A focus on the public health/clinical lab connection

The Clinical Laboratory Improvement Advisory Committee (CLIAC) met in Atlanta, Feb. 8-9, 2006. Its focus was illustrating the importance of enhancing connectivity between the public health and clinical laboratories. Updates were given by the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and the Centers for Disease Control and Prevention (CDC). Discussion ensued on cytology proficiency testing, coordinating councils on a national level between clinical labs and the Michigan compact, and the Michigan compact. The current status is that these organizations are working on cytology proficiency testing, and the Michigan compact. The current status is that these organizations are working on cytology proficiency testing, and the Michigan compact. The current status is that these organizations are working on cytology proficiency testing, and the Michigan compact.

FDA and HIV tests
The FDA updated CLIAC on the CLIA-waived HIV test, OraQuick Oral Fluid Testing, that has been reported in the press as having a higher than expected false-positive rate in San Francisco, New York City, and Los Angeles. The current status is that these false-positives have only occurred in a small number of sites in San Francisco and New York City. An investigation into the results showed that the test is performing within the manufacturer’s specifications for sensitivity and specificity. The lot numbers do not appear to be a factor, nor does it appear that the devices are problematic. At this time, the suspicion is that, most likely, the problem is site-specific. An effort is under way to determine the root cause of the higher false-positive rate.

The FDA is looking into the possibility of approving HIV test kits for over-the-counter sales. The next steps would be to evaluate comments from the Blood Products Advisory Committee meeting, set criteria for validation of home-use HIV tests kits for test performance, examine the capacity of instructional materials to substitute for live counseling, and assure that benefits outweigh risks.

CMS details
Judy Yost, director, Division Laboratories Services, Center for Medicaid and State Operations, CMS, announced that taking the cytology proficiency test would be required but would be — as it was in 2005 — an educational, rather than punitive, exercise. In addition, CMS is working toward updating the proficiency-testing program requirements.

Regular meetings of CMS’ Partners in Laboratory Oversight group — composed of individuals from various accreditation agencies — has completed a project identifying the most critical issues in a survey process and has developed a charge for its members. Future projects will include improving consistency with policies among different organizations. Another is the possibility that the laboratory director’s responsibilities could be changed to increase the authority of that position.

CMS is still working with the Clinical and Laboratory Standards Institute (CLSI) to finalize a document for manufacturers and one for the laboratory to address quality-control aspects of testing. Once these documents have been approved by CLSI, the organization anticipates that they will be incorporated into the surveyor guidelines.

The Government Accountability Office has been conducting a comprehensive audit of the CLIA program, which sources say is the most complicated review the agency has ever undertaken. This report was due out in March.

The long-awaited genetic-testing proposed rules for CLIA have been completed between CMS and CDC, and now the regulatory process begins. The rules include the recommendations from CLIAC and the Secretary’s Advisory Committee on Genetic Testing, or SACGT, at the National Institutes of Health. Once published (possibly by the end of 2006), comments will be requested for technical information and definitions.

CCCLW and med lab careers
Joeline Davidson, administrative director, Laboratory Services, West Georgia Health System and CLIAC committee member, gave an update on the Coordinating Council for Clinical Laboratory Workforce (CCCLW). Its participants include 21 professional and government organizations whose task is focused on scrutinizing issues surrounding the decline of individuals entering the laboratory workforce. The Bureau of Labor and Statistics Workforce Projections has estimated that 138,000 CLS/MT and CLT/MLT positions will be open by 2012. The dwindling number of workers in the field due to retirement and the lack of new workers being recruited into the profession has prompted a plan by CCCLW to increase public visibility of medical laboratory careers.

Michigan’s lab-pro career tool kit
The Michigan Association of Laboratory Science Educators — supported by a grant from CDC and the Michigan Department of Community Health, Bureau of Laboratories — created a tool kit geared toward high-school students to encourage them to consider a laboratory profession prior to college. The tool kit includes CDs with vignettes from laboratory professionals in various jobs. Copies are available upon request from medtech@msu.edu and can be viewed online at http://medlabcareers.msu.edu.

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