

**Clinical  
Laboratory  
Improvement  
Advisory  
Committee**

**Summary Report**

**September 5-6, 2007  
Atlanta, Georgia**

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

**Clinical Laboratory Improvement Advisory Committee  
September 5-6, 2007, Summary Report  
Table of Contents**

- I. Record of Attendance**
- II. Clinical Laboratory Improvement Advisory Committee (CLIA) – Background**
- III. Call to Order and Committee Introductions**
- IV. Agency Updates and Committee Discussion**
  - **Food and Drug Administration (FDA)**
  - **Centers for Medicare & Medicaid Services (CMS)**
  - **Centers for Disease Control and Prevention (CDC)**
- V. Presentations and Committee Discussion**
  - **The Status of Laboratory Medicine – Working Draft**
  - **Current Status of Proficiency Testing (PT) in the U.S.: Summary Report from a PT Working Group**
  - **Assessment of Best Practices for Standardized Quality Assurance Activities in Pathology and Laboratory Medicine**
  - **Laboratory Medicine Best Practices**
  - **2007 Institute: Managing for Better Health – *Charting a Strategy to Shape the Future of Laboratory Medicine***
  - **Laboratory Systems Research: Future Activities**
  - **Oversight of Genetic Testing**
  - **SACGHS Task Force on the Oversight of Genetic Testing: Status Report**
  - **Guidelines for Quality Assurance in Molecular Genetic Testing, The Organisation for Economic Co-operation and Development**
  - **Regulation of In Vitro HIV Drug Resistance Genotype Assays/Overview of Genetic Testing from the FDA Regulatory Perspective**
  - **Oversight for Genetic Testing – MMWR Report Development and Issues Needing Input**
  - **Beyond CLIA Regulation: Quality Management Systems International Guidelines & Standards**
- VII. Public Comments**
- VIII. Adjourn**
- IX. Addenda**

## ***Record of Attendance***

### Committee Members Present

Dr. Lou Turner, Chair

Dr. Ellen Jo Baron

Ms. Susan Cohen

Ms. Joeline Davidson

Dr. Nancy Elder

Ms. Marilyn Francis

Dr. Carol Greene

Dr. Chip Harbaugh

Dr. Lee Hilborne

Dr. Kevin Mills McNeill

Dr. Dina Mody

Dr. James Nichols

Dr. Gary Overturf

Ms. Elissa Passiment

Dr. Stephen Raab

Dr. Jared Schwartz

Dr. David Smalley

Dr. Thomas Williams

Dr. Emily Winn-Deen

Ms. Luann Ochs, Roche Diagnostics Corporation (Liaison Representative – AdvaMed)

### Committee Members Absent

Dr. Gerri Hall

### Executive Secretary

Dr. Thomas Hearn

## ***Record of Attendance, continued***

### Ex Officio Members

Dr. Devery Howerton, CDC

Ms. Judith Yost, CMS

Dr. Alberto Gutierrez, FDA

Centers for Disease Control and Prevention

Ms. Nancy Anderson	Ms. Andrea Scott Murphy
Dr. Joe Boone	Ms. Sandra Neal
Ms. Diane Bosse	Ms. Anne O'Connor
Dr. Roberta Carey	Ms. Anne Pollock
Dr. Bin Chen	Ms. Emily Reese
Dr. Suzanne Cordovado	Ms. Diane Ricotta
Ms. Deborah Coker	Dr. Shahram Shahangian
Ms. Stacey Cooke	Ms. Colleen Shaw
Mr. David Cross	Mr. Darshan Singh
Dr. Jan Drobeniuc	Ms. Joanne Eissler
Ms. MariBeth Gagnon	
Ms. Zoe Gibson	Dr. Susan Snyder
Ms. Sharon Granade	
Dr. Scott Grosse	Dr. Julie Taylor
Mr. James Handsfield	Mr. David Turgeon
Dr. Lisa Kalman	Mr. Howard Thompson
Dr. John Krolak	Ms. Pam Thompson
Dr. Ira Lubin	Ms. Leigh Vaughan
Dr. Adam Manasterski	
Ms. Leslie McDonald	Ms. Irene Williams

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

Ms. Carol Benson (FDA)	Ms. Penny Mattingly (CMS)
Dr. Elliot Cowan (FDA)	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. Lou Turner, Chair, Clinical Laboratory Improvement Advisory Committee (CLIAC), welcomed the Committee members and called the meeting to order. All members then made self-introductions and financial disclosure statements relevant to the meeting topics.

Dr. Thomas Hearn, Executive Secretary, CLIAC, and Deputy Director, National Center for Preparedness, Detection and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC), welcomed the members and introduced Dr. Rima Khabbaz, Director, NCPDCID, CDC. Dr. Khabbaz also welcomed the members and thanked them for their service.

## **AGENCY UPDATES AND COMMITTEE DISCUSSION**

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

### *Addendum A*

Alberto Gutierrez, Ph.D.

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

Dr. Gutierrez reviewed recent personnel changes at the Center and Office levels and updated CLIAC on matters of FDA guidance documents, Medical Device User Fee and Modernization Act (MDUFMA II), and pre- and post-market developments. He noted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver guidance document has not yet been published but is working its way through the system and that MDUFMA must be reauthorized by the FDA before 2008. He discussed the specific goals OIVD has been asked to achieve with the renewal of MDUFMA. Dr. Gutierrez clarified that “Post-Market-Transformation” is an OIVD pilot effort to bring pre- and post-market programs together and includes handling recalls and inspections. He said post-market surveillance is being strengthened by the establishment of new teams and nine new networks at the Center level. Finally, commenting on LabNet, an adverse event reporting program that works collaboratively with the clinical laboratory community to identify, understand, and solve problems with the use of medical devices, he said that the biggest problem was in educating the laboratories as to what they should report.

### **Committee Discussion**

Many of the Committee's questions to Dr. Gutierrez focused on communication of the updates that he cited as well as other current laboratory issues.

- A member asked if links could be provided to information referred to in the updates so that rapid review of the information would be possible since some issues are particularly relevant. Dr. Gutierrez said this could be done.
- A Committee member wondered if the FDA is still recruiting laboratories to be a part of LabNet and, if so, suggested that the FDA publicize this information, including instructions on how laboratories could join the network. Dr. Gutierrez agreed that the information should be made broadly available and explained that, as a matter of convenience, LabNet began by “piggybacking” on existing projects and connections, so now most of the laboratories in this

network are affiliated with hospitals. However, LabNet could be extended to other types of laboratories.

- In response to the question of whether the FDA avails itself of information and issues communicated on listserves, Dr. Gutierrez replied that, in fact, FDA does make use of listserves and has become aware of problems through them. Because LabNet is in its early stages, laboratories are not always sure what is useful for them to report so FDA hopes to increase the network.
- A Committee member requested further explanation of an item in the slide set under MDUFMA II regarding the goal of a "clear path for review of molecular diagnostic tests," and whether that referred to genetic testing. Dr. Gutierrez could not answer that question specifically, but mentioned one item industry has requested FDA to address is leftover samples. FDA will be reviewing last years' document on leftover samples and determining if there are changes that can be made to it.

### **Centers for Medicare & Medicaid Services (CMS)**

### ***Addenda B & B-1***

Judy Yost, M.A., MT (ASCP)  
Director, Division of Laboratory Services  
Survey and Certification Group  
Centers for Medicare & Medicaid Services

Ms. Yost provided updates on the current and future status of CLIA beginning with current statistics on laboratory demographics. She reviewed the path leading to the development of the cytology proficiency testing (PT) Notice of Proposed Rulemaking and commented on the initial failure rates based on participant types for cytology PT in 2005-2006. She stressed the importance of the reliability of the Electronic Health Records system and how it relates to the requirements mandated by CLIA. Ms. Yost then presented a follow-up on the Government Accountability Office (GAO) 2006 CLIA report that cited the limitations of laboratory surveys. She discussed the steps CMS is taking to upgrade the survey processes in collaboration with the accreditation organizations and state agencies. She reviewed the steps CMS is taking to provide oversight of genetic testing and provided an update on the development of the Clinical and Laboratory Standards Institute (CLSI) Evaluation Protocol 22, which describes manufacturer validation of QC recommendations, and Evaluation Protocol 23, which entails how these recommendations are implemented based on an individual laboratory's patient and testing demographics. In closing her presentation, Ms. Yost briefly mentioned other ongoing CMS projects and collaborations related to CLIA and laboratory oversight.

### **Committee Discussion**

Committee members offered the following comments, questions, and suggestions for Ms. Yost:

- Unannounced inspections are beneficial, and the results are frequently different from those of scheduled inspections.
- Signs (perhaps accompanied by brochures) might be clearly posted indicating where consumers can call with concerns about the laboratory; these would be helpful and an inducement to better laboratory performance.
- Consumers should also be able to obtain a record of complaints against a laboratory. Ms.

Yost stated that this information is available to the public, but not on the website where it might be more easily accessible.

- CLIA could learn from the Federal Trade Commission, which does comparable work and deals with deceptive trade practices.
- Regarding the slides on cytology proficiency testing, a Committee member requested raw numbers in addition to percentages. Ms. Yost said the raw numbers are lower than the previous year, however, the final data have not been compiled and the 2006 data are preliminary.
- A further comment on cytology PT was that the initial 10-slide test is statistically meaningless; more important is the number of failures on the fourth test. Ms. Yost stated this has been discussed previously and recommendations made for the proposed rule, which is currently under development.
- CMS is to be commended for its CLIA website, which is helpful as an informational source for laboratories that are not certified.

### **Centers for Disease Control and Prevention (CDC)**

### ***Addendum C***

D. Joe Boone, Ph.D.

Acting Director

Division of Laboratory Systems

National Center for Preparedness, Detection, and Control of Infectious Diseases

Centers for Disease Control and Prevention

To introduce the main topic for this meeting, Dr. Boone provided a discussion of the issues and processes for formulating a CLIA-based research agenda for DLS. To add perspective to this theme, he chronicled CLIAC discussions and DLS research-focused activities since Spring 2006, introduced the six speakers who would describe the ongoing and future DLS activities, and posed several questions for Committee consideration. In concluding his update, Dr. Boone added DLS is looking for a new director since both Dr. Martin and Dr. Hearn have moved into other positions at CDC and said announcements and a Search Committee will be forthcoming.

### **Committee Discussion**

- **No Committee Discussion**

### **The Status of Laboratory Medicine – Working Draft**

### ***Addenda D\* & D-1***

Clifford Goodman, Ph.D.

Senior Vice President

The Lewin Group, Inc.

Dr. Goodman gave a comprehensive review of the working draft of the upcoming 2007 report entitled “The Status of Laboratory Medicine,” being drafted for the CDC by the Lewin Group through a subcontract to the Battelle Memorial Institute. This DLS-sponsored effort will describe the current state of the field and project the expected evolution of laboratory medicine over the next decade. The report will address nine broad healthcare trends affecting laboratory

medicine: demographic, science and technology, data and evidence, regulation, payment, quality, workforce, consumers, and health information technology. Dr. Goodman's presentation included selections of draft content and concluded with mention of possible additional topics for inclusion in the 2008 update. He commented it was difficult and humbling to encompass the entire field of laboratory medicine—because of the complex science, rapid innovation, shifting payment, and regulatory environment. He said the report would consider what elements in the laboratory medicine field are value-added and how the field contributes to overall healthcare, describe the evolution of CLIA, and cover workforce issues. He then suggested several items that would benefit from CLIAC input.

### **Committee Discussion**

Committee members reacted favorably to Dr. Goodman's report and engaged in an extensive discussion encompassing numerous points.

- In response to Dr. Goodman's inquiry that the Committee identify who the report audience should include, members responded the audience should be policymakers, insurers, government, and the public. The importance of including third-party payers and policymakers was emphasized, to aid in their understanding of the total testing process and the importance of ensuring and paying for quality throughout the process.
- Several members concurred that, because of changing practices and technology, the traditional areas of "anatomic" and "clinical" pathology are becoming blurred and likely outdated, and a more modern definition of laboratory medicine should be crafted. In addition to recognizing the changes taking place within the traditional laboratory, the definition should recognize the interplay between the laboratory and new technologies being used in areas of medicine such as radiology.
- It was stated that due to growing trends in healthcare, a significant percentage of laboratory tests are not ordered by physicians but by "physician extenders." This has an impact on the tests that are ordered and their interpretation. Dr. Goodman agreed this should be included when considering the total testing process.
- Members discussed situations that might be described as 'a lack in the continuity of care' or 'managed discontinuity of care' and how these changes in healthcare affect almost everything Dr. Goodman covered in his report. Several examples were given that include:
  - Specimen referral to specialty laboratories for testing - because the process is often contractual and may be affected by insurance coverage, a physician or laboratory may not be able to choose their referral laboratory, even if they have a preference or know that one laboratory performs better testing than another. Thus, quality may be improved because of access to off-site laboratories and a larger test menu, but may be decreased if tests are not sent to a reliable referral or specialty laboratory. In addition to these points, when specimens are referred for testing, there is usually an increased physical distance between the physician ordering the test and the laboratory and therefore less opportunity to educate physicians on appropriate testing. A distant laboratory is more likely to perform a test, appropriate or not, than to first discuss its appropriateness with the physician or other person ordering the test.
  - Specimen handling - if several laboratories are involved prior to testing, improper transport or storage of specimens may compromise the quality of patient results.

- Test requests and result reporting – there are many more sources of potential error when test requests and results pass through multiple individuals and laboratories as part of the testing process.
- It was agreed that although most laboratory data are derived from testing conducted in the hospital setting, many more patients are tested through physicians' offices, which involves numerous steps and multiple individuals as part of the total testing process. In these instances, there are many complexities that can affect the quality of the testing.
- Many Committee members commented on attitudes, philosophy, and knowledge regarding the use and interpretation of laboratory tests, and the roles they play in medical treatment and healthcare. They noted there are increased pressures on the laboratory field and stated that in some cases, the current driver in managed care is testing. Rather, there needs to be a better understanding that test results provide only one piece of information for medical decision making and they should be considered in the context of total patient care. The members provided numerous examples to underscore that point:
  - There is less time to perform the evaluations that used to precede any laboratory testing (i.e., physical exam, history) so the physician's attitude is that the laboratory provides the entire answer and the results are unequivocal. For example, many things, such as positive and negative predictive values, are not taught in medical schools any more.
  - Often, unnecessary laboratory tests are ordered and “pan-ordering” is sometimes done on the off chance that a patient's diagnosis might otherwise be missed with the physician potentially subject to a malpractice claim.
  - Because of limited training related to laboratory testing in medical schools, and massive amounts of information pertaining to the growing numbers of tests available, it is impossible for physicians to have a thorough understanding of what tests to order and the significance of each.
  - Physicians are taught that in the absence of identified risk factors test ordering is unjustified; under managed care, physicians' time is not rewarded, so testing is increased to obtain reimbursement.
- In 2000, the Institute of Medicine published a report on Medicare reimbursement and the reimbursement process. The report provided insight into the impact of reimbursement and how it has changed health care dramatically, particularly laboratory medicine.
- Several members pointed out the need to factor in that educated consumers are now able to order their own drugs and tests as well as obtain information through the internet and are pushing towards more personalized health care. In light of this, members commented that laboratorians have a phenomenal opportunity to take a greater role in consumer education by providing information that is appropriate and useful for the consumer.
- Several members noted that Dr. Goodman's report was centered on how laboratory testing is done in the United States, although data included international studies. They suggested CDC might consider how other nations have addressed similar issues.
- As the Committee concluded its discussion of the report, members congratulated the Lewin Group on its attempt to provide a broad report that touches on many different topics of concern in terms of laboratory quality and safety. They identified several areas that do not appear to be covered in detail in this initial report and proposed additional topics for more in-depth coverage in future reports:

- More information should be provided on laboratory information systems and electronic medical records.
- It was suggested that a chapter discussing patient-centered care be included, one that focuses on the impact of contractual relationships and regulations on care coordination or on the relationships between physicians and the laboratory or the laboratory and patients.
- It is important that the report clearly explains that quality is different from regulations. People need to understand that regulation is minimal and quality management is much more than that.

In conclusion, Dr. Hearn suggested that the report discuss how to measure outcomes, and the data needed to do so. He asked about potential adverse events and their magnitude. He emphasized that these types of data could be used to show that although striving for quality in healthcare systems requires an initial investment, it will save money overall.

**\*Note:** The addendum was revised from material provided in the Committee's notebooks to reflect last minute updates by the presenter.

**Current Status of Proficiency Testing (PT) in the U.S.: Summary Report from a PT Working Group** *Addendum E & E-1*

Robert Rej, Ph.D.  
Wadsworth Center  
New York State Department of Health

Dr. Rej outlined the objectives, methods, findings, and recommendations of a proficiency testing (PT) workgroup formed through a CDC task order with Battelle Memorial Institute to address the current status of PT in the United States and to determine whether current CLIA-approved PT programs are meeting expectations. This 15-member workgroup consisted of PT users, PT providers, and representatives of accrediting organizations. After two meetings of the workgroup and information sharing with stakeholders, a report was generated that identified priorities to be considered by the CLIA program and incentives for changes to the system. Dr. Rej discussed the findings in the report, some of which included the following:

- There is no direct evidence that participating in PT reduces the rate of error in testing of patient specimens although experience with PT reduces PT failure rates
- Because the list of regulated analytes has not been revised since CLIA was implemented, laboratories are not required to participate in PT for many tests that are currently performed. Consideration needs to be given to updating the regulated analytes
- PT performance may not reflect results obtained using biological specimens
- Slow turnaround time is a limiting factor for usefulness of a PT program
- Method performance does not fulfill CLIA analyte PT requirements. Perhaps PT should

evaluate classes of methods rather than analytes

- A need exists for a PT generic technical scheme to meet the demands of molecular genetic technologies.

Dr. Rej said that the group formulated general recommendations to include potential studies directed at assessment of PT performance versus testing error rates, research on unsatisfactory PT results, database consolidation of complaints and PT performance, and development of a periodic review/update process for CLIA PT analytes. He also elaborated on the workgroup's recommendations to PT providers with an emphasis on electronic submission and reporting, educational programs to aid in user interpretation, maintenance of a national and international PT website, and consideration of evolving technologies.

### **Committee Discussion**

- A Committee member questioned Dr. Rej about his reference to minimizing artificial matrix effects and asked whether the Committee had an interest in encouraging PT providers to periodically have "matrix neutral" challenges that are value assigned. Although speculative on the term "matrix neutral," Dr. Rej agreed that the goal should be to challenge laboratories in the same manner as would have occurred with authentic clinical specimens. He opined that much of the inter-method bias is attributed to "matrix effects" so that laboratories are not penalized due to uncertainty in material, and that national peer analysis is embraced rather than accuracy.
- Another member commented that PT is a form of simulation, and the use of simulation for quality improvement, in medicine and other fields, is raising many of the questions that were brought up regarding how the data are to be used to drive improvement. Dr. Rej did not comment directly on that issue, but said the report was intended to stimulate thinking about other mechanisms to evaluate the usefulness of PT and how it is tied to patient outcome.
- A member commented that the value of PT should not be discounted and that caution should be exercised in unraveling PT as a process, because it has been very successful. Dr. Rej agreed that was the consensus of the workgroup and that something like accuracy-based proficiency testing would add substantial value to PT.
- A member commented that the educational part of the PT program is probably the most beneficial because of variety and unusual challenges. Dr. Hearn summarized the three major purposes of PT (regulatory, educational, a research tool) and said the challenge is to examine PT broadly while satisfying those three needs. Dr. Rej added that the report looks at the entire PT process rather than one area of laboratory medicine.
- A Committee member questioned whether the workgroup had discussed sending samples through testing without informing laboratories that they were PT samples. Dr. Rej responded that "blind" testing had been discussed; there is no convincing evidence that it results in better performance.
- Another point mentioned was that some laboratories resort to special handling of PT samples and the key to getting the challenge right is how the sample is handled. Dr. Rej agreed there is a chance the laboratory will make more mistakes if special handling is incorporated into testing of PT samples.

- A member said the scope of PT should be broadened because of problems in the pre- and post-analytical phases of testing. Dr. Rej said the focus of the workgroup was to look at PT as it is approved by CLIA and how it can be improved. He acknowledged that PT is aimed at the analytical process, not necessarily the pre- or post-analytical phases, and noted that is its area of strength. Another member said the scope of PT should be broadened because of problems in the pre- and post-analytical phases.
- A member noted that errors have been made in the post-analytic process, i.e., people using wrong code numbers. He questioned whether the workgroup had discussed how laboratories are getting feedback from PT programs and how they are using the results. Dr. Rej responded that this was considered in the workgroup report and that an ideal system would be one in which the code did not matter, and there was one correct result.
- A member's question initiated discussion on CLIAC's role in and, more broadly, the target audience for this report. Dr. Rej responded that the report, intended for distribution to a wide audience, was brought to CLIAC for members to identify priority issues. Once the full report is disseminated, specific actions may be taken.
- Dr. Boone noted that the laboratories, regulators, and PT providers are currently very comfortable with the status quo. There will have to be incentives to cause changes to occur in this system. Dr. Rej noted that some models for implementing change had been discussed. For example, a model such as that used in the environmental sector where changes might be made by a group that functions outside the regulatory process could make the process more dynamic. Rather than just update the list of analytes, this model might update the mechanism by which the analyte list is derived.
- A Committee member pointed out that, regarding the issue of whether PT has actually improved laboratory performance, studies with resistant organisms indicated that laboratories performed poorly at first but improved with experience. Dr. Rej concurred that the disconnect is in correlating this improvement with improved patient outcomes. Indications are that this improves with PT, but confirmatory studies are not available. Another member commented that perhaps patient outcome studies are not always necessary because accurate laboratory results will obviously result in a more accurate diagnosis for the patient.
- Discussion followed about qualitative issues in laboratory performance that are not addressed by PT or covered elsewhere by CLIA; e.g., complaints about laboratories by physicians or medical societies, timeliness, lost specimens, and the inability to use another provider in the case of unsatisfactory service. It was noted that CMS has a new data system to record complaints and plans for its expansion. A request was then made to make more laboratorians aware that the complaint system is available.
- A Committee member commented that an educational component is missing from PT because after a few years, most laboratories will pass, but the mechanics of passing PT do not make a laboratory better or more current. Continuing education should be required as it is in other fields.
- A member noted that the original CLIA PT regulations stipulated that the ideal method was to grade specimens on an accuracy-based system, with peer group rating as a default. However, there has been a universal default to peer group rating and it is possible to pass PT with as much as a 25% difference in some values. Therefore, inserting an accuracy-based method for some challenges periodically would be useful. In addition, acceptability criteria should also be reviewed, including how these criteria were derived.

- A member commented that it might be useful to look to organizations outside the field of laboratory medicine to find models that address the issues of linking to outcomes and quality, and gave the Agency for Healthcare Research and Quality (AHRQ) funding research into simulation and testing as an example.
- Another comment was that the value of PT might be for those who are simply concerned with passing PT, rather than those who are seeking to use it to improve performance and serve as an educational tool.
- Dr. Boone summarized the next steps in the process: The workgroup report needs to be finalized, and then recommendations will be prioritized. He said the challenge is to find incentives to change from the status quo and acknowledged the difficulty in progressing toward accuracy-based decisions on PT results; bridging the gap between regulatory and educational activities will require incentives for laboratories that are now taking cost containment measures.

\***Note:** The addendum was revised from material provided in the Committee's notebooks to reflect last minute updates by the presenter.

**Assessment of Best Practices for Standardized Quality Assurance Activities in Pathology and Laboratory Medicine**

*Addendum F*

Dana Marie Grzybicki, M.D., Ph.D.  
 Assistant Professor of Pathology  
 University of Pittsburgh Medical Center Shadyside, Department of Pathology

Dr. Grzybicki presented an overview of the University of Pittsburgh/CDC Cooperative Agreement, “Assessment of Best Practices for Standardized Quality Assurance Activities in Pathology and Laboratory Medicine.” She discussed the project purposes and objectives, major project activities, basic project methods, project findings, and preliminary assessments. Major activities included identifying six quality assessment measures and for each measure determining potential appropriate, clinically relevant linked outcome measures; generating data collection tools for both laboratory and clinical information; and recruiting laboratories to share quality assessment and clinical information. In general, each of the measures studied was related to one phase of the total testing process: pre-analytic – specimen identification errors and deficiencies, and blood culture contamination rates; analytic – turn-around-time, and gynecologic histologic/cytologic correlation/discrepancy rate; post-analytic – critical value reporting and point-of-care (POC) testing glucose accuracy. In describing these activities, she said determining appropriate, clinically relevant outcomes were a major challenge and not much information is available in the literature. Dr. Grzybicki concluded by describing the project findings and preliminary assessments of each of the quality assessment measures.

**Committee Discussion**

The Committee discussed the correlations between histology and cytology, the many variables in how tests are performed, and the discrepancies affecting the results.

- It was noted that data on biopsies performed following abnormal Pap tests show that the major reason for non-correlation is biopsy sampling variance. Correlating histology and cytology is an extraordinarily complicated and frustrating process exacerbated not only by biopsy sampling error but also by the decision to send samples to two different locations or to obtain samples at two separate points in time. This can result in patient harm.
- A member noted the ability to compare across laboratories is limited and either there needs to be a way to standardize biopsy sampling and this used as a benchmarking tool, or laboratories should perform immediate correlation.
- Another member remarked using histologic/cytologic correlation in its current state is limited as a quality metric for performance measurement due to the numerous steps and variance in the pre-analytic side of the surgical biopsy specimen. The member suggested using data, such as Dr. Grzybicki presented, as a Continuous Quality Improvement tool until a more standardized design for meaningful benchmarking can be developed.

### **Laboratory Medicine Best Practices**

### ***Addenda G & G-1***

Susan R. Snyder, Ph.D., MBA

Economist

Division of Laboratory Systems

National Center for Preparedness, Prevention, and Control of Infectious Diseases

Centers for Disease Control and Prevention

Dr. Snyder described Phase I of a multi-phase project funded by CDC's Division of Laboratory Systems to create a process to identify, review, and evaluate evidence on existing pre- and post-analytic practices in laboratory medicine. The objective is to address an unmet need for a concerted national effort to apply an evidence-based approach to improve quality in laboratory medicine consistent with the Institute of Medicine (IOM) recommendations. The process, developed by CDC and Battelle Memorial Institute Project Teams with the assistance of an external workgroup of multidisciplinary experts, applies defined constructs to review methods and evaluation criteria to yield a graded, evidence-based recommendation for a defined laboratory practice. In Phase I of the project, a "Proof of Concept" was applied to eight practices for reducing errors in patient/specimen identification, which resulted in the expected challenge of evidence gaps. Dr. Snyder closed by detailing the next steps for Phase II of the project, which include refining process methods, including non-traditional evidence to close evidence gaps, creating a laboratory network for soliciting practice evidence, pilot testing the process, and creating an organizational structure for implementation.

### **Committee Discussion**

- Acknowledging that consensus documents published by the American Society of Microbiology (ASM), the Clinical and Laboratory Standards Institute (CLSI), and others lack the outcomes measurement, one member suggested using these guidelines as a starting point. This lack of outcomes measurement causes problems in getting the guidelines implemented in the healthcare setting.
- A member asked if the proposed organization is going to be viewed as another organization that generates standards or if the approach is to produce a goldmine of evidence that can be

presented and ranked so that other organizations use this freely to generate standards. Dr. Snyder responded the Laboratory Medicine Best Practices process began with CLSI consensus documents and other similar documents. This project is primarily focused on making evidence-based recommendations.

- One member inquired who would convene and support the Laboratory Medicine Best Practices recommendations process and suggested DLS with all its partners would be an obvious choice. Dr. Hearn replied DLS in association with CLIAC and other advisory committees would be an option for supporting the Laboratory Medicine Best Practices evaluation process and emphasized that the process needs to include a rigorous science evaluation. He commented the project focuses on deciding what constitutes a best practice, what body of evidence currently exists and what needs to exist, how gaps can be filled, how the evidence can be evaluated, and how evidence-based recommendations are made. Dr. Snyder added current, readily available analogies for making recommendations for best practices include the U.S. Preventative Services Task Force and the National Academy of Clinical Biochemistry.

**2007 Institute: Managing for Better Health – Charting a Strategy to Shape the Future of Laboratory Medicine** *Addenda H, H-1, & H-2*

Linda McKibben, M.D., Dr.P.H.

Health Policy Research Consultant to the Division of Laboratory Systems, CDC

Dr. McKibben described the vision for the “2007 Institute: Managing for Better Health” and the steps and barriers to realizing the vision. She explained the three theme groups - Advancing Collaborative Care, Measuring Performance, and Preparing for the Future - and the goals of each, emphasizing the focus on how healthcare policy can be made more specific to laboratory medicine. In closing, Dr. McKibben said the primary goal for the 2007 Institute is a strategic action plan for transforming laboratory medicine in the areas of leadership; networks and champions; capacity and resources; systems improvements; and innovation momentum.

**Committee Discussion**

The Committee was supportive of the upcoming Institute and offered that a feedback mechanism needs to be reflected in the Transformation Model.

**Laboratory Systems Research: Future Activities**

*Addendum I*

Devery Howerton, Ph.D.  
Acting Associate Director for Science

Division of Laboratory Systems  
National Center for Preparedness, Prevention, and Control of Infectious Diseases  
Centers for Disease Control and Prevention

Dr. Howerton presented an overview of the Division of Laboratory Systems' (DLS) planned projects for 2008. She said the DLS research goal is to develop a comprehensive research agenda that will drive laboratory medicine quality improvement through research and development of evidence-based practices and standards. After enumerating the Division's overall research objectives, she described each of five projects and the corresponding objectives for each one. Dr. Howerton closed her presentation with a series of questions for the Committee designed to provide DLS with improved focus for projects undertaken in 2008 and beyond.

### **Committee Discussion**

- In response to a suggestion that DLS should set up meetings with research partners to avoid overlap and promote synergy, Dr. Howerton stated that the Division is considering a kickoff meeting with the partners.
- A member commented a research project involving a specific test should have implicit goals of determining net benefit and patient outcomes and this appeared to be overlooked in the influenza rapid test project. Dr. Howerton responded there are plans to evaluate how results could be used in the clinical care setting and incorporated into treatment decisions, and that this could be extended to looking at actual patient outcomes.
- Several members suggested that if a laboratory practice is shown to improve outcomes through extensive reviews or studies, it may not be necessary to prove the principle for each test. A member cautioned that generalizing broadly from one experience may be dangerous due to variations in epidemiology, effectiveness of treatment, specificity/sensitivity, and negative and positive predictive values for different diseases.
- Another member stated when literature reviews and even randomized controlled trials provide evidence, hospital administrators tend to require proof in their hospitals before making a change.
- Noting the evolution in best practices over time for PSA, H. pylori, and cholesterol testing, a member emphasized the necessity for ongoing evidence of outcomes in order for practice change to occur.
- Citing issues of fragmentation in laboratory services and communication challenges such as lack of interoperability, a member proposed developing a realistic model of current laboratory practice as a research topic and proposed identifying specific research questions to elucidate the forces driving decisions, the problems generated, the consequences, and recommendations. Another member stated research needs to extend to health services, i.e., the systems of health care delivery, to assess the extent to which these underlying systems of care facilitate translation of research findings to implementation of best practices.
- Considerable discussion arose as to the questions of who will monitor and reinforce best practices, who will determine whether best practices are implemented, and how will best practices be incentivized, in the absence of regulatory requirements for their adoption. Dr. Hearn responded that, with CLIA as a minimum standard, there is a need for research to identify an evidence base for additional best practices that can then be provided as broad guidance for laboratory medicine. He acknowledged that there is little incentive for exceeding CLIA requirements without this evidence.
- Committee members agreed that incentives are the drivers for quality. Several members commented that users must perceive how they benefit from best practices before they will

implement them. A member stated part of the development of these practices has to be a practical plan for how they will be implemented and what forces will drive their implementation. Pay for performance or participation was identified as an effective incentive, exemplified by the 0.4% annual payment update that Medicare recently adopted for pay for performance, which resulted in over 90% of hospitals participating with data showing improvement across the board in those facilities. Members stated it is essential to engage public and private sector payers and hospital administrations, as they benefit most from cost savings.

- Several members warned adopting a best practice will not necessarily reduce cost because the value of a given practice may not be reflected in accounting costs. Adoption of best practices may at best be cost-neutral. A member emphasized physicians receive incentives for seeing more patients and improving their outcomes, whereas laboratories are only paid for results. Quality management practices are costly and not incentivized with reimbursement for quality.
- Numerous members remarked on regulation as an incentive for quality. Difficulty exists in getting laboratories to adopt best practices unless they are forced to by regulation. For example, one member noted the majority of the laboratory community are waived laboratories that are not required to perform proficiency testing (PT). As PT adds cost and penalties for failing, there is no incentive for these laboratories to perform PT, even though it has been shown to improve quality.
- Dr. Turner further pointed out the difficulty in getting new practices implemented that come across as guidelines or recommendations. She added research is needed to evaluate how guidelines are presented, marketed, and implemented. To aid in this understanding, a member commented that marketing and implementation of best practices should be part of each of the research projects Dr. Howerton discussed.

### **Oversight of Genetic Testing**

### ***Addendum J***

D. Joe Boone, PhD  
Acting Director  
Division of Laboratory Systems  
National Center for Preparedness, Detection, and Control of Infectious Diseases  
Centers for Disease Control and Prevention

At the conclusion of the February 2007 meeting, CLIAC agreed that CMS and CDC should work with experts to clarify critical issues in genetic testing oversight and subsequently include presentations by CDC staff and the perspectives of other representatives for consideration at the next meeting. To that end, Dr. Boone provided an introduction to the topic of “Oversight of Genetic Testing” with a timeline of the history of government oversight of genetic testing since the implementation of CLIA. He expressed that although genetic testing provides great opportunity to improve health, it also offers growing concerns, many of which are beyond the purview of the CDC and FDA. He noted that new applications of genetic testing, i.e., the expansion of genetic testing via the internet, merit guidance in this area. Dr. Boone described key U.S. players and various international players in genetic testing oversight and posed several important questions pertaining to the level of oversight, requirements of the oversight process,

voluntary and incentive-based approaches, and the integrity of the oversight framework in this rapidly moving field. In concluding his introductory remarks, Dr. Boone introduced the next four speakers and their presentation titles.

### **Committee Discussion:**

The discussion on Dr. Boone's presentation focused on the definition of genetic testing.

- A member asked if there was a uniformly accepted definition of genetic testing. Dr. Boone responded that is one of the big challenges. There was a definition that may no longer be workable because one must consider a test's intended use.
- Another member asked if several international groups use a slightly different definition of genetic testing. Dr. Boone responded the definitions are similar but problems arise when attempting to apply them to the real world where things cannot always be put into distinct categories. Another member commented that the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) Oversight Task Force decided to confine themselves to journaling human genetics; each group must define the scale and scope of what that group has decided to focus on.
- Another member stated that the Organisation for Economic Co-operation and Development (OECD) document is confined to human genetics and it addresses "genetic testing for variations in germ line DNA sequences or products arising directly from changes in heritable genomic sequences that predict effects on the health, or influence the health management, of an individual." However, the question of intent plays an important role. A test that is not a genetic test in one context could be defined as genetic if genetic risk factors are found. The test purpose also plays a role; whether a test is diagnostic or is looking for future risk of disease would determine whether consent is needed.

### **SACGHS Task Force on the Oversight of Genetic Testing: Status Report**

#### *Addendum K*

Andrea Ferreira-Gonzalez, Ph.D.  
Molecular Diagnostics Division, Pathology Department  
Virginia Commonwealth University

Dr. Ferriera-Gonzalez began her presentation with a review of the mandate of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) Oversight Task Force. She reviewed the scope of SACGHS, Oversight Task Force membership, the HHS Secretary's charge, and previous reports on oversight provided by the NIH-DOE Task Force in 1997 and the Secretary's Advisory Committee on Genetic Testing in 2000. Dr. Ferriera-Gonzalez reviewed the activities of SACGHS, provided an overview of their draft report on genetic testing oversight, and gave a projected timeline for completion of the draft report, solicitation of public comments, and publication of the final report in 2008.

### **Committee Discussion**

The Committee expressed much interest in the SACGHS report and posed a number of questions for Dr. Ferriera-Gonzalez.

- A member asked if protein expression is still considered a genetic test. Dr. Ferreira-Gonzalez responded yes. Another question related to education of health-care providers about genetic testing and whether this was part of the SACGHS mandate. The response was they are interested in both the genetics professional and the non-professional. They are not addressing medical schools specifically but are addressing education of the non-genetic healthcare providers. She indicated that at the November meeting SACGHS would have a roundtable looking at the status of education of genetics in non-genetics fields.
- A Committee member suggested that in addition to searching peer-reviewed literature for information on real versus possible harms related to genetic testing, the task force should also examine lawsuits. Dr. Gonzalez responded that this has been done and SACGHS is aware of that information.
- Another question focused on the problems inherent in the transfer of samples and information between laboratories. Dr. Ferreira-Gonzalez responded that the report deals with those specific issues. She said this ties in nicely with the personalized health care workgroup that is specifically working on the development of electronic medical records.
- In response to a question about whether the SACGHS has made a recommendation for a genetic specialty in CLIA, Dr. Ferreira-Gonzalez stated that this is still being deliberated.
- A Committee member asked if the SACGHS plans to establish criteria for analytical validity and clinical validity based on the risk of harm of the test. Dr. Ferreira-Gonzalez indicated SACGHS will make such recommendations. A question followed regarding whether those recommendations would apply to whoever made that test. This has not been decided, but there is a general sense that some kind of oversight or review of that testing will be necessary.
- Another question was about how the task force envisioned a public-private organization or partnership working for oversight. Dr. Ferreira-Gonzalez responded that this would not be thought of from a traditional regulatory perspective, like FDA or CMS. It might be modeled after a program such as the Collaboration, Education, and Test Translation (CETT) Program for Rare Genetic Diseases at the National Institutes of Health (NIH)—genetic experts would review data compiled by laboratories regarding analytical validity of the testing and make recommendations prior to a test being offered. Because, for rare disorders, looking at clinical validity from one laboratory is difficult, peer-reviewed literature supporting that test is reviewed before CETT approves the test. In some cases, understanding the clinical validity of a test may require that data be gathered from many laboratories before a recommendation could be made.
- A follow-up question concerned how a laboratorian would know that a test has gone beyond the research phase, that it is a valid clinical test, and that a particular laboratory is competent. Dr. Ferreira-Gonzalez stated that she does not have the answer to that specific issue, as it is still being debated. However, establishing that a laboratory is CLIA-certified provides assurance that the laboratory meets minimum requirements for verifying or establishing the analytic validity of the test.
- In response to a question about the makeup of the task force, Dr. Ferreira-Gonzalez said that it includes ethicists, social scientists, and advocates as well as a priest and a lawyer. Individuals have expertise in different areas but do not represent an organization.
- A suggestion was made that the task force keep in mind the future use of the assays in question. Some common assays become genetic assays in certain circumstances. The task

force is aware of this and has looked into the intended use for the oversight they plan to recommend.

- A member asked if the report was going to attempt to characterize the risk level of a genetic test as a basis for the required level of oversight. Dr. Ferreira-Gonzalez indicated that the group is not trying to come up with a scheme on risk, but is exploring different options and how to provide appropriate oversight for different types of testing, including a scheme to classify high-risk tests.
- A member acknowledged the difficulty in defining a genetic test and asked for other examples of tests that are defined by their intended use. Another member responded with a list of common analytes to include coagulation factors, ceruloplasmin, protein C, and blood type, all of which could potentially be classified as genetic tests.
- Dr. Ferreira-Gonzalez closed stating there seems to be a concern about the definition of genetic testing and the intended use, and that she would take the concern back to the SACGHS Oversight Task Force for further deliberations.

**Guidelines for Quality Assurance in Molecular Genetic Testing, The Organisation for Economic Co-operation and Development** *Addenda L & L-1*

Ira M. Lubin, Ph.D., FACMG  
Division of Laboratory Systems  
National Center for Preparedness, Detection, and Control of Infectious Diseases  
Centers for Disease Control and Prevention

Dr. Lubin began his presentation with an overview of the Organisation for Economic Co-operation and Development (OECD) and its overarching purpose. He reviewed the path taken to developing the most current guideline, its salient features, and critical components that include general principles and best practices, quality assurance systems, PT, quality of result reporting, and education and training standards. He discussed implementation of the guideline on both a national and international basis and closed his presentation with an overview of the potential benefits of implementation for the U.S.

**Committee Discussion**

- One member asked if there was collaboration between groups to share information. Dr. Lubin responded yes, and that it was very impressive compared to the past.
- A member asked how outcomes might be measured without implementation. Dr. Lubin said a model for that analysis exists; each country will need to determine how they will implement the guideline and provide a trial period.
- Another member stated the U.S. currently does not have a transparent process to allow tests to be ordered out of country if the laboratory is not CLIA-certified and encouraged CMS to examine processes by which such laboratories could be recognized under CLIA.

\***Note:** The addendum was revised from material provided in the Committee's notebooks to reflect last minute updates by the presenter.

**Regulation of In Vitro HIV Drug Resistance Genotype Assays/Overview of Genetic Testing from the FDA Regulatory Perspective** *Addenda M&N*

Elliot P. Cowan, Ph.D.  
Chief, Product Review Branch  
Division of Emerging and Transfusion Transmitted Diseases  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research  
Food and Drug Administration

Dr. Cowan announced that two FDA documents are now available. The first is a newly issued Final Rule (21CFR 866.3950 – Assay, Genotype, HIV Drug Resistance, In Vitro) that pertains to in vitro HIV drug resistance assays used as an aid in monitoring and treating HIV infection. A second document, and companion to the first, is a Class II Special Controls Guidance intended to downclassify these assays from Class III to Class II and to ensure reliability of these assays for recognized mutations and show how the assays may be developed for review by the FDA. He stated that in terms of risks to health these assays are used in conjunction with viral load assays and to mitigate those risks FDA is asking for performance data to support performance characteristics as well as other considerations such as critical assay components and performance validation. He detailed other standard parameters to be included such as controls, statistics, device information, software, modifications and labeling. He also mentioned implementation of a 30-day review to update interpretation algorithms for this rapidly changing field.

**Committee Discussion**

- A member commented that another use for the assays described by Dr. Cowan is initial testing of patients with HIV, not just for those patients on therapy.
- Another member said that, like previous discussions, the point is really the impact on the patient. He questioned how the HIV testing, in which molecular methods are used to determine and target a specific group or specific drug, differs from any other type of therapy that will be using this type of molecular testing, e.g., cancer or inherited diseases.
- A Committee member questioned whether this document refers only to probing for specific mutations or to re-sequencing the whole area, as is done traditionally. This member also asked what is done with mutations whose significance is not known. Dr. Cowan responded that the document contains tables listing commonly accepted mutations and their impact on drug resistance as well as those for which the clinical significance has not been firmly established. As more of these arise, they will be treated on a case-by-case basis. In addition, validation can consist of relying on the literature. If studies have documented a definitive correlation, that mutation could be listed.

Dr. Alberto Gutierrez  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health  
US Food and Drug Administration

Dr. Gutierrez discussed the two paths to market for In Vitro Diagnostic (IVD) products. He pointed out that in 1997 the FDA passed the Analyte Specific Reagent (ASR) Rule, which was to ensure the quality of reagents used in laboratory-developed tests. He described the unexpected consequences of that rule, which led to the publication of the ASR Draft Guidance document in 2006 in an attempt to clarify the ASR definition. Dr. Gutierrez gave an update on the In Vitro Diagnostic Multivariate Index Assays (IVDMIA) guidance document and closed his presentation with an outline of the current state of legislative affairs and FDA request for input from all stakeholders.

### **Committee Discussion**

- A Committee member remarked that the current IVDMIA guidance document was much improved over the previous one but questioned how FDA intends to enforce this regulation if a laboratory did not want to go through this process. Dr. Gutierrez responded that, in fact, FDA has tools that can be used, beginning with warning letters. However, it is preferable to bring a laboratory willingly into compliance rather than to force it to comply.

### **Oversight for Genetic Testing – MMWR Report Development and Issues Needing Input**

*Addenda O, O-1, & O-2*

Bin Chen, Ph.D., FACMG  
Division of Laboratory Systems  
National Center for Preparedness, Detection, and Control of Infectious Diseases  
Centers for Disease Control and Prevention

Dr. Chen reviewed the current regulatory oversight and voluntary efforts for quality assurance of genetic testing in the U.S. She then described CDC's plans to develop and publish a document in the *Morbidity and Mortality Weekly Report Recommendations & Report (MMWR R & R)* on good laboratory practices for genetic testing. She outlined the structure and content of the *MMWR R & R*, which is intended to 1) clarify the applicability of the current CLIA requirements for laboratories performing genetic testing, 2) discuss strategies for enhancing the oversight for genetic testing under the current regulatory framework, 3) summarize the CLIAC recommendations for areas in need of additional quality assurance measures, and 4) solicit input on issues and challenges in genetic testing. Dr. Chen presented the Committee with several issues that are particularly challenging in considering appropriate oversight for genetic testing, including applicable performance characteristics for method validation, control procedures for molecular amplification assays, alternative approaches to proficiency testing, result interpretation in genetic test reports, personnel competency assessment, and the definition of genetic tests. Dr. Chen asked for CLIAC recommendations on how to best approach issues needing further input.

### **Committee Discussion**

- One member inquired how the questions Dr. Chen posed to the Committee were compiled and was told that many of the questions came from previous CLIAC workgroups that were

formed to make suggestions to the full Committee regarding areas of genetic testing in need of additional oversight.

- One member commented that a single set of quality assurance standards might not be able to accommodate all tests that could be considered genetic tests, such as biochemical genetic tests and newborn screening tests, and suggested the Association of Public Health Laboratories (APHL) might be able to help with some of the issues.
- Several members commented that it would require time and expertise beyond that of CLIAC to answer all the questions posed by Dr. Chen. They suggested assembling a workgroup to address the issues and develop a document that would clarify the applicability of CLIA requirements to genetic testing and recommend more specific guidance or additional quality assurance measures needed to ensure the quality of genetic testing.
- One member agreed that the *MMWR R & R* document could educate the public about genetic testing issues and would help to solicit their input.

### **Beyond CLIA Regulation: Quality Management Systems International Guidelines & Standards** *Addenda P & P-1*

Devery Howerton, Ph.D.  
Acting Associate Director for Science  
Division of Laboratory Systems  
National Center for Preparedness, Detection, and Control of Infectious Diseases  
Centers for Disease Control and Prevention

Dr. Devery Howerton gave an overview of international standards and guidelines for quality management systems (QMS) relevant to clinical laboratories and explained that QMS does not focus just on quality control or quality assurance but has a much larger scope. She discussed how the standards from the Clinical and Laboratory Standards Institute (CLSI) and the International Organization for Standardization (ISO) compare to the CLIA regulations, and posed questions for the Committee to consider. These questions centered on looking at ways the international QMS standards are being implemented inside and outside the U.S., advantages and barriers to implementing them, and incentives that may be needed for their implementation. The questions were intended to serve as an introduction to QMS discussion planned for the February 2008 CLIAC meeting. Dr. Howerton also informed the Committee that CDC is currently developing plans to implement QMS standards throughout its laboratories.

### **Committee Discussion**

- **No Committee Discussion**

### **PUBLIC COMMENTS**

- **George Birdsong, MD, FCAP, for the Cytology Proficiency Improvement Coalition/H. R. 1237 (Cytology Proficiency Improvement Act of 2007)** *Addenda Q & Q-1*

- **Orkideh Malkoc, MS, Associate Director of Public Policy, Genetic Alliance** *Addendum R*
- **CMS-Response-Petition for Genetic Testing-8/15/07** *Addendum S*

**NOTE:** The Chair approved a Committee member's request to make the CMS response to the Genetics and Public Policy Center made part of the official record. This document was distributed electronically to the CLIAC members and meeting attendees on 11/30/2007 and is included here as an addendum.

- 
- **ASCP Framework for a Revised Cytology Proficiency Testing Regulation** *Addendum T*

**NOTE:** Following the meeting, the American Society for Clinical Pathology (ASCP) requested this document be made part of the official record. It was distributed electronically to the CLIAC members and meeting attendees on 11/30/2007 and is included here as an addendum.

## **ANNOUNCEMENT**

- Dr. Turner recognized Dr. Elliot Cowan who made a brief announcement concerning the upcoming 2007 HIV Diagnostics Conference (December 5-7, Atlanta) sponsored by CDC and co-sponsored by APHL. He explained the purpose of this conference is to evaluate data supporting the use of alternative HIV testing strategies that would make use of multiple enzyme immunoassays for HIV testing in a laboratory-based setting or of multiple rapid tests in settings where rapid testing is used, for example, point of care. The working group that developed some of these strategies will soon be soliciting abstracts for supporting data. These abstracts, along with presentations on new and emerging technologies, will be presented at the December conference. Dr. Cowan suggested the Committee may need to be informed of outcomes from the conference given the numbers of people who will be affected and concluded his announcement by extending an invitation to sign up for the conference and providing a web URL ([www.hivtestingconference.org](http://www.hivtestingconference.org)) for further information.

## **MISCELLANEOUS**

- **APHL/NLTN Urine Dipstick Handout** *Addendum U*

At the beginning of meeting, the members received a courtesy copy of the APHL/NLTN Urine Dipstick job aid, for which the Committee provided significant input during the February 2007 meeting.

## **ADJOURN**

Dr. Turner acknowledged the CDC staff that assembled the meeting program and thanked the CLIAC members and partner agencies for their support and participation. The following reflects outcomes from this meeting:

- With respect to genetic testing oversight, CLIAC registered concern about the definition of genetic testing and issues of intended use. The Chair, SACGHS Task Force on Oversight,

stated these matters would be presented to the task force for further deliberations.

- Concerning DLS' research goals and objectives and planned projects for 2008, the following specific suggestions were provided by the Committee:
  - Conduct meetings with research partners to avoid overlap and promote synergy regarding the planned projects.
  - Develop recommendations and plans for marketing and implementation for each of the projects.
  - Develop a realistic model of current laboratory practice as a research topic and identify specific research questions to elucidate the forces driving decisions, the problems generated, the consequences, and recommendations.
  - Extend research to health services, i.e., the systems of health care delivery, to assess the extent to which these underlying systems of care facilitate translation of research findings to implementation of best practices.
  - Engage public and private sector payers and hospital administrators, as they benefit most from any cost savings that may accrue from adoption of identified best practices.

Dr. Turner announced the 2008 CLIAC meeting dates as February 20-21 and September 10-11, and adjourned the Committee meeting.

I certify this summary report of the September 5-6, 2007, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

---

Lou Flippin Turner, Dr.P.H., CLIAC Chair

Dated: 11/27/2007