CLIAC welcomes new members; covers broad agenda

The Clinical Laboratory Improvement Advisory Committee (CLIAC) met at the Centers for Disease Control and Prevention’s (CDC’s) Tom Harkin Global Communications Center in Atlanta on Sept. 5-6. The CDC campus has evolved and is still growing into a technical and architectural showcase.

The September meeting concentrated on government-agency updates and oversight of genetic testing. The following six new members were welcomed to their first CLIAC meeting:

- Ellen Jo Baron, PhD, D(ABMM), F(AAM); director, Clinical Microbiology Laboratory, Stanford University Medical Center; chair-elect, Clinical Microbiology Division, American Society for Microbiology;
- Susan Cohen, consumer advocate;
- Elissa Passiment, EdM, CLS(NCA); executive vice president of the American Society of Clinical Laboratory Science;
- Norman “Chip” Harbaugh, MD; Children’s Medical Group; CEO and chairman of the board emeritus, Kids First Pediatric Alliance; steering committee of Quality Improvement, American Academy of Pediatrics;
- Steven Raab, MD; laboratory director, University of Pittsburgh Medical Center; and
- Emily Winn-Deen, PhD, vice president, Strategic Planning and Business Development, Cepheid.

FDA update

The Food and Drug Administration (FDA) update, given by Alberto Gutierrez, PhD, officer for In Vitro Diagnostic Device (OIVD) Evaluation and Safety, provided updates on organizational changes, FDA guidances, user fees, and pre-/post-market areas. The FDA List of Guidances, some in draft form (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfgpp/Results.CFM?Doc_Type=1&Doc_IsCurr=1&Doc_OFFICE=OIVD&lookandfeel=1&SORT_ORDER=o rigin,documentdate%20desc.), includes in vitro diagnostic multivariate index assays (IVDMIA); analyte specific reagents (ASR); assayed and unassayed quality-control material; pharmacogenetic tests and genetic tests for heritable markers; review criteria for assessment of qualitative fecal occult blood in vitro diagnostic devices; and IVD devices to detect influenza A viruses; labeling and regulatory path. Guidances are available at www.fda.gov.

CMS report

Judy Yost, director of the Clinical Laboratory Improvement Amendments (CLIA) program at the Centers for Medicare and Medicaid Services (CMS), reported that her group celebrated the certification of more than 200,000 registered laboratories. To date, 200,677 laboratories are registered under CLIA. In response to the 2006 Government Accounting Office’s report of the CLIA program, inspector training was intensified to bring about uniformity in citing CLIA deficiencies. Although the inspection process is still educational, deficiencies that lack educational components must be cited (e.g., a laboratory not enrolled in a proficiency-testing [PT] program, a laboratory director not meeting qualification requirements). CMS is updating the website (www.cms.gov/clia) to be more user-friendly. In the future, users will be able to search for a CLIA-registered laboratory.

CDC agency update

Joe Boone, PhD, CDC, gave a report on the CLIA research agenda. Three groups have looked at what the laboratory industry’s baseline is and what the laboratory may need to do to prepare for the future. The research agenda includes defining best practices in laboratory medicine by studying three areas: status report, workgroup on best practices and policy, and evaluation of proficiency-testing services.

The Lewin Group, a health services and policy consulting firm, Falls Church, VA, in partnership with Contractor Battelle Memorial Institute, Columbus, OH, was tasked to write a report, to provide a comprehensive picture of the current laboratory status and probable challenges coming in the next five to 10 years.

In addition, another purpose is to provide baseline information to professional organizations, government agencies, and others who provide, use, regulate, or pay for laboratory services. The report will include the following:

1. introduction;
2. value of laboratory medicine;
3. market profile;
4. workforce;
5. total testing process — factors affecting quality;
6. quality systems and performance measurement;
7. laboratory information systems;
8. regulation;
9. reimbursement; and
10. future in laboratory medicine.

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www.mlo-online.com
The Proficiency Testing Workgroup (PTW) presentation included an analysis of the current CLIA PT program. The PTW made numerous recommendations for the programs and the providers of PT. Overall, PT programs are recognized as being highly valuable to laboratories.

**Genetic-testing oversight**

Although CMS stopped the progression to implement a subspecialty for genetic testing, CLIA is still focused on ensuring there is appropriate genetic-testing oversight. Handout materials included cross-references of CLIA recommendations for a subspecialty to CLIA rules, emphasizing CLIA’s general rules are broad enough to require genetic-testing laboratories provide accurate and reliable test results.

Bin Chen, PhD, FACMG, CDC, presented the CDC plans to submit a report on Nov. 16, 2007, for publication in the Morbidity and Mortality Weekly Report (MMWR). The report will address how current CLIA regulations provide adequate oversight of genetic testing. At a previous CLIAC meeting, after the CMS determination to strengthen current CLIA regulations rather than implement a genetic-testing subspecialty, CLIAC recommended CDC publish a report in MMWR. The 2001 CLIAC genetic-testing subspecialty recommendations are to be the basis of the MMWR publication. This led the current CLIAC to strongly object to publishing the 2001 recommendations on the basis that those are outdated.

It is not just CLIA that can provide oversight of genetic testing; the FDA can as well. The FDA’s Gutierrez stated that Congress, through the Medical Device Amendments of 1976, gave the FDA authority to regulate *in vitro* diagnostics. Authority did not distinguish between manufacturers and laboratories. At the same time, Congress did not give the FDA unlimited resources to provide oversight. Therefore, clinical laboratories traditionally have not seen the presence of the FDA on site. Many genetic tests fall into the regulated FDA categories of laboratory-developed tests (LDTs) and ASRs. ASRs must be manufactured under current good manufacturing processes, or cGMP, rules and registered with the FDA. The FDA can use its discretionary authority to inspect laboratories performing LDTs.

**Next CLIAC meeting**

The next CLIAC meeting is scheduled for Feb. 20-21, 2008. The agenda will focus on quality-management systems for the clinical laboratory. Devery Howerton, PhD, CDC, presented an introduction to the subject matter. All CLIAC presentations are or will be available at the CLIAC website, [www.cdc.gov/cliac](http://www.cdc.gov/cliac).