Clinical Laboratory Improvement Advisory Committee Meeting

February 17-18, 1993

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The Clinical Laboratory Improvement Advisory Committee (CLIAC) met at the Centers for Disease Control and Prevention (CDC) Auditorium A in Atlanta, Georgia on February 17-18, 1993. Those in attendance are listed below:

COMMITTEE MEMBERS
Dr. Paul Bachner
Ms. Michele Best
Ms. Virginia Charles
Dr. Raymond Gambino
Ms. Lynne Garcia
Dr. Stanley Inhorn
Ms. Sandra Johnson
Dr. Stephen Kroger
Dr. Kenneth Matthews
Dr. Brenda McCurdy
Dr. Robert Nakamura
Dr. Wendell O'Neal
Dr. Robert Pierre
Dr. Charles Ray
Dr. Dorothy Rosenthal
Dr. Morton Schwartz
Dr. Ronald Zabransky

Ex Officio Members
Dr. Carlyn Collins, CDC
Mr. Thomas Tsakeris, FDA
Ms. Judith Yost, HCFA

Executive Secretary
Dr. Edward Baker

Centers for Disease Control and Prevention
Ms. Rosemary Bakes-Martin
Ms. Louise Barden
Mr. James Bloom
Dr. Joe Boone
Ms. Genoria Bridgeman
Mr. Henry Colvin
Ms. Carol Cook
Ms. Iris Dixon
Mr. Tom Hearn
Mr. Edwin Holmes
Dr. Devery Howerton
Mr. Kevin Malone
Ms. Marta Ramirez
Dr. John Ridderhof
Ms. Elva Smith
Mr. John Spiegel
Ms. Rhonda Whalen

Oral Presentations
(presenters are listed under appropriate topics within the report)

Estimated Number of Public in Attendance: 75

INTRODUCTION TO THE CLIAC COMMITTEE MEETING

The CLIAC Committee members were welcomed by Edward L. Baker, M.D., Director, Public Health Practice Program Office (PHPPO), CDC, Executive Secretary of the Committee.

Additional welcoming remarks were made by the Chairman of the Committee, Morton K. Schwartz, Ph.D.

Executive Summary Report of CLIAC Meeting - October 28-29, 1992

The Committee Chairman provided a summary of the issues, discussion and recommendations of the CLIAC meeting held October 28 and 29, 1992. The Committee accepted, as recorded, the minutes of that meeting.

Report from Subcommittee on Test Categorization

The Committee Chairman introduced J. Stephen Kroger, M.D., Chairman of the Test Categorization Subcommittee, who provided a summary of the issues and discussion, and the recommendations of the Subcommittee's meeting held at the CDC, January 29, 1993 (See Addendum A).

- The Committee voted unanimously to accept the Subcommittee recommendation:
  - The HDL-cholesterol performed on the Kodak Ektachem DT 60 should be recategorized from high to moderate complexity and the Kodak Ektachem DT 60 should serve as an "index" test system for the review of similar HDL cholesterol test systems.
- In response to the issue of whether or not the Gram Stain and Tzanck test should be included in the physician-performed microscopy category, several committee members noted that some medical specialists use these procedures routinely and are trained to perform them as part of their medical residency. In these instances, the criteria for physician-performed microscopy test categorization are a barrier to the inclusion of those tests specifically performed by certain medical specialists. Another Committee member noted that at the first CLIAC meeting, the full Committee recommended that the physician-performed microscopy category not include any tests that are limited to performance by a particular medical specialty.

Although the Committee expressed concern about not including provisions to address specialty medical practice procedures, the

Committee noted that the Gram stain and Tzanck test do not meet the current criteria for inclusion in the physician-performed microscopy category. After discussion, the Committee voted to accept the following Subcommittee recommendation:

- + Gram stain and Tzanck test not be included in the physician-performed microscopy category.

- ○ While all Committee members agreed that rapid strep tests do not meet the criteria for physician-performed microscopy procedures, a few Committee members felt that rapid strep tests should be waived because of the potential for limiting access to care. It was suggested that without easy access to these tests, physicians may choose to initiate antibiotic therapy without testing or refer the test to a reference laboratory with a delay in diagnosis and treatment and possible increased cost and inconvenience to the patient. One Committee member stated that certain methodologies used in rapid strep tests are simple to perform and possess a high level of accuracy and reliability and such procedures could be included in the waived category. Other Committee members felt that rapid strep tests were appropriately categorized as moderate complexity and that there are benefits from the required inspections, quality control and proficiency testing which assure accurate and reliable test results. After some discussion, the Committee Chairman requested that CDC attempt to organize the list of rapid strep tests according to the degree of complexity. The Committee then voted to accept the following Subcommittee recommendations:

  - + Rapid strep tests not be included in the physician-performed microscopy category; and

  - + Rapid strep tests not be added to the list of waived tests.

- ○ The Executive Secretary noted that CDC is completing the compilation of all the tests categorized to date for publication in the Federal Register.

THE ISSUES

This portion of the meeting was devoted to presentations, public comments and discussions concerning the CLIA personnel requirements for the physician-performed microscopy category, high complexity testing personnel, and high complexity general supervisor. The issues were selected because of substantive comments received in response to the Final Rule published February 28, 1992 and the Federal Register notice published January 19, 1993 which included the physician-performed microscopy category.

For each issue, CDC provided a technical overview which included background information, the rationale for the current personnel requirements and a sampling of the comments received in response to the Final Rule with comment published February 28, 1992 and the Federal Register notice published January 19, 1993.

In response to the Federal Register notice published, January 27, 1993, announcing the CLIAC meeting, individuals requested permission and were granted the opportunity to make an oral presentation addressing the personnel requirements. The public comments were incorporated into the meeting, as appropriate.

PHYSICIAN-PERFORMED MICROSCOPY CATEGORY

I. PRESENTATION

The technical presentation was made by John C. Ridderhof, Dr.P.H., Chief, Laboratory Practice Standards Branch, Division of Laboratory Systems (DLS), PHPPO, CDC (See Addendum B).

II. ISSUE

Should nurse practitioners and physician assistants be included in the physician-performed microscopy category?

III. PUBLIC COMMENTS

See Addendum C for copies of materials supplied by individuals making oral presentations.

College of American Pathologists
William Hamlin, M.D.

American Academy of Nurse Practitioners
Melanie S. Harris, N.P.

Nat'l Association of Nurse Practitioners in Reproductive Health
Susan Wysocki, RNC, NP

American College of Nurse-Midwives
Ellen Martin., CNM, MS

American Academy of Pediatrics
Thomas Tonniges, M.D.

Nat'l Association of Pediatric Nurse Associates and Practitioners
Leah Harrison, RN, MSN, CPNP

American Academy of Physician Assistants
Randy Spear, PA-C

American Academy of Dermatology
William Dobes, M.D.

American Dental Association
James B. Bramson, D.D.S.

American Medical Association
J. Edward Hill, M.D.

American Society of Clinical Pathologists
Cynthia S. Johns, MT(ASCP)

IV. DISCUSSION

Presentations

Several presenters stated that in addition to physicians, mid-level practitioners personally perform microscopic examinations as part of a patient's physical examination; and, that the physician-performed microscopy category should be expanded to include them. In addition, it was suggested that the exclusion of mid-level practitioners from the physician-performed microscopy category would result in limiting patient access to services and affordable healthcare.

Committee Discussion

Several Committee members questioned whether access to services was limited since mid-level practitioners are not precluded from performing these tests, but can perform them as moderate complexity tests. Another Committee member inquired whether public health clinics perform tests other than waived and physician-performed microscopy procedures. The presenter acknowledged that additional testing is performed, thus reducing certification for moderate complexity testing. A Committee member noted that cost may not be a factor, if these procedures are performed in public health clinics that qualify for the exemption to the certification requirement for each location. This exemption for limited public health testing allows not-for-profit or Federal, State, or local government laboratories at multiple sites performing not more than a combination of 15 moderately complex or waived tests, to file a single application thus reducing certification fees. Another Committee member noted that confusion and misinformation exists concerning the CLIA regulations and suggested that additional materials may be needed to aid laboratories in understanding and complying with the requirements. Committee members questioned several presenters about their respective training programs and the comparability and equivalency of these programs to the education and training of physicians for performance of microscopic examinations.

One laboratory professional organization was opposed to adding other healthcare practitioners to the physician-performed microscopy category, and presented information comparing curricula from three schools of nursing with the science courses required for a baccalaureate degree in medical technology. They stressed that most science courses taken in nursing programs are survey courses and are not considered as prerequisite courses for further scientific study or admission into a school of medical technology.

The Committee requested that the presenters submit data/information concerning their training programs to CDC. This information will aid the Committee in formulating its

recommendation. Several Committee members suggested that the Committee delay making a recommendation until the evaluation of the public comments received in response to the notice published January 19, 1993 in the Federal Register creating the physician-performed microscopy category is completed.

V. RECOMMENDATIONS

Defer Committee discussion and recommendation until after the presenters representing professional associations for nurse practitioners, nurse midwives, pediatric nurse practitioners, and physician assistants submit data/information concerning their training programs to CDC and public comments are evaluated concerning the physician-performed microscopy category which was added to the CLIA regulations on January 19, 1993 by publication in the Federal Register.

TESTING PERSONNEL-HIGH COMPLEXITY

I. PRESENTATION

The technical presentation was made by Rhonda S. Whalen, Health Scientist, Laboratory Practice Standards Branch, DLS, PHPPO, CDC (See Addendum D).

II. ISSUE

Are the qualification requirements for testing personnel-high complexity appropriate?

III. PUBLIC COMMENTS

See Addendum E for copies of materials supplied by individuals making oral presentations.

American Medical Technologists
Jerry Bennington

American Society for Medical Technology
Joeline D. Davidson, MS, CLS(NCA)

American Society for Microbiology
Alice S. Weissfeld, Ph.D.

International Society for Clinical Laboratory Technology
Jo Lynn Koehler, RMT
Levi Walls, III, RMT

IV. DISCUSSION

Presentations

Several of the presenters expressed concern that requiring high complexity testing personnel to have an associate degree will disenfranchise many individuals, who have been successfully performing high complexity testing (e.g., individuals who have completed a 50 week military training program or an accredited medical laboratory/ clinical laboratory technician training program), and exacerbate medical laboratory personnel shortages in rural and inner city areas. It was noted that in many instances, obtaining an associate degree would be a hardship financially, geographically prohibitive and impractical for full time personnel currently employed. One presenter stated that the performance of high complexity testing requires extensive knowledge and judgement skills, and the minimum requirement for

testing personnel should be a baccalaureate degree. Another presenter noted the.linkage between the personnel requirements and Lest categorization and expressed concern that the test categorization criteria do not address risk of harm to the patient when an erroneous result occurs.

Committee Discussion

Several Committee members were concerned that the individual trained on the job (OJT) was not being represented by the laboratory professional organizations providing public comments and that these OJT individuals should be included in any "grandfather" provision recommended by the Committee. One Committee member commented that too much emphasis is being placed on the personnel requirements. It was noted that the laboratory director is ultimately responsible for the competency of his/her employees, and that the Committee should avoid regulatory micromanagement of personnel qualifications.

Several Committee members stated that, in addition to personnel requirements, the regulations include requirements for proficiency testing (PT), patient test management (PTM), quality control (QC), and quality assurance (QA) to ensure quality testing. In regard to PT, some Committee members questioned whether PT should be used as an indicator of personnel competency or a measure of laboratory excellence. In any event, one Committee member pointed out that due to the phase-in of PT requirements, it will be some time before PT performance data is available for all laboratories.

A Committee member questioned why the examinations for qualifying laboratory personnel are no longer administered by the Department of Health and Human Services (HHS). The Committee Chairman explained that the rationale for the development of the examination was to provide an alternative mechanism to qualify as technologists, those testing personnel (e.g., military trained individuals) not meeting the Federal educational requirements and to alleviate the shortage of laboratory personnel in rural areas. The examination was authorized by Congress, under previous Federal regulations, for a limited period of time that has since expired.

One Committee member questioned why the regulations did not recognize certification by a laboratory organization as a route for qualifying testing personnel. CDC responded that, while certification may be an appropriate route for credentialling personnel, there are numerous certification agencies, each with different pathways for qualifying laboratory personnel, making it extremely difficult to determine comparability and equivalency.

The majority of the Committee members were in agreement that a broad or liberal "grandfather" provision should be added to

permit individuals who were performing high complexity testing on September 1, 1992, and who did not possess an associate degree, to continue testing after September 1, 1997. Specifically, individuals currently enrolled in accredited medical laboratory/clinical laboratory technician training programs or 50 week military training programs should be allowed to qualify as high complexity testing personnel. Additionally, high school graduates performing high complexity testing on September 1, 1992 should be allowed to continue to perform high complexity testing indefinitely -- provided that any high complexity testing performed by them is reviewed within 24 hours by a qualified general supervisor. However, they stressed that individuals subsequently hired to perform high complexity testing should be required to have, at minimum, an associate degree.

Four Committee members were opposed to a broad "grandfather" provision and wanted to restrict the provision to those individuals who have completed an accredited medical laboratory/clinical laboratory technician training program or a 50 week military training program.

V. RECOMMENDATIONS

No change in the minimum standard of associate degree. However, the following provisions should be added:

- In lieu of requiring an associate degree in laboratory science or medical laboratory technology, qualify those individuals, who as of September 1, 1994 have graduated from a medical laboratory/clinical laboratory technician training program accredited by the U.S. Department of Education (e.g., Commission on Allied Health Education Accreditation (CAHEA) or Accrediting Bureau of Health Education Schools (ABHES)], or have completed a 50 week military training program, to perform high complexity testing without supervisory review; and,

- High school graduates performing high complexity testing on September 1, 1992 may continue to perform high complexity testing indefinitely provided that any high complexity testing performed by them is reviewed within 24 hours by a qualified general supervisor.

GENERAL SUPERVISOR-HIGH COMPLEXITY

I. PRESENTATION

The technical presentation was made by Louise S. Barden, Health Scientist, Laboratory Practice Standards Branch, DLS, PHPPO, CDC (See Addendum F).

II. ISSUE

Are the qualifications for general supervisor of high complexity testing appropriate?

III. PUBLIC COMMENTS

See Addendum G for copies of materials supplied by individuals making oral presentations.

Clinical Laboratory Management Association
Marianne C. Watters, MT(ASCP)

Coalition: American Society for Medical Technology
American Society of Clinical Pathology
American Society for Microbiology
Janet Pailet

IV. DISCUSSION

Presentations

Laboratory professional organizations presented viewpoints for changing the high complexity general supervisor qualification requirements. There was agreement among the presenters that the minimum requirement should be a bachelor's degree; however, there was no consensus on the type of baccalaureate degree or the number of years of experience required. There was also support for providing a "grandfather" provision for individuals employed as general supervisors on September 1, 1992. Again, there was no consensus on the details of this provision.

Committee Discussion

The Committee members discussed the educational requirements and experience needed to fulfill the responsibilities of a general supervisor of high complexity testing. Several Committee members commented on the key role played by the general supervisor in ensuring quality laboratory testing. While some Committee members believed that a bachelor's degree was necessary, other

Committee members felt that an associate's degree should be the minimum education requirement. The Committee was not in agreement about the number of years of experience that should be required. The Committee discussed the various requirements for general supervisor and their impact on staffing large and small laboratory operations as well as hospital laboratories in rural and inner city areas.

The Committee was in general agreement about considering a "grandfather" provision to permit individuals employed as general supervisors on September 1, 1992 to continue functioning in that capacity. However, prior to making a formal recommendation, the Committee requested that CDC gather additional information concerning laboratory personnel currently employed, employment vacancies and personnel shortages. In addition, information was requested from the presenters concerning the types of laboratory training programs available, number of positions available for student enrollment and current enrollment figures for training programs.

V. RECOMMENDATIONS

Defer Committee discussion and recommendation until after CDC gathers additional information about current employment status; and, professional organizations provide information regarding training programs.

PUBLIC COMMENTS

The Committee heard public comments pertaining to personnel qualifications and test categorization

PERSONNEL

See Addendum H for copies of materials supplied by individuals making oral presentations.

American Association of Blood Banks
Charles H. Wallas, M.D.

American Association of Bioanalysts
Alvin Salton, BLD

American Academy of Neurology
David A. Krendel, M.D.

American Association for Respiratory Care
Susan Blonshine, RPT, RPFT

Joint Council of Allergy and Immunology & American Board of Allergy and Immunology
Thomas A. Fleischer, M.D.

American Hospital Association
Dan S. Maddock

American Society of Internal Medicine
M. Boyd Shook, M.D.

TEST CATEGORIZATION

See Addendum I for copies of materials supplied by individuals making oral presentations.

Wampole Laboratories
Jean Zych

ChemTrak
Michael P. Allen

DISCUSSION

Following each presentation, the Committee asked questions of the presenter and participated in limited discussion concerning the issues presented.

COMMITTEE RECOMMENDATIONS

Based on the presentations and Committee discussion, the Committee Chairman recommended that the CDC:

- Consider expanding the qualification requirements for technical supervisor of immunohematology to include individuals having a doctorate, master's, or bachelor's degree with appropriate experience;

- Determine if the credentials of neurologists are appropriate qualifications to serve as technical supervisors, general supervisors and testing personnel of anatomic pathology limited to neuromuscular pathology;

- Compare curriculum of training programs for respiratory care with the course work included in medical technology programs to determine appropriateness of the qualifications for blood gas testing personnel.

- Include in the physician-performed microscopy category, the examination of stained nasal smears for the presence of leukocytes;

- Determine if the CLIA standards for Laboratory Director, High Complexity and for Technical Supervisor, High Complexity should list all Professional Board certifications which qualify physicians through laboratory training during medical residency, OR if the use of interpretive guidelines and notification is sufficiently clear and understandable to avoid confusion;

- Consider the development of a grandfather provision to permit individuals who have served for 5 years prior to September 1, 1992 as Laboratory Director or Clinical Consultant for High Complexity Laboratories to quality in lieu of other requirements.

- Develop definitive criteria for categorizing tests as waived. Moreover, declare a moratorium on further review of tests for waived status until the definitive criteria are developed.

GENERAL COMMENTS

The Executive Secretary announced the formation of the following subcommittees:

Test Categorization

Dr. J. Stephen Kroger-Chair
Dr. Paul Bachner
Ms. Michele Best
Dr. Stanley L. Inhorn

Personnel

Ms. Virginia W. Charles-Chair
Dr. J. Scott Abercrombie, Jr..
Ms. Lynne S. Garcia
Ms. Sandra F. Johnson
Dr. Kenneth E. Matthews

Proficiency Testing, Quality Assurance, and Quality Control

Dr. Wendell R. O'Neal-Chair
Dr. S. Raymond Gambino
Dr. Brenda W. McCurdy
Dr. Robert V. Pierre
Dr. Charles G. Ray
Dr. Ronald J. Zabransky

Cytology

Dr. Dorothy L. Rosenthal-Chair
Dr. George D. Lundberg
Dr. Robert M. Nakamura

The Executive Secretary of the full committee will serve in the same capacity for all subcommittees. The ex officio members of the full committee will serve on all subcommittees. The Chairman of the full committee will serve as needed on any subcommittee.

- The Committee was informed that Henry Colvin is retiring on April 30, 1993 and will no longer be CDC's coordinator of the CLIAC meetings.

- The Committee was informed that Tom Tsakeris, ex officio Committee member from the FDA, is leaving the FDA. A new FDA ex officio member has not been named at this time.

- Judy Yost, ex officio Committee member from HCFA, provided the Committee with a report of HCFA's CLIA activities to date.

- The next three Committee meetings are scheduled for May 26 and 27, August 12 and 13, and December 14 and 15, 1993.

The Committee:

- A request was made for CDC to distribute to the Committee a brief summary of the CLIAC's recommendations from the February 17 and 18, 1993 meeting prior to the completion of the official Summary Report.

- A request was made for CDC to provide the Committee members with written copies of the public comments, accepted for presentation, prior to the scheduled meeting. This would allow the Committee members to thoroughly review the comments for discussion and prepare questions ahead of time.

- A request was made to provide each Committee member with a copy of the FDA document, "Draft Guidance to Manufacturers of in Vitro Analytical Test Systems for Preparation of Premarket Submissions Implementing the Clinical Laboratory Improvement Amendments of 1988."

I certify that this summary report of the February 17-18, 1993 meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Morton K. Schwartz, Ph.D.
Chair