Clinical Laboratory Improvement Advisory Committee

May 26-27, 1993

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Record of Attendance

The Clinical Laboratory Improvement Advisory Committee (CLIAC) met at the Centers for Disease Control and Prevention (CDC), Auditorium A, in Atlanta, Georgia on May 26-27, 1993. Those in attendance are listed below:

Committee Members
Dr. Paul Bachner
Ms. Michelle 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. Morton Schwartz

Ex Officio Members
Dr. Carlyn Collins, CDC
Dr. Steve Gutman, FDA
Ms. Judith Yost, HCFA

Executive Secretary
Dr. Edward Baker

Centers for Disease Control and Prevention
Ms. Nancy Anderson
Ms. Rosemary Bakes-Martin
Ms. Louise Barden
Mr. James Bloom
Dr. Joe Boone
Ms. Genoria Bridgeman
Dr. Sandra L. Bullock-Iacullo
Ms. Cheryl Coble
Ms. Carol Cook
Ms. Crystal Frazier
Ms. Clio Friedewald
Mr. Edwin Holmes
Dr. Devery Howerton
Dr. John Ridderhof
Ms. Eunice Rosner
Ms. Elva Smith
Ms. Julie Wasil
Ms. Rhonda Whalen
Mr. Mark White

Introduction to the CLIAC Meeting

May 26-27, 1993

The CLIAC members were welcomed to the meeting by Executive Secretary Baker and Chairman Schwartz.

Executive Summary Report of the February 17-18,1993 CLIAC Meeting

Committee Chairman Schwartz provided a summary of the issues, discussions and recommendations of the previous CLIAC meeting, which was held on February 17-18, 1993. The committee accepted the minutes of that meeting as recorded.

Discussion: Health Care Reform and CLIA

Dr. Schwartz and Dr. Baker reported on the meeting with the Assistant Secretary for Health-Designate, Dr. Phil Lee. They informed the committee that Dr. Lee was very complimentary of the committee and of the recommendations generated by the committee. Dr. Lee indicated that while there was no intention to repeal CLIA, amending or revising the law was still a possibility. He stated that he would welcome input from the committee. Other topics discussed were personnel standards for physician's office laboratories (POL's), the fiscal cost of CLIA, and the need for additional research to determine the efficacy of CLIA. Dr. Lee urged the cooperation of all federal agencies involved.

The Issues

This portion of the meeting was devoted to presentations and discussions concerning the inclusion of mid-level practitioners in the physician-performed microscopy category, the qualification standards for general supervisor and testing personnel of high complexity laboratories, criteria of wavier, general personnel issues and several status reports. The issues were selected primarily in response to the substantial numbers of comments received in response to the *Final Rule* published in the Federal Register dated February 28, 1992 and the *Technical Correction* published in the Federal Register dated January 19, 1993. Public comments made during the February 18-19, 1993 CLIAC meeting were also considered during the selection process.

For each issue, CDC provided a technical overview including background information, the rational for current requirements, and a sampling of the comments received.

The public was permitted to address the committee during the afternoon session on May 27, 1993. Their comments and presentation materials are incorporated into this summary as appropriate.

Physician-Performed Microscopy Category

I. Presentation (See Addendum A)

The technical presentation was made by Carlyn L. Collins, M.D., M.P.H., Director, Division of Laboratory Standards, PHPPO, CDC.

II. Issue

Should mid-level practitioners be included in the physician-performed microscopy (PPM) category?

III. Committee Discussion

The committee recommended that mid-level practitioners be defined to include nurse practitioners, nurse mid-wives and physician assistants. After extensive discussion concerning patient access to health care versus the competency of mid-level practitioners, the committee had not come to a clear consensus and Chairman Schwartz called for a vote. Eleven committee members voted for inclusion of mid-level practitioners in the PPM category. Six members opposed inclusion. Eighteen members were present.

IV. Recommendations

The committee suggested that mid-level practitioners be defined as nurse practitioners, nurse mid-wives and physician assistants. The committee recommended that these mid-level practitioners be included in the physician-performed microscopy category. They indicated that these mid-level practitioners could function independently or under the supervision of a laboratory director.

I. Presentation (See Addendum B)

The technical presentation was made by Ms. Rhonda S. Whalen, Health Scientist, Laboratory Practice Standards Branch, DLS, PHPPO, CDC.

II. Issue

Are the personnel requirements for general supervisor of high complexity testing appropriate?

Ms. Whalen clarified "bachelor's degree" as requested by the committee in the previous CLIAC meeting. She then presented CDC's recommendation that the requirements for general supervisor be revised to prospectively require a bachelor's degree and one year of training. This clinical laboratory training need not be subsequent to acquiring the bachelors degree. For example, individuals with a bachelor's degree in medical technology or clinical laboratory science that includes a one year clinical laboratory training program are not required to have additional experience to qualify as a general supervisor. CDC also recommended that those individuals who were serving as general supervisor on or before the publication date of these regulations, and who meet the alternative requirements, qualify as general supervisor.

III. Committee Discussion

Several committee members noted that the proposal permitted an individual with a non-science bachelor's degree, the appropriate course work, and the completion of a one year accredited laboratory training program, to qualify as general supervisor of high complexity testing. The committee questioned whether additional experience should be required. CDC responded that the proposal set minimum standards requiring these individuals to complete a formal laboratory training program of one year which must include instruction in the specialties of chemistry, hematology, microbiology, immunology and immunohematology. While the committee agreed that this training represented an absolute minimum of experience required, they recognized that imposing additional requirements for training or experience may result in personnel shortages and limit access in rural areas and facilities performing limited high complexity testing. It was noted that the regulations provide minimal standards for all laboratories and individual institutions may need to establish additional personnel specifications based on the volume of services and the complexity of testing performed at their facility.
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III. Committee Discussion (continued)

Most committee members believed that the recommendations provided a good balance between patient access to health care and minimal personnel requirements for education and training. The committee recognized Blaine Miller of the Kansas Hospital Association and permitted him to present data concerning the impact of CLIA on small and rural hospitals.

IV. Recommendations

The committee endorsed the alternative qualifications as recommended. The committee also recommended acceptance of the proposed requirements for a bachelor's degree and agreed that it should include a core curriculum in biology and chemistry, with CDC to determine the acceptable courses within this curriculum.

Testing Personnel - High Complexity

I. Presentation (See Addendum C)

The technical presentation was made by Ms. Louise Barden, Health Scientist, Laboratory Practice Standards Branch, DLS, PHPPO, CDC.

II. Issue

Are the personnel requirements (at minimum an associate degree in medical laboratory technology or laboratory science) appropriate for high complexity testing personnel?

Ms. Barden presented CDC's proposal to establish requirements (number of hours and course work) equivalent to the associate degree, recognize accredited laboratory training programs, and allow those individuals currently performing high complexity testing but who do not hold an associate's degree to continue testing. Individuals would have until 1994 to complete accredited laboratory training programs. High school graduates currently performing high complexity testing could continue testing, provided they have on-site supervision.

III. Committee Discussion

The committee agreed with the provision to qualify those individuals who complete an accredited laboratory training program (including military training) by 1994. CLIAC also supported the proposal to allow high school graduates to continue testing, provided that this provision apply only to individuals who currently perform high complexity testing and do not meet the qualifications for the associate degree or equivalent. The committee emphasized that in the future all high complexity testing personnel entering the field should be required to have at least an associate degree or equivalent. The committee agreed that the current provision permitting laboratories to continue hiring high school graduates until 1997 should be eliminated. The committee recommended that the requirement for on-site supervision of high complexity testing performed by high school graduates be amended to state "on-site supervision **or** review of all test results by the supervisor within twenty-four hours." Several committee members noted that the proposals should prevent qualified individuals from being disenfranchised and avert immediate personnel shortages.

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III. Committee Discussion (continued)

Two committee members asserted that microbiology was more complex and that the baccalaureate rather than the associates degree should be the minimum qualification for performing high complexity testing in that area. Others maintained that many areas of the laboratory were equally complex. Chairman Schwartz called for a vote. Twelve committee members voted in favor of accepting the recommendations as proposed and two were opposed. Eighteen committee members were present. One committee member suggested that the results of formal votes be recorded and include the number of abstentions.

IV. Recommendations:

The committee suggested that the requirement for on-site supervision be amended to state "on-site supervision **or** review of all test results by the supervisor within twenty-four hours." The proposals were otherwise recommended for acceptance.

I. Presentation (See Addendum D)

The status report was presented by Mr. Jim Bloom, Senior Advisor for Public Health Management, Office of the Director, CDC.

II. Issue

How can definitive criteria be developed and applied to meet the statutory requirement for categorizing tests as waived?

Mr. Bloom reported on potential strategies for interpretation of criteria of waiver. He requested approval or redirection by the committee prior to the formulation of a recommendation.

III. Committee Discussion

Following a far ranging discussion on the possible interpretations of the law as it is written, committee members requested a legal interpretation be provided. Executive Secretary Baker indicated that CDC attorneys would provide the committee with this information. This issue was then referred to the test categorization subcommittee. The subcommittee will be provided with a description of the FDA process for clearing tests for home use and other guidance documents.

IV. Recommendations

The committee deferred making a recommendation until the test categorization subcommittee has had the opportunity to acquire the necessary documents, descriptions and interpretations and report back to the full committee.

I. Presentation (See Addendum E)

The presentation was made by Dr. J. Stephen Kroger and the other members of the test categorization subcommittee.

II. Issue

The subcommittee had divided the comment letters received in reference to waived testing among the subcommittee members. Each member read or reviewed their packet of letters including various strategies for criteria of waiver.

III. Committee Discussion

While Chairman Schwartz concluded that there was no consensus, several committee members expressed the view that the operable phrase in the law is "Simple laboratory examinations and procedures which employee methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible" and that this should be the primary criterion in deciding which tests should be considered for waiver. A discussion followed focusing on whether any test cleared for home use by the FDA was consequently waived. Dr. Collins suggested that this issue be referred to the test categorization subcommittee for further discussion. The subcommittee accepted this charge with the request that the FDA attend and participate and that legal definitions be rendered prior to the beginning of their deliberations. The subcommittee will be provided with a description of the FDA process for clearing tests for home use and other guidance documents.

Chairman Schwartz asked the committee to consider the issue of whether the Chemtrak Accumeter or StatCrit instruments should be moved into the waived test category. He then clarified the reasons for considering two tests for waiver when the committee had declared a moratorium on classifying waived tests at the last CLIAC meeting. He stated that the reason he was comfortable with considering only these two tests was that they were "old business" left over from a previous meeting.

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III. Committee Discussion (continued)

The committee discussed the instruments and were generally in favor of moving

the Chemtrak Single Analyte Cholesterol Accumeter into the waived category. It was decided that a review of the information on the StatCrit system would be necessary. Chairman Schwartz left the meeting during the presentation and discussion of the StatCrit system. Mr. Glenn Neuman from Wampole reviewed the information on the StatCrit system for the committee. The committee was not in favor of moving the StatCrit system into the waived category for a variety of reasons. The primary objections were that the hemoglobin was derived and the performance statistics were generally inappropriate to prove the instrument worthy of waived status. Several committee members encouraged the manufacturer to resubmit a similar instrument without a derived hemoglobin and with more relevant and substantial performance statistics.

IV. Recommendations

CDC suggested that the test categorization subcommittee meet for further discussion of the criteria of waiver.

The committee recommended that the Chemtrak Single Analyte Cholesterol Accumeter instrument be moved to the waived category.

The committee advised that the StatCrit Hemoglobin instrument should **not** be moved to the waived category in its current configuration.

I. Presentation (See Addendum F)

This issue was not formally presented in an effort to clear time on the agenda for the committee to continue their discussion of health care reform and CLIA. In lieu of a presentation, Dr. Collins requested that the committee review their handouts on the subject in preparation for a discussion on the following day.

II. Issues

- Should the qualification requirements for technical supervisor of immunohematology be expanded to conform with the qualification requirements for technical supervisor of other specialties and permit individuals with a baccalaureate, master's, or doctoral degree in a science and experience in immunohematology to qualify?

- Should those neurologists who have specialized training in neuromuscular pathology qualify to serve as technical supervisors, general supervisors, and testing personnel of neuromuscular histology?

- Should a provision be made to the blood gas general supervisor and high complexity testing personnel standards to qualify respiratory therapists?

- Should nasal smear examinations for the presence of granulocytes be included in the physician-performed microscopy category?

- Should the CLIA standards for high complexity laboratory director and high complexity technical supervisor list all professional board certifications that qualify physicians through laboratory training during residency **or** is the use of the interpretive guidelines and notifications sufficiently clear to avoid confusion?

- Should a provision be added to the technical supervisor requirements to qualify those individuals who were qualified or could have qualified as technical supervisors under the March 14, 1990 regulations?

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II. Issues continued

- Should individuals who qualify as laboratory directors of high complexity

testing be qualified as clinical consultants in lieu of other requirements?

III. Committee Discussion

The committee was in general agreement that the alternative qualifications proposed for the technical supervisor of immunohematology were appropriate. One committee member expressed concern over a nonphysician serving in this capacity. The committee then turned to the discussion of permitting neurologists to serve as technical supervisors, general supervisors and testing personnel of neuromuscular anatomic pathology testing. One committee member suggested that the CDC recommendation be amended to reflect the correct certification board. The consensus of the committee was that the recommendation was appropriate.

The provision to the blood gas general supervisor was then addressed. One committee member wished to know whether those individuals serving in cardiovascular laboratories would be included. CDC was asked to review the qualifications of these individuals for possible inclusion in this provision. The addition of this proviso was otherwise endorsed by the committee.

The next discussion focused on the addition of nasal smear examinations for granulocytes to the physician-performed microscopy category. Several committee members commented that mid-level practitioners may not be qualified to perform these examinations. One member added that some nurse practitioners may be qualified. Another committee member suggested that the physician-performed microscopy category be divided into subcategories in order to regulate which test the mid-level practitioners may perform. As a whole the committee believed this examination should be added to the PPM category. There was little discussion of the remaining issues as the committee considered the CDC proposals to be proper. Fourteen committee members voted to accept the recommendations as proposed, three opposed and one abstained.

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IV. Recommendations

· The committee recommended expansion of the requirements to permit

those individuals who hold a bachelor's, master's or doctoral degree in a science and have appropriate experience to qualify as technical supervisor of immunohematology.

- The committee accepted CDC's recommendation that those neurologists with specialized training in neuromuscular pathology be qualified as technical supervisors, general supervisors and testing personnel of neuromuscular pathology testing if formal recognition or certification of this training is provided by the American Board of Psychiatry and Neurology.

- The committee endorsed the addition of respiratory therapists to the blood gas general supervisor and high complexity testing personnel.

- The committee recommended the addition of nasal smear examinations for granulocytes to the physician-performed microscopy category.

- The committee advocated the use of the interpretive guidelines instead of regulations as the mechanism to list various qualifications (including physician board certifications) that meet the personnel requirements.

- The committee advised the addition of a provision to the technical supervisor requirements to qualify those individuals who were qualified or could have qualified as technical supervisors under the March 14, 1990 regulations.

- The committee was not in favor of permitting individuals who qualify as laboratory directors of high complexity testing to qualify as clinical consultants in lieu of other requirements.

Dr. Collins reported that cytology proficiency testing cannot be provided by the January 1994 implementation date due to the failure to obtain any bids on a contract for collection of cytology slides. This was followed by some committee discussion.

One committee member inquired as to how many state programs applied for approval of their cytology proficiency testing programs. CDC responded that only the state of Maryland had applied. Another committee member then asked how many slides would be required per proficiency testing event. CDC responded that approximately two thousand sets of ten slides each would be required and that this was the primary reason that the professional organizations felt they could not undertake the program. One member suggested that a requirement that participants contribute slides to the proficiency testing program might help to solve the problem. Other members felt that this program was not feasible on a national basis and that proper solution was to provide proficiency testing state by state. CDC indicated that they would appreciate the involvement of the cytology subcommittee.

- Status of Comments to the February 28, 1992 and January 19, 1993 Rules

- General Updates
- Committee Discussion and Summary Remarks

These informational updates were not formally presented in an effort to clear time on the agenda for the committee to continue the discussion of health care reform and CLIA.

General Discussion of Health Care Reform and CLIA

The committee cleared the agenda so that they might resume the discussion of health care

reform and CLIA. The primary topic of discussion was the validity of site neutrality as a guiding concept in the CLIA '88 regulations. After deliberation, the consensus was that site neutrality was probably still a valid concept, but that site specific implementation may be necessary. Consumer advocate Charles recommended that any inspection process for previously unregulated laboratories needed to be "user friendly" and not be an intimidating process with no opportunity to learn or adapt. It was suggested and generally agreed upon that the educational component of CLIA, i.e., the provision of information to previously unregulated laboratories concerning how they can comply with CLIA, needs to be pursued more aggressively in order to ease regulation anxiety and speed registration and general implementation. It was further suggested that the publications of professional societies and organizations could be instrumental in the distribution of this information.

Public Comments

(See Addendum H)

Edward L. Erickson of Cholestech Corporation voiced his concern over the FDA test categorization backlog then requested that the committee direct CDC to review all

cholesterol systems similar to the Chemtrak Accumeter for possible inclusion in the waived test category.

Kay McCurdy from the American Association of Blood Banks addressed the committee to object to the high complexity general personnel proposal # 1 (Technical Supervisor of Immunohematology). She suggested that the proposal specify that when a non-physician served as the technical supervisor, a physician director would be required. She indicated that AABB would like a physician involved in the day to day operation of the Blood Bank and that the clinical consultant would not be acceptable since this individual does not have broad oversight responsibilities.

Janet Pailet, Director of Government and Regulatory Issues for the American Society of Medical Technology, spoke against moving away from a site-neutral model. She invited the committee to review ASMT complexity models and encouraged them to seek input from the professional organizations.

Mark Birenbaum for the International Society of Clinical Laboratory Technicians asked the committee to modify the language for High Complexity General Supervisor from " individuals who were serving as general supervisor on or before the publication date of these regulations" to those individuals who were qualified or could have qualified as general supervisor on or before the publication date of these regulations." The committee commented that the objective was to prevent disenfranchising those individuals who were currently earning a living in these positions, not to lower the standards for those entering the profession.

Robert Bray, United Network for Organ Sharing - Submitted a written comment.

Kara Anderson for Planned Parenthood of America spoke against proficiency testing for the PPM category indicating she believed it to be without merit.

Jim Branson of the American Dental Association urged the committee to add dentists to the PPM category. The committee indicated they would not make a recommendation without considerably more data on the training and education of dentists in laboratory techniques and the usefulness of the tests being performed.

I certify that this summary report of the May 26-27, 1993 meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

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Morton K. Schwartz, Ph.D
Chairman