Clinical

Laboratory

Improvement

Advisory

Committee

Summary Report

September 22-23, 1999

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

Clinical Laboratory Improvement Advisory Committee (CLIAC)

September 22 - 23, 1999

Summary Report

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Record of Attendance

Committee Members
Dr. Toby Merlin, Chair
Dr. David Baines
Dr. George Birdsong
Dr. Thomas Bonfiglio
Dr. Mary Burritt
Dr. Ronald Cada
Dr. Joseph Campos
Dr. Patricia Charache
Dr. Brenta Davis
Dr. Andrea Ferreira-Gonzalez
Dr. Jaime Frias
Dr. Susanne Gollin
Dr. Edward Hook
Dr. Verlin Janzen
Ms. Diana Mass
Dr. Timothy O'Leary
Ms. Sharon Radford
Dr. Larry Silverman

Ex Officio Members
Dr. Steven Gutman, FDA
Dr. Robert Martin, CDC
Ms. Judith Yost, HCFA

Liaison Representative
Ms. Kay Setzer, HIMA

Executive Secretary
Dr. Edward Baker

Centers for Disease Control and Prevention
Ms. Nancy Anderson
Dr. Rex Astles
Dr. Joe Boone
Ms. Gail Bosley
Ms. Diane Bosse
Ms. Carol Cook
Ms. Crystal Frazier
Ms. Sharon Granade
Dr. Thomas Hearn
Dr. Ed Holmes
Dr. Devery Howerton
Dr. Ira Lubin
Mr. Kevin Malone
Dr. Adam Manasterski
Dr. John Ridderhof
Dr. Eunice Rosner
Ms. Renee Ross
Ms. Marianne Simon
Mr. Darshan Singh
Ms. Elva Smith
Dr. Steven Steindel
Ms. Rhonda Whalen
Ms. Shelba Whaley
Dr. Laurina Williams

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; the Administrator, Health Care Financing Administration; and such additional officers of the U.S. Government that the Secretary deems are necessary for the Committee to effectively carry out its functions. CLIAC will also include a non-voting liaison representative who is a member of the Health Industry Manufacturers Association and such other non-voting liaison representatives that the Secretary deems are necessary for the Committee to effectively carry out its functions.

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 regulations, the reader should not infer that all of the advisory committee's recommendations will be automatically accepted and acted upon by the Secretary.

CALL TO ORDER AND INTRODUCTORY INFORMATION

Dr. Toby Merlin, CLIAC Chair, called the meeting to order and presented a brief overview of the agenda for the meeting. The Committee members made self-introductions and disclosure statements of their relevant financial interests as they relate to the topics to be discussed during the CLIAC meeting. Dr. Edward Baker, Director, Public Health Practice Program Office (PHPPO), Centers for Disease Control and Prevention (CDC) welcomed the CLIAC and emphasized the importance of their input on the role of CLIA in addressing critical issues such as genetic testing and reporting laboratory information of public health significance.

PRESENTATIONS AND COMMITTEE DISCUSSION

CLIA Update

Centers for Disease Control and Prevention (CDC) **Addenda A-B**

Dr. Devery Howerton, Chief, Laboratory Practice Standards Branch (LPSB), Division of Laboratory Systems (DLS), PHPPO, CDC, summarized a panel meeting held at the CDC on July 22 - 23, 1999, to consider the impact of new technology on cytology workflow and workload (Addendum A). The panel at this meeting consisted of pathologists and cytotechnologists, cytology instrument manufacturers, and representatives from the CDC, the Health Care Financing Administration (HCFA), and the Food and Drug Administration (FDA). The meeting was to gather information on a variety of issues pertaining to cytology workload, productivity, and performance assessment, and no consensus was sought or recommendations made at the meeting. Following Dr. Howerton's presentation, several CLIAC members commented on the developing technology for cytology, and need for appropriate standards for manual methods, instrumentation and associated computer hardware. The need for security and confidentiality related to computer images was also emphasized.

Dr. Patricia Charache reported on the Secretary's Advisory Committee on Genetic Testing (SACGT) (Addendum B), established as a result of a recommendation made by the National Institutes of Health/Department of Energy Task Force on Genetic Testing. Dr. Charache is a member of the SACGT and is the CLIAC liaison to the group. The SACGT is beginning the process of evaluating optimal oversight of genetic testing, and is seeking broad input from government agencies, professional organizations, and the public on relevant issues. Dr. Charache reviewed the CLIAC recommendations on genetic testing made on September 16 - 17, 1998, and said the SACGT is considering these recommendations in its deliberations. CLIAC discussion on Dr. Charache's presentation was deferred until the second day of the meeting (September 23, 1999).

Health Care Financing Administration (HCFA) **Addenda C-D**

Ms. Judy Yost, Director, Division of Outcomes and Improvements (DOI), Center for Medicaid and State Operations (CMSO), HCFA, reviewed HCFA's CLIA implementation activities (Addendum C). She included HCFA data from July 1999 on laboratory certification, CLIA-

exempt States, accreditation organizations, survey deficiencies, and enforcement. The 1997 CLIA statistics are now on the HCFA website for DOI - CLIA (http://www.hcfa.gov). Also on this website are links for laboratories seeking assistance with Y2K compliance. Last, Ms. Yost noted the recent fee increases for exempt States, and said the Government Accounting Office has been asked to perform an audit of CLIA activities and expenses. In response to Ms. Yost's report, a few CLIAC members commented on CLIA funding, one suggesting that manufacturers requesting test categorization pay a fee for the service, and another questioning whether CLIA staffing levels are affected by increasing numbers of exempt States. Ms. Yost replied there are basic resources and costs required to operate the CLIA program, which do not change based on the number of exempt States.

Ms. Kathy Todd, Medical Technologist, DOI, CMSO, HCFA, presented the results of a post inspection questionnaire used by HCFA to assess their laboratory survey process (Addendum D). In 1995, the questionnaire was pilot tested by laboratories and HCFA surveyors, and was revised in 1996 to be used by laboratories only. It is currently distributed to all laboratories after an onsite inspection conducted by HCFA (or HCFA's agent) or completion of the alternate quality assessment survey. The data collected via the questionnaire are kept confidential, are disclosed to the public in aggregate form, and are provided to each HCFA Regional Office in a quarterly summary. The questionnaire is not used to evaluate any surveyor or laboratory. The data presented by Ms. Todd were for responses to the questionnaire received by HCFA from September 1, 1998 to June 30, 1999. During this nine month period, there was an 18.2% response rate for the questionnaire. The data reported included laboratory testing volumes, and laboratory responses to a number of statements regarding the survey process and any deficiencies found. Ms. Todd noted that a majority of the results received on the questionnaire are positive, and mirror results obtained in the HCFA pilot questionnaire.

CLIAC members asked for clarification of several points made by Ms. Todd. Some members expressed the opinion that due to the low response rate on the questionnaire, no valid conclusions could be drawn from the data, and one member suggested potential ways to increase the response rate (i.e. personal or phone interviews). Another CLIAC member said potential bias could be decreased by the use of an outside agency to distribute and collect the questionnaires. In response to the comments, Ms. Yost noted this is HCFA's first attempt to obtain feedback on the inspection process, and no conclusions are being drawn from the data at this time. She welcomed the suggestions made for improving the process. Dr. Baker concluded the HCFA presentation by commending the HCFA and State surveyors for a job well done, and the Committee agreed these efforts should be recognized.

Food and Drug Administration (FDA)

Dr. Steven Gutman, Director, Division of Clinical Laboratory Devices, Office of Device Evaluation, Center for Devices and Radiological Health, FDA, updated the CLIAC on FDA activities pertaining to CLIA and recent changes in the review and classification of clinical laboratory devices and reagents (Note: Dr. Gutman's overheads not available for inclusion as an addendum). He announced that Dr. Joe Hackett has been detailed to oversee CLIA policy development and Ms. Clara Sliva is the CLIA coordinator. He mentioned the FDA's special

510(k) and revised premarket approval (PMA) processes, intended to make the review processes more streamlined and user friendly. The PMA process now includes a provision for submission of modular PMA's, in which a manufacturer works interactively with the FDA to obtain approval for a complex, "avant garde" submission piece by piece. He also discussed product development protocols, in which a research plan and goals for a new product are presented to the panel prior to development, and streamlined PMA's, which significantly decrease administrative time in the approval process. Last, Dr. Gutman made the CLIAC aware the FDA is currently soliciting public comment on several new guidance documents available on the FDA website.
Several questions were posed to Dr. Gutman regarding the transfer of the CLIA test categorization and waiver processes to the FDA. He emphasized that measures are being taken to ensure that these processes are standardized and product reviews are consistent with those conducted by the CDC. He acknowledged that the proposed waiver regulations will be finalized by the FDA, and the FDA could continue to rely on the CLIAC for input on CLIA related test categorization/waiver issues. Dr. Baker reminded the Committee that they are an advisory group to the Department of Health and Human Services, and their role will not change with the transfer of responsibility for test categorization/waiver from the CDC to the FDA.

Laboratory Workforce Shortages **Addendum E**

Dr. Thomas Hearn, Acting Deputy Director, DLS, PHPPO, CDC, introduced the topic of laboratory workforce shortages. He explained that CLIAC members had asked that this issue be considered by CLIAC, as it is an area of concern related to laboratory quality, and is an increasing problem in laboratories throughout the country. Dr. Hearn presented background information on laboratory personnel and CLIA, and on research findings and strategies pertaining to the linkage between adequate numbers of qualified personnel and laboratory quality. He outlined presentations to be made at the meeting, noting that speakers from a variety of professional organizations and academic institutions had been invited to present relevant data. Dr. Hearn then posed several questions for the CLIAC to consider after hearing the presentations, and gave expectations for the Committee discussion. He acknowledged that CLIA may not be the correct vehicle for resolution of personnel shortages, and recommendations for professional organizations may be appropriate.

The Hidden Health Care Workforce - University of California at San Francisco (UCSF) Center for the Health Professions **Addendum F**

Ms. Susan Chapman presented data from a study that was part of the California 21st Century Workforce Project, conducted by the UCSF Center for Health Professions, a research institute. The project was an 18-month initiative which used a self-administered survey to assess the allied and auxiliary health care workforce in California within the changing health care environment. The laboratory workforce is a part of the more than 200 allied health professions included in the study. However, Ms. Chapman clarified that physician office laboratories were not part of the study, which primarily included larger laboratory facilities. Although the data was limited to the California workforce, Ms. Chapman suggested the findings could be generalized across the country. She reported there are 10.5 million health professionals nationwide, and 60% of them are allied health care workers. The findings of this study indicate that in the currently shifting

environment, the division of labor is changing in health professions to require a more flexible, multi-skilled workforce (including the laboratory). However, there are no data showing that this results in decreased costs or increased quality of health care. The study also found that salaries are decreasing, while responsibilities are increasing, and highlighted the struggle to attract and retain a quality workforce. Ms. Chapman identified specific skills and competencies now needed by clinical laboratory workers. The report included recommendations to assist the health care workforce in adapting to the changing environment, and concluded with steps to be undertaken in phase two of the project.

American Society for Clinical Pathology (ASCP) Wage and Vacancy Survey Addendum G

Ms. Ann Tiehan summarized the 1998 ASCP wage and vacancy rate survey, conducted biennially to document wage levels and vacancy rates for ten medical laboratory positions commonly found in U.S. medical laboratories. The survey consisted of a questionnaire randomly sent to 2,500 laboratory managers. The response rate for the survey was 25%, with 618 laboratories returning the questionnaire. Although the survey data varied slightly according to laboratory position and geography, overall, salaries increased, but less than in previous two year survey cycles, and vacancy rates in laboratories increased. Ms. Tiehan attributed these changes to the decrease in laboratory training programs, the merging of hospitals, corporations hiring individuals out of the laboratory workforce, and limited financial resources for laboratory salaries. In light of these issues and changes on the horizon affecting laboratory testing (i.e. more molecular testing, increasing numbers and complexity of biopsy specimens as a result of the aging population), she emphasized that laboratories must insist on highly educated and trained personnel. She concluded by describing the following ways to address the personnel problems. Laboratory training programs are becoming more flexible by including alternative training sites; ASCP is working with HCFA and Congress to increase laboratory reimbursement; and grants could be made available to attract individuals into the laboratory field.

Laboratory Personnel Changes in the Pacific Northwest, 1995 and 1997 - Washington State Department of Health Addendum H

Ms. Kathy LaBeau discussed a survey designed to identify changes in the number and background of laboratory personnel in Alaska, Idaho, Oregon, and Washington from 1995 to 1997, and the impact of these changes on the quality and practices of diagnostic testing laboratories. The survey was sent to 436 members of the Laboratory Medicine Sentinel Monitoring Network, and 323 members responded. From 1995 to 1997, more laboratories in this study reported an increase in the numbers of testing and support personnel than a decrease. There was no significant change in the mix of professional background of testing personnel, and no evidence that medical technologists (MT) and medical laboratory technicians (MLT) had been replaced by individuals with different professional backgrounds. Ms. LaBeau reported that, for the Pacific Northwest, this study indicates despite changes in the marketplace, the declining number of training programs, and the “need to do more with less,” MT and MLT positions have remained stable, and the number of people leaving these positions is balanced by the number of people replacing them.

National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) Report on Training Program Closures **Addendum I**

Ms. Joeline Davidson reported on the NAACLS accredited laboratory training programs from 1970 through the present. These data illustrated the change in numbers of programs, especially decreases in baccalaureate degree medical technology programs. A significant number of programs have closed in the last ten years, primarily in hospital sponsored programs due to a lack of funding. Ms. Davidson expressed concern about the closures, and said that in addition to a lack of money, the closures are partly due to an increase in bedside (less complex) testing, and environmental changes such as hospital mergers and alliances in health care. She noted that NAACLS is developing proposed essentials and competencies for laboratorians at the baccalaureate degree level and possibly those at the level of an advanced degree. The NAACLS has recommended a futures conference be held next fall to discuss essential competencies for each level of laboratorian.

American Society for Microbiology (ASM) Benchmarking Survey - Microbiology Productivity '99 **Addendum J**

Dr. Roberta Carey described several ASM surveys that have dealt with personnel and laboratory employment issues, and presented data from the most recent survey, conducted in the spring of 1999. The purpose of this survey was to ascertain the number of billable tests performed per full time employee (FTE) in microbiology laboratories, and determine the productivity of a variety of microbiology laboratory types. It was sent out via Internet to approximately 315 Ph.D. microbiology laboratory directors and members of ASM's Clinical Microbiology Division C. The number of responses was 119. In addition to the numbers of tests performed per FTE (including supervisory and clerical employees) and technical FTE (only individuals performing testing), the survey looked at microbiology laboratory testing practices. The data showed that productivity in laboratories with increased automation is higher than those performing manual testing. It also indicated that laboratories are continuing to perform a significant percentage of mycology, mycobacteriology and parasitology tests in-house, and that the percentage of molecular methods used for identification and susceptibility testing is high. As a result of these findings, Dr. Carey emphasized the importance of maintaining a highly educated and skilled microbiology workforce to perform the complex testing currently being done in laboratories. She also noted that as laboratory employees are required to do additional tasks, testing workloads should be decreased to maintain the quality of testing results.

Impact of New Technology on the Clinical Laboratory Workforce - University of Pennsylvania Medical Center (UPMC) **Addendum K**

Dr. Peter Wilding gave a presentation on current trends in health care affecting the clinical laboratory, and the impact of the trends on laboratory operations and the workforce. He included factors such as reduction in hospital and laboratory revenue, consolidation, increases in point-of-care testing, and new technology. Dr. Wilding said that laboratories must accept a "culture of change", and be prepared to remain efficient in light of these changes. He suggested ways for laboratories to respond to the current trends, including increasing productivity levels, decreasing

costs, increasing revenue, decreasing numbers of staff, reducing turn around times, and increasing automation. He gave several examples of the types of changes mentioned above, and their impact on UPMC, and concluded by showing some emerging technology that will affect the laboratory and its workforce in the future.

Public Comments **Addendum L**

1. Barbara Brumagim, Director of Research, Clinical Laboratory Managers Association, described the 1999 CLMA Staffing Survey, which questioned laboratory administrators about the supply of qualified laboratory personnel (MTs and MLTs) and workload demands in their facilities. More than half of the respondents replied they do not have enough qualified personnel, and a large percentage indicated a lack of qualified applicants for open positions.
2. Shirley A. Van Duzer, Legislative Consultant, American Society for Cytotechnology (ASCT), commented on personnel shortages in cytology laboratories, mentioning a vacancy rate survey currently being conducted by the ASCT.
3. Alice Weissfeld, Ph.D., Chair, Professional Affairs Committee, ASM, stated ASM's position that under CLIA, the minimum required education for bench level microbiologists should be a baccalaureate degree. The current requirement for an associate degree should be changed.
4. Ronald Luff, M.D., M.P.H., President-elect, American Society of Cytopathology, commented on the predicted shortage of cytotechnologists, the aging of the cytotechnologist workforce, and the impact this would have on gynecologic cytology (Pap smear) screening nationwide.

Committee Discussion

Dr. Merlin was joined by Dr. Robert Martin, Director, DLS, PHPPO, CDC, as the CLIAC discussed workforce shortages. In framing the discussion, Dr. Merlin referred to the presentations on the issue, and noted differences in perceptions as to the nature and extent of the problem. Dr. Martin reviewed a slide from Dr. Hearn's presentation, giving the expectations for the CLIAC discussion on this topic. These were to explore the problem, assess the adequacy of the data, propose strategies for further studies, and propose solutions.

The CLIAC discussed the presentations and public comments addressing laboratory workforce shortages. Although different views were expressed as to the scope and magnitude of the problem, Committee members noted the data identified definite shortages in some areas. In addition, since much of the data presented were several years old, it was suggested the problems may be more significant at this time than indicated in the studies. A number of CLIAC members said that data currently available are not sufficient to draw comprehensive conclusions as to the shortages and their impact on patient care. Committee members acknowledged that, although new technology holds some promise for alleviating workforce shortages in the future, it will be a number of years before this impact is felt. This is especially true for gynecologic cytology (Pap smear) screening. In the meantime, ways are needed to address the problem for the immediate future. Several members encouraged the government to work with academic institutions and professional organizations to obtain more and better data on laboratory workforce shortages and related issues, and develop plans for addressing shortages in the near and long term future.

Additional points made by one or more CLIAC members in response to the presentations and

public comments follow:

- Personnel problems and workforce shortages differ depending on the laboratory size and type (e.g. hospital versus physician office laboratories).
- Needs are emerging for multi-skilled, flexible laboratorians. However, as laboratorians are required to take on additional or different duties, work quality may be affected.
- Training and educational programs must address new essentials for laboratory practice, such as advanced knowledge of scientific and clinical aspects of testing, and reimbursement issues.
- Laboratory training programs must be innovative to succeed and be recognized as being of value to a hospital, since the return on investment is not seen immediately.
- There is a need to recognize the professional stature of laboratorians, and to help prospective employees or students understand what medical technologists do. Mentoring programs and active recruiting are needed to bring people into the laboratory field.
- As laboratory scientists are required to perform additional tasks, there is less time for research or new methods development. As a result, the publication rate drops and there is less publicity about the laboratory field when more is needed.
- Financial incentives, including increased salaries, are needed to attract high quality individuals to work in laboratories. However, this is difficult when hospital revenues are decreasing. In some cases, reimbursement for testing is lower than the cost of performing a test.
- Financial incentives such as grants, scholarships, or loans are needed for people who wish to enter the laboratory field but can't afford the necessary education.
- Job satisfaction is an important incentive for people to enter the laboratory field.
- People may be hesitant to enter the laboratory field because of safety concerns and concern there could be personal liability for errors in testing.
- Publicity about new technology may discourage people from entering the laboratory field, thinking they will soon be replaced by a machine. It is important to let potential laboratorians know there will be opportunities in the future. In fact, some testing may be more complex and require more expertise than previous methods.
- Changes in demographics (e.g. aging population), patient care (e.g. more immunocompromised patients), and the development of new diagnostic tests (e.g. molecular or genetic) are resulting in more complex testing being performed. As new tests are introduced or tests requiring considerable interpretation are used, physicians will need more assistance from the laboratory in the analysis of test results.
- Tests for antimicrobial susceptibility or resistance, molecular identification and typing, and other special tests in microbiology require a high level of expertise and education. This is becoming more critical with the increase in resistant organisms, the need for bioterrorism response preparedness, and the need to rapidly identify emerging pathogens.

- Although new technology may reduce the demand for manual Pap smear screening in the future, there will be an increased demand for other types of cytologic screening as the population ages. The difficult, time-consuming cases will require manual screening.
- As technology develops and testing changes, a dichotomy in educational and/or training requirements is emerging. At one end of the spectrum, simple, accurate, automated methods and instrumentation are being made available for use by those with minimal

laboratory background and experience. At the other end of the spectrum, highly complex manual testing is required in areas such as cytotechnology, microbiology, molecular pathology, and genetic testing, and oversight of testing is important. In these areas, extensive education and laboratory expertise is necessary to accurately perform and interpret the testing.

- CLIAC might re-examine whether an associate degree is adequate for newly emerging complex testing, or whether a baccalaureate degree should be required for some procedures.
- There could be problems in some geographical areas if a baccalaureate degree is required for testing, and technologists with this educational level are not available.
- In some situations, medical technologists with a baccalaureate degree feel overqualified for the tasks they perform and feel that their technical skills are underused.
- In attempting to resolve workforce shortages, laboratories and regulators should look at how to effectively use individuals with lower levels of education.
- Error rates are good indicators of adequate and appropriate staffing. However, it is difficult for laboratories to publish or openly discuss error rates.
- Laboratory accuracy and turn around time, and their affect on length of hospital stay, are valuable data in looking at workforce issues, and can be published.
- There are inherent difficulties in assessing productivity and comparing microbiology data to that of other laboratory specialties. Due to the nature of the testing, it is hard to compare like to like when even the workload for a single culture type can vary extensively, depending on the organism(s) present or positivity of the culture.
- The data presented are inadequate for making decisions to be applied to Public Health. Studies should also include economic and labor analyses.
- Data must be collected systematically and be published to be effective.
- CDC should do a consequence analysis for proposals made by the CLIAC. We live in a market driven society.
- For a short term solution to the personnel shortage, laboratories must keep current employees from leaving the field.

Dr. Martin summarized the CLIAC discussion on workforce shortages. He questioned whether shortages are a global problem throughout the laboratory industry, or only in local areas, saying there were some data and many anecdotes available. He noted that shortages are due to economic factors, including competition in institutions for FTE's and increases in salary between the laboratory and other health care professions, and asked what could be done to increase visibility for the laboratory. Dr. Martin then reviewed suggestions made by CLIAC members regarding ways to solve some of the workforce shortage issues. These included Federal agencies working with professional organizations to gather data to support the fact that workforce shortages result in an increase in error rates, and increased health care costs. He concluded by acknowledging that this is a complex issue that will take some time to correct.

Oversight of Genetic Testing - Committee Discussion **Addendum M**

Dr. Joe Boone, Assistant Director for Science, DLS, PHPPO, CDC, re-introduced the topic of oversight of genetic testing for CLIAC discussion with an overview of the implementation plans

for the genetic testing recommendations made by the CLIAC. He explained that additional public input on the CLIAC genetic testing recommendations will be obtained by publication of a Federal Register Notice of Intent seeking comments on the appropriate CLIA requirements for genetic testing. Dr. Charache added the SACGT has also been charged with soliciting public input on options for oversight of genetic testing. The SACGT is hoping to expedite the process of policy setting, and will look at the conflicts of access versus control of testing, and protection of patients versus availability of testing. Dr. Merlin asked Dr. Charache to remind the SACGT that in the process of developing recommendations for genetic testing, the CLIAC reviewed current CLIA requirements and found many of them to be adequate. He made a motion recommending the SACGT formally review the CLIAC recommendations regarding human genetic testing in making decisions, and the motion passed.

> RECOMMENDATION: CLIAC recommended that the SACGT formally review the CLIAC recommendations regarding human genetic testing in making decisions.

In light of the various Federal agencies and private organizations potentially involved in mandatory or voluntary oversight of genetic testing, Dr. Boone asked the CLIAC for input on the optimal approach to oversight. He described a three-tiered model that follows the development of testing from the research to the clinical setting. The Committee deliberated considerably on the issue of research only, and determination of when a test is validated for use of the results in patient care. CLIAC members noted it is difficult to draw the line as to when data are adequate for clinical use to begin in some circumstances. Dr. Boone agreed, but emphasized that for CLIA applicability, it is necessary to know when a research protocol becomes a valid clinical test in which results are linked to patients and subject to CLIA. In the three-tiered model he presented, tests in levels two and three would be considered clinical tests used for patient care. The difference between these levels would be the review process, the validation data required, and the type of approval given to a test. CLIAC members expressed concern and raised several questions as to which organization or governmental agency would review tests, the criteria used, and potential delays in testing that could result during the review process. Although these concerns are valid, Dr. Merlin stated there are sufficient public concerns and expectations about genetic testing to warrant more stringent oversight than for other clinical laboratory tests.

Dr. Charache led the remaining portion of the CLIAC discussion, posing several questions as guidance in obtaining CLIAC input for the SACGT. The first question asked for CLIAC comments on the concept of a graded approach to oversight. If such an approach were to be implemented, what would be appropriate for determination of levels (i.e. research versus level of testing, volume versus risk)? A number of CLIAC members expressed their views that some sort of tiered approach is favorable, one member stating that the process should be kept as simple as possible. The Committee then discussed how such a system of oversight would be monitored, and which authority would have the responsibility for ensuring compliance. Concerns expressed by CLIAC members included how the process might work for if the same test was performed by a single institution at multiple sites, and whether the scheme should differentiate between tests for heritable and non-heritable conditions.

Dr. Charache next asked the CLIAC if and how risk assessment should be considered in the

approach to oversight of genetic testing. Should oversight be more permissive for low risk tests? The Committee acknowledged the difficulty in attempting to address this question and categorize risk. There are different types of risks, and the degree of risk can change depending on the situation. In addition, a single test can be used for more than one purpose, which may have different levels of risk. The CLIAC concluded that although risk assessment should be a factor in determining oversight, the complexities and difficulties in attempting to quantify or categorize risk should be taken into consideration.

The third question posed by Dr. Charache was whether regulations, or oversight, should be more permissive for rare diseases than common conditions. She noted that it may be difficult to validate and use a test for diseases found only in small numbers. Again, CLIAC members indicated the complexities of this issue. They said that validation is necessary for every test, but that it may be limited in very rare conditions where few families are affected or it is difficult to obtain large numbers of samples to test. They also suggested clinical implications be considered in these circumstances, such as purpose of the test or effect on patient care.

Dr. Charache's last series of questions dealt with the role of the Institutional Review Board (IRB) in oversight of genetic testing. She reminded the Committee that any testing in which results are provided to patients, family members, or health care providers is subject to CLIA. She asked whether current IRB's have policies for permitting the investigator to provide patients with the results of tests. If so, are the policies followed? She also asked the CLIAC members who are laboratory directors whether IRB's permit them to determine when tests are appropriate for use in patient care. The responses were mixed for both questions. Last, Dr. Charache noted that criteria are needed for institutions with no IRB's, specifying the questions that must be answered before introducing a new test into the laboratory.

In concluding the discussion on genetic testing oversight, Dr. Boone thanked the CLIAC for the helpful information they provided. He asked for comments on the Notice of Intent being developed. One member suggested asking, in general, whether a new level of oversight is needed for genetic testing, and whether oversight at the Federal level is appropriate. Several Committee members said the concept of a graded or tiered approach to oversight should be in the Notice for comment, but that inclusion of a specific model should be avoided. Another member mentioned that some professional and deemed organizations have guidelines and processes that address the issues discussed by the CLIAC, and noted it may be helpful to obtain input from these groups for further consideration.

PUBLIC COMMENTS

There were no additional public comments for the CLIAC (see previous public comments on laboratory workforce shortages).

CONCLUDING REMARKS

Prior to adjourning the meeting, a motion was passed by the CLIAC to recognize and commend HCFA surveyors for their efforts in protecting the public. No recommendations were made

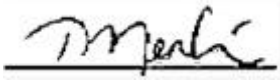
regarding action to be taken on laboratory workforce shortages. However, the CLIAC acknowledged that the numerous presentations at the meeting raised concerns about a broad shortage of qualified individuals in the laboratory workforce, and the Committee requested that Federal agencies investigate this further and take appropriate actions to prevent a crisis in the workforce. Dr. Merlin suggested two topics for future consideration by the CLIAC. They are:

- What process(es) could be used for collection of information on laboratory error rates
- Problems of the underserved population in Pap smear testing

Dr. Merlin thanked the CLIAC for their participation and adjourned the meeting.

Future dates for CLIAC meetings: April 5 - 6, 2000; September 27 - 28, 2000.

I certify that this summary report of the September 22 - 23, 1999, meeting of the Clinical Laboratory Improvement Advisory Committee is an accurate and correct representation of the meeting.



Toby L. Merlin, M.D.
Chairman