Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

September 11-12, 2002

Atlanta, Georgia

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Clinical Laboratory Improvement Advisory Committee
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Summary Report

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Record of Attendance

Committee Members

Dr. Toby L. Merlin, Chair
Dr. George Birdsong
Dr. Joseph Campos
Dr. Patricia Charache
Dr. Brenta Davis
Dr. Andrea Ferreira-Gonzalez
Dr. Kathryn Foucar
Dr. Ronald Gagné
Dr. Cyril (Kim) Hetsko
Ms. Cynthia Johns
Dr. Ronald Luff
Dr. Valerie Ng
Dr. Timothy O'Leary
Mr. Stewart Lee Richardson
Dr. Lawrence Silverman
Mr. Albert Stahmer
Dr. Lawrence Sturman
Dr. David Sundwall
Dr. Roland Valdes
Dr. Alice Weissfeld

Ex Officio Members

Dr. Robert Martin
Dr. Steven Gutman
Ms. Judith Yost

Liaison Representative

Ms. Kay A. Setzer, AdvaMed

Centers for Disease Control and Prevention

Ms. Nancy Anderson
Ms. Diane Bosse
Ms. Carol Bigelow
Dr. Joe Boone
Dr. Bin Chen
Ms. Carol Cook
Ms. Judy Delany
Ms. MariBeth Gagnon
Ms. Sharon Granade
Dr. Tom Hearn
Ms. Jerri Holmes
Ms. Stacey Holt
Ms. Helen Kuykendall
Mr. David Lyle
Mr. Kevin Malone
Dr. Adam Manasterski
Ms. Anne Pollock
Ms. Andrea Pratcher
Ms. Cathy Ramadei
Dr. Shahram Shahangian
Mr. Darshan Singh
Mr. Howard Eric Thompson
Ms. Pam Thompson
Ms. Glennis Westbrook
Ms. Rhonda Whalen

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

Ms. Valerie Coppola (CMS)
Ms. Cecelia Hinkel (CMS)
Ms. Ronalda Leneau (CMS)
Ms. Gwendolyn Williams (CMS)
Dr. Elliot Cowan (FDA)
Dr. Joe Hackett (FDA)
Ms. Clara Sliva (FDA)

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 (formerly, Health Care Financing Administration); 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 (formerly, Health Industry Manufacturers Association) 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 advisory committee's recommendations will be automatically accepted and acted upon by the Secretary.

CALL TO ORDER – INTRODUCTIONS/FINANCIAL DISCLOSURES

Dr. Toby Merlin, CLIAC Chair, welcomed the Committee members and called the meeting to order. He reviewed the role of CLIAC and introduced Mr. Kevin Malone, Attorney-Advisor, Office of General Counsel, CDC. Mr. Malone explained the requirements and process for public disclosure, including those for conflicts of interest. All members then made self-introductions and financial disclosure statements relevant to the topics to be discussed during the meeting.
Dr. Merlin welcomed four of CLIAC's newest members--Dr. Kathryn Foucar, Dr. Cyril (Kim) Hetsko, Dr. Albert Stahmer, and Dr. David Sundwall. Dr. Margaret Mary McGovern, another new Committee member, was unable to attend the meeting.
Since this was the first anniversary of the tragic events of September 11, 2001, the Committee observed a moment of silence to reflect on the many heroic efforts and loss of lives on that day.

AGENCY UPDATES

- **Food and Drug Administration (FDA) Update** **Addendum A**

Dr. Steven Gutman, Director, Division of Clinical Laboratory Devices, Office of Device Evaluation, Center for Devices and Radiological Health (CDRH), FDA, updated CLIAC on FDA activities. He reviewed FDA staffing changes and plans to consolidate all premarket, compliance, and postmarket in vitro device regulatory activities into a single functional unit, the Office of In Vitro Diagnostic Evaluation and Safety. He also provided status reports on several of CDRH's program activities, including the premarket review processes and the CLIA test categorization program. Dr. Gutman discussed FDA's strategic plan, which includes as one of its goals the total product life cycle (TPLC), a new review process designed to ensure "cradle to grave," seamless oversight of in vitro devices. Dr. Gutman pointed out the 510(k) review process has many limitations since it is based on the equivalency of a new product to one on the market on or after 1976. He stated that while the strengths of a premarket review include the Quality Systems Regulation (QSR), which requires quality assessments, process controls, and corrective actions, the limitations are that it only provides a snapshot in time and the data submitted for the review are not based on the actual performance of a product in the field. Dr. Gutman explained the Food and Drug Administration Modernization Act (FDAMA), encourages improved market access and increased interaction with industry through a "least burdensome pathway" and a premarket to postmarket balance. FDA's strategy to focus on TPLC, while still an evolving program, will help to meet these goals.

Committee Discussion

- Committee members expressed support for FDA's TPLC initiative.
- One member commented that FDA's law addressing the intended use of products should require manufacturers of home-use products to submit studies relating to their performance in all settings where they are likely to be used, since products approved for home-use are automatically waived under CLIA. Dr. Gutman agreed this topic warrants further discussion.
- Members discussed the challenge of validating tests using analyte-specific reagents (ASRs) and felt some manufacturers are abusing the ASR regulation. For example, some manufacturers are reluctant

to supply reagent information to laboratories for validation studies, citing this information is confidential. Frequently, a laboratory cannot obtain materials, such as particular strains of bacteria or viruses, necessary to validate their tests. One member stated genetic laboratories must do an enormous amount of work to validate methods using ASRs. Dr. Gutman responded the FDA is aware of this problem, but is unsure if regulatory tools can address it. Basically, it is up to the laboratory to develop quality assessment systems and act as a "mini FDA." Ms. Setzer pointed out that the ASR regulation added current Good Manufacturing Practices (cGMPs) to assure ASRs are manufactured consistently. Dr. Merlin acknowledged that the inability to validate tests using ASRs represents a gap in safe and accurate testing and noted the importance of CLIAC presenting this issue to FDA and CDC.

- The Committee members noted that, as a result of bioterrorism concerns, more clinical laboratories are performing environmental testing and increasing numbers of environmental laboratories are performing clinical testing. Although the Committee understands environmental testing is not covered under CLIA, members pointed out that clinical decisions are sometimes based on the results of this testing. Dr. Merlin suggested documenting CLIAC's concern regarding appropriate oversight of environmental testing to prevent potential public health problems. He added, if such oversight is lacking, Congress should be informed that legislation may be needed in this area. Members agreed, while acknowledging that oversight can also be accomplished through voluntary professional guidelines and established standards of practice.

■ Centers for Disease Control and Prevention (CDC) Update

Towards a National Laboratory System **Addendum B**

Dr. Rex Astles, Division of Laboratory Systems (DLS), Public Health Practice Program Office (PHPPO), CDC, began his presentation by describing the current network of laboratories performing public health testing (e.g., testing for agents of bioterrorism, tuberculosis, HIV, blood lead, and syphilis) as a loose association of public health, hospital, and independent laboratories throughout the country, whose collaboration and communication is often inconsistent and uncoordinated. He noted, although the perception is that public health testing is performed in public health laboratories, in reality, much of this testing is performed in clinical laboratories. Dr. Astles reviewed the different roles for public health and private laboratories and the need for an interdependent relationship in identifying public health threats. In this regard, he explained, CDC's Office of Laboratory Systems Development, within PHPPO, has developed strategic initiatives with a goal to create a National Laboratory System (NLS) consisting of a mutually collaborative network of public health and private laboratories. These initiatives include utilizing professional organizations, federal partners, and federally-funded state projects to assess laboratory capabilities, address gaps in training, establish uniform standards of laboratory practice, and improve collaboration of clinical laboratories with state and local public health departments and CDC. Dr. Astles then described demonstration projects in the states of Michigan, Minnesota, Nebraska, and Washington, funded by the NLS and the Association of Public Health Laboratories, which focus on various aspects of these initiatives. Dr. Astles concluded by sharing plans for future activities and the expected outcomes.

Committee Discussion

- One member inquired about plans to involve states that do not currently have any clinical laboratory surveillance activities. Dr. Astles stressed the importance of making these states aware of available tools such as workable models and the national laboratory database created by CDC, as well as the

benefits of participating in the NLS. Another member asked how data collection and reporting costs would be addressed. Dr. Astles acknowledged these issues need to be addressed, possibly through the development of more simplified data collection methods.

- Another member commented that at the Department of Health and Human Services' (HHS) meeting on Strategic Planning for Homeland Security, the American Society for Microbiology suggested the Laboratory Response Network (LRN) be rolled into the NLS. Dr. Astles explained the two programs serve different purposes. The LRN focuses on response to specific events, whereas the NLS provides for a national system comprised of private and public laboratories that would be supportive of any CDC initiative, whether that be bioterrorism, foodborne disease, or other outbreaks. This is accomplished by NLS proactively addressing training needs, leadership development, and informatic integration of clinical laboratories with public health laboratories.
- A member inquired if there were any initiatives at CDC to provide training to laboratory directors. Dr. Martin replied that some activity already exists in this area; DLS's National Laboratory Training Network has developed training and educational materials in a variety of formats, including CD-ROMs, videotapes, printed manuals, and electronic media, which are available for loan to laboratory scientists.
- Members commended CDC for its leadership role in fostering collaborations among public and private laboratories and encouraged continuing its efforts to provide vital and up-to-date information to the laboratory community.

Summary of International Conference on Proficiency Testing for Medical Laboratories -Global Odyssey 2002 **Addendum C**

Dr. Joe Boone, DLS, PHPPO, CDC, presented a summary of the 2002 Global Odyssey Conference, which was sponsored by CDC and held in Atlanta, Georgia on February 24-26, 2002. He explained the objectives of this conference were to explore advances in external quality assessment (EQA), to create global opportunities for sharing and partnerships, and to promote the role of EQA in global health. Approximately two hundred attendees from 54 countries participated. Dr. Boone reviewed the conference outcomes, which included the development of a global inventory of EQA programs, the creation of a website for conference presentations, and the definition of seven postconference workgroups. He shared a vision of improved communication, collaboration, and global health as a result of international partnerships.

Quality Institute Conference 2003 **Addendum D**

Dr. Joe Boone also presented plans for a Quality Institute Conference to be held April 13-15, 2003, in Atlanta, Georgia. The goals for this conference are to develop a framework for a national report on the quality of laboratory services, to develop criteria for quality indicators for laboratory services, and to develop a process for ongoing data collection and analysis. The program for the conference will involve representatives from diverse backgrounds, such as healthcare providers, policy makers, laboratory professionals, accrediting and standard setting groups, diagnostics industry, patient advocates, hospital administrators, and payers/insurers. The conference will include plenary sessions, workgroups, and posters. It is hoped an ongoing Quality Institute will be created to foster better collaboration and coordination between health laboratories and other parts of the healthcare system and continuous data collection and analysis related to the quality of the nation's health laboratory services.

Committee Discussion

- Members expressed support for the conference and asked whether efforts were being made to involve hospital administrators, and if the conference will qualify for CMEs, an incentive for physician participation. Dr. Boone replied that plans include involving hospital administrators and to offer CEUs, as well as CMEs.
- One member asked about Dr. Boone's statement that the conference will be limited to 400 attendees, and commented there may be a greater demand than this. Dr. Boone responded the limitation is due to the capacity of available meeting space.
- Some of the members suggested patient safety relevant to laboratory staffing shortages would be a relevant topic for the meeting.

Rapid HIV Tests (CDC and FDA Updates)

Dr. Robert Martin, Director, DLS, PHPPO, CDC, provided a brief update on the status of and issues surrounding rapid HIV tests. Recently, two manufacturers announced that they have rapid HIV tests in FDA's premarket approval process. Dr. Martin commented that several advocacy groups see widespread access to these tests as pivotal in reducing the incidence of HIV infection, especially in hard-to-reach high-risk populations. In addition, they believe this access can only be attained if the tests are waived when they have been cleared for marketing. However, other groups are concerned that test quality will suffer and the public's health will be compromised if the tests are waived. Dr. Martin noted the challenge of assuring access to rapid HIV testing while maintaining test quality, and reviewed the recommendations made by FDA's Blood Products Advisory Committee (BPAC) and the Presidential Advisory Council on HIV and AIDS (PACHA). At its June 14, 2001 meeting, BPAC voted unanimously against waiving rapid HIV tests from CLIA oversight. This vote occurred after CMS presented data from a pilot study in which on-site inspections of a number of laboratories performing waived tests identified significant testing problems, most notably, failure to follow manufacturers' test system instructions. In contrast, PACHA recommended that rapid HIV tests be waived after representatives from the National Alliance of State and Territorial AIDS Directors presented a statement to the Council at its June 21, 2002, meeting, citing the need for waiver to assure widespread access and reduce HIV infections. Dr. Martin informed the Committee members that a CDC Consultation Meeting on the implementation of rapid HIV testing was being held concurrently with this CLIAC meeting and efforts were underway to educate all involved on the existing options for addressing both sides' concerns. However, he acknowledged that these issues are complex and that some options may not be workable in all states due to individual state laws. He pointed out that developing countries with a higher prevalence of HIV than the United States offer rapid HIV testing, but rapid testing is implemented in these settings with appropriate training, quality assurance (QA), proficiency testing (PT), and oversight.

Committee Discussion

- A Committee member stated that in his experience as a physician treating HIV patients, many people at high risk for HIV infection do not want to know their status or change their behavior and thus, do not enter into treatment. He conveyed the American Medical Association (AMA) does not agree with waiving a rapid HIV test in the absence of sufficient data. This member provided the Committee with a copy of a letter to HHS Secretary Tommy Thompson, co-signed by the AMA and the American Association of Bioanalysts, stating these tests should not be waived **(Addendum E).**
- One member pointed out the CLIA requirements for waiver specify that a waived test be robust, with low risk of harm if performed incorrectly; an incorrect HIV test result would have significant

consequences and not meet the risk of harm criterion for waiver. Also, home-use testing by third parties is a concern and illustrates the problem with the statutory language which requires tests cleared for over-the-counter use to be automatically waived. This member suggested professional organizations work with their Congressional liaisons to pursue legislative changes to the CLIA statute. Another member agreed, commenting these issues will not go away and legislative correction is needed.

- Another member commented that while the analytic phase of rapid HIV testing may be simple, the pre- and postanalytic phases, including patient counseling, are critical. In particular, data shows that up to 20 percent of HIV tests are false positives and confirmatory testing is sometimes not performed. Patient stress due to positive results can be great, resulting in severe depression and other adverse reactions. The Committee member cautioned that if a rapid HIV test is waived without considering the pre- and postanalytic phases, it may set a precedent for waiving other tests with significant pre- and postanalytic issues such as genetic tests. This member pointed out that, under CLIA, a limited public health certificate would allow access to moderate complexity rapid HIV testing in nontraditional sites while assuring minimum requirements for QA, PT, and training are met. Another member agreed, and emphasized QA, PT, and training will not occur unless they are required.
- Dr. Martin summarized the difficulty in determining the appropriate level of CLIA oversight for rapid HIV tests. Some groups don't believe the tests should be waived because there would be no regulation of these tests, but they also do not believe categorizing them as moderate complexity is appropriate. He questioned whether there is a need to create a new category for tests of public health significance.

Dr. Elliot Cowan, Office of Blood Research and Review, Center for Biologics Evaluation and Research, FDA, updated the Committee on the progress made toward the FDA premarket approval of rapid HIV tests since the last CLIAC meeting **(Addendum F)**. He reminded the Committee that FDA is prohibited from releasing any information related to manufacturers' premarket approval submissions, as this is considered proprietary and any discussion of a submission's status is limited to discussion of public information only, or information authorized for release by the applicant. He then informed the Committee that MedMira, Inc. has permitted FDA to disclose it has received an "approvable" letter from FDA for its *Reveal™ Rapid HIV Test*. Dr. Cowan also informed the Committee that OraSure Technologies, Inc. publicly announced it has received an "approvable" letter for its *OraQuick® Rapid HIV-1 Antibody Test*. Final marketing approval for each test is subject to the manufacturers meeting conditions imposed by FDA. OraSure Technologies has announced they plan to seek waiver approval for the *OraQuick® Rapid HIV-1 Antibody Test* once it receives final FDA marketing approval.

Dr. Tom Hearn, Deputy Director, DLS, PHPPO, CDC, gave an overview of the CDC Consultation Meeting proceedings. He explained the purpose of the meeting was to provide a forum for the interchange of viewpoints on rapid HIV testing issues. As background, Dr. Hearn pointed out that CDC has a 5-year HIV prevention strategic plan with a goal to reduce HIV infection by 50 percent and, to reach this goal, there is a need to increase the number of people tested. He also explained that two Centers and one Office within CDC have specific interests in HIV testing: the National Center for HIV, STD, and TB Prevention (NCHSTP); the National Center for Infectious Diseases (NCID); and PHPPO. NCHSTP works with a variety of partners on public health surveillance, prevention research, and programs to prevent and control HIV. NCID conducts basic and applied studies to better

understand and detect HIV infection. PHPPO focuses on the quality processes and systems essential to the public health system. Dr. Hearn reported that HHS is aware of the debate about waiver for the new rapid HIV tests. An interagency HHS task force has been meeting by teleconference for the purpose of having a discussion among the agencies and Department about the key issues and data around this debate. Dr. Hearn encouraged CLIAC members and organizations that have relevant data to share it with CDC and HHS to help inform decision-making.

Committee Discussion

- Members reiterated their concerns with waiving rapid HIV tests (At the Committee's May 2001 meeting, it recommended that rapid HIV tests not be waived). Members noted that data and information presented by CMS and others indicate incorrect performance of waived testing may result in incorrect test results. One member again commented there is not a test for HIV that renders negligible an erroneous result for the patient.
- Members agreed the perceived urgency to waive rapid HIV tests is not based on data, but by concerns of promoting access. They also expressed concern that no data is currently available on how well these tests might perform if waived. The members emphasized the necessity of considering the pre- and postanalytic issues surrounding this testing and further recommended that a decision on whether to waive rapid HIV tests not be made until objective data are available on their performance in a waived setting.
- The Committee unanimously voted to send a letter to Secretary Thompson recommending that appropriate oversight, training, QA, QC, and PT are required for even the simplest HIV testing device (**Addendum G**). Although the members support making HIV testing widely accessible, CLIAC does not believe the waiver category is appropriate for these tests at this time and suggests that existing mechanisms, such as the limited public health certificate exception under CLIA, will allow these tests to be used without compromising public health.

■ Centers for Medicare & Medicaid Services (CMS) Update — Addendum H

Ms. Judy Yost, Director, Division of Outcomes and Improvement, Center for Medicaid and State Operations, CMS, provided an update on CMS's recent CLIA activities and laboratory statistics as of January 2002. This included information and data from CMS's Waived Laboratory Survey Project. She explained that while studies by CMS and others indicate 50 percent of waived laboratories have quality problems, they also show compliance is maintained 75 percent of the time when education is provided. As a result of these findings, beginning April 15, 2002, CMS initiated a three-year study in which each state will evaluate 2 percent of waived laboratories each year. In addition, Ms. Yost noted that CMS is working with manufacturers to improve the clarity of their test system instructions and is compiling a "clearinghouse" of existing educational programs for waived testing, which will be added to the CMS CLIA website. She also mentioned some of the other information available on the CMS CLIA website (www.cms.hhs.gov/clia/), such as special alerts; the 2001 Laboratory Registry that lists the names of laboratories receiving CMS sanctions and any related hearing decisions; CMS Regional Office contacts; and CLIA-approved proficiency testing program providers. In closing, Ms. Yost briefly discussed the re-approval of the Department of Defense's laboratory oversight program, the Secretary's Regulatory Reform Initiative's draft recommendations relative to CLIA, and the status of the final quality control regulation and the waiver regulation.

Committee Discussion

- One member questioned whether the Waived Laboratory Survey Project was a study of randomly-selected laboratories. Ms. Yost confirmed that while the sample of laboratories was randomly selected, efforts were made to include both urban and rural laboratories, as well as large volume and small volume laboratories.
- Another member, while pleased that the study was capturing information relative to waived test performance and patient outcomes, expressed continuing concern about the use of tests approved for home use in clinical settings. Ms. Yost replied that the CLIA statute provides for an automatic waiver of tests approved for home use, but does not address intended use. She suggested, as an alternative, monitoring the postmarket performance of these tests. Dr. Gutman clarified that the real issue is the incongruence between the laws, the FDA law pertaining to premarket clearance of tests for home use and the CLIA law, which was revised in 1997 to automatically waive tests approved by the FDA for home use. While Dr. Gutman acknowledged the Committee's concern, he noted that changes in the law require Congressional legislation.
- Ms. Setzer requested an update on the inspection data for moderate and high complexity laboratories. Ms. Yost replied the decrease in the number of moderate and high complexity laboratories makes it hard to compare data from survey cycle to survey cycle. However, she noted that while the top four deficiencies cited remain the same, the number of laboratories having problems has decreased.

PRESENTATIONS AND COMMITTEE DISCUSSIONS

- **Coordinating Council on the Clinical Laboratory Workforce (CCCLW)**

April 2002 Summit Meeting Report to CLIAC **Addendum I**

Ms. Cynthia Johns, Laboratory Manager, Colorado Coagulation Esoterix, Inc. and CLIAC member, reported on the April 2002 summit meeting of the CCCLW, previously known as the Summit on Laboratory Workforce Shortage. She presented an overview of the CCCLW strategic plan with associated goals and activities developed to address laboratory workforce shortages. She described the Council's various workgroups; summarized the completed, in-progress, and future activities of each workgroup; and identified the lead laboratory professional organization responsible for facilitating each workgroup activity. Ms. Johns reported that continuous communication among workgroups, professional organizations, and the steering committee was critical to accomplishing the Council's goals.

CCCLW Activity – Update since April 2002 **Addendum J**

Dr. Brenta Davis, Chairman, Department of Clinical Laboratory Sciences, University of Tennessee-Memphis and CLIAC member, updated the Committee on the activities of the CCCLW workgroups since the April 2002 summit meeting. She reviewed current data on the status of clinical laboratory educational programs and workforce salaries, announced the recognition of CCCLW as a focal point for laboratory workforce information and action, and described several laboratory career promotional projects targeting high school and college students. She concluded her presentation with a request that CLIAC continue to: (1) voice concern about the laboratory workforce shortage and its significance to the healthcare community and government; (2) participate in and support CCCLW activities; and (3) participate in other meetings and informational sessions about workforce issues.

Committee Discussion

- Committee members acknowledged the critical workforce shortage in the clinical laboratory and noted that similar shortages exist in all fields of healthcare. When asked whether current data identifies deterrents to choosing a career in laboratory medicine and to retaining laboratory staff, Dr. Davis and Ms. Johns responded increased stress in the work place, competing career choices that are more lucrative, and lack of professional image are significant deterrents. When asked how to attract former laboratory workers back to the field, Ms. Davis replied that workers who leave the field do not return; however, continuing and re-education programs have not been fully utilized.
- Dr. Merlin suggested more data is needed to link salaries with the quality of healthcare workers and patient outcomes.
- CLIAC lauded the united effort of professional organizations and the success of the CCCLW activities over the last two years. The members also acknowledged the continuing need for coalitions of professional organizations and healthcare communities to market the laboratory profession and address workforce shortage issues.

■ Healthcare Workforce Issues — Addendum K

Dr. Rumay Alexander, President and CEO, The Roxie Company, representing the American Hospital Association (AHA), defined the current shortages of all categories of hospital workers as a "looming crisis in care" and a "long-term problem that will become worse with time." She reviewed the AHA's 2001 hospital data showing continuing increases in vacancy rates and difficulty in recruitment and retention of hospital workers. Dr. Alexander then discussed the January 2001 establishment of the AHA Commission on Workforce for Hospitals and Health Systems, of which she was a member, to address both the identified causes and solutions for workforce shortages. Dr. Alexander's presentation concluded with a summary of the Commission's April 2002 report, *In Our Hands – How Hospital Leaders Can Build a Thriving Workforce*, noting the report can be found on AHA's website: www.hospitalconnect.com/aha/key_issues/workforce/commission/InOurHands.html. The report includes a strategic plan and recommendations to hospital leaders, local communities, professional organizations, and educators on immediate and sustained activities needed to reverse the workforce shortage and to establish a strong foundation for our healthcare's future.

Committee Discussion

The Committee applauded the efforts of AHA and supported the Commission's recommendations for improving the healthcare workforce environment, in recognizing the need for a more diverse workforce, and in supporting healthcare career initiatives that target the educational system and provide incentives for choosing a career in healthcare.

■ Sentinel Event Data and Staffing Effectiveness — Addendum L

Ms. Joanne Born, Executive Director, Laboratory Program, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), described the JCAHO accreditation program as promoting patient safety and performance improvement through a process that includes a professionally-derived standards of compliance survey and a sentinel events voluntary self-reporting system. (A sentinel event is defined as any unexpected occurrence involving death or serious physical or psychological injury or the risk

thereof.) She summarized current data from the JCAHO sentinel events database, including types of events reported, settings where events occur, and the root causes of the events. She noted that communication problems are responsible for 63 percent of all reported events, with orientation and training issues the second most commonly identified cause (53 percent). JCAHO has been concerned with the shortage of qualified professional personnel and the sentinel events data do identify linkages between staffing effectiveness and patient safety. In this regard, Ms. Borne pointed out that various problems related to staff training and competency have ranked in the top 5 laboratory compliance issues over the last 3 years. She concluded her presentation by summarizing the findings of a national panel of experts, representing various settings and disciplines, charged with analyzing staffing models and identifying indicators that could be used as effective screening tools for staffing issues in future JCAHO compliance surveys.

Committee Discussion

- In response to several questions regarding the sentinel events database, Ms. Born informed CLIAC members the database is accessible on the JCAHO website. Several members expressed concern that voluntary self-reporting of sentinel events would result in under-reporting. Ms. Born concurred, but stressed that even with under-reporting, if institutions effectively use the process of root cause and analysis internally, errors can be averted, resulting in the absence of a sentinel event to report.
- Members discussed the pros and cons of deemed status organizations implementing unannounced inspections. A majority of members recognized the advantages of unannounced inspections, but agreed that current staffing shortages would make it difficult for laboratories to meet both patient care service needs and the demands of an unannounced on-site inspection.
- The JCAHO laboratory accreditation process was discussed, with members specifically inquiring about JCAHO formats for evaluating laboratory validation of new methods, staffing models, and the impact of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) on the accreditation process. Ms. Born explained that JCAHO has always addressed patient confidentiality issues in its process, has standards that are used for evaluating how a laboratory validates new methods, utilizes a certification examination to qualify its site surveyors, and expects the healthcare organization to have policies that address the services it provides and the staff needed to deliver those services.
- The discussion concluded with all members agreeing performance improvement is a very important part of the JCAHO accreditation process, sentinel events reporting is an effective tool for measuring the quality of a healthcare delivery system and, in particular, capturing data relating laboratory services to patient outcomes is essential and very much needed.

■ Congressional Activities Update - Legislative Solutions to the Laboratory Workforce

Addendum M

Ms. Robin E. Strombler, Vice President, Government Affairs, American Society for Clinical Pathology (ASCP), identified laboratory budget issues and educational incentives as critical factors impacting laboratory workforce retention and attraction of professionals to both laboratory medicine and underserved communities. She summarized current legislative actions affecting laboratory budgets and reported on the status of allied health project grants, citing the implementation of four laboratory training sites in rural Nebraska as a project grant success story. She then reviewed the findings of the ASCP Board of Registry and Morpace Wage and Vacancy Survey of March 2001, listed ASCP's additional

workforce shortage concerns, and discussed the content of HR 1948, the Medical Laboratory Personnel Shortage Act of 2001 and two provisions included in the Bioterrorism Preparedness and Response Act of 2002. Ms. Strombler ended her presentation by soliciting CLIAC to encourage HHS to address workforce shortage issues in clinical and public health laboratories as part of its strategic plan goal to enhance the ability of the nation's healthcare system to effectively respond to bioterrorsim and other public health challenges. The associated strategy should include educational funding as a mechanism for facilitating a competent and adequate workforce.
Committee discussion was deferred until the completion of Dr. Atul Grover's presentation on Laboratory Workforce Analysis Activities.

- **Laboratory Workforce Analysis Activities – Clinical Laboratory Workers**

Addendum N

Dr. Atul Grover, Chief Medical Officer, National Center for Health Workforce Information and Analysis, Bureau of Health Professions, Health Resources and Services Administration (HRSA), began his presentation by reviewing the mission and functions of the National Center for Health Workforce Information and Analysis and the Bureau of Health Professions. He then gave an overview of the products and activities of the Center, both nationally and regionally, including an 18-state comprehensive health workforce profiles project. Dr. Grover summarized the trends, issues, and supply and demand projections for the healthcare workforce and discussed the impact of changing demographics on the requirements for healthcare providers. He also reviewed ASCP 2000 and 2001 survey data on clinical laboratory training programs; the 1994-2000 trends in vacancy rates for selected laboratory personnel; and the Bureau of Labor Statistics' data of mean annual salaries for medical technologists and medical laboratory technicians. Dr. Grover highlighted some of the factors affecting the laboratory labor market, reasons for increased demand for laboratorians, and potential causes for staffing shortages. He concluded by identifying barriers to addressing laboratory worker shortages and presenting key questions that will be addressed in a 2003 HRSA-funded Clinical Laboratory Sciences Personnel Shortage Study.

Committee Discussion

- Several members voiced concern about funding sources needed for medical education programs and asked if student financial aid was addressed in the two provisions of HR 1948 included in the Public Health Security and Bioterrorism Preparedness and Response Act. Ms. Strombler indicated the Act has provisions for low interest loans and partial scholarships and there is a possibility that it may provide for loan forgiveness programs at the state and local level.
- The importance of establishing partnerships between healthcare providers and educators and the funding of training programs in non-traditional settings were then discussed, with members agreeing that without increased resources available to healthcare institutions and education and training programs, the number of programs and access to continuing medical education will continue to decrease. Several members asked for clarification on California bill SB 1809, recently signed into law, addressing laboratory workforce shortages in California. Ms. Strombler and Dr. Ng, a CLIAC member from California, stated SB 1809 creates a new California license category for a medical laboratory technician (MLT), explaining that current California law does not recognize the MLT. They noted that while the California has enacted the law, regulations implementing the provision have not yet been developed.

- One member commented that advances in technology combined with laboratory workforce shortages made for a driving force, increasing the demands for point-of-care and waived testing, and are changing the spectra of the workforce. Several members agreed, noting the broadening scope of practice will require appropriate standards of practice to maintain quality and assure minimal competency of testing personnel. One member asked if there are objective data linking state personnel licensure requirements to higher levels of competency in testing personnel. Dr. Grover responded that the Center currently lacks sufficient resources to collect data linking objective measures to outcomes. Members again reiterated the need for funding of educational programs and studies that link objective data to patient outcomes.
- A final discussion centered on laboratory workforce shortages and salaries, with one member reminding the Committee that without changes in current reimbursement regulations, salaries will not increase and the laboratory workforce will continue to decrease.

■ Genetic Testing

Secretary's Advisory Committee on Genetic Testing (SACGT) Meeting Report **Addendum O**

Dr. Patricia Charache, CLIAC and SACGT member, informed the Committee that SACGT's charter expired in August 2002. She summarized the activities and accomplishments of SACGT, particularly regarding its recommendations for enhancing the oversight of genetic tests through proposed FDA responsibilities, CLIA provisions for genetic testing, and postmarket data collection. Dr. Charache reviewed SACGT's definitions for analytical validity, clinical validity, and clinical utility, and its proposed oversight for transition of genetic tests from research phase to clinical use. Her report highlighted activities of SACGT workgroups and task forces on education, informed consent and institutional review boards (IRBs), rare disease testing, access, and data collection. Dr. Charache also summarized SACGT's additional concerns and outstanding issues, including pre- and postanalytic considerations of waived tests, gene patenting and licensure, provision of education/guidance documents for IRBs and research laboratories interested in providing patient care, oversight of laboratory-developed tests, informed consent procedures relative to requests for genetic testing, reimbursement for laboratory expenses associated with obtaining necessary information regarding genetic test orders, and education of laboratory personnel specific to genetic testing.

Molecular Genetic Test Orders **Addendum P**

Ms. Kathy LaBeau from the Washington State Department of Health and Network Director, Pacific Northwest Laboratory Medicine Sentinel Monitoring Network, presented a summary of molecular genetic testing in Washington State and the Pacific Northwest region: the types of tests being ordered, where the tests are performed, and the reasons/criteria for choosing the laboratory to perform the testing. This information was collected via a survey of laboratories performing moderate and high complexity testing in the Network from October through December 2001.

Committee Discussion on Presentations by Dr. Charache and Ms. LaBeau

- Several Committee members voiced concern about the use of exclusive patents for some genetic tests, noting that this practice could become more widespread in the future causing a variety of testing and access issues. One Committee member pointed out that recent National Institutes of Health (NIH) grants to commercial laboratories for test development have prohibited the use of exclusive

patents. Dr. Merlin suggested that because of the Committee's concern about the use of exclusive patents and the impact they may have on access to and quality of genetic testing, the issue be further reviewed and discussed at a future Committee meeting or by other committees in another forum.

- One Committee member questioned whether CLIAC's recommendations and proposed definition for genetic tests would be applicable to pharmacogenetic testing, which is usually performed to determine individual response to medicine rather than for assessment of disease and health conditions. Several members responded that the proposed definition of molecular genetic testing would include analysis of human DNA or RNA to detect heritable or acquired disease-related genotypes, mutations, or phenotypes, and pharmacogenetic tests would meet this proposed definition. As well, the Committee's recommendations relative to the quality control and quality assurance of genetic testing would also be appropriate for pharmacogenetic tests.
- Several Committee members inquired about the timeframe for developing the proposed rule that would revise the current CLIA regulations to include specific requirements for genetic testing. Ms. Rhonda Whalen, Chief Laboratory Practice Standards Branch, DLS, PHPPO, CDC, responded that a regulatory impact analysis for the proposed rule is in development; however, the timeframe for publishing the Notice of Proposed Rule Making (NPRM) can not be determined at this time because of other regulations currently under development and in clearance.
- One Committee member expressed concern about the length of time for developing the NPRM and inquired whether the Committee could provide help on data collection for the regulatory impact analysis.
- Committee members commented that the terms analytical validity, clinical validity, and clinical utility are not well understood and need to be better defined. They suggested voluntary practice guidelines and laboratory standards developed by professional organizations, such as the College of American Pathologists and the American College of Medical Genetics, might be helpful in defining these validation criteria for genetic tests. Dr. Charache responded that genetic test validation is an extremely complex issue and postmarket validation data for these tests are currently being evaluated by a CDC project under the direction of Dr. Muin Khoury, Director of Office of Genomics and Disease Prevention, National Center for Environmental Health, CDC. One Committee member suggested inviting Dr. Khoury to present results of this evaluation project at a future CLIAC meeting.

■ Public Comment

Mr. Phil Bongiorno, Assistant Director, Public Health and Scientific Affairs, College of American Pathologists (CAP), informed CLIAC of two pieces of legislation endorsed by CAP that may address some of the Committee's concerns relative to exclusive gene patents: the 'Genomic Science and Technology Innovation Act of 2002' (HR 3966) and the 'Genomic Research and Diagnostic Accessibility Act of 2002' (HR 3967).

■ Adjourn

Before adjourning the meeting, Committee members voted on dates for two CLIAC meetings in 2003. The agreed upon dates are March 12-13, 2003, and September 17-18, 2003.
Dr. Merlin adjourned the meeting.

I certify that this summary report of the September 11-12, 2002, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

/s/

Toby Merlin, M.D., CLIAC Chair Date: 12/4/2002