Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

SEPTEMBER 27-28, 1994

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Clinical Laboratory Improvement Advisory Committee

September 27-28, 1994

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 A, in Atlanta, Georgia on September 27-28, 1994. Those in attendance are listed below:

Committee Members
Dr. J. Scott Abercrombie
Dr. Regina Benjamin
Ms. Michelle Best
Ms. Virginia Charles
Dr. Susanne Gollin
Dr. Stanley Inhorn
Dr. Verlin Janzen
Ms. Sandra Johnson
Dr. J. Stephen Kroger
Dr. Aliza Lifshitz
Dr. Bereneice Madison
Dr. Kenneth Matthews
Dr. Wendell O'Neal
Dr. Glenda Price
Ms. Deborah Reed
Dr. Patricia Saigo
Dr. Morton Schwartz
Mr. Elliott Segal

Ex Officio Members
Dr. Carlyn Collins, CDC
Mr. David Lyle, FDA
Ms. Judith Yost, HCFA

Executive Secretary
Dr. Edward Baker

Liaison Representative
Dr. Fred Lasky (HIMA)

Consultants
Ms. Jane Bacher, CAP
Ms. Dawn Crawford, Idaho
Mr. David Hassemer, Wisconsin
Dr. Ira Salkin, New York
Mr. Nick Serafy, AAB

Centers for Disease Control and Prevention

Ms. Nancy Anderson
Ms. Rosemary Bakes-Martin
Ms. Louise Barden
Ms. Sharon Blumer
Dr. Joe Boone
Ms. Genoria Bridgeman
Ms. Sandra Bullock-Iacullo
Ms. Cheryl Coble
Ms. Debbie Coker
Ms. Carol Cook
Ms. Lisa Cooper
Mr. David Cross
Ms. Judy Delany
Ms. Iris Dixon
Ms. Crystal Frazier
Ms. MariBeth Gagnon
Ms. Angela Glaude-Hosch
Ms. Sharon Granade
Mr. Tom Hearn
Mr. Edwin Holmes
Dr. Richard Keenlyside
Dr. Katherine Kelley
Mr. Patrick Minor
Ms. Anne O'Connor
Ms. Pat Podeszwik
Dr. John C. Ridderhof
Ms. Eunice Rosner
Dr. Shahram Shahangian
Ms. Elva Smith
Ms. Julie Wasil
Ms. Rhonda Whalen
Mr. Mark White
Ms. Darlyne Wright

Welcome and Opening Remarks

The meeting was called to order by Dr. Morton Schwartz, CLIAC Chairman, who extended a welcome to the new members of CLIAC. Self-introductions were made by all members of CLIAC, and Dr. Schwartz announced that Dr. Philip Lee, Assistant Secretary of Health, would be joining the meeting via closed circuit television.

Dr. Lee, speaking from Washington, acknowledged the committee and its past accomplishments. He stated that CLIAC is considered one of the more important advisory committees to the Department of Health and Human Services (HHS); one that offers good advice in regard to key issues; and one that helps to expedite the review process through his and the Secretary's office, and the Office of Management and Budget. He conceded that this process is not always a smooth one due to the seriousness of the problems to be solved, and the significant disagreement that arises concerning some issues. He expressed his thanks to the committee and to Dr. Schwartz, and indicated that he would look forward to working with them in the future.

Dr. Edward Baker, CLIAC Executive Secretary and Director of the Public Health Practice Program Office for CDC, extended his welcome to the committee and its new members. He recognized the past contributions of the committee, which he considers an essential component in the CLIA implementation process, and voiced his appreciation for the members' time and efforts.

Dr. David Satcher, Director of CDC, expressed his welcome to the committee and its new members. He acknowledged that the implementation of the CLIA regulations is now marking its two-year anniversary, and that these regulations have been difficult to communicate to the public and the clinical laboratory community. He indicated that CLIAC is important in providing an open forum for discussion and serving in an advisory capacity to balance the need for requirements that are appropriate for quality laboratory testing while maintaining the public's access to health care. He further observed that the committee is willing to tackle difficult issues and provide consultation and advice, and noted that the physician-performed microscopy (PPM) category was established in 1993 following recommendation by this committee. Dr. Satcher reiterated CDC's vision of "healthy people in a healthy world through prevention," and outlined CDC's four priorities:

1. To strengthen the core functions of the public health system;

2. To enrich capacity to respond to urgent threats to public health, such as, emergency epidemics, emerging infections, environmental toxins, and intentional and unintentional injury (violence);

3. To develop and implement nationwide prevention strategies, such as child immunization, AIDS education, and programs on teenage use of tobacco; and

4. To promote women's health, focusing on domestic violence, early detection of cervical and breast cancer, sexually transmitted diseases, etc.

Dr. Schwartz and Dr. Lee both saluted CDC and applauded its past accomplishments and future commitments.

Orientation for New Members

Dr. Schwartz explained to the new committee members that CLIAC was established by the Department of Health and Human Services (HHS) in section 493.2001 of regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and that the charter, which defines the composition and term requirements of the committee, was signed into law by Dr. Louis Sullivan in February 1992. He emphasized that the charge to the committee is to advise and make recommendations on technical and scientific aspects of the provisions, and that implementation of any such recommendations is not automatic, but rather is taken into consideration as a part of HHS decision making.

History of CLIA **Addendum A**

Dr. Baker presented a brief history of CLIA from the enactment of the statue in 1988 to the present. He stressed to committee members that it is their responsibility to provide advice to HHS, and it is the responsibility of HHS to consider their advice. If HHS does not agree with the advice it receives, it will return to CLIAC and explain its reasons for disagreement. He stated that in particular, he would look to CLIAC for advice on CLIA's impact on access to health care.

Dr. Baker then reflected on the revisions to the regulations, PPM and the waiver of certain hemoglobin tests, that occurred in 1993, and the role the committee played in these revisions. He also summarized the key features of the act; discussed the CLIA standards, including quality assurance, proficiency testing, patient test management, quality control, and personnel requirements; reviewed the complexity model and test categorization; and reiterated CLIAC's responsibilities.

Committee discussion ensued and one member asked for an explanation of patient test management. Dr. Baker responded that it relates to how pre-analytic and post-

analytic test information on the patient is handled. The committee member then brought up the problems associated with shared laboratories, and asked what role the committee has played in this area. The committee member expressed concern about who, in a shared laboratory situation, is responsible for the quality of laboratory services provided, and how to handle the billing problems that arise. Dr. Schwartz stated that CLIAC has discussed the situation of shared laboratories, but has not made any recommendations in this regard. Ms. Judith Yost, of the Health Care Financing Administration (HCFA), offered to discuss HCFA's policies in regard to shared laboratories with the commenter. Dr. Baker stated that the issue of billing in shared laboratories is not a CLIA issue, but rather pertains to laboratory reimbursement. Dr. Schwartz commented that laboratory quality is a CDC and a HCFA issue.

Administrative Procedures and the CLIAC Process **Addendum B**

Dr. Carlyn Collins, Director of the Division of Laboratory Systems, CDC, outlined the structure of HHS, and described CLIAC's relationship to this structure. She also referred the committee to the brochure which had been distributed entitled "The Federal Advisory Committee Act: An Overview" and pointed out that the information contained therein applies to CLIAC and its members.

Dr. Collins then detailed how the rule making process occurs and explained why this process is so time consuming. She stressed that the rule making process is deliberative by necessity since the end results affect many people. Therefore, all comments to proposed rules are considered, and much time is spent meeting, considering, discussing and, hopefully, resolving the issues. She went on to explain that consensus among all interdepartmental components and affected agencies is required before regulations can be enacted.

A committee member then asked Dr. Collins to provide an estimate of the time required for a CLIAC recommendation to go through the process and become part of the regulation. Dr. Collins replied that this time frame can vary considerably depending on the complexity of the issues involved. She pointed out that a CLIAC recommendation is only one part of the process, albeit an important part. In response to this remark, a committee member asked how an issue might be brought before CLIAC. Dr. Schwartz replied that potential issues for CLIAC discussion should be submitted to him in writing, and that he would attempt to have them placed on the CLIAC agenda. Dr. Schwartz also asked Dr. Collins for an update on prior CLIAC recommendations, and Dr. Collins indicated she would provide this update later in the meeting.

A committee member inquired as to the obligation of HHS to respond to both

negative and positive comments on the regulations. Dr. Collins replied that most comments submitted are from people who want a change; in general, those who favor the regulations do not comment. However, HHS is required to respond to all comments. The committee member indicated that it would appear that public health is driven by negative comments and special interests. Dr. Schwartz responded that this committee (CLIAC) should act as a buffer to political pressure exerted by special interest groups, and Dr. Collins stated that HHS intends to make decisions and implement policies that will best serve the public.

Another committee member expressed concern about the length of time required for the regulatory "process," citing the numerous meetings and discussions that are included in the overhead entitled "Detailed Process for Regulation Publication". Dr. Collins responded that these meetings and discussions reflect the layers of negotiations required to come to resolution. She explained that many people who participate in the process do not have scientific or technical expertise; for example, some in the process have concerns regarding access to care, while others have cost concerns. All agencies within HHS have the option to question and object to any proposed regulations as they see fit.

A committee member then asked for the specific names of persons or departments that are responsible for delaying publication of these regulations. The member expressed concern that some laboratories are being given deficiency citations that they would not receive if the regulations were revised in accordance with the CLIAC recommendations. Dr. Collins summarized the agencies involved in the regulatory process and explained that communication occurs staff-to-staff as well as agency-to-agency, and that pertinent discussions and reviews can take place simultaneously. Ms. Yost stated that the regulatory staff decides the itinerary of a proposal, and that proposals related to CLIA are widely distributed. She further explained that HCFA must conduct inspections based on current, not pending, regulations.

Further discussion revolved around the possibility of a spreadsheet outlining the recommendations made by CLIAC and their current status in the regulatory process. Dr. Schwartz pointed out that the College of American Pathologists (CAP) had developed such a spreadsheet and asked that it be provided to the committee.

One committee member asked if there were ground rules for CLIAC and another member suggested that the matter of voting should be considered. Dr. Schwartz replied that there are no ground rules, per se, and that CDC usually chooses the issues for the meetings based on comments from the public. However, he noted that the CLIAC committee members have the obligation to propose issues for discussion that they consider relevant. Dr. Schwartz indicated that it was not always necessary to bring issues to a vote if there was general consensus in the committee, but that votes were sometimes solicited.

Conflict of Interest

Mr. Kevin Malone, General Council, Office of the Director, CDC, gave a brief overview of the conflict of interest rules pertaining to the members of the CLIAC. He stated that committee members should be aware that they are Federal employees when serving on CLIAC, and as such, should not have financial interests that would compromise their participation. However, he explained, in as much as financial conflicts of interest are inherent in advisory committee membership, waivers are granted.

Travel Guidelines — Addendum C

Ms. Julie Wasil reviewed the guidelines and rules that apply to the members of CLIAC when they are in travel status. She briefly outlined travel policies, allowances, and methods for claiming reimbursement for allowable travel expenses. Some discussion ensued concerning travel that does not originate or terminate at the member's official duty station. Ms. Wasil indicated that the member is entitled to cost reimbursement for that portion of the ticket that would only cover travel between the member's official duty station and the location of the meeting.

CLIA Information Activities — Addendum D

Dr. Kati Kelley, Chief of the Laboratory Practice Training Branch, CDC, presented an update on past, current, and anticipated activities related to the dissemination of CLIA information to laboratory professionals and the general public. Such information is provided in publications, in presentations offered by professional organizations, in training programs sponsored by the National Laboratory Training Network, in workshops and lending libraries, and by other means such as the recently offered satellite course that was primarily designed for physicians in public health clinics and physician office laboratories.

Future plans call for the provision of CLIA information via direct computer access. Currently, the complexity test system categorization list is available by computer disc, and CDC is actively investigating the possibility of using Internet to provide this same test categorization information, as well as pertinent CLIA Federal Register publications and updates on CLIA issues.

As a preview of the Internet capabilities, a demonstration was presented by Ms. Darlyne Wright of the Information Systems Activity Branch, CDC. This computer demonstration displayed the CLIA Test Complexity Categorization List in

a variety of configurations, and illustrated the capability of obtaining categorization information based upon an analyte, test system, or the Food and Drug Administration (FDA) 510(k) number for a specific analyte/test system combination.

Following the demonstration, Dr. Kelley discussed recently negotiated cooperative agreements between CDC and the Commission on Laboratory Accreditation and the American Society for Clinical Laboratory Science to develop other avenues for distribution of CLIA information and training to the physician office laboratory community. She also announced the possibility of a Laboratory Institute conference in Atlanta in 1995 to bring together laboratorians, physicians and policy makers to discuss present research activities and plans for the future, to develop mutual objectives, and to provide additional means of information exchange.

Subcommittee Meeting on Proficiency Testing, Quality Assurance and Quality Control

The subcommittee meeting was presided over by Dr. Wendell O'Neal and the summary report may be found in a separate document. Please note that on the subcommittee report Dr. Collins and Mr. David Lyle, representing FDA, should have been listed as voting members of the subcommittee. However, Dr. Collins and Mr. Lyle abstained from participation in both votes taken.

Presentation of Issues and Committee Discussion

Dr. Schwartz called the meeting to order and asked that the committee members consider the dates for the next two CLIAC meetings. The members agreed to cancel the meeting scheduled for December 13-14, 1994, and to schedule full committee meetings on January 11-12 and May 10-11, 1995. (The CLIAC meeting scheduled for January 11-12, 1995 was subsequently cancelled.)

The spreadsheet developed by CAP containing information on previous CLIAC recommendations was distributed to the committee members.

General CLIA Update — Addendum F and G

Dr. Carlyn Collins began her update on the status of CLIA regulatory revisions by addressing the prior CLIAC recommendations as outlined on the CAP spreadsheet. However, in response to questions from the committee members, Dr. Collins decided that it would be less confusing to begin by explaining the content of the various regulatory revisions and their current location in the review process.

Dr. Collins explained that revisions to the phase-in dates established in the February 1992 regulation, were continued in the Date Extension Regulation. This regulation, includes revisions to the effective date for cytology PT enrollment, phase-in of QC for moderate complexity laboratories, requirement for board certification for directors of high complexity laboratories, and announces HHS recognition of the American Society of Clinical Pathologists as a certifying agency for cytotechnologists. Dr. Collins noted that this regulation is ready for the Secretary's signature and should be published in the next few weeks. (The regulation was published in the Federal Register on December 6, 1994.)

Dr. Collins indicated that the Interim Final regulation is currently in departmental clearance. Work began on this revision to the regulation in the summer of 1993, and it contains many of the CLIAC recommendations, including addition of mid-level practitioners and dentists to PPM and revisions to the qualification requirements for high complexity testing personnel and general supervisor.

Committee members had numerous questions regarding the regulatory documents and their status in the review process. One member was concerned about the possibility of additional delay in approval for publication. Dr. Collins conceded that this is a possibility, but an unlikely one as the issues are in review concurrently by staff in more than one department component or agency.

One committee member asked if the accurate and precise technology (APT) category was contained in the interim final rule, and pointed out that CLIAC had previously expressed opposition to addition of this new subcategory of moderate complexity. Dr. Collins indicated that APT is now included in a proposed rule that would offer opportunity for public comment. She explained that CDC believes we need a subcategory that allows opportunity for new technology with quality assurance and quality control protocols included and requires less stringent oversight. Another member countered that this new subcategory is contrary to the advice offered by CLIAC. Dr. Schwartz replied that CLIAC is, in fact, an HHS advisory committee and that CLIAC can only expect that CDC will explain instances which the Department did not take CLIAC's advice. It was then pointed out by other committee members that CLIAC had supported the general concept that there be some kind of regulatory relief for the physician office laboratory.

Another committee member stated that industry was concerned that the proposed requirements for APT were unachievable. Ms. Rhonda Whalen, Division of Laboratory Systems, CDC, responded that in response to the CLIAC concerns, APT was included in a proposed rule that will contain a comment period to solicit comments and allow all concerned parties an opportunity to express their views.

Dr. Collins was asked whether other recommendations made by CLIAC had been accepted by CDC. Dr. Collins indicated that, in general, all of the CLIAC recommendations had been accepted by CDC and most would be included in one of these publications.

Additional discussion centered on the length of time required to move a regulation through the clearance process for publication, and one committee member indicated that the public deserves a more efficient process.

HCFA Update and PT Implementation **Addendum G and H**

Ms. Judith Yost presented an update on CLIA enrollment and a review of HCFA's survey and certification activity. Details of this information are contained in the overheads and materials provided with this summary. Ms. Yost stressed that HCFA is approaching laboratories with the view that the inspections are being conducted to assist laboratories in achieving compliance with the CLIA requirements, and that sanctions would only be taken in the case of immediate jeopardy or refusal to comply.

One committee member asked for an elaboration of "immediate jeopardy," and Ms. Yost replied that it could mean that the laboratory was reporting results without any type of quality control, was reporting values inconsistent with life, or was employing unqualified personnel. Another member asked for clarification of shared laboratories, and Ms. Yost defined such a laboratory as one that was utilized by several different physicians who were all located in the same building, but not necessarily in the same office.

Other committee members expressed their concerns about the cost to the physician for CLIA certification. Ms. Yost indicated that compliance fees are based on laboratory size, with the cost of inspection varying by the number of specialties and test volume. HCFA is aware of, and is giving consideration to, the cost problem. Dr. Schwartz commented that fee collection is part of CLIA implementation, and that CLIAC has been concerned about the costs associated with CLIA.

Ms. Yost then addressed the subject of proficiency testing (PT) in the clinical laboratory. She stated that PT is only one aspect of quality control in the laboratory, and that PT is only required on regulated analytes. There are no PT requirements for laboratories issued a certificate of waiver, and no approved PT programs include analytes or tests categorized in the PPM subcategory. Cytology PT will be implemented through a sequential process. PT requirements are detailed in the overheads and information provided with this summary. She pointed out that there is a strong focus on education in PT programs, which is a

positive aspect for both the laboratory and the inspector, and PT surveys indicate that compliance with the PT requirements is being achieved.

PT Update and Subcommittee Report **Addendum I**

Dr. Wendell O'Neal presented a summary of the subcommittee meeting on proficiency testing, and a detailed synopsis of this meeting is included in the subcommittee report. The subcommittee voted five in favor and one against recommendation #1, i.e., changing the consensus required for PT grading from 90% to 80% for microbiology organism identification and stain reactions based on the results of referee laboratories. The subcommittee voted six in favor and zero against recommendation #2, i.e., changing from 90% to 80% consensus, based on the PT provider's choice of referee laboratory or peer groups, for all tests **except** those in immunohematology, hematology blood cell identification (morphology), and microbiology organism identification and stain reactions. This change also applies to microbiology rapid antigen detection and susceptibility testing.

Committee discussion of the PT subcommittee report ensued with the request for clarification of the difference between reference and referee laboratories. In response, it was stated that the definition of reference and referee laboratories has not changed since the 1967 regulations, and that a reference laboratory is a laboratory that does **not** participate in the PT survey. The reference laboratory can be utilized as an outside source to substantiate the expected result values the PT provider has determined for its PT samples. Referee laboratories are the better performers from the population of laboratories participating in a given survey. If 90% of the referee laboratories must agree before a PT sample can be considered valid, the number of gradable PT results will be less than if only 80% of the referee laboratories must agree. Discussion then centered on the value of having more gradable PT samples, and it was generally acknowledged that having more gradable samples provided more educational opportunities for the laboratories.

Dr. Schwartz then called for a full committee vote on the subcommittee recommendations. The committee voted 14 for and 4 against subcommittee recommendation #1; a unanimous vote was voiced for subcommittee recommendation #2.

Committee Discussion

Dr. Schwartz opened the meeting to general discussion on any topic related to CLIA.

The first committee member asked about the status of CLIA funds allocated to the FDA. Ms. Yost and Mr. Dave Lyle, of FDA, both replied that FDA had received virtually no CLIA funds. Another committee member then stated that it appears that QC clearance by the FDA is in a "bottleneck," and that there has been a delay in test categorizations, and asked how these issues are to be handled.

Dr. Collins responded that although FDA was supposed to take over test categorization on September 1, 1992, and was to have QC clearance in place by September 1, 1994, neither have occurred. HHS is currently reviewing the situation and is considering eliminating the FDA CLIA role. If this happens, CDC will likely assume responsibility for test categorization. The clearance of quality control protocols for CLIA compliance will need to be resolved.

Another committee member addressed the APT subcategory in relation to the physician office laboratory, and expressed his concern that the change in the regulations which created PPM, and the proposed change to create the APT subcategory, were lowering CLIA requirements and prohibiting adequate inspections for POLs. Other committee members countered that the private physician needs to be able to do some laboratory testing without regulatory oversight. Another member felt that CLIA had evolved into a workable situation as evidenced by the small number of laboratories being sanctioned.

A committee member then asked how CLIA information is disseminated. Dr. Schwartz replied that professional organizations are usually very quick to publish updates. But another member inserted that frequently information about a regulatory change is published before a regulation actually goes into effect and it causes confusion. Dr. Schwartz commented that the possibility of disseminating CLIA information on the Internet was demonstrated for the committee, and that, hopefully, technology will help resolve this problem.

The question was then raised as to whether or not the committee members could establish a subcommittee among themselves. Another committee member indicated that a subcommittee on patient test management might be in order. Dr. Schwartz responded that there is an established process for creating a subcommittee, and that the issue of forming additional subcommittees should be discussed with CDC.

Public Comments

Dr. Schwartz then opened the meeting to public comments.

Mr. Robert J. Slomoff, representing HemoCue, saluted CLIAC and HHS for their waiver of the HemoCue hemoglobin instrument stating that this action had

benefited the public, women and children in particular. He then stated that HemoCue also manufacturers a glucose instrument which is very similar to the hemoglobin instrument and that his company currently has a petition with FDA to classify it as a "home use" instrument. He asked if the HemoCue glucose would become waived if approved by FDA for home use. Dr. Collins responded that in as much as the current regulations include in the waived category, blood glucose monitoring devices cleared by the FDA specifically for home use, the HemoCue glucose would be waived if approved by FDA for home use.

Ms. Chris Paul, representing the State of Georgia, spoke about the educational processes that have been developed and utilized to assist clinical laboratories in understanding and complying with the CLIA regulations. She cited the guidelines that were developed and distributed by HCFA, and the many seminars presented by the State of Georgia to explain the CLIA requirements and the certification process. She indicated that inspections are now scheduled in advance with the facilities, and pointed out that inspectors are restricted to citing deficiencies according to published regulations not to proposed regulatory changes until they are published and effective. Ms. Yost clarified that HCFA is allowing laboratories to respond to certain cited deficiencies in personnel standards by identifying compliance with impending regulations.

Ms. Jill Findlay, representing ChemTrak, addressed the company's request to waive the ChemTrak Accumeter for cholesterol, citing CLIAC's recommendation in favor of this recategorization and the clearance by the FDA in 1993 for its over-the-counter use. She explained that it has now been more than 16 months since the company had been told the instrument would be waived, and that the delay is translating into layoffs and reduced research and development in their small company. (On December 19, 1994, CDC notified manufacturers that the moratorium on considering requests for waiver was lifted and waiver will be granted to any test system that meets the statutory criteria for waiver provided scientifically valid data are submitted verifying the waived criteria. In addition, CDC included guidelines to assist applicants in submitting waiver requests. These guidelines that clarify the waived criteria are included in a notice of proposed rule making that is scheduled for Federal Register publication.)

As there were no other public comments, Dr. Schwartz adjourned the meeting.

I certify that this summary report of the September 27-28, 1994, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.

Morton K. Schwartz, Ph.D.
Chairman