# Clinical Laboratory Improvement Advisory Committee

## Summary Report

**February 9-10, 2010**

**Atlanta, Georgia**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

**Clinical Laboratory Improvement Advisory Committee**
**February 9-10, 2010 Summary Report**
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## *Record of Attendance*

Committee Members Present

Ms. Elissa Passiment, Chair
Dr. Judy Daly
Dr. Nancy Elder
Dr. John Fontanesi
Ms. Julie Gayken
Dr. Geraldine Hall
Dr. Norman Harbaugh, Jr.
Dr. Paul Kimsey
Dr. James Nichols
Dr. Stephen Raab
Dr. Linda Sandhaus
Dr. Paula Santrach
Dr. Gail Vance
Dr. Emily Winn-Deen
Dr. Rosemary Zuna
Ms. Luann Ochs, AdvaMed (Liaison Representative)

Committee Members Absent

Dr. Ellen Jo Baron
Dr. Christine Bean
Dr. Gary Overturf
Ms. Susan Cohen

Executive Secretary

Dr. Thomas Hearn

Ex Officio Members

Dr. Alberto Gutierrez, FDA
Dr. Roberta Carey, CDC
Ms. Judith Yost, CMS

## *Record of Attendance - cont'd.*

Centers for Disease Control and Prevention (CDC)

Mr. Todd Alspach
Ms. Nancy Anderson
Dr. Rex Astles
Ms. Inger Baker
Ms. Diane Bosse
Dr. Bin Chen
Dr. Carlyn Collins
Ms. Joanne Eissler
Ms. MariBeth Gagnon
Dr. Genny Barkog Gallagher
Dr. James Handsfield
Ms. Pat Haskell
Dr. Lisa Kalman
Dr. Joan Knapp
Ms. Debra Kuehl
Dr. Ira Lubin
Ms. Leslie McDonald
Dr. Joanne Mei
Ms. Andrea Murphy
Ms. Jan Nicholson
Mr. Richard Olney
Ms. Abrienne Patta
Ms. Anne Pollock
Dr. Angela Ragin-Wilson
Ms. Cheri Rice
Dr. Shahram Shahangian
Mr. Darshan Singh
Ms. Theresia Snelling
Dr. Susan Snyder
Ms. Heather Stang
Ms. Cynthia Sturchio
Dr. Shambavi Subbarao
Dr. Julie Taylor
Mr. Howard Thompson
Ms. Pamela Thompson
Ms. Irene Willaims
Dr. Barbara Zehnbauer

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

Ms. Carol Benson (FDA)
Mr. Michael Brophy (VA)
Ms. Minnie Christian (CMS)
Dr. Elliot Cowan (FDA)
Ms. Karen Dyer (CMS)
Ms. Daralyn Hassan (CMS)
Mr. Jonathan Ishee (ONC-HHS)
Ms. Penelope Meyers (CMS)
Mr. Charles Reynolds (CMS)
Ms. Ann Snyder (CMS)
Ms. Kathleen Todd (CMS)
Ms. Harriet Walsh (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. Thomas Hearn, Designated Federal Official, CLIAC, Acting Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) (Proposed), CDC, welcomed the Committee and the members of the public, acknowledging the importance of public participation in the advisory process. He explained the meeting would focus on three main topics: "Good Laboratory Practices for Biochemical Genetic Testing;" "Electronic Health Records (EHRs) and CLIA;" and "Electronic Transmission of Laboratory Information and Oversight of Laboratory Information Systems."

Focus would be placed on the Biochemical Genetic Testing Workgroup's report in order for CLIAC to provide recommendations to the Department of Health and Human Services (HHS) for good laboratory practices for genetic testing. These recommendations are intended to be published in a Morbidity and Mortality Weekly Report Recommendations and Reports (*MMWR R&R)*. With respect to the other topics, an overview of the progress that the Office of the National Coordinator for Health Information Technology has made towards implementation of Electronic Health Records, implications of EHRs in the context of CLIA regulations, and the FDA's classification of and the regulations that apply to laboratory information systems will be discussed.

**Board of Scientific Counselors - Update** ***Addendum A***

Ms. Elissa Passiment, Chair, CLIAC
Executive Vice President
American Society for Clinical Laboratory Science

Ms. Passiment reported on the November 2009 meeting of the Board of Scientific Counselors (BSC), a federal advisory committee that serves the CDC infectious disease centers and meets to discuss high priority infectious disease issues. The two day agenda included an overview of CDC's environmental microbiology activities; a review of the American Recovery and Reinvestment Act (ARRA) funding for immunization programs; updates on the peer reviews for programs within two infectious disease centers; an update on CDC's organizational changes and priorities by Dr. Rima Khabbaz, the acting Deputy Director of Infectious Diseases at CDC, Dr. Steve Blount, the acting Director of the Center for Global Health, and Director of CDC, Dr. Thomas Frieden; and a report on CDC's activities in the investigation of influenza H1N1.

Ms. Passiment provided a summary of the environmental microbiology workgroup activities, which included describing how the physical structure of healthcare facilities may affect the rate of healthcare acquired infections. She related that CDC's scientists have interests in carrying out research in aerobiology (the study of the dispersion of airborne biological materials such as pollen, spores, microorganisms, or viruses); however, as CDC facilities may not be able to support the research, alternative sites such as Fort Detrick are being considered. The BSC recommended that the environmental

microbiology workgroup coordinate its activities with the Environmental Protection Agency, the Department of Homeland Security, and CDC's infection control and epidemiology groups. Ms. Passiment said the BSC suggested the environmental microbiology workgroup be more proactive with regards to communication and education across all disciplines.

The H1N1 report covered testing, response, laboratory communications, the factors surrounding the susceptibility of children to the disease, and how deaths relate to pregnancy and obesity. CDC is in the process of analyzing data collected to determine the actual impact of H1N1disease in the U.S. Ms. Passiment concluded the presentation by noting the need for more public relations in the "regular community" regarding vaccination.

## AGENCY UPDATES AND COMMITTEE DISCUSSION

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

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

Dr. Gutierrez listed recent FDA staffing changes, notably Dr. Jeff Shuren as Director of the CDRH. He reported on agency initiatives, including efforts to pro-actively manage public health issues such as use of glucose meters in healthcare settings, the implementation of personalized medicine, and responding to emerging infectious diseases. He also described FDA's attempts to ensure transparency of their actions and processes using communication outlets like Twitter, YouTube, and public meetings. Dr. Gutierrez explained at the Center level, the 510(k) program will be undergoing internal and Institute of Medicine reviews allowing outside entities an opportunity to provide feedback. He reviewed recently published FDA guidances for antimicrobial susceptibility tests, part of a joint effort between OIVD and the Center for Drug Evaluation and Research concerning labeling; detection or detection and differentiation of HPV; several special controls guidances; and H1N1 Emergency Use Authorizations (EUA) for both manufacturers and laboratories. Dr. Gutierrez commented on one notable new clearance, OVA1, used for the detection of ovarian cancer. He also noted 14 EUAs for influenza H1N1 will expire in April 2010 unless reauthorized by the Secretary of HHS. He detailed agency postmarket actions which included Class I recalls, public health notifications, and warning letters. Dr. Gutierrez concluded his presentation by briefly reviewing CLIA waivers, including a summary of tests waived by FDA, as well as examples of the FDA timeframes for waiver reviews.

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

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

***Addendum C***
***Addendum D***
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***Addendum G***
***Addendum H***

Ms. Yost began her presentation with an overview of current CLIA statistics showing a large percentage of the laboratories perform 10,000 tests per year or less and that the number of waived laboratories continues to increase. She reported on the progress of the cytology proficiency testing (PT) proposed regulation, stating suggestions and comments are being analyzed. Next, she reviewed CMS's most cited deficiencies and enforcement data. Ms. Yost then updated the Committee on alternative quality control (QC) development including the collaboration between CMS and the Clinical and Laboratory Standards Institute (CLSI). She said the new alternative QC will be phased in by CMS and the interpretive guidelines will be revised. She also reported on the CMS plan to update all aspects of the PT regulations. Ms. Yost said a CLIAC PT workgroup meeting is scheduled for March 2010, and the workgroup report will be presented to CLIAC at the next meeting in September 2010. Ms. Yost presented statistics on certificate of waiver (CW) laboratory performance including voluntary PT and detailed the next steps towards efforts to improve the quality of waived testing. She listed CMS' short term goals which include continuing the CW project indefinitely, soliciting data from accrediting organizations and other sources that have CW standards, and coordinating with the FDA to address overlapping issues. Finally, she stated the ideal long term goal would be to improve the level of oversight of sites that perform waived testing by changing the CLIA law. Ms. Yost summarized the CLIA requirements and issues pertaining to EHRs and said new CMS guidance pertaining to EHRs is forthcoming. She also noted a new brochure that provides simple mechanisms to file a complaint has been developed and is accessible on the CLIA website. The brochure will be distributed to all laboratories over the next two years. Ms. Yost concluded her presentation with a review of CLIA personnel requirements and inspection policies, focusing on personnel qualifications and the ramifications that could occur if the requirements are not being met.

## Committee Discussion

- One member voiced support for getting feedback from accrediting and professional organizations regarding waived testing. Inspecting waived testing sites could have the potential to improve test quality, but physicians may view inspections as an imposition in terms of time, money, and aggravation. Ms. Yost noted that a certain percentage of waived laboratories or other sites that only perform waived testing receive educational visits from CMS. CMS is exploring the possibility of minimal periodic oversight, although not to the extent of non-waived laboratory inspections. The same member replied voluntary oversight will not be accepted. Ms. Yost responded CMS would like

to see the CLIA law minimally changed thereby giving CMS some oversight discretion. The agency would appreciate insight and suggestions from professional organizations and is seeking a constructive approach.

- Another member inquired whether CMS or the accrediting organizations have a list of certified laboratories. Ms. Yost referred the member to the "Laboratory Demographics Lookup" tool on the CMS CLIA website. If additional information is required, Ms. Yost suggested contacting the relevant state agency.
- One member asked what the ramifications are if a laboratory does not follow the manufacturer's instructions for a waived test or engages in off-label use of the test i.e., in a different clinical setting for uses not specified in the manufacturer's instructions. Ms. Yost responded a laboratory's waiver certificate can be removed if manufacturer's instructions are not being followed, especially if there is immediate jeopardy to the patient. If a waived test is performed outside of its intended use, it defaults to a high complexity test, and the laboratory must meet the standards for high complexity testing or stop using the test. Dr. Gutierrez added this is a complex and challenging issue. He cited, as an example, waived devices or tests that measure hemoglobin A1c. The American Diabetes Association has put forth new recommendations to allow diagnosis of diabetes based on hemoglobin A1c results. Since the intended use of waived tests for hemoglobin A1c does not include diagnosis of diabetes, their use for this purpose would be outside of the intended use and considered off-label. Dr. Gutierrez stated as medicine and technology change, similar issues will continue to arise.

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

Roberta B. Carey, Ph. D.
Acting Director, Division of Laboratory Systems
National Center for Emerging and Zoonotic Infectious Diseases (proposed)
Division of Laboratory Systems
Centers for Disease Control and Prevention

Dr. Carey presented an overview of the reorganization taking place at CDC, noting the Division of Laboratory System's move to the Office of Surveillance, Epidemiology, and Laboratory Services headed by Dr. Stephen Thacker. She described the CLIAC Proficiency Testing Workgroup's charge and topics to be addressed at the March 2010 meeting. Dr. Carey reported two cytology cooperative agreements were funded in 2010-2011 to the College of American Pathologists and Michigan Public Health Institute to gather information on cytology laboratory testing and reporting practices. She summarized the post-publication activities of the *MMWR R&R* article titled "Good Laboratory Practices for Molecular Genetic testing for Heritable Diseases and Conditions." Dr. Carey reviewed the goal and status of CDC's Laboratory Medicine Best practices project. She stated three pilot test topics and seven practices have been reviewed, four of which had sufficient evidence to recommend as best practices. As a result of the success of this project, several products are in preparation, including manuscripts, presentations, a technical guide, and a web-based tutorial to educate

laboratory scientists regarding evidence-based reviews. Also, in the area of evidence-based laboratory medicine, DLS has been examining quality/performance measures and Dr. Carey discussed three ongoing initiatives as well as the progress and future plans for this activity.

Next, Dr. Carey described an interactive training module, "Genetic Testing in Clinical Practice: A Team Approach," a case-based interactive module designed for clinicians or students to work their way through a simulated clinic to learn about the use of genetic tests in medical practice. She outlined the Genetic Testing Reference Material Program, which seeks to improve the availability of reference materials for genetic testing. She described the goals and findings of the Rapid Influenza Testing Survey, performed under a cooperative agreement with The Joint Commission, and said a second survey is to be conducted later this year. Dr. Carey concluded her presentation by giving status reports on the Laboratory Medicine Roadmap and the Laboratory Medicine Integrations Workgroups.

**Committee Discussion**

- One member asked Dr. Carey if she anticipated any interagency work in the area of best practices with the Agency for Healthcare Research and Quality (AHRQ). Dr. Carey responded that AHRQ would be a natural partner, but their focus is not on the laboratory.

## PRESENTATIONS AND COMMITTEE DISCUSSION

**Introduction: CLIAC Biochemical Genetic Testing Workgroup – Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Heritable Diseases** ***Addenda J & K***

Bin Chen, Ph.D., FACMG
Laboratory Research and Evaluation Branch (Proposed)
Division of Laboratory Science and Regulation (Proposed)
Laboratory Science, Policy and Practice Program Office (Proposed)
Office of Surveillance, Epidemiology and Laboratory Services (Proposed)
Centers for Disease Control and Prevention

Dr. Chen presented the introduction for the CLIAC Biochemical Genetic Testing Workgroup. She provided background information on the current oversight for biochemical genetic testing (BGT) derived from the CLIA regulations, the FDA requirements for in vitro diagnostic devices, state requirements, voluntary professional practice guidelines, and accreditation requirements. She reviewed the CLIAC activities related to BGT since 2007, including the recommendation in September 2008 to form a workgroup on BGT for good laboratory practices (GLP). Dr. Chen addressed the CDC assessment of the BGT landscape and quality assurance (QA) gaps including issues for

workgroup consideration, areas of expertise needed for the workgroup, and information needed to facilitate the workgroup's evaluation of current standards. One example of an issue needing the workgroup's input was the determination of which tests the prospective good laboratory practice recommendations should apply. Dr. Chen explained that existing definitions for BGT vary depending on the context and purpose of testing; although CLIAC recommended a definition "analysis of human gene products, metabolites to detect inborn errors of metabolism (IEM), heritable genotypes or disorders," most BGT laboratories are currently self-designated. On the other hand, most of the diseases screened for by state newborn screening (NBS) programs are IEM and the presumptive positive NBS cases need to be confirmed with diagnostic testing such as specialized biochemical genetic tests. She also addressed the lack of up-to-date, comprehensive data for test volume and the number of BGT laboratories. Dr. Chen stated that, in preparation for the BGT Workgroup deliberations, CDC prepared 19 comprehensive crosswalks and identified additional issues to be resolved. CDC anticipates publication of an *MMWR R&R* in 2011 that will incorporate CLIAC's recommendations for GLPs for BGT.

## Good Laboratory Practices for Biochemical Genetic Testing and Newborn Screening for Heritable Diseases

***Addenda L & M***

Carol Greene, M.D., FACMG
Director, Clinical Genetics and Metabolism Service
Department of Pediatrics
University of Maryland School of Medicine

Dr. Greene, Chair, CLIAC BGT Workgroup, introduced the workgroup members and ex officio participants whose primary charge was to provide input to CLIAC leading to the development of recommendations for GLPs for BGT. She said the workgroup reviewed the 19 comprehensive crosswalks prepared by CDC and used them as the starting point for their discussions about each of the eight BGT key areas. The workgroup report provided suggestions and clarifications on the scope and applicability, total testing process (i.e., preanalytic, analytic, postanalytic phases), PT and alternative assessments, confidentiality, personnel qualifications and responsibilities, considerations before introducing genetic testing or offering new BGTs, and quality management systems (QMS).

## Committee Discussion

***Addendum N***

Ms. Passiment and the Committee commended Dr. Greene and the workgroup members for their efforts to provide a comprehensive list of suggestions for GLPs for BGTs. The Chair directed Committee members to discuss each aspect of the workgroup report. The Committee recommended adopting the document with the following additions or modifications.

**CLIAC Additions or Modifications to BGT Workgroup Suggestions** ***Addendum O***

**Scope and Applicability:**

- One member commented that many non-geneticists do not understand BGT and a geneticist should be consulted, when needed, for ordering or interpretation of tests. Dr. Greene responded that this comment pertains to physician education and clarified that the document covers GLPs for the laboratory performing the test but encourages physicians to consult with geneticists.
- There was discussion about which tests were considered biochemical genetic tests. A member said there is crossover between biochemical testing for other purposes and BGT, making it difficult to determine which tests to include in BGT. Therefore, the BGT GLPs could be applied to most testing performed in biochemical genetic laboratories but not to all. Dr. Greene agreed and stated the workgroup also included tests for the diagnosis and monitoring of IEM which include NBS and rare genetic testing performed by a biochemical genetic testing laboratory.
- A member suggested simplifying the document by focusing on the preanalytic and postanalytic phases of testing where BGT differs from other laboratory testing. Dr. Greene replied the intent of the workgroup deliberations and report was to provide guidance for CLIAC to consider on GLPs for laboratories that want to start performing BGT, laboratories that want to add new biochemical genetic tests to their menus, and for use as comprehensive guidance for any laboratories that perform BGT.
- A member suggested the title of the summary of CLIAC recommendations be changed to "Biochemical Genetic Testing and Newborn Screening for Diagnosis and Monitoring of Inborn Errors of Metabolism" or "Good Laboratory Practice for Diagnosis and Monitoring of Inborn Errors of Metabolism using Biochemical Genetic Testing and Newborn Screening" to address the clinical aspect of testing.
- One member suggested the *MMWR R&R* introduction needs to stress that much of the information on GLPs applies to all laboratory testing, with BGT differing in the preanalytic and postanalytic phases of testing.

**Preanalytic Phase:**

**Information to be Provided to Users of Laboratory Services**

- One member inquired about pre-authorization for BGT, noting it was included in the *MMWR R&R* for molecular genetic testing. The workgroup agreed pre-authorization should be part of any published GLP guidelines.

**Informed Consent**

- For the topic of informed consent, one member suggested separating NBS from other BGT. Dr. Greene suggested that a clarification of the differences be addressed in the *MMWR R&R* publication. Dr. Chen added that CDC subject matter experts and BGT workgroup experts on NBS were consulted and had determined that most of the key points applied to both NBS and other BGT, so there was no need to separate them. However, the *MMWR R&R* document will offer a more user-friendly explanation of the differences in informed consent.
- Dr. Gutierrez suggested the workgroup consult with the Secretary's Advisory Committee for Genetics, Health, and Society (SACGHS) and the Advisory Committee

for Heritable Diseases in Newborns and Children (ACHDNC), which is also considering best practices for informed consent and sample retention in NBS, to ensure agreement on recommended GLPs. Dr. Greene informed CLIAC that the workgroup was provided with documents from SACGHS and ACHDNC to use for reference. Updates will be provided to both SACGHS and ACHDNC regarding CLIAC recommendations for BGT and NBS.

**Test Request**

- No additions or clarifications.

**Specimen Submission, Handling, and Referral**

- The Chair suggested clarification of the terminology on inadequate specimens and how these specimens would still meet the laboratory's acceptance criteria for testing. Dr. Greene clarified that in certain BGT laboratories the entire specimen is judged as adequate or inadequate for all testing to be done, so the specimen would be reported as inadequate if it was inadequate for any test in the panel even though it was adequate for a specific test. The Chair commented such specimens, therefore, should not be reported as inadequate for all tests requested, but just for those tests for which the specimen is truly unacceptable, and re-iterated the need for clarity in CLIAC recommendations and a subsequent *MMWR R&R*.
- The Chair also commented that if a laboratory accepts a suboptimal or non-ideal specimen, such as a hemolyzed specimen, it should have documentation of studies to prove that the test to be performed and performance specifications will not be compromised.
- Several CLIAC members said specimens for patient testing referral must be referred to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. They suggested the removal of language in any CLIAC recommendation addressing referral of specimens to foreign non-CLIA certified laboratories.
- Ms. Yost commented that CMS has been exploring strategies for oversight of non-CLIA-certified foreign laboratories that perform patient testing for U.S. patient specimens. Determining equivalency has been a challenge due to the numerous different policies in countries outside of the U.S.
- One member commented that the Collaboration Education and Test Translation Program in The Office of Rare Diseases Research at the National Institutes of Health (NIH) facilitates the translation of genetic tests from the research setting to CLIA-certified laboratories through collaborations among clinicians, laboratories, researchers, and disease-specific advocacy groups.
- CLIAC recognized that some rare biochemical genetic tests are needed for patient care, but are not currently offered in CLIA-certified laboratories. The Committee recommended that CMS and the Office of Rare Diseases Research at NIH identify specific test gaps that exist today and seek support from the Office of Rare Diseases Research to set up these tests in CLIA-certified laboratories. Support could include assisting laboratories which currently offer these tests to obtain CLIA certification or offering assistance in setting up these tests in existing CLIA laboratories.

**Preanalytic Systems Assessment**

- No additions or clarifications.

**Analytic Phase:**

**Performance Establishment and Verification**

- One member commented on establishing performance for a diagnostic test or specimen type when sufficient numbers of normal and positive controls are not available. Another member suggested including a reference for performance establishment or verification requirements of low volume or rare tests. Dr. Greene commented SACGHS and other groups have tried to address this issue and provide guidance but have not been successful in coming up with a numerical requirement for establishing or verifying performance for tests when specimens are not readily available.
- The Chair commented that it is not acceptable for a laboratory to test a specimen and report results if they have not established or verified performance for that specimen type using their test system. Even if this specimen is the only one available for testing, accurate results cannot be assured.

**Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies**

- No additions or clarifications.

**Calibration and Calibration Verification Procedures**

- No additions or clarifications.

**Control Procedures**

- No additions or clarifications.

**Proficiency Testing (PT) and Alternative Performance Assessment**

- Dr. Greene commented PT for BGT is often complicated due to lack of certain specimen matrices such as spinal fluid and muscle biopsies. She stressed the importance of alternative PT assessments in BGT.

**Postanalytic Phase:**

**Test Report**

- No additions or clarifications.

**Retention of Records and Reports**

- One member inquired whether the workgroup's suggested 21 year retention of records was for all documents associated with testing or just the test report. Dr. Greene clarified that the test report should be retained for 21 years and other documents retained as required by CLIA. She commented that for rare conditions, the workgroup suggested retaining some records, such as QC and PT, for a longer period of time to be used for educational purposes.
- One member asked why the workgroup proposed a 21 year record retention time for BGT when 25 years was recommended for molecular genetic testing. Dr. Greene responded that currently 21 years is the maximum amount of time an NBS testing facility will retain documents. The workgroup has no objections to changing 21 years to 25 years to maintain consistency with the molecular genetic testing guidelines.

**Retention of Specimens**

- One member suggested changing the wording from "low volume tests" to "low frequency tests" when addressing the retention of specimens until the next PT event or external quality assessment.

**Postanalytic Systems Assessment and Other Issues**

- No additions or clarifications.

**Confidentiality**

- No additions or clarifications.

**Personnel Qualifications and Responsibilities:**

**Laboratory Director Qualifications and Responsibilities**

- No additions or clarifications.

**Technical Supervisor Qualifications and Responsibilities**

- No additions or clarifications.

**Clinical Consultant Qualifications and Responsibilities**

- No additions or clarifications.

**General Supervisor Qualifications and Responsibilities**

- No additions or clarifications.

**Testing Personnel Qualifications and Responsibilities**

- No additions or clarifications.

**Personnel Competency Assessment**

- No additions or clarifications.

**Additional Issues:**

**Considerations before Introducing Genetic Testing or Offering New Biochemical Genetic Tests**

- Dr. Greene stressed the focus should be patient care when considering the introduction of low volume tests.
- Dr. Chen commented ACHDNC operates a systematic evidence-based review process to determine which disorders will be recommended for inclusion into newborn screening test panels nationwide. The workgroup encourages ACHDNC to consider the availability of confirmatory tests in CLIA-certified laboratories before the introduction of a new screening test.

**Quality Management System (QMS) for Biochemical Genetic Testing**

- One member suggested principles of quality assessment and quality management should be stressed throughout the document.

## Introduction: Electronic Health Records and Electronic Transmission of Lab Information *Addendum P*

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

Ms. Yost introduced the topic of Health Information Technology (HIT) and EHRs providing some background on the subject. Under Title 4 of the American Recovery and Reinvestment Act ARRA, an incentive program was established for physicians who adopt, implement, or use HIT. The HIT Committee in the Office of the National

Coordinator for Health Information Technology (ONC) (http://healthit.hhs.gov) was established and reports to the Secretary of HHS. Together, the HIT Committee, CMS, and the Office of E-Health Standards and Services have been working on the issues that currently hinder electronic transmission of laboratory information.

## Issues Surrounding the Electronic Exchange of Laboratory Data

***Addendum Q***

Jonathan Ishee, JD, MPH, MS, LLM
Office of the National Coordinator for Health Information Technology

Mr. Ishee provided an update on the progress that the ONC has made pertaining to EHR. Under the ARRA, an incentive program was established for the meaningful use of certified EHR technology by eligible professionals. As a result, CMS was charged with writing a Notice of Proposed Rulemaking (NPRM) on the incentive program's meaningful use of certified EHR technology by eligible professionals and ONC was charged with writing an Interim Final Rule (IFR) on standards and certification criteria. The ONC supported a study on state laws concerning persons authorized to order tests and receive results and found 23 states did not identify who could be considered an authorized person while others were prescriptive in their definition of an "authorized person," with no uniform standard applied by all states. On October 20th, 2009, a hearing was convened with EHR stakeholders to discuss issues surrounding the electronic exchange of laboratory data. During the hearing, impediments to this exchange of information were identified that fell into three major categories: standards/technological, business, and perceived regulatory impediments. After the October hearing, CMS developed a Survey and Certification letter for laboratory surveyors, to facilitate the electronic exchange of laboratory information. The letter included information that will become part of updated CLIA interpretive guidelines and answers to frequently asked questions. Longer term next steps will include the HIT Standards Committee recommending standards, certification criteria, and implementation specifications. ONC and CMS will also monitor feedback from the Survey and Certification letter and consider possible regulatory changes if issues cannot be resolved through the ONC standards or CLIA interpretive guidelines.

## CLIA and EHRs

***Addenda R & S***

Judy Yost, MA, MT (ASCP)
Director, Division of Laboratory Services
Centers for Medicare & Medicaid Services (CMS)

Ms. Yost discussed the implications of EHRs in the context of CLIA regulations. She related that there are currently several systems for transmitting electronic health information already in use and issues outside of the CLIA purview, such as terminology, standardization, and complexity, may create challenges in the future. The Survey and Certification letter mentioned in the previous presentation is the predecessor to policy

that will be incorporated in the CMS interpretive guidelines for surveyors and laboratories. She explained the new interpretive guidelines being written outlines each aspect of the regulations with interpretations and suggestions for laboratories on how the CLIA requirements can be met. The guidelines will be available on the CMS website. Ms. Yost listed the specific sections of the CLIA regulations impacted by EHR, including the preanalytic phase with test ordering (§493.1105) and test request (§493.1241) as well as the postanalytic phase with test reporting (§493.1291). She then elaborated on common misperceptions laboratories have with regard to CLIA regulations and EHRs and provided clarification for each misperception.

**High-Value Health Care Project: An Initiative of the Quality Alliance Steering Committee** ***Addendum T***

Min Gayles Kim, MPH
Engelberg Center for Health Care Reform at Brookings Institution

Scott Endsley, MD, MSc
Co-Chair
Expert Panel on Laboratory Data Integration for Diabetes Care Improvement

Ms. Kim began the presentation with a brief background on the Brookings Institution Quality Alliance Steering Committee (QASC) which oversees the High-Value Health Care Activities sponsored by the Robert Wood Johnson Foundation. The QASC includes stakeholders from all areas of healthcare and has as its goal to provide national coordination for advancing quality, cost-effective, patient-centered healthcare. One of the major activities of the High-Value Health Care project is data integration, which includes an on-going laboratory data integration project related to diabetes. Ms. Kim noted one of the greatest barriers to coordinating care and improving patient outcome, as well as measuring provider performance, is the lack of a national health data infrastructure that can link clinical, administrative, and other electronic health information at the patient level. She presented the laboratory data integration project's phased approach beginning with identifying existing challenges and barriers followed by prioritizing those barriers and proposing solutions. The barriers identified and discussed included technical, regulatory, financial, and access barriers.

Dr. Endsley continued the presentation and discussed a number of technical issues regarding laboratory data integration as well as two CLIA-related issues identified by the laboratory data integration expert panel. The first CLIA-related issue he discussed focused on the varying state laws and interpretations of CLIA with respect to the term "authorized person." He presented the panel's recommendation that CMS, through collaboration with advisory bodies, should update and disseminate the interpretive guidelines with specific clarification on the definition of "authorized person" to include other non-ordering providers, EHR, and other Health Insurance Portability and Accountability Act (HIPAA) covered entities. The second CLIA-related issue he discussed dealt with the verification by the laboratory of appropriate laboratory data display in the EHR. The panel recommended that CMS should explicitly describe the

verification process in the absence of electronic verification and said laboratory data transmitted to an EHR in the endorsed messaging format should be deemed compliant, provided the EHR system has been certified to display laboratory result data in compliance with the CLIA requirements. The third CLIA-related issue concerned the meaningful user requirements. The panel recommended CMS amend the CLIA regulations to align with these requirements and set a target date for achieving them.

**Electronic Transmission of Laboratory Information and Oversight of Laboratory Information Systems – CDC Perspective.** ***Addendum U***

Joan S. Knapp, PhD
Lead subject matter expert: Infectious Diseases Laboratories, Public Health Laboratory Interoperability Project (PHLIP) Core Vocabulary Team
Centers for Disease Control and Prevention (CDC)

Dr. Knapp presented the PHLIP which actualized the Laboratory Information System (LIS) that CDC is currently using to receive and transmit data to approximately fifty state public health laboratories. The first step PHLIP made was to establish a vocabulary team to work on a common set of agreed upon terms (harmonized vocabulary) while accommodating multiple terms (exchange of precise terms). She indicated the number of Logical Observation Identifiers, Names, and Codes (LOINC) available was limited and not specific enough for PHLIP to use as test codes. She then mentioned that the Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT) used for result codes were also often insufficient for PHLIP's purposes. Therefore, the PHLIP team developed its own test and report codes. Dr. Knapp concluded her presentation by illustrating some challenges the team had encountered and describing lessons learned and the need for standardized reporting terms.

**FDA Oversight of Laboratory Information Systems** ***Addendum V***

Alberto Gutierrez, PhD
Director, Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD)
Center for Devices and Radiological Health
Food and Drug Administration (FDA)

Dr. Gutierrez presented FDA's classification of and the regulations that apply to LISs. Under 201(h) of the Federal Food Drug and Cosmetic Act (FDCA). The FDCA considers an LIS a component part or accessory of a medical device. Under Subpart C – Clinical Laboratory Instruments, Section 862.2100, an LIS is further classified as a calculator/data processing module for clinical use and falls under Class 1 (general controls) which is exempt from pre-market review. Under Class 1, the device must be registered and the manufacturer must follow good manufacturing practices, report device failures, have an inventory of tests/software on the market, and have a system for remedying device failures. Dr. Gutierrez discussed a proposed rule on Medical Device Data Systems currently in the comment period which discusses software and the electronic storage, retrieval, transfer, display, and conversion of medical device data. He then provided a list

of guidance documents currently available, including guidance on communication between software that can be found on the FDA website. He concluded his presentation with a recommendation that laboratories report to FDA discrepancies found in laboratory data transmission as a result of software malfunction. Reports can be submitted anonymously via FDA's MedWatch (http://www.fda.gov/safety/MedWatch/default.htm).

**Electronic Transmission of Laboratory Information and Oversight of Laboratory Information Systems** ***Addendum W***

Anne Delaney, EJD
Sunquest Information Systems, Inc.

Ms. Delaney began her presentation by noting, based on information from their clients, greater than 75% of laboratory testing is performed by hospitals and the majority of these results are delivered via paper to the ordering physician. She pointed out that several variations of HL7 standards are being used by LIS vendors with LOINC and the latest version of HL7 is rarely being utilized. She then provided several reasons why providers of laboratory data (e.g., hospitals, laboratories) are resistant to adopting an LIS, including cost, personnel issues, lack of interoperability between other LIS products, and non-standard results management and display by ordering physicians. She concluded her presentation by saying CLIA regulations should be aligned with new and current practices of EHR, laboratory interfaces should be standardized, and standards should be implemented to translate test codes.

**Committee Discussion** ***Addendum X***

The CLIAC chair requested the Committee address ten questions in regards to EHR, Electronic Transmission of Laboratory Information, and CLIA. The questions are provided below, followed by points made during the discussion.

*How can the CLIA requirements be clarified as related to electronic*

a. *Test ordering*
b. *Result reporting*
c. *Sharing of test information*

- A member commented that up to 70% of their test requisitions lack specific information required by CLIA, yet the laboratories are being held responsible for obtaining this information. Electronic ordering and EHRs could, potentially, help solve this issue. Ms. Yost responded that CMS understands laboratories cannot meet these requirements 100% of the time, but must do their best to obtain the information from physicians or other authorized persons who order tests. She agreed simplification of the process by electronic ordering may be one way to remedy these situations. Ms. Yost went on to explain that the CMS interpretive guidelines clarify the CLIA regulations and often include explanations of how the laboratory can meet the requirements. They follow the order of the regulations for ease of use by both

surveyors and laboratories. She said the new guidelines affecting EHRs, which are currently under review, will not be prescriptive and do not change the regulations.

*Are there mechanisms that could be used to assist in the dissemination of accurate information pertaining to CLIA and electronic health records?*

- A member pointed out how a supervisor's needs differ from those of a laboratory technologist's and requested the interpretive guidelines be subdivided and written for particular target audiences in order to facilitate dissemination of the material. Ms. Yost responded that the guidelines are directly tied to specific sections of the CLIA regulations and are written for all audiences.

*In light of advancements in information technology, electronic health records and laboratory information transfer since CLIA was implemented, are there remaining gaps that need to be addressed?*

- Several members raised concerns about the definition of "authorized person" under CLIA. A member provided an example of a patient's cardiologist ordering a laboratory test and the primary physician needing to re-order the same test in order to view the results. Another member pointed out that it is not the laboratory's responsibility to keep a registry of all patient data, but they are the only ones that have the information. Mr. Ishee acknowledged this as an issue that is being examined. CLIA doesn't necessarily restrict data exchange, he said, but laboratories tend to be conservative when defining who is considered an authorized person and are inclined not to provide data to others in order to avoid issues with enforcement later. Ms. Yost responded that the authorized person should work to facilitate data exchange, but often competition for patients between doctors as well as unwillingness among patients to share their data can block this exchange. She noted that state laws must be followed with regard to health information access.
- A member commented on the disconnect between a laboratory's responsibility and their authority regarding decisions pertaining to the electronic exchange of information. Laboratories cannot tell physicians what system to purchase, yet the responsibility for verification falls on the laboratory. Another member stated that the laboratory should establish the gold standard for electronic information exchange. Physicians want quality results and the cost to both the doctor and patient for missing or incorrect data is too great. He further offered that physicians could receive a discount on liability insurance if they chose to use a certified EHR system. Ms. Yost responded it may be possible to certify EHR vendors thereby assuring appropriate information is captured and recognized the need to alleviate the laboratory's responsibility in the electronic exchange of information. However, the laboratory would still need to verify that the results reach the authorized person.

*Are there other CLIA issues related to information technology and exchange that should be brought to CLIAC's attention in the future?*

- Numerous examples were related by members that illustrated instances where corruption of data had taken place during data exchange. In these examples, incorrect data, missing data, or misinterpreted data resulted after customized viewing screens were developed for individual physicians. Several members said eliminating customization and applying standards along with certification of EHR systems would alleviate most of these issues. The Committee requested a meeting with ONC to discuss this as well as a follow-up at a future CLIAC meeting.

*How can accurate and complete exchange of laboratory information through electronic channels be assured?*

- A member commented that the laboratory must determine who is authorized to receive results as well as verify correct data transmission. The entire process has become more complex when the authorized person designates EHRs or others to receive data, thereby placing greater burden on the laboratory. Ms. Yost responded that the laboratory's responsibility ends once the data is received by the authorized person and that the authorized person is not required to designate an EHR or other individual to receive data, it is simply an option. Also, an example of how the laboratory can verify transmission of data would be to have the authorized person print their screen and send it back to the laboratory.
- Several members agreed LIS vendors should be responsible for assuring accurate and complete exchange of laboratory information. Dr. Gutierrez replied that software is regulated as Class 1, which allows the FDA to set special controls or limit requirements that vendors must meet.
- It was noted by several members that vendors are not familiar with laboratory data and terminology and the laboratory should be more involved in the development of LISs and EHRs. Several members of the Committee agreed that standardization among the vendors is needed, and healthcare should be treated like a business in order to receive vendor support. An example was given of cell phone standardization where "3G" has the same meaning for all vendors. Dr. Gutierrez cautioned that if the laboratory doesn't become more involved in the decision making process on standards, others will decide for them.
- One member asked if there was a test bed available that could be used in developing and testing the certification process for EHRs. Mr. Ishee responded ONC has a test bed and plans to ensure the appropriate systems are certified although ONC will probably not be the certification body. He added there is an IFR with specific certification criteria and a comprehensive NPRM on the certification process is being drafted. The member responded that the FDA should be responsible for the test bed.
- A Committee member asked how ONC will ensure that international software manufacturers will meet US standards. Mr. Ishee replied that ONC recognizes and is examining these issues.

*What are the gaps related to electronic information transfer and exchange?*

- Several members urged that the issue of having universal patient identifiers be addressed as soon as possible. Mr. Ishee explained that the federal government will

not be adopting universal patient identifiers and ONC is prohibited by Congress from spending money on this issue.

- Several members commented on the difficulties of mapping electronic laboratory data from one system to another. An example was presented of an EHR system that began installation in 2005 and is currently only halfway completed. There are no standard laboratory test names or reports from one system to the next, so it takes a great deal of time and effort to map the data.
- Concerns were raised by several members regarding the use of LOINC (created by the Regenstrief Institute) as the vocabulary standard in electronic information exchange. A member proposed that the top 100 laboratories submit their test menus and use this information to create a standard vocabulary. Another member requested CDC or the CLSI, with input from all stakeholders, be tasked with putting together a standard vocabulary for electronic information exchange.
- Several members observed that laboratory data is only part of the data transmittal issue. The human component of those receiving the data must also be considered. Laboratories do not always understand the context when results or other information is received; only the recipients know this information. The members asserted information exchange needed to move toward intelligent systems and referred to Google and Microsoft as examples. The EHR should be an enabler of quality, not simply used as a document system, so that accurate information is presented at the right time.

*Are there unique needs for electronic information exchange among laboratories, and between laboratories and other healthcare providers?*

- Mr. Ishee indicated that there is a push for a health information exchange system where all authorized persons can access data. Currently over 10% of laboratory results are never reviewed by the ordering physician. One of the biggest issues is that the paper based system does not allow for meaningful use of information. A member commented an electronic exchange system would eliminate the laboratory's responsibility of sending information to an authorized person. Another member asked if the intent is to have a single repository or to have regional repositories of health information. Mr. Ishee clarified that there is no plan for a centralized database. Funding is provided to the states for infrastructure development; the states decide how the health information should be handled.
- A member observed that, on some occasions, physicians request access to laboratory data for research purposes or quality improvement projects that are not subject to Institutional Review Board approval. However, the laboratory is only permitted to release data to the authorized person or their designee. The member asked how would the use of data be regulated or controlled once a repository was created. Another member replied that patient data exchange in the context of patient care falls under the HIPAA. Once the data reaches the authorized person, CLIA regulations no longer apply. Patient notification and consent would then be required for data sharing.
- A Committee member said the patient should have access to their medical information and the right to grant access to physicians who care for them. The member elaborated the reason to have the EHR is to facilitate a doctor's ability to see the patient's history

in order to provide the best care. A system similar to those used on social networking sites, where the patient owns the data and invites others to view it, was provided as a possible solution. The chair stated the original intent of HIPAA was to allow the patient access to their medical information; however, HIPAA has become a significant privacy concern for the medical community.

*Who are other stakeholders that need to be part of both short and long term solutions?*

- The Committee agreed representation by the laboratory is often absent during the policy and decision making processes and laboratories should be more involved as EHR implementation moves forward. The need for the laboratory community to identify current, on-going efforts and involve themselves in the discussions was recognized. Mr. Ishee invited the members of CLIAC to attend the next public hearing of ONC where recommendations will be discussed and to submit official comments to ONC during the public comment period. He also volunteered to facilitate discussions with members of CLIAC and the HIT Standards Committee's Vocabulary Task Force.
- The Committee discussed specific laboratory departments, such as microbiology and pathology, which often have unique data transmission challenges and requested that these areas be included in the development and decision making process regarding EHRs.

*Are steps already underway to address the issues?*

- A Committee member asked if the use of HL7.2.5.1 will address the issues of physicians not receiving complete and correct laboratory information. Mr. Ishee answered he believed it would and elaborated ONC is also focusing on language standardization using LOINC to establish a base level from which the standard can be further developed. He added that he believes the American Clinical Laboratory Association (ACLA) is also working on a standardized compendium of vocabulary.
- Several members discussed the ARRA incentive program established for physicians who adopt, implement, or use HIT (http://bphc.hrsa.gov/recovery/). A member noted many doctors will not participate unless there is a penalty or a law requiring them to do so. Another member commented the incentive is not global and there are many doctors who are not eligible for the incentive. Mr. Ishee replied eligibility was decided by Congress and ONC has heard several concerns from those individuals not considered eligible professionals under the ARRA such as long-term care providers, chiropractors, dentists, and podiatrists. Also, he said, under the program there is a monetary penalty for those who are not meaningful EHR users.
- A request for the identification of successful EHR business models was made by a Committee member. Mr. Ishee responded that ONC is looking at several models including Kaiser, Medicaid, and those of various states.

*Are there additional related items that should be on the CLIAC agenda for a future meeting?*

- A formal recommendation was made to create an EHR workgroup tasked with writing a work statement that includes specific issues and recommendations for stakeholders to address. The Committee requested updates regarding the progress of the identified issues in future meetings.

**PUBLIC COMMENTS**

**ACLA Statement to CLIAC Electronic Transmission of Laboratory Information** ***Addendum Y***

**Department of Veterans' Affairs Electronic Health Records** ***Addendum Z***

**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:

- A recommendation was passed stating CLIAC recognizes that there are some rare biochemical genetic tests which are needed for patient care, but are not currently offered in CLIA-certified laboratories. CLIAC requests that CMS and the Office of Rare Diseases Research at NIH identify specific test gaps that exist today and seek support from the Office of Rare Diseases Research to set up these tests in CLIA-certified laboratories. This could range from assisting laboratories which currently offer these tests to obtain CLIA certification to setting up these tests in existing CLIA laboratories.
- A recommendation passed to accept the BGT Workgroup report with accepted changes as discussed and approved by the Committee.
- A recommendation was made to create an EHR workgroup tasked with writing a work statement that includes specific issues and recommendations for stakeholders to address. The Committee requested updates regarding the progress of the identified issues in future meetings.

Ms. Passiment announced the next CLIAC meeting would be September 1-2, 2010 and adjourned the Committee meeting.

I certify this summary report of the February 9-10, 2010 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 5/03/ 2010