Clinical Laboratory Improvement Advisory Committee

Summary Report

December 14-15, 1993

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Clinical Laboratory Improvement Advisory Committee

December 14-15, 1993

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 December 14-15, 1993. Those in attendance are listed below:

Committee Members

Dr. J. Scott Abercrombie
Dr. Paul Bachner
Ms. Michelle Best
Ms. Virginia Charles
Dr. S. Raymond Gambino
Ms. Lynne Garcia
Dr. Stanley Inhorn
Ms. Sandra Johnson
Dr. J. Stephen Kroger
Dr. George Lundberg
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
Ms. Jan Ohrmundt, FDA
(for Dr. Steve Gutman)
Ms. Judith Yost, HCFA

Executive Secretary

Dr. Edward Baker

Non-voting Liaison Representatives

Dr. Fred Lasky (HIMA)

Centers for Disease Control and Prevention

Ms. Nancy Anderson
Ms. Rosemary Bakes-Martin
Ms. Louise Barden
Mr. Jim Bloom
Dr. Joe Boone
Ms. Genoria Bridgeman
Ms. Cheryl Coble
Ms. Carol Cook
Ms. Crystal Frazier
Ms. Clio Friedewald
Ms. Sharon Granade
Mr. Tom Hearn
Mr. Edwin Holmes
Ms. Anne O'Conner
Dr. John C. Ridderhof
Dr. Shahram Shahangian
Ms. Elva Smith
Dr. Steven Steindel
Dr. Andrew St. John
Dr. Tina Stull
Ms. Julie Wasil
Ms. Rhonda Whalen
Mr. Mark White

Clinical Laboratory Improvement Advisory Committee

The Secretary of Health and Human Services is authorized under Section 353 of the Public Health Service Act, as amended, to establish standards to assure consistent, accurate, and reliable test results by all clinical laboratories in the United States. The Secretary is authorized under Section 222 to establish advisory committees.

The Clinical Laboratory Improvement Advisory Committee (CLIAC) was chartered in February 1992 to provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

The Committee consists of 20 members, including the Chair. Members are selected by the Secretary from authorities knowledgeable in the fields of microbiology, immunology, chemistry, hematology, pathology, and representatives of medical technology, public health, clinical practice, and consumers. In addition, CLIAC includes three ex officio members, or designees: the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; and the Administrator, Health Care Financing Administration.

Due to the diversity of its membership, CLIAC is at times divided in the guidance and advice it offers to the Secretary. Even when all CLIAC members agree on a specific recommendation, the Secretary may not follow their advice due to other overriding concerns. Thus, while some of the actions recommended by CLIAC may eventually result in changes to the law, the reader should not infer that all of the advisory committee's recommendations will be automatically accepted and acted upon by the Secretary.

Welcome and Announcements

Dr. Baker greeted the Committee members and thanked them for their attendance and efforts. He announced that Assistant Secretary for Health, Dr. Phil Lee, would meet briefly with the Committee via Envision during the December 15 session. He indicated that CDC Director, Dr. David Satcher had expressed a desire to address the Committee at a later date. Dr. Baker also announced that Dr. John Ridderhof has replaced Dr. Joe Boone as the CDC liaison officer for CLIAC activities. He then welcomed Dr. Fred Lasky as the Health Industry Manufacturers Association (HIMA) liaison representative to the Committee.

Assistant Secretary for Health: Dr. Phil Lee

Dr. Lee thanked the Committee members for their efforts to date and indicated that CLIAC is one of the most productive and valued advisory committees in the Public Health Service. He stated that the basic CLIA legislation was sound and would not require any significant revision. Dr. Lee again thanked the Committee members and told them that he looks forward to continuing to receive recommendations from CLIAC.

Meeting Agenda and Summary Report of August Meeting

Dr. Schwartz reviewed the minutes of the Clinical Laboratory Improvement Advisory Committee (CLIAC) meeting held August 12, 1993. He stated that the CDC is in the process of reviewing and responding to large amounts of correspondence received in response to the previously published regulations. The Committee accepted the minutes of the previous meeting as presented.

Summary of Cytology Subcommittee Meeting

Dr. Rosenthal thanked the cytology subcommittee for their efforts and recommendations. She then asked Dr. Ridderhof to summarize the November Cytology Symposium. Dr. Ridderhof briefly differentiated locator skills from interpretive skills and indicated that the ideal form of cytology proficiency testing (PT) should examine both of these abilities. He stated that referenced glass slides are the only format currently available for testing both of these skills. He then explained that a national glass slide PT program administered at either the state or federal level is not logistically or financially feasible.

Dr. Ridderhof noted that while neither computer images nor transparencies can test an individual's locator skills, they are readily available and reproducible and, therefore, can be implemented. He suggested that the implementation of workload limits has alleviated some of the concerns pertaining to locator skills and false negative results. He stated that the recognition and interpretation of abnormal cells is requisite to their detection, and that an individual demonstrating good interpretive skills may at least possess the potential for locating such cells. He indicated that proficiency testing can demonstrate an individual's aptitude, but is not necessarily representative of their day-to-day work.

He stated that there are two forms of computerized PT which may eventually provide the capacity for examining locator skills. One form is an extensive database which permits simulated object location and focusing. The other is a modem-operated, computer-driven microscope, which allows an individual to find and identify cells on a glass PT slide located at another site.

He briefly reviewed other suggestions for, or alternatives to, cytology PT proposed at the November symposium, which included:

- the implementation of state administered cytology PT
- a form of internal quality control using new liquid-based slide preparation methods to assess performance which is uniform, and could potentially be administered without the testing personnel knowing that it is a proficiency test
- the use of retrospective review or random rescreening of each individual's work

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Summary of Cytology Subcommittee Meeting (Con't)

Dr. Ridderhof stated that the only short term solutions to providing PT nationwide are state glass slide-based programs, and permitting development of programs to evaluate only interpretive skills through the use of facsimiles of glass slides such as transparencies and computer imaging. He also stated that it is important to encourage the private sector to continue improving computer driven technology so that in the future it will be possible to implement PT that reflects both locator and interpretive skills.

He then presented the CDC proposal for the following phased implementation:

- approve private or state administered programs that provide supervised glass slide PT and meet the current regulations

- pursue the legislative and/or regulatory changes necessary to concurrently develop alternative PT programs

- encourage development of programs that:

    1. allow the use of facsimiles of glass slides such as computer imaging or transparencies to evaluate interpretive skills

    2. require that testing be supervised, but not necessarily performed on-site

- promote the development of computer technology that will allow testing for both locator and interpretive skills

- conduct research evaluating the effectiveness of either glass slide or facsimile based PT as a long term solution for assuring the quality of cytology testing

(Please see Addendum A for the presentation materials.)

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Summary of Cytology Subcommittee Meeting (Con't)

Discussion Summary:

Dr. Rosenthal pointed out that permitting such alternatives would not provide equitable PT since some states would be using glass slides, and others would be using facsimiles. She then turned the meeting over to Dr. Schwartz so that she could participate in the discussion.

Dr. Schwartz opened the topic for discussion. Dr. Rosenthal indicated that she did not wish to see vast sums of state monies wasted in developing PT programs that cannot succeed long term. Dr. Inhorn stated that he did not believe the subcommittee should declare that state glass slide programs could not work long term. Dr. Rosenthal asked how long it took to implement the Wisconsin State program. Dr. Inhorn replied that it had taken about twelve months. Dr. Inhorn indicated that it may be difficult to decide when the computer based technologies have become equivalent to glass slide PT. He stated that the subcommittee could not put these laboratorian's jobs at risk by implementing PT in a form that is inconsistent with typical work conditions.

Dr. Collins stated that computer technologies could be used as a screening test, and that those individuals who fail would take a glass slide test.

Dr. Rosenthal asked Dr. Collins to explain the CDC position on extending the January 1994 deadline. Dr. Collins stated that the deadline must be extended since there had been no bids to provide a national PT program. She indicated that depending upon cooperation and funding, it may be possible to have a program ready sometime in 1994. Dr. Lundberg arrived, introduced himself, and spoke on the benefits of testing the laboratory rather than the individual. Dr. Collins indicated that the New York state program operates in that manner and that the Maryland program scored the individuals, but graded the laboratory. Dr. Rosenthal stated that the laboratory's continuing education requirements should also be reviewed. An Abbott Laboratories representative asked why split samples between laboratories could not be used. Dr. Inhorn stated that this would be time consuming, and that many of the slides would yield negative results. A medical technologist from the audience asked if referees were used in cytology PT. Dr. Collins answered by stating that an individual must fail three times before

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they are barred from testing, and that if a non-glass slide method was used, the final test should be a glass slide test. Dr. Nakamura asked if the scoring system should be revised since one study showed a 40 percent failure rate. Dr. Ridderhof answered that each individual's performance improves as they are exposed to PT and that the scoring scheme should not be adjusted based on initial PT results.

Dr. Rosenthal then asked Dr. Paul Krieger from Metpath to speak on the effects of PT testing on false negatives in cytology. Dr. Krieger stated that PT testing did not test an individual's concentration, nor their locator skills. He also stated that an individual can do very well at PT, but have lapses when screening slides. He suggested that expansion of the rescreening program would do more to protect American women than any form of proficiency testing. Dr. Schwartz asked Dr. Krieger to estimate the false negative rate based on a five percent rescreening of current material. Dr. Krieger responded that he typically saw between five and eight percent false negatives and that individuals experiencing lapses of concentration may exceed that by threefold. Dr. Inhorn suggested that expansion of the rescreening program was an expensive alternative. Ms. Yost stated that it currently cost between $400,000 - 600,000 per year for HCFA's rescreening program for a very limited number of laboratories. Dr. Paul Bachner then addressed the subcommittee, stating that he believed state administered glass slide PT programs would be feasible if given sufficient commitment from the pathology organizations. He questioned the term "supervised" and how it would apply to these programs. He indicated that "hand carried" or "supervised" programs are not necessary, and that additional alternatives such as mailed-in slides must be considered. Dr. Rosenthal agreed, voicing concern that individual PT was not the answer, and that more vigorous inspection of the laboratory may be a more suitable alternative.

Dr. Lundberg posed several questions concerning the reduction of false negative results through rescreening with the testing personnel both blinded and not blinded to the fact that it is a rescreen. He also asked the Committee to consider the possibility that multiple rescreens could reduce or eliminate the need for proficiency testing. Dr. Bachner suggested that a cost versus benefits study be performed, indicating that he believed the laboratory false negative rate to be much smaller than the rate for either sampling or biologic false negatives. Dr. Inhorn stated that PT was necessary not only to eliminate false negatives, but also to evaluate cytologists' interpretive skills. After further discussion,

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Summary of Cytology Subcommittee Meeting (Con't)

Dr. Lundberg moved that the subcommittee advise CLIAC that the regulation as it stands is fundamentally flawed, and should be revised to provide PT to the laboratory and not to the individual. Members of the subcommittee wished to phrase the proposal in a more positive manner. Dr. Lundberg objected and asked the subcommittee to vote on the proposal as he had originally phrased it.

The subcommittee voted down the proposal three to two, with Dr. Lundberg and Dr. Nakamura in favor, and Dr. Rosenthal, Dr. Collins, and Ms. Yost opposed. The subcommittee then rephrased Dr. Lundberg's proposal to state that the necessary legislative and/or regulatory changes should be pursued so that proficiency testing in cytology will be applied to the laboratory and not to the individual.
Dr. Rosenthal called for the vote, and the proposal was passed with all three subcommittee members in agreement and the ex officio members abstaining.
Dr. Lundberg suggested that the subcommittee recommend the development of standards for measuring cytology laboratory outcomes. The other members concurred.

Dr. William Fidler representing the College of American Pathologist (CAP), welcomed the subcommittee's recommendation to open discussions for revising the law in regards to cytology proficiency testing. He asked if these discussions were to be include revision of the scoring schemes, rescreening numbers, retesting, etc.
Dr. Collins indicated that there had been little discussion of any substantial changes in the regulations.

The subcommittee then reached a consensus to present the CDC proposal in a report to the full committee with the following modifications:

> The Subcommittee on Cytology agrees with the CDC that a national glass slide PT program, administered at the Federal level, is not logistically or financially feasible.
>
> The necessary legislative and/or regulatory changes should be pursued so that proficiency testing in cytology will be applied to the laboratory and not to the individual.

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Summary of Cytology Subcommittee Meeting (Con't)

Research is needed to evaluate the clinical effectiveness and costs of either glass slide or alternatives for PT as a long term solution for the assurance of quality testing in cytology.

Outcomes must be defined and developed to measure the effectiveness of PT in cytology.

Phased Implementation:

- encourage the development of private or state administered programs that provide supervised glass slide PT and meet the current regulations

- concurrently pursue the legislative and/or regulatory changes necessary to:

    1) develop approvable alternative PT programs

    2) allow testing to be supervised, but not necessarily performed on-site

    3) allow the use of simulations of glass slides, e.g., computer images or transparencies

- promote the development of computer technology that will test both locator and interpretive skills

Update on Regulations

Dr. Collins indicated that the CDC was in the process of responding to the large numbers of public comments received to previous regulations and spoke of the need to bring some of the resulting issues before the Committee. She gave a brief update on two CLIA regulation packages currently in preparation. The "interim" regulation targeted for earliest publication includes: 1) changes to the Physician Performed Microscopy (PPM) subcategory; 2) alternative pathways for currently employed individuals to meet personnel qualifications; 3) expanded criteria for waiver; and 4) criteria for a new subcategory of moderate complexity testing designated as Accurate and Precise Technology (APT). Dr. Collins then reviewed some of the issues that will be resolved by the final regulation.

Discussion Summary:

Ms. Charles asked if all test currently on the waived list would be required to meet the expanded criteria for waiver. Dr. Collins indicated that the decision has not yet been made.

Ms. Best stated that she was not comfortable with the APT category being incorporated into the regulations before the Committee had been given an opportunity to discuss the criteria and make recommendations. Dr. Collins indicated that the CDC had reviewed the concept of an additional subcategory at an earlier meeting of CLIAC. Ms. Best then asked the CDC to provide details of the APT category and indicate whether these tests would be subject to the same QC/QA/PT requirements as other moderate complexity testing. Dr. Schwartz summarized the discussion, stating that the Committee was uncomfortable with the addition of the APT category to the regulations. He read from the previous CLIAC minutes where the Subcommittee on Test Categorization had indicated that the CDC would develop this category and make a report to the full committee at a future meeting. Dr. Baker stated that the CDC would make a presentation on the APT category during the session on December 15, 1993.

Ms. Charles indicated that she was displeased that the CDC had changed the wording of committee recommendations in the PPM regulations without conferring with the Committee. Dr. Schwartz disagreed, and stated that the changes had not been substantive. Dr. Baker reminded the Committee that it serves an advisory role.

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Update on Regulations (Con't)

Discussion Summary (Con't)

Ms. Yost was asked when these regulations would be published. She stated that in the absence of delays, HCFA anticipated an April publication date for the "interim" or fast track regulation, and a September or October publication date for the Final Regulation. In response to a question, Dr. Collins stated that there were other changes incorporated in these regulations which had not been brought before the Committee. Dr. Schwartz interceded, stating that he had been well pleased with the CDC's efforts and that its cooperation and willingness to bring the issues before the Committee had been a primary factor in CLIAC's success. Dr. Bachner concurred with Dr. Schwartz comments.

Revised Research Strategy: the New Evaluation of Quality Laboratory Practices and Standards (EQLPS)

Dr. Boone stated that the goal of EQLPS was to improve the quality of laboratory testing by providing a scientific and technical basis for laboratory practices and standards. He summarized the objectives of the research plan, the available data sources, and the CLIA studies in progress. He then reviewed the requirements for implementing EQLPS. (Please see Addendum B for the presentation materials.)

Discussion Summary:

Dr. Ray asked if this strategy would be able to evaluate the effectiveness of the regulations in resolving the problems CLIA was originally intended to address. Dr. Boone's response was that it might be possible to evaluate some aspects of the impact of CLIA, but all questions could not be addressed with the planned research activities.

Dr. Rosenthal asked if the "weight" of the components described in the slide titled *"Integration of Data and Information"* would be considered, and if so, would the studies indicate what would happen to the other components when one is neglected. Dr. Boone indicated that they hoped to include that information.

Dr. Inhorn asked if new or prospective information would be collected or if it would be limited strictly to previously collected data. Dr. Boone indicated that some new data would need to be collected.

Dr. O'Neal asked for an evaluation of the funding status for this project and an approximate timeline for when data might be available. Dr. Boone indicated that although funding was not what had been anticipated, the CDC expected to prepare some data for publication during 1994.

Dr. Rosenthal proposed that additional groups be encouraged to collect similar data for collaboration and perhaps subsequent publication. Dr. Boone concurred.

Ms. Best asked if CDC would consider incorporating the concepts of Total Quality Management (TQM) or Quality Management Improvement (QMI) into this model. Dr. Boone indicated that the concept of improving the Total Testing Process encompasses QMI or TQM as one of its goals.

Dr. O'Neal asked how the information would be dispersed. Dr. Boone stated they

were considering the publication of an annual report, which would be peer reviewed.

Results from Ambulatory Sentinel Practice Network (ASPN) Project with Family Practitioners

Dr. Stull presented data from a pilot study performed in collaboration with the family practices of the Ambulatory Sentinel Practice Network (ASPN). The study was designed to provide an initial assessment of the feasibility of evaluation of the magnitude and nature of problems in the primary care laboratory setting. (Please see Addendum C for the presentation materials.)

Discussion Summary:

Dr. Pierre questioned the validity of the results. He stated that an error rate of one in one-thousand was not consistent with his knowledge of laboratory practice. He asked for the total number of tests performed. (This information was not readily available.)

Dr. Lundberg believed the study praiseworthy, but stated that it did not begin early enough in the pre-analytical phase and failed to follow through far enough in the post-analytical phase. He questioned how the information was collected. Dr. Stull responded that it was collected from primary care physicians interested in performing research. He stated that the use of this group in itself may have been sufficient to bias the study. He then asked who determined when there was a problem? She responded that anyone in the practice (excluding the patient) could identify the problem. Dr. Rosenthal concurred with Dr. Lundberg.

Dr. Zabransky requested information concerning the size of these practices, the number of physicians, and the size of the reference laboratories. Dr. Stull replied that she did not have a breakdown on the size of the POLs or the number of physicians at each site. She indicated that any testing performed off-site was considered reference laboratory testing.

Ms. Best asked how analytical errors at the reference laboratory were identified. Dr. Stull stated that these problems were only identified when the reference laboratory communicated the problem to the POL or when the results were inconsistent with the patient's condition.

Dr. Bachner commented that in the absence of a specific model for error identification these results may not be valid.

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Result from Ambulatory Sentinel Practice Network (ASPN) Project with Family Practitioners (Con't)

Discussion Summary (Con't)

Dr. Ray asked if these laboratories were CLIA regulated. Dr. Stull indicated that this data was not readily available.

Dr. Gambino stated this study indicated that we need better devices for following patients and assessing pre-analytical and post-analytical error.

Ms. Best expressed concern that the studies performed by the CDC may be biased by the groups from which they obtain data.

Results from Commission on Laboratory Accreditation (COLA)

Dr. Kroger presented information on COLA. He briefly reviewed the many regulatory changes effecting physicians in the United States. He discussed the American Medical Association's initial efforts to repeal CLIA '88. He stated that COLA was conceived by primary care physicians in the mid 1980's and incorporated as a non-profit accrediting agency for Physician's Office Laboratories (POL) in 1988. He indicated that the original founders of COLA were the American Association of Family Physicians (AAFP), American Medical Association (AMA), American Society for Internal Medicine (ASIM), and the College of American Pathologists (CAP). He said that peer review and proficiency testing became the lynch pins of COLA activity.

COLA implemented a second program in 1992 to conform more closely with CLIA. COLA experienced a tripling of members in early 1992 as a reaction to the implementation of CLIA '88. Dr. Kroger indicated that all COLA surveys are performed by medical technologists that are full time employees of COLA (as opposed to CAP using volunteers). He said that PT is no longer offered COLA (but is required). He noted that many physicians are waiting for their first inspection to find out where they must improve, rather than attempting to interpret the regulations. As a result, these physicians have many more deficiencies than would be expected.

Dr. Kroger then presented data showing the complexity of testing performed at the surveyed POLs. Data was also presented concerning the education of the testing personnel staffing these laboratories. Dr. Kroger stated that he did not know if COLA laboratories were representative of the nations POLs.

He then showed data concerning the deficiencies of the COLA POLs during inspection. There appeared to be some implementation pains for QC, but QA seemed to be the least understood by the physician. There were few citations for instrument maintenance, personnel, procedure manuals, patient test management and proficiency testing. He stated that the blood bank was the area most frequently cited for proficiency testing deficiencies.

He said that COLA also employs a STAT team for dealing with those laboratories with serious deficiencies (~5 percent of COLA laboratories). This team can also prevent the laboratory from reporting results if the problems warrant it and can

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Results from Commission on Laboratory Accreditation (COLA) (Con't)

recommend denial of accreditation. Dr. Kroger indicated that the self survey process markedly improved initial compliance. He noted that compliance was also improved during second inspections.

(Please see Addendum D for the presentation materials.)

Discussion Summary:

Dr. Ray asked for an example of how the surveyors approached quality assurance. Dr. Kroger responded that in the past it has been evaluated based primarily on patient test management, but was now more in line with the method of Total Quality Management (TQM).

Dr. Zabransky asked what percentage of the nations POLs this study represented. Dr. Kroger responded that he did not have a accurate number but would estimate that there are approximately 40,000 - 50,000 POLs nationwide and about 7,000 had enrolled in COLA. He stated that COLA had inspected some 550 of these laboratories.

Dr. Rosenthal complimented COLA on their sensitivity to the POL situation and for making inspections an educational rather than punitive experience.

Dr. Inhorn asked if COLA assessed the physician or clinical supervisor responsibilities for QA/TQM/Patient Test Management. Dr. Kroger said that COLA focused primarily on the director.

Ms. Best commented on the percentage of medical technologists in POLs, stating that it would be a great research opportunity. Dr. Kroger indicated that some studies of laboratory problems relative to the education of the testing personnel had been performed, but that he did not feel there was sufficient data to present at a public forum.

Dr. Bachner asked if the COLA internal medicine specialty also included subspecialties. Dr. Kroger replied that it did.

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Results from Commission on Laboratory Accreditation (COLA) (Con't)

Discussion Summary (Con't)

Dr. Bachner asked if COLA planned to perform real time monitoring of proficiency testing results. Dr. Kroger stated he felt that this was imperative to the program, but that all the different PT programs report the results in a different manner and utilize a different scoring scheme. He indicated that without uniform data reporting, real time monitoring is virtually impossible. Ms. Yost said that HCFA has been working on standardizing PT datastreams.

Dr. Abercrombie inquired about the cost of COLA inspections. Dr. Kroger said it cost approximately $800 every 2 years, plus $100 for each specialty.

Ms. Ohrmundt asked how much the POLs depended on the manufacturers for training and compliance information. Dr. Kroger replied that the smaller POLs depended on them a great deal.

Dr. Gambino stated he would like to see uniformity of proficiency testing input as well as output. Dr. Kroger agreed.

Dr. McCurdy suggested tightening up the COLA procedure manual requirements.

Dr. Laskey asked if the POLs are using guidelines to develop procedure manuals. Dr. Kroger responded that many hire a medical technologist to write the manual.

Dr. Baker asked about the impact of PPM in the POLs. Dr. Schwartz asked how often the surveyors are seeing waived tests. Dr. Kroger replied that the PPM subcategory has stimulated a tremendous response from physicians. He stated that many laboratories now perform only PPM and waived testing. He also stated that COLA does not recognize any waived testing.

Results from HCFA Inspections of Physician Office Laboratories

Ms. Yost presented data obtained from the HCFA's inspections of laboratories. She stated that the inspectors averaged about six years of laboratory experience with approximately two years of inspection experience. She indicated that the inspectors are now providing an educational component and the laboratory's organization and experience tend to determine the length of time it takes to perform the inspection. Ms. Yost stated that HCFA was extending the first inspection cycle until March of 1995. She presented information indicating that the laboratories with trained personnel and enrolled in PT tend to have fewer deficiencies.

(Please see Addendum E for the presentation materials.)

Discussion Summary:

Ms. Charles asked how many of the complaints investigated by HCFA were filed by the consumer. Ms. Yost indicated that she did not have specific numbers, but that complaints were filed most frequently by employees, then patients or their family, followed by those reported anonymously and those reported by "others," some of which could be consumers.

Ms. Garcia inquired as to the types of complaints most frequently filed. Ms. Yost stated that the type of complaint varied considerably but that often it was an employee who felt he/she were not given adequate materials or sufficient training to perform his/her job, or a patient who believed the specimen was not properly collected or the result was incorrect.

Dr. Gambino stated that the breakdown on the percentage of complaints based on the type of laboratory should take into account the volume of testing, since larger testing volumes will naturally provide more opportunities for complaint.

Dr. Rosenthal asked if any of the cytology laboratories that were closed had been reopened. Ms. Yost responded she believed that none had reopened.

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Discussion Summary (Con't)

Dr. Lundberg requested additional information concerning the data comparing previously regulated to previously unregulated laboratories. Ms. Yost indicated that under CLIA '67, physician laboratories receiving referral specimens were regulated. Dr. Lundberg remarked that the data shows no difference between previously regulated and previously unregulated laboratories and that this would seem to indicate that regulation is of no practical benefit. She replied that under CLIA '88 laboratory surveyors assist POLs in meeting requirements. Much time is now spent educating the laboratories, whereas, previously regulated laboratories were provided no assistance in correcting deficiencies. Therefore, they may not have corrected them or retained the correction. She also stated that HCFA's position for the first survey cycle has been that no enforcement action would be taken unless there was risk to the patient. Therefore, surveyors didn't cite deficiencies. Ms. Yost emphasized that the determination as to whether a laboratory was previously regulated or not was made by the laboratory and may not be entirely reliable. The point of the information is mainly that POLs seem to consistently have the same deficiencies and other providers vary significantly.

Dr. Zabransky asked how many surveyors were employed and how HCFA could assure that the inspection process is uniform. Ms. Yost responded that there are 171 HCFA inspectors that were trained at several levels including the central, regional, and state offices. She indicated that in addition, they receive extensive field training with experienced surveyors prior to performing their first inspections.

Results from Other Surveys

Dr. Steindel presented information on sources of laboratory characteristics from the National Ambulatory Medical Care Survey (NAMCS), FDA POL Survey, OMB Survey, and HCFA 109 Registration forms. He introduced preliminary results from studies being performed on the data acquired from the sources mentioned above. Included were reports of office laboratory distribution by physician specialty, test volumes by personnel type, most commonly performed test in the POL, and proficiency test enrollment and failure rates.

(Please see Addendum F for the presentation materials.)

Discussion Summary:

Dr. Lundberg asked how the PT failure rate had been defined. Dr. Steindel indicated that they had looked to see if the laboratory results fell below the level of acceptable performance established by the PT provider. Dr. Lundberg said that he felt this was soft data since there are 19 different PT programs. He also indicated that he would question any data from the OMB survey since two-thirds of the laboratories failed to return the survey forms. Dr. Steindel agreed.

Dr. Kroger suggested that data acquired from the HCFA registration forms is also suspect since this information was most likely provided by the business manager or receptionist.

Dr. Schwartz questioned the logic of continuing these studies knowing that the data is suspect. Dr. Lundberg agreed. Dr Steindel stated that there is a problem in looking at individual survey vehicles, but that good data can still be obtained from the comparison of surveys.

Dr. Laskey urged caution in using this data (PT failure rate).

Dr. Bachner recognized the limitations of the survey vehicles and recommended that the Secretary provide funding and planning sufficient to properly design these surveys and ensure the reliability of the data.

Dr. Lundberg suggested the adoption of a single PT form nationwide to provide uniform data. Dr. Schwartz indicated that the standardization of PT would be on the agenda for the next CLIAC meeting.

Accurate and Precise Technology (APT)

Ms. Bakes-Martin presented the criteria for a new subcategory of moderate complexity testing that has been designated as Accurate and Precise Technology (APT). This subcategory is expected to be incorporated into the regulations in an April 1994 publication of the Federal Register.

(Please see Addendum G for the presentation materials.)

Discussion Summary:

Ms. Charles asked if PT would be required. Ms. Bakes-Martin replied that PT is required.

Dr. Bachner asked if a test was categorized as APT and the laboratory modified the procedure, would the test default to moderate or high complexity.
Ms. Bakes-Martin responded that it would default to high complexity.

Dr. Rosenthal commented that she did not feel that three field studies with a total of 60 participants would be adequate. Ms. Bakes-Martin indicated that this was intended as the minimum number of sites and participants and agreed that more may be required.

Ms. Garcia asked why this was a subcategory of moderate complexity testing and not a separate category. Dr. Collins replied that the moderate category already has clearly defined standards which would be applied to this class of testing.

Dr. Inhorn asked for an outline of the benefits the POL which drops all testing except waived and APT might expect. Ms. Bakes-Martin stated that they should see lower costs (registration), fewer inspections and reduced responsibilities for the director.

Dr. Gambino inquired if future technology might allow a high complexity test to meet these criteria. Ms. Bakes-Martin stated that it should need to be categorized as moderate complexity first.

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Accurate and Precise Technology (APT) (Con't)

Discussion Summary (Con't)

Ms. Charles asked if there would be a delay in the FDA categorizing these tests. Ms. Ohrmundt indicated that the CDC had cleared up the categorization backlog and by mid-January (1994) the FDA should be categorizing tests as part of the routine product reviews.

Ms. Charles then asked if there would be a 60 day comment period for this rule. Ms. Best was also concerned with this process and inquired why this was being published as a final rule and not a proposed rule. Dr. Collins and Ms. Yost pointed out that although it would be a final rule, provision was being made for public comment. They stated that the attorneys had indicated the appropriateness of a final rule since these changes are in response to public comments.

Ms. Best asked why the lower scoring tests in the moderate complexity category were not being examined. Ms. Bakes-Martin replied that the scoring criteria used in test categorization measure complexity whereas the criteria used for APT measure performance.

Ms. Best asked if site neutrality would apply to the APT subcategory, i.e., could hospitals also use these tests? Ms. Bakes-Martin indicated that site-neutrality would apply to the tests in the APT subcategory.

Dr. Lasky indicated that the criteria specifying that no imprecision is allowed for qualitative tests makes it impossible for the manufacturers to meet the requirements. He expressed concern over several implementation and management issues which he felt could provide a market advantage to some manufacturers. He also expressed concern with the FDA's track record for workflow. He stated that there were important issues to consider and that time must be made for public comment.

Dr. Gambino suggested that the process of evaluating performance may require something more sophisticated than Tonk's formula.

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Accurate and Precise Technology (APT) (Con't)

Discussion Summary (Con't)

Ms. Ohrmundt said that the FDA shares some of Dr. Lasky's concerns. She indicated that the FDA would be drafting a guidance document, but reminded the Committee that the FDA did not have sufficient funding or personnel to perform these functions.

Ms. Best stated that while there may be political motivations for including this subcategory in the "fast track" regulation, she felt this concept was ill conceived. She said that APT could have a tremendous effect on CLIA and that CLIAC must be given an opportunity re-evaluate the implications.

Dr. Gambino stated that he sees this new category as imperfect, but an improvement. He indicated he would support this new subcategory.

Dr. Schwartz asked if there might not be a better alternative.

Ms. Charles said that just because the lawyers said that this could be published as a final rule does not make it right and that the Department had subverted the purpose of the Committee. She stated there were more important issues to address than putting this subcategory in the "fast track" regulation. She indicated that the removal of glucose monitors from the waived testing list was one of those issues.

Dr. Collins said that the waived test category must be very limited since they are essentially unregulated, but that there are some good tests out there that do not require extensive regulation. She stated she did not feel like the Committee had been bypassed, since the issue had been presented in detail at the last meeting.

Dr. Schwartz stated that the Committee was greatly concerned with this subcategory and that there was little point in putting it in the "fast track" regulation when it is unlikely the FDA will be able to implement it.

The Committee recommended that the CDC delay incorporating this category into the "fast track" regulation and that public comments be solicited and discussed.

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Discussion Summary (Con't)

Dr. O'Neal suggested that the Committee try to work faster perhaps through a subcommittee. Dr. Schwartz acknowledged that the Committee would be willing to do this, but reminded the members that this regulation was in the process of being published.

Ms. Charles motioned that waived testing be brought back before the Committee during the March 1994 session. There was general consensus to forward this as a recommendation.

Public Comments

Dr. Basil Doumas representing the American Association for Clinical Chemistry (AACC) asked that those doctoral scientists who were board eligible on February 28, 1992, be included in the listings of personnel qualified to function as Clinical Consultant. Dr. Gambino stated that this was appropriate. The Committee unanimously recommended that the CDC support this recommendation.

A representative from the American Association of Family Physicians (AAFP) asked that CLIAC discuss the complexity of culture kits at a future meeting. Dr. Schwartz recommended that he obtain the complexity scores for these tests and submit suggestions for where the scores could be changed.

An attorney for Hemocue Inc. addressed the Committee to encourage them to implement a fast mechanism for putting tests in the waived category once the expanded criteria are approved. He indicated that his company did not believe the FDA had the resources to process these submissions in a timely manner, and asked that he be allowed to bring the Hemocue Glucose Monitor back before the CDC and CLIAC for possible inclusion in the waived category. The Committee members essentially agreed that the delays are unacceptable. Again several committee members asked that the tests on the waived list be reviewed and those tests which do not fit the criteria be removed prior to the addition of other tests.

Toni Casey, a health care consultant, asked that the "fast track" regulation not be delayed due to CLIAC's concern with the APT category as this would also delay the lifting of the moratorium on the addition of tests to the waived category.

Anne Pontico, an independent laboratory consultant, indicated that frequently the individuals filling out forms in POLs do not have an adequate understanding of what is required. She suggested that the data extracted from these forms may therefore be invalid.

Alice Weissfeld representing the American Society for Microbiology (ASM) wished to make CLIAC aware that they are working on data to present to the Committee, CDC, and the AAFP concerning urine susceptibility testing.

A representative of the Health Industry Manufacturers Association (HIMA) objected to home-use criteria being used to establish the waived criteria, e.g., the requirement that written materials be drafted at a 7th grade reading level.

Summary of Recommendations

Cytology proficiency testing:

The full committee agreed with the recommendations of the Subcommittee on Cytology and CDC, that a national glass slide PT program, administered at the Federal level, is not logistically or financially feasible.

The necessary legislative and/or regulatory changes should be pursued so that proficiency testing in cytology will be applied to the laboratory and not to the individual.

Research is needed to evaluate the clinical effectiveness and cost of glass slide or alternatives for PT as long term solutions for the assurance of quality testing in cytology.

Outcomes must be defined and developed to measure the effectiveness of PT in cytology.

Phased Implementation:

- encourage the development of private or state administered programs that provide supervised glass slide PT and meet the current regulations

- concurrently pursue the legislative and/or regulatory changes necessary to:

    1) develop approvable alternative PT programs

    2) allow testing to be supervised, but not necessarily performed on-site

    3) allow the use of simulations of glass slides, e.g., computer images or transparencies

- promote the development of computer technology that will test both locator and interpretive skills

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Summary of Recommendations (Con't)

Additional recommendations:

- The CLIAC should be given further opportunity to review the new Accurate and Precise Technology (APT) subcategory.

- Present an update on the current status of waived testing criteria to CLIAC during the March 23-24, 1994 meeting.

- Those doctoral scientists who were board eligible on February 28, 1992, should be included in the listings of personnel qualified to function as Clinical Consultant.

Concluding Remarks

The Committee proposed the following dates for future CLIAC meetings:

- March 23-24, 1994
- June 8-9, 1994
- September 27-28, 1994
- December 13-14, 1994

Ms. Charles indicated that she would appreciate receiving any written materials which will be presented during the meeting prior to the meeting so the members have ample time to review the material for discussion.

Dr. O'Neal said that the AACC has asked for a meeting of the PT subcommittee. Dr. Schwartz indicated that this would probably be made a part of the PT standardization discussions slated for the CLIAC meeting in March.

Dr. Kroger asked Ms. Yost to specify which implementation dates are to be extended. Ms. Yost indicated that the dates for Cytology PT, and FDA QC clearance.

I certify that this summary report of the December 14-15, 1993, 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

Summary of
Cytology Subcommittee Meeting

Addendum B

Revised Research Strategy: the New Evaluation of Quality Laboratory Practices and Standards (EQLPS)

Addendum C

Results from Ambulatory Sentinel Practice Network (ASPN) Project with Family Practitioners

Addendum D

Results from Commission on Laboratory Accreditation (COLA)

Addendum E

Results from HCFA Inspections of Physician Office Laboratories

Addendum F

Results from Other Surveys

Addendum G

Accurate and Precise Technology