Clinical Laboratory Improvement Advisory Committee

Summary Report
March 23-24, 1994

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Clinical Laboratory Improvement Advisory Committee

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Summary

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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 B, in Atlanta, Georgia on March 23-24, 1994. Those in attendance are listed below:

Committee Members
Dr. Scott Abercrombie
Dr. Paul Bachner
Ms. Michelle Best
Ms. Virginia Charles
Ms. Lynne Garcia
Dr. Stanley Inhorn
Dr. Stephen Kroger
Dr. George Lundberg
Dr. Brenda McCurdy
Dr. Robert Nakamura
Dr. Wendell O'Neal
Dr. Robert Pierre
Dr. Charles Ray
Dr. Dorothy Rosenthal
Dr. Morton Schwartz

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

Executive Secretary
Dr. Edward Baker

Non-voting Liaison
Dr. Fred Lasky (HIMA)

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
Ms. Cheryl Coble
Ms. Deborah Coker
Ms. Iris Dixon
Ms. Crystal Frazier
Ms. Clio Friedewald
Dr. Edwin Holmes
Dr. Katherine (Kati) Kelley
Ms. Doris Pattillo
Ms. Patricia Podeszwik
Dr. John Ridderhof
Dr. Shahram Shahangian
Ms. Julie Wasil
Ms. Rhonda Whalen
Ms. Shelba Whaley

Preliminary Business and Meeting Protocol

The meeting was called to order by Dr. Morton Schwartz; welcoming remarks and announcements were made. A summary of the minutes of the December 1993 CLIAC meeting was presented by Dr. Schwartz and approved by the committee.

Presentation of Issues and Committee Discussion

Update on CLIA

Dr. Carlyn Collins presented the following status report on the CLIA documents that are currently in departmental review: the regulation extending a number of CLIA implementation dates is nearing completion of review for publication; the notice of test categorizations completed since July 26, 1993 (publication date of the test categorization compilation) should be published in the near future; the interim regulation remains in the review process, with no projected publication date at this time. Dr. Collins also reported that research activities related to the CLIA studies are in progress. Several requests for proposals and cooperative agreements for cytology studies have been prepared and will be published in the Federal Register.

APT Status

Appendix A

A review and summary of the proposed subcategory of moderate complexity, Accurate and Precise Technology (APT), previously referred to as "robust" testing, was then presented by Dr. Collins. Dr. Collins stated that the establishment of the APT subcategory would maintain appropriate quality standards for those tests that are "almost waived". Under current regulations, no standards apply to waived tests; whereas, standards that are somewhat less stringent than those currently applicable to other moderate complexity tests would apply to the APT subcategory. Creating the subcategory should drive technology toward the development of better quality tests because quality control (QC) protocols would be included in the APT test instructions or would be built into the testing procedure. APT will provide some regulatory relief in that only random inspection of approximately 5% of APT laboratories would be conducted annually.

To qualify for APT subcategorization, a test would be simple and easy to perform, require little or no interpretation, and have demonstrated, through scientific studies, a high level of accuracy and precision. Dr. Collins summarized by saying that the type of tests that might qualify for APT are point-of-care devices, self-contained test kits, small desk top analyzers, and new technology.

Dr. Collins also mentioned that the regulatory proposal for the APT subcategory is currently under review by the Department of Health and Human Services (DHHS). The decision about whether APT should be included in a proposed rule or a final regulation with comment has not yet been made.

Committee Discussion and Recommendation on APT:

A majority of the committee members expressed disagreement with the establishment of the APT subcategory at this time, stating that it would not accomplish what is intended. They felt that APT would not provide sufficient regulatory relief for physician's office laboratories (POLs); that implementation would take too long; and that it would be burdensome for manufacturers.

Considerable committee discussion was focused on the issue of inspections for the APT category, in as much as only random inspections would be required for this subcategory. One committee member stated that since APT is a subcategory of moderate complexity, random inspection is in conflict with inspection being required every two years for moderate complexity. Other committee members also expressed concern about the elimination of routine inspections of APT testing, citing the benefits to laboratorians of an outside audit to evaluate the quality of testing. Dr. Collins responded that Physician-performed Microscopy (PPM), which is also a subcategory of moderate complexity, requires no inspections, and said that there is some flexibility in the law and the regulations as to how inspection is to be done. Random inspection would save money and time, but would still provide enough information to determine if the system is working.

Another committee member then pointed out that moderate complexity laboratories, including the smaller laboratories and POLs which might be in the APT category, are the laboratories that need regulation the most. He stated that inspectors are able to determine quickly the competency of laboratory personnel, and referred to the large number of quality control and quality assurance deficiencies reported by COLA and HCFA from inspections of POLs. He expressed concern that POLs may continue to have quality problems if only 5% of the APT laboratories are randomly inspected annually, since POLs learn and correct deficiencies as a result of inspections. Dr. Collins reemphasized that requiring the manufacturer to include QC and QA in test system instructions would build quality into the testing that is performed in the APT subcategory.

Other committee members supported the subcategory, stating that APT would be beneficial, especially if it provides incentives to drive technology towards better quality tests in the future. One committee member pointed out that the implementation of CLIA has increased the number of inspected laboratories from 12,000 to 157,000, many of which are POLs. The committee should consider that

political pressure to provide regulatory relief to POLs includes an option of no regulation of POLs, suggesting that APT with random inspection would be preferable to no regulation at all.

A committee member asked if the intent was for APT to arrive on the scene with a list of tests in the category and if there are government resources to bring APT to reality. Dr. Collins responded that there would be a set of criteria for APT and that studies would be done to determine if tests met the criteria. She said that Dr. Philip Lee, Assistant Secretary for Health, does not intend to implement something the government cannot support.

Dr. Fred Lasky, a non-voting liaison to CLIAC, reported that the manufacturers and HIMA had discussed which tests should be available in POLs to improve patient care and which tests would meet the APT criteria. They felt that the studies required to qualify for APT are costly and not trivial, and that the proposed criteria are so stringent that only a small proportion of tests would meet the criteria. There would be no benefit for a POL if all tests performed in the POL did not meet the APT criteria. He questioned if the cost of implementing APT would be counteracted by the savings in inspection cost, or if the cost eventually would be passed on to the consumer. Another committee member expressed concern that testing personnel in POLs might not have the background necessary to recognize and investigate failures of tests in the APT subcategory. The lack of the personnel requirement for a technical consultant in the APT subcategory was discussed. Dr. Collins indicated that the role of technical consultant for the moderate complexity tests in APT would essentially be performed by the manufacturer.

Dr. Schwartz summarized the committee discussion by stating that some committee members felt that APT would be appropriate for future technological development and might provide some relief for POLs, while other committee members felt that APT would be of no benefit to laboratories unless all tests performed in a particular laboratory were APT tests, and that implementation would take too long. He indicated that APT is probably not feasible for the manufacturer. Therefore, the consensus reached by the committee was that now is not the appropriate time to create this new subcategory as described, although it might warrant future consideration. Sentiment was expressed, however, in favor of minimizing the regulatory burden on POLs.

CLIA Information and Education Plans

Dr. Kati Kelley, Chief of the Laboratory Practice Training Branch (LPTB) and a former State Public Health Laboratory Director, presented an overview of the history, function, and activities of the LPTB and the National Laboratory Training Network (NLTN). She emphasized the value of the importance of bringing

education and training to laboratorians by developing course materials and training programs in response to needs assessment, and discussed interactive computer based training and distant based satellite courses. She indicated that the LPTB continues to work with the National Center for Infectious Diseases (NCID) in the development of training focused on emerging pathogens, CD4 testing, multidrug-resistant TB, and hantavirus.

Dr. Kelley highlighted the role that the NLTN has played in co-sponsored educational courses relating to CLIA. A segment of "CLIA by Satellite" was shown to the committee. This course was developed in cooperation with the State of Florida in response to requests for orientation and training appropriate for physicians who, under CLIA regulations, would be directors of moderate complexity testing. Included in the course were post-training assessment "self-studies", panel discussions, and opportunities for the participants to telephone or fax questions to receive additional information. More than 200 physicians participated in this course.

Following Dr. Kelley's presentation, the committee discussed alternative methods of bringing CLIA-related educational materials to physicians and laboratorians. Members of the committee stressed that personnel employed in previously unregulated laboratories have the greatest need for education to assist them in meeting the CLIA requirements to provide quality laboratory services.

Subcommittee report on Proficiency Testing (PT) Appendix B

Dr. Wendell O'Neal summarized the meeting of the PT subcommittee, and presented its position on CDC's proposed regulatory changes that are focused on increasing the number of PT samples that can be graded. Currently, a large number of PT samples cannot be graded by the PT providers due to the parameters which determine the gradability of a sample, i.e., the percent and type of consensus necessary to determine the target value or correct response. When a PT sample is ungraded, the participating laboratory automatically receives a score of 100% on that sample, a process that can inadvertently mask poor performance by the laboratory. The regulatory changes proposed by CDC to increase the gradability of PT scores entail the use of referee laboratory results rather than peer group laboratory results for determining target values for specific areas of PT, and changing consensus requirements from 90% to 80% to determine gradability of PT samples. The subcommittee recommended that the full committee support three of the CDC proposed changes and suggested that additional data was needed concerning the fourth. The full committee discussed each of the CDC's specific proposals and made its recommendations, as follows:

- For immunohematology, change the regulations to require that PT grading be based on the results of referee laboratories, with no change in the consensus required for grading, which is 100% for ABO group, Rho(D) type, and compatibility testing, and 95% for unexpected antibody detection and identification.

- For hematology blood cell identification (morphology), change the regulations to require that PT grading be based on the results of referee laboratories, with no change in the 90% consensus required for grading.

- For microbiology organism identification and stain reactions, change the regulations to require that PT grading be based on the results of referee laboratories, with no change in the 90% consensus required for grading.

- For tests not included in the previous three recommendations, CDC should present data to the CLIAC on the impact of changing the consensus required for grading from 90% to 80%. This information should also include data relevant to susceptibility testing and rapid antigen detection.

In considering the use of referee laboratories, the committee suggested, but did not make a formal recommendation, that these laboratories: 1) be demographically representative of the participating laboratories; 2) be randomly chosen (within demographic considerations) from a select pool of laboratories having successful PT performance records; 3) perform testing in a manner identical to other participating laboratories; and 4) be unaware of their status as referee laboratories.

In response to public comment that some laboratories have received unsatisfactory grades due to clerical or administrative errors in the submission of PT results, even though these errors do not necessarily reflect performance problems in testing patient specimens, the committee recommended that HCFA reiterate the policy of surveyor intercession to assess the nature of a problem before any sanctions are applied. The committee further indicated that efforts should be made to shorten the process of recertification for laboratories that lose their certification as a result of PT failures, albeit for legitimate performance problems.

Public Comments

Public comments were presented by Mr. R.J. Slomoff, representing HemoCue, Ms. Toni Casey, a health care consultant, and Ms. Ann Strength, a laboratory manager.

Mr. Slomoff inquired if all spun microhematocrit tests and all glucose meters cleared by the Food and Drug Administration (FDA) for home use are waived. Dr. Collins responded in the affirmative. He then requested that the committee support expeditious publication of the waived criteria. Dr. Schwartz stated that no effort has been made by CDC or the CLIAC to delay publication, and Dr. Collins indicated that the waived criteria are currently in departmental review.

Ms. Casey requested the CLIAC consider a change in the CLIAC meeting format to allow public comment after each subject. She then commented that although waived tests are not subject to Federal quality control standards, many laboratories routinely perform quality control on these tests. In addition, she pointed out that the moratorium on the addition of tests to the waived category, which theoretically was to last for three months, has now been in effect for over a year. She commented that although the ChemTrak cholesterol test system had been approved by CLIAC for addition to the waived category, the company cannot market the product as a waived test because the waived categorization has not yet been published in the Federal Register.

Dr. Schwartz responded that Ms. Casey's request for a change in the meeting format would be considered. He also pointed out that the committee does not approve tests for the waived category, but instead recommends that tests meet the criteria for waived categorization. Ms. Charles asked for, and received, confirmation from Dr. Collins that Federal Register publication of the waived criteria would clarify that tests cleared by the FDA for home use are not automatically waived.

Ms. Ann Strength indicated that physicians are having difficulty obtaining current, reliable, and official information on CLIA regulations and interpretive guidelines for implementation, and asked if, in addition to the publication of the regulations in the Federal Register, the NLTN could be a source for this information . The committee discussed various means of responding to requests for correct, up to date information on CLIA, including an E-mail system, hotlines, summary documents, and electronic access.

Concluding Remarks

Concluding remarks by committee members addressed two concerns: the first, that educational aspects of CLIA inspections might be reduced due to lack of funding; and the second, that since the FDA will apparently not meet the September 1, 1994 date for review and clearing quality control protocols for laboratories to use in meeting the CLIA requirements, there may need to be some regulatory relief for affected laboratories.

The proposed dates for future CLIAC meetings in 1994 are June 8-9, September 27-28, and December 13-14.

I certify that this summary report of the March 23-24, 1994 meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Morton K. Schwartz, Ph.D.
Chairman

Addendum A

Accurate and Precise Tests (APT)

Addendum C