previous Pap test had not been interpreted correctly. He followed with an account of a cytotechnologist who was unable to meet the laboratory's upper screening rate and therefore was threatened with termination. The point of contrasting the stories was to highlight the issue of ethics giving way to laboratory profits and to endorse ASC's published workload recommendations for screening Pap tests.

ASC Task Force Recommendations for Productivity and Quality Assurance in the Era of Automated Screening ***Addendum O*** ***Addendum P***

Tarik Elsheikh, M.D.
Director of Cytology
Ball Memorial Hospital

Dr. Elsheikh began with an overview of image-assisted cytology Pap screening practices, noting 85-90% of Pap smears are processed using liquid-based systems and 50-65% of these are screened using image-assisted devices. He stated the higher workload maximums for the assisted screening devices had encouraged increased productivity without increasing sensitivity. He acknowledged the work of the ASC in convening a task force in May 2009 whose charges were to research and evaluate quality assurance monitors available for automated screening instruments and recommend monitors for automated Pap test screening, create a statement of appropriate workload and screening practices for cytologic specimens when automated screening is employed, and monitor emerging screening technologies and make recommendations for best practices for quality assurance and workload. The task force's September 2011 evidence-based recommendations, resulting from literature review and available research, were endorsed by five professional organizations involved with cytopathology. He briefly reviewed the four areas of evidence; FDA clinical trial studies, literature review, laboratory survey, and longitudinal studies, used by the task force. Dr. Elsheikh closed his presentation by commenting on each of the six ASC task force recommendations.

Committee Discussion *Addendum* **Q**

- A member stated there was a gap in the information presented and noted that the presenters had failed to recognize that laboratories, as businesses, have profit targets that must be balanced with establishing screening workload.
- A member commented while no data were presented to show that any laboratories are exceeding the regulatory workload limits, some may be using the maximum limits as productivity targets that exceed the abilities of certain individuals. As such, the member questioned whether this is a regulatory issue.
- Dr. Elsheikh explained one of the shortcomings of the cited survey studies was that they included only the smaller quality-minded laboratories. They did not include the large commercial laboratories which perform a majority of the Pap tests nationally and set higher screening targets for cytotechnologists. He stated the current FDA workload limits are unrealistically high and are not based on scientific data. Evidence now indicates that screening limits should be lower than those used by the FDA or required by CLIA.
- Two other members asked for clarification of the issue being debated. The Chair summarized saying the upper regulatory screening limit was set for manual screening when CLIA was published. Now, semi-automated screening has raised questions about whether the limits are appropriate. Some laboratories are using the upper screening limit as a productivity standard, which introduces a patient safety issue. This discussion is to focus on the two questions posed, not to endorse any of the screening limits proposed.
- A member noted the importance of Pap test sensitivity, and questioned whether the cytotechnologists in Dr. Elsheikh's study were considered high performers based on screening speed or accuracy. The member added that the limits determined in the study may have been lower if moderate or average performers had been used, and suggested more data may be needed. Dr. Elsheikh responded that performance was defined in terms of speed and that cytotechnologists of various experience levels and capable of different screening rates were chosen to avoid bias, and agreed with the member's comment. Ms. Faison and Dr. Gutierrez noted that in the clinical studies to determine safety and effectiveness the FDA looked at other data sets and that the FDA studies comparing the screening workloads of manual versus semi-automated testing did not demonstrate accuracy differences. Human papillomavirus (HPV) testing was used to verify missed diagnoses in the FDA studies. Dr. Gutierrez revealed the FDA had performed studies that showed significantly lower performance in afternoon screening work versus work done in the first four morning hours.
- A member suggested that analyzing cytology workload involves asking two questions, one, finding the appropriate rate of presentation of the task, and the other, determining the time at which the performance starts to deteriorate, with neither being linear. Focusing on a mean to derive a workload maximum does not address the issue. He further added that the methodologic approach for determining workload needs to be nonlinear.
- The Chair asked how the technical supervisor sets the screening level for each cytotechnologist and if the method used was evaluated in laboratory inspections. She said this is a patient safety issue and asked if standardizing the process used to

determine individualized screening limits might decrease the CLIA upper limit as a productivity target.

- One member expressed the opinion that workload limits are linked to turnaround time (TAT) and wondered if there was a TAT standard used for Pap testing. Ms. Faison and a Committee member responded there is no standard TAT. Another member said increased TAT could drive up cost and accessibility, but it is important to have the test performed correctly.
- A member pointed out the original workload limit in CLIA was based on what was known at the time, but the present consensus of national cytology organizations suggesting that the upper limit is being used inappropriately and should be lowered, is persuasive.
- Another member stated the cytotechnology profession must not only ensure that cytotechnologists are trained but also retained in the profession by providing them with variety of tasks to perform in the laboratory. The member also acknowledged the complexity of setting appropriate workload limits, especially in laboratories that have high rates of abnormal Pap tests requiring manual reviews of numerous slides.
- Dr. Elsheikh commented on the difficulty of having adequate time and personnel resources to conduct a study related to workload limits in addition to performing routine testing. He also noted the ability to accurately determine screening sensitivity is easily compromised by poor or incomplete rescreening. His study incorporated 100% rescreening and HPV testing for further test result validation.
- A member noted the large laboratories are increasingly becoming members of accountable care organizations (ACO) and promoting workload targets that spawn errors would not be in their interests. Therefore, the issue might resolve itself.
- Dr. Crabtree mentioned women are still losing their lives because of misinterpreted Pap tests. He said there are little data available about Pap smear performance in large commercial laboratories. He added there are many stories of cytotechnologists leaving the field in disillusionment because they feel they are being pushed to reach unreasonable workload targets. He mentioned such internet discussions are affecting the applicant rates at his training program and there is already a shortage of cytotechnologists nationally. He concluded by asking that HHS consider the evidence for evaluating workload limits and whether it takes into account routine operations in the cytology laboratory.
- A member commented the ASC proposal on workload was evidence-based and was not sure of what more should be done.
- A member noted there had been no discussion of HPV testing as an alternative screening tool which some believe is more sensitive than the Pap test and will potentially make the Pap screening workload limit moot. Another member thought increased cost might influence ACOs to consider HPV screening in lieu of the Pap test. One member said discussions on HPV testing generally agree there would not be an immediate impact on Pap testing. A member added HPV testing has been adapted as an alternative in some European countries. The Chair suggested HPV testing as a possible future discussion item for CLIAC.
- A motion was passed that stated:
    1) CLIAC supports the use of data from operational studies, such as those presented, to determine if the maximum workload limit using semi-automated screening

instruments is appropriate. To discourage the use of maximum workload limits as productivity expectations, CLIAC recommends that standardized criteria be developed for use in determining workload limits for each individual performing screening.

2) Lowering the workload limits for screening Pap smears using a semi-automated device may result in improving the quality of testing. However, it could also lead to increased turnaround time and costs for obtaining test results and could have implications for access to testing.

Emerging Issues in Digital Pathology

Introduction to Digital Pathology *Addendum R*

Ms. Maribeth Gagnon, M.S., CT (ASCP) HTL
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. Gagnon began her presentation by defining digital pathology. As background, she listed development milestones, including the 1993 CDC Symposium on Cytology Proficiency Testing that decided one alternative to glass slide testing might be a computer-based test. Following this, CDC developed and tested a prototype computer-based proficiency test called CytoView™ which utilized a glass-slide digitizing system called Microscreen. In 2003, the Medical University of South Carolina sponsored the first meeting for pathologists interested in digital pathology titled "First Annual Virtual Slide Symposium." Presenters at this meeting contributed articles to a compendium published by CRC Press - *Virtual Microscopy and Virtual Slides in Teaching, Diagnosis, and Research.* Before introducing the speakers, Ms. Gagnon described several advantages of digital pathology and several shortcomings of the manual, conventional methods. She noted that rapid progress in the area of digital pathology has led to enhancements that pathologists may use to assist their diagnosis. She posed three questions for the Committee:

- What steps can HHS take to facilitate the safe development and implementation of digital pathology?
- Should HHS provide a clarification of the requirements that impact digital pathology?
- Are there non-CLIA regulatory issues to consider?

Digital Pathology: The Pathologist's Perspective *Addendum S*

Richard C. Friedberg, M.D., Ph.D.
Chairman, Dept. of Pathology Baystate Health
Professor and Deputy Chairman
Department of Pathology

Tufts University School of Medicine

Dr. Friedberg provided an overview of digital pathology, listing several reasons why the transition to this technology would take off and benefit the profession. After defining digital pathology, he stated it was not the elimination of glass slides and histology, but that it would affect everything after the slide is created to the delivery of the final interpretation to the healthcare provider. He said it would extend diagnostics by complementing a century of morphology knowledge with the emerging world of functional and structural molecular biomarkers, effectively redefining the diagnostic process by comprehensively integrating consultations with imaging, biochemical, histologic, molecular, cytogenetic, and epigenetic data. He noted it is already being used to train medical students and in veterinary medicine. Among several specific reasons for its adoption he listed:

- Productivity increases due to workflow enhancements
- Improved report TATs – days to hours
- Facilitation of archiving and retrieval of images allowing comparisons
- Easier sharing of images at tumor boards and conferences
- Capability to conduct remote case reviews

Concluding, Dr. Friedberg also listed several obstacles that need to be addressed, notably:

- Integration of the technology into pathology practice
- Quality requirements for instrumentation (accuracy, sensitivity, specificity, reproducibility, validity)
- Financial-reimbursement levels
- Regulatory requirements
- Medical ethical issues

FDA Regulation of Whole Slide Imaging (WSI) Devices: Current Thoughts

Addendum T

Ms. Tremel Faison, M.S., 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. Faison informed the Committee that the role of CDRH regarding digital pathology is defined by its regulatory authority and the application of specific criteria and key definitions to the devices. CDRH's responsibility is to regulate firms involved with medical devices sold in the United States and defined medical device as an item or instrument intended for use in the diagnostic examination of specimens taken from the human body. Approval for the sale or distribution of any medical device is predicated by FDA's determination that it is safe and effective. In addition, devices are classified by risk which is based on the intended use. While a device determined to be of low risk would be Class I, a whole slide imaging (WSI) device intended for use diagnosing cancer would be high risk and Class III. Class III devices require studies be performed that demonstrate safety and effectiveness before they obtain pre-market approval (PMA).

After citing regulatory language applicable to WSI and noting gynecologic cytology imaging systems were Class III devices, Ms. Faison said WSI raises new questions of safety and effectiveness that must be answered through PMA. She reviewed the FDA's plans to ensure the safety and effectiveness of digital pathology devices and listed several clinical study design challenges for a prospective study. Ms. Faison concluded by mentioning two recently published guidance documents relevant to digital pathology, a research use only guidance and a mobile medical application guidance.

FDA Research and Scientific Issues in Digital Pathology ***Addendum U***

Aldo Badano, Ph.D., M.E.
Division of Imaging and Applied Mathematics
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health
Food and Drug Administration

Dr. Badano reviewed some of the challenges in evaluating digital pathology systems and hardware and provided a partial list of the technical specifications being studied. He said the migration from optical to digital technologies involves the parallel use of both systems. CDRH's task is to determine how to leverage laboratory measurements to ensure the safety and effectiveness of digital pathology WSI for routine surgical pathology. He detailed issues within WSI systems that were under study in order to achieve device effectiveness. He listed ten stakeholder partnerships, including government and private entities, involved with technical issues. He commented on additional issues needing study. In summary, Dr. Badano mentioned the need for new standard methodologies for device assessment and noted CDRH research informs FDA guidance development and provides data that helps minimize the need for resource-intensive clinical studies.

CLIA Guidance for Digital Pathology ***Addendum V***

Ms. Debra Sydnor, CT (ASCP) IAC
Division of Laboratory Services
Survey and Certification Group
Centers for Medicare & Medicaid Services

Ms. Sydnor reviewed the basic intent of CLIA and the CMS approach to oversight of medical laboratory testing, focusing on the quality standards for all nonwaived test systems. She then applied relevant portions of CLIA to histology and digital pathology. CLIA QC for the analytic phase of testing requires monitoring the testing personnel, the test system, and the laboratory environment. Among other quality standards that apply to all testing are requirements for performing function checks including calibrations, establishing or verifying performance specifications, test system or equipment maintenance, test results comparisons, corrective actions, having a back-up plan for

instrument failure, and a procedure manual. She specifically discussed establishing performance specifications (validation) of equipment used in digital pathology and concluded by citing the CLIA requirements for test reports. She noted that the test report needs to state the location where the test was performed and described the challenge in doing such when the interpretation of a digital image is performed at a separate location.

Committee Discussion ***Addendum W***

- One member expressed appreciation to CDRH for using solid comprehensive bench test data thereby minimizing the need for resource intensive clinical studies of new digital technology. The member cautioned that any new regulations not hinder the utility of pathologists to work remotely on laboratory testing, as this may help ease the shortage of pathologists.
- Dr. Gutierrez commented that Dr. Badano had already helped clear mobile devices for certain images in radiology. He said that interpretation of where reading of laboratory test images may be done will need to be determined under CLIA.
- A member commented there has been a slow degradation in the quality of histology slide preparations. Taking steps to advance the role of histotechnologists would enhance quality in that very important pre-analytical step. Also, the effectiveness of the technology in the diagnosis of the difficult or very difficult cases should be the focus of the clinical studies.
- Dr. Gutierrez agreed and said there are advantages to using digital technology in some areas, but sometimes the pathologist requires greater image quality than can be found on a whole slide image scan.
- Dr. Friedberg clarified that while teleradiology can be used for telediagnosis, in his experience telepathology is only used for teleconsultation. Teleradiologists typically are aware of the anatomy or organs they are viewing, while pathologists may be unaware of the organ systems with which they are dealing, especially in cases of metastatic cancers, until they view the images. He warned of potential pathologist frustrations if imaging technologies were to be approved only for certain organs, and a tumor was determined after diagnosis using an unapproved technology for a primary organ. A member reiterated Dr. Friedberg's point that pathologists often do not know the difficulty of a case until they look at the slides or images.
- Ms. Faison said manufacturers of telepathology systems are interested in FDA approval for primary diagnosis, not just consultation. The FDA considers the highest bar and most serious consequences when approving test systems. Dr. Gutierrez said the FDA does not regulate the practice of medicine, so Dr. Friedberg's fear would not be realized on FDA's account. The FDA seeks to have manufacturers show the performance of a device in one anatomic area to determine the maximum capabilities of a system. It is up to the pathologist to determine if another area is equivalent for similar use by the device.
- A member commented on problems with the lack of standards for imaging software. Ms. Faison agreed there are currently no standards for imaging although some groups are beginning to address this. Dr. Gutierrez added standardization was part of what Dr. Badano was working on.
- A member mentioned comments made by Dr. Friedberg that the human brain processes images seen through a microscope differently than images viewed on a

monitor. Dr. Friedberg replied a researcher in human factors engineering in Tucson was doing work in this area.

- The Chair requested clarification regarding CLIA and the location of making diagnostic decisions in terms of whether it takes place in a laboratory. Ms. Yost responded that question would have to be revisited with changing technologies. She expressed the need for caution in moving forward, noting security issues have to be considered and added there are presently cytologists who have CLIA certificates for their homes, where they perform microscopic work.
- The Chair summarized the responses to the question regarding steps HHS should take to facilitate safe development and implementation of digital pathology.
  - Apply digital pathology broadly enough to not limit it to particular diagnoses.
  - Use a phased approach to the implementation of digital pathology.
  - In clinical studies use the most challenging cases to test the limits of digital pathology.
  - In evaluating digital pathology, it is important to understand human factors issues in terms of how people interact with a computer screen to make diagnoses.
  - Ensure continued quality of glass slide preparations with whatever opportunity evolves for histotechnologists because that is the critical preanalytic step.
- To the second question, "Should HHS provide a clarification of the requirements that impact digital pathology?" the members suggested the following areas of CLIA be clarified:
  - Definition of "laboratory"
  - Test system verification
  - Quality control required for digital images
  - Record retention
  - Personnel requirements, including pathologist competency
  - Information technology (IT) security with encryption, especially when test interpretation is done off-site

Communication and Electronic Health Records ***Addendum X*** ***Addendum Y*** ***Addendum Z***

Ms. Megan Sawchuk, MT (ASCP)
Lead Health Scientist, 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 overview of the Electronic Health Record (EHR)/Electronic Laboratory Reporting (ELR) issues raised and the resulting recommendations captured from the September 2011 CLIAC meeting. She discussed the formation of a DLSS informatics team and their current participation in national health information technology (HIT) activities and workgroups. She also elaborated on the team's Communication in Informatics project proposal and monitoring of the emerging HIT regulatory landscape. Ms. Sawchuk posted a new email address where questions

regarding EHR or ELR activities having national impact and not identified in her presentation could be sent. In highlighting the content and recommendations from the November 2011 Institute of Medicine report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, she emphasized the need for public reporting of adverse events related to laboratory information and EHRs and provided instructions on how to report such events. She concluded her presentation by asking CLIAC to consider the following questions:

1. Does CLIAC have comments or guidance on the proposed Communication in Informatics project?
2. Are there other EHR or ELR workgroups or activities that should be included on the "bubble chart?"
3. Are there other databases in which healthcare professionals are reporting issues with laboratory information in the electronic health record?

Committee Discussion ***Addendum AA***

- One member stated that while most IT efforts, with respect to EHRs, have been centered on concerns of interoperability, data mining, and surveillance, other areas of focus are warranted. How laboratory information is presented to and used by the provider at the point-of-care is an equally important concern since test selection and result interpretation significantly impact patient outcomes and patient safety. Another member strongly concurred, adding how patients receive and utilize information from laboratory test reports is equally as important and encouraged inclusion of this topic in the Committee's discussion.
- A member recommended representatives from healthcare systems recognized for excellence in provider and patient connectivity be included when laboratory EHR issues are addressed. Another member urged that physicians be included when EHR/laboratory connectivity issues are discussed since they are the primary end-users of laboratory information.
- One member felt strongly that known areas of risk, such as corrected results, comments, and reference laboratory reports, be addressed through EHR certification requirements. The member also noted that two other areas of concern directly related to basic patient safety issues, usability and context, are not being addressed. The member suggested the laboratory community develop an EHR developers' guide as a tool to ensure laboratory issues are addressed, noting laboratory professionals will not always be present to guide decisions.
- One member suggested tying decision support at the point of test ordering to billing thereby providing the healthcare provider with price transparency and knowledge of the out of pocket patient costs associated with the test ordered. After noting EHRs' and laboratory information systems'(LIS) functionalities are often the drivers of how and what laboratories communicate, the member then asked the Committee to think about how to switch this so that patient safety becomes the driver. The member emphasized the importance of "telling the entire medical story" and ensuring communicated information keeps the patient safe.
- The Chair commented that EHRs can be a clerical burden for healthcare providers, who sometimes spend more time in front of the computer than with their patients. She asked the Committee to consider how the laboratory can contribute to providing

answers to the patient's questions and assure that results are delivered in an easily understandable format. She also informed the Committee of the Leapfrog Group's electronic medical record (EMR) testing center used to evaluate an EMR's ability to communicate pharmacy information with end users and suggested it might have similar application in the laboratory domain.

- Several members alluded to the National Institute of Standards and Technology (NIST) and the usability standards being developed for EHRs as a possible route to attain more effective drivers of HIT. One member elaborated that physicians, consumers, and the users of the interface are the best source to determine what the issues are, what the workflow is, and what the rationale should be behind the NIST decision-making. The member went on to emphasize grading the system against reality, not against test cases, makes a system more powerful and dynamic. The member urged the Committee to think about the issues in terms of what they would want as consumers and recommended the provider, provider organizations, laboratory professionals, and laboratory professional organizations drive the standards, rather than having the standards driven by technology.
- Another member concurred, adding that having patients' input into what laboratory data ought to look like is a very powerful factor. The member stated there is good evidence suggesting that laboratory results can be used to motivate patients to change behavior if presented appropriately. Ms. Sawchuk commented the activities of the Office of the National Coordinator for Health Information Technology (ONC) have progressed at a very rapid pace and perhaps have not been able to engage clinical people in a proactive way. She said laboratory representation on ONC committees and workgroups has frequently included IT people from commercial reference laboratories who do not have direct knowledge of what is happening in non-commercial laboratories. Ms. Sawchuk noted DLSS has been successful in calling attention to the value of the laboratory professionals' involvement on ONC workgroups and ONC is ready and willing to include laboratory professionals on their workgroups.
- Several Committee members commented that each commercial laboratory sets up the interfaces with clinician offices and determines their alert values. A physician member explained that when ordering multiple tests on a patient, it is rare to have completely normal results for every test and very frustrating when communicating the meaning of results flagged as abnormal to the patient. Another member agreed stating a lack of common standards, not just those related to varying alert values and reference intervals, has resulted in frustration for providers. A third member commented non-text results are even more difficult because they often do not get flagged and sometimes are dropped from the end user report. In response one member noted there is a CLSI committee looking at how to categorize and standardize actionable results.
- A member spoke about the importance of tracking and reporting laboratory data of public health significance, noting the current lack of standardization in what is reported has resulted in differences in what states report. A second member added public health incidence data needs to be shared in real time when the provider is seeing the patient so they can order the most appropriate tests.

- A member stated providing discreet data helps in clinical decision support but providers often have a hard time interpreting only the discreet data. The member asked the Committee to consider how best to convey to the healthcare provider the interpretive component of a test result. In response to this comment, another member noted anatomic pathology reports can be long, verbose reports and recounted how on one occasion the very important last two lines of the report were deleted from the provider's printed copy. The member reminded the Committee to be cognizant of the fact pathology reports' formatting and construct differ from laboratory to laboratory, making them confusing and difficult to interpret both for providers as well as other pathologists.
- The Chair concluded this part of the meeting by emphasizing the importance of standardizing practices to assist the laboratory community. She observed "we are still stuck on process when ultimately we really want better outcomes for our patients, not just better processes."
- Ms. Sawchuk added a final statement, reiterating the DLSS team's objectives to help assure that laboratory professionals are aware of the issues relevant to EHR implementation on a national level. She also informed CLIAC of NIST's announcement to establish usability framework workgroups indicating the proposed workgroups would offer the best opportunity to address many of the Committee's concerns.

Integrating Laboratory Services into Evolving Healthcare Models

Introduction and Background ***Addendum BB***

Ms. Megan Sawchuk, MT (ASCP)
Lead Health Scientist, 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 began the presentation by providing background on ACOs; referencing the September 2011 CLIAC meeting discussion, Dartmouth Atlas Project, and several influential papers. She reviewed accountable care principles, barriers to improving the value of care, and the resulting delivery system redesign and payment reform. Ms. Sawchuk elaborated on the tenets of ACOs, their varied configurations, and how they differ from managed care organization models. She described the Patient Centered Medical Home/Primary Care Medical Home (PCMH) models, compared them to ACOs, and discussed how the Medicare Shared Savings Program quality measures relate to laboratory services. In closing, Ms. Sawchuk sought CLIAC's advice on supporting the effective integration of laboratory services and resources into evolving healthcare models, posing three questions for CLIAC to consider:
1. Where have laboratory services and resources already been incorporated in evolving healthcare models, such as ACOs and PCMHs?

2. Are there gaps with integration of laboratory services and resources in evolving healthcare models?
3. What can HHS do to support the effective integration of laboratory services and resources into the development and implementation of evolving healthcare models?

Ms. Sawchuk concluded her introduction by introducing the next three speakers: Ms. Elizabeth November, Dr. Ira Sussman, and Dr. Michael Barr.

Medicare Shared Savings Program ***Addendum CC***

Ms. Elizabeth November, J.D., MPH
Health Insurance Specialist
Performance Based Payment Policy Staff
Centers for Medicare & Medicaid Services

Ms. November provided CLIAC with CMS's Medicare Shared Savings Program's background, congressional concept, goals, vision, and definitions. She emphasized the approach of the Shared Savings Program is to lower expenditures and improve patient health by promoting accountability for the care of Medicare fee-for-service beneficiaries, enhancing coordination of care for services provided under Medicare Parts A and B, and encouraging investment in infrastructure and redesigned care processes. She provided information on what entities could form an ACO, the Program's ACO structure, statutory eligibility requirements, agreement tracks, and quality performance standards and data reporting. She reviewed CMS's ACO strategy and innovative initiatives indicating further information could be obtained from www.cms.gov/sharedsavingsprogram/ and aco@cms.hhs.gov .

Accountable Care Organizations and the Laboratory – The Montefiore Experience
Addendum DD

Dr. Ira Sussman, MD
Vice Chairman of Pathology
Director, Moses Laboratory
Montefiore Medical Center
Bronx, NY

Dr. Sussman began by describing the Montefiore system: a four hospital, three campus system located in Bronx, NY, which serves as the University Hospital for the Albert Einstein College of Medicine. He outlined the Montefiore Integrated Provider Association, which has contracts with managed care organizations to accept and manage risk. He also defined Montefiore's Care Management Company, which performs credentialing, claims adjusting, and care management delegated by health plans. In detailing the pathology services' evolution as a service line, he stressed the major goal was to align incentives between the pathology department and Montefiore administration. Dr. Sussman emphasized the pathology department's value to the ACO as administering

cost effective laboratory services, helping clinicians choose the right test, reducing unnecessary testing, assisting in personalized therapies, and designing laboratory information solutions that promote accurate and complete data mining. Dr. Sussman concluded by describing Montefiore as a model for ACOs at an academic medical center.

ACOs & Medical Homes: What's the Lab Got to Do with It? ***Addendum EE***

Dr. Michael S. Barr, MD, MBA, FACP
Senior Vice President
Division of Medical Practice, Professionalism & Quality
American College of Physicians
Washington DC

Dr. Barr began by outlining the ideal model for the Patient-Centered, Physician-Guided Care Core of Team-Based Care and asked what is necessary to implement this model of healthcare. He discussed critical tactics and strategies before defining ACOs. Dr. Barr introduced a stratified model of an ACO structure and focused on what laboratory services must consider when attempting to achieve peak performance within this model. He concluded the presentation by defining a close-to-patient laboratory testing service model.

Committee Discussion ***Addendum FF***

- One member asked how information is communicated to physicians in the Montefiore system, wondering if they used information integrated with practice guidelines for certain diseases and also whether the information was delivered in a weekly, monthly, or real time electronic report. Dr. Sussman replied all of those modes are used and explained it is an evolving process that begins with the laboratory's management reports that are built using existing laboratory information system tools to reports. Montefiore is currently using a hybrid of electronic systems in an effort to get the information out.
- One member asked Dr. Sussman how data are made available to a physician on a patient treated at multiple sites and/or a site not in their system. Dr. Sussman acknowledged this is a challenge and emphasized reliance on providers voluntarily submitting all information obtained on a Montefiore patient to the Montefiore laboratory database either electronically or manually. He explained the submitted information is then in the main hospital database along with that patient's inpatient record and clinic record. He indicated the voluntary provider can get access to anything in the database as long as they have privileges at the hospital. He noted that currently one challenge to be addressed is consistency in demographic information between the hospital system and each of the independent provider systems. He indicated Montefiore was installing a new laboratory system with a master patient index and the capability to echo back demographics regardless of the provider's IT system.
- A member asked Dr. Sussman about their strategy to decrease test utilization while at the same time ensuring that the correct test is performed. Dr. Sussman answered they

have begun to use a screening program where the pathology residents analyze any request for an expensive test, request patient information, and then call the clinician to discuss whether that particular test is meaningful. He added they were investigating the use of ordering algorithms.

- Another member proposed a laboratory representative be involved in the development of all clinician order sets in a hospital information system as an approach to reducing unnecessary testing. Dr. Sussman agreed, stating no one at Montefiore can build or change anything in the information system related to the laboratories without laboratory approval.
- One member inquired if an ACO was a voluntary system or if providers were mandated to participate? Ms. Sawchuk and Ms. November both replied currently it is voluntary for providers as well as beneficiaries. Ms. November went on to explain once an ACO is formed it may apply to participate in the CMS program, adding beneficiaries retain their ability to choose the fee for service model. A member asked the panel what impact ACOs might have on patient choice as well as the potential limitations of patient movement among systems. Dr. Barr replied ACOs should not limit patient choice or movement among systems. Hopefully, patients will enroll in the systems that demonstrate improvements in care, access, quality, and reduction in any out-of-pocket costs because they are more effective and efficient. Ms. November added many of the program's features are designed to make it a model of care that is more attractive to beneficiaries. Dr. Sussman commented that care management organizations offer patient-centered activities a private practice can't offer which are a big inducement for providers to join the system.
- A member asked Ms. November how CMS was setting future quality measure benchmarks and how CMS would approach the potential benchmarks for organizations new to the accountable care model. Ms. November replied the number of quality measures was reduced from over 60 to approximately 30 in response to public comments indicating they were seen as too rigorous and burdensome, particularly for organizations new to the accountable care model. She stated a phase-in period had been established for the measures. She explained this would allow organizations to become more familiar with quality reporting before their amount of shared savings is linked to their performance on those measures. Ms. November added the agency has the regulatory flexibility to assess measures over time and make changes.
- A member expressed concern regarding duplicative testing being performed in multiple sites, especially as more point-of-care testing is being performed. The member encouraged the reduction of unnecessary testing and improved sharing of results and information conducted at each point-of-care site. Dr. Barr replied he hoped point-of-care testing results would be captured as structured data within a patient's EHR and thereby easily shared among medical practices. Patients could become part of the care plan and maintain their results on paper, flash drive, or other media, or by having their personal health record accessible from any location. A different member noted the concept of health information exchange is to share patient information without having the patient bear the burden. Dr. Barr agreed.
- A member asked if representatives from laboratory medicine are participants on any of the large healthcare organizations' governing boards and how the laboratories

operate within these organizations. A member from an integrated healthcare system answered it is important for the laboratory to be a participant during the creation of an ACO, engaged from the beginning in making decisions in all areas of test utilization and partnering with providers to ensure laboratory services are appropriate for each patient type.

- The Chair stated that providing value (quality divided by cost over time) is essential for the laboratory in the emerging healthcare models. The critical components of value include effective and efficient test utilization that allows providers to achieve stated quality goals in a cost effective way. She reminded the Committee the cost of care, which includes laboratory testing, impacts the amount of shared savings realized by the healthcare organizations.
- In closing the discussion a member said the laboratory community strategy has been articulated. The tactics will depend on the organizational structure. The goal is to be a participant.

PUBLIC COMMENTS

- **American Society for Cytotechnology (Letter), Janie Roberson, SCT (ASCP)** ***Addendum GG***
- **American Society for Cytotechnology (Presentation), Janie Roberson , SCT (ASCP)** ***Addendum HH***
- **Papanicolaou Society of Cytopathology, Lester J. Layfield, M.D.** ***Addendum II***
- **Independent Cytological Consultant, Gary W. Gill, CT (ASCP)** ***Addendum JJ***
- **Cytology Education and Technology Consortium, George Birdsong, M.D.** ***Addendum KK***
- **American Society for Clinical Pathology, George Birdsong, M.D.** ***Addendum LL***
- **Becton-Dickinson (BD), Peggy Parker, B.A., SCT (ASCP)** ***Addendum MM***

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:

1) CLIAC supports the use of data from operational studies, such as those presented, to determine if the maximum workload limit using semi-automated screening instruments is appropriate. To discourage the use of maximum workload limits as productivity expectations, standardized criteria should be developed for use in determining workload limits for each individual performing screening.
2) Lowering the workload limits for screening Pap smears using a semi-automated device may result in improving the quality of testing. However, it could also lead

to increased turnaround time and costs for obtaining test results and could have implications for access to testing.

Dr. Santrach announced the fall 2012 CLIAC meeting dates as August 29-30, and adjourned the Committee meeting.

I certify this summary report of the February 14-15, 2012, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Dated: 05/ 02/2012

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Paula Santrach, M.D., CLIAC Chair