

**Clinical
Laboratory
Improvement
Advisory
Committee**

**Subcommittee Meeting on Proficiency Testing,
Quality Assurance and Quality Control**

September 27, 1994



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service



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Record of Attendance

The Clinical Laboratory Improvement Advisory Committee (CLIAC) Subcommittee on Proficiency Testing, Quality Assurance, and Quality Control met at the Centers for Disease Control and Prevention (CDC), Auditorium A, in Atlanta, Georgia on September 27, 1994. Those in attendance are listed below:

Committee Members

Dr. Susanne Gollin
Dr. Verlin Janzen
Dr. Bereneice Madison
Dr. Wendell O'Neal
Dr. Glenda Price
Dr. Morton Schwartz

Consultants

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

Executive Secretary

Dr. Edward Baker

Ex Officio Members

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

Liaison Representative

Dr. Fred Lasky (HIMA)

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 Podeszwick
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 Announcements

Dr. Wendell O'Neal, Chairman of the Subcommittee on Proficiency Testing, Quality Assurance, and Quality Control, introduced and welcomed the members of the subcommittee, noting that, with the exception of himself and Dr. Schwartz, all the members were new to the subcommittee.

Presentation of Issues

Dr. O'Neal reviewed the PT issues that were addressed at the March 23, 1994, subcommittee meeting. He stated that three of the four proposed changes addressed at that time had been recommended for acceptance to the full CLIAC committee, and that the fourth proposed change was to be considered following the provision of more information on the impact of that proposed change on the laboratory community. It is the consideration of this fourth recommendation, i.e., the recommendation to change consensus requirement for grading of PT samples from 90% to 80% consensus, that will be discussed at this meeting.

Ms. Rosemary Bakes-Martin provided background information on this fourth issue stating that data accumulated by PT providers over the last year has shown that 90% consensus is too high a requirement for true performance assessment. Because of the high consensus requirement, the number of ungraded PT samples has been much larger than anticipated, while analysis of these samples indicates that they are not true "problem" samples. Consequently, the educational component of PT is being lost in that the laboratories are not receiving the benefit of feedback in identifying and correcting actual problems that may exist. The challenge in establishing consensus percentage is to determine that percentage at which detected failures are true failures.

PT Provider Presentations

Ms. Bakes-Martin introduced the guest speakers who provided technical information pertinent to grading proficiency testing. The guest speakers were: Ms. Jane Bacher, College of American Pathologists (CAP); Ms. Dawn Crawford, Idaho Bureau of Laboratories; Mr. David Hassemer, Wisconsin State Laboratory of Hygiene; Dr. Ira Salkin, State of New York, Department of Health; and Mr. Nick Serafy, American Association of Bioanalysts (AAB).

Each of the PT providers presented data to support the return to 80% consensus (a requirement in previous Federal regulations) as a more realistic cutoff point for ungraded samples. They indicated that using 80% consensus would permit a better assessment of whether failures were due to sample variation or were, in fact, true

failures. The change to 80% consensus would increase the number of gradable samples, and consequently hold laboratories more accountable for poor performance. The PT providers expressed the view that the educational benefit of PT is diminished when there is no risk of failure to draw attention to improper PT test results. Copies of the data presented by the PT providers are attached.

Subcommittee Discussion and Recommendation

Subcommittee discussion was initiated by Dr. O'Neal. Questions were raised about the downside of using 80% consensus, and Ms. Bakes-Martin acknowledged that there would be an increase in PT failures. However, as a result of more failures, the educational aspect of PT would come into play and the second round of results should show an improvement in overall PT scores. Another subcommittee member pointed out that historically the 80% consensus had been required and that there has been no data presented to support the change to 90% consensus. The commenter stated that the issue should be whether or not laboratories are providing accurate results, not how many will fail. Each of the PT providers then stated their organizations' support for a return to 80% consensus.

Two recommendations were presented for vote:

Recommendation 1: Change consensus required for grading from 90% to 80% for microbiology organism identification and stain reactions based on the results of referee laboratories.

Recommendation 2: Change 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 recommended change would also apply to rapid antigen detection and susceptibility testing.

The subcommittee voted five in favor and one against the first recommendation and voted six in favor and zero against the second recommendation.

Dr. Lasky commented that laboratory performance, sample quality, and state-of-the-art of testing are all factors reflected in PT scores. He recommended that CDC re-evaluate the PT "criteria for acceptable performance" for those analytes in which the number of failures increase after the change to the 80% consensus. The subcommittee unanimously supported this additional recommendation.

Dr. O'Neal then opened the meeting to public comments related to the PT subcommittee. As there were no public comments, the meeting was adjourned.

I certify that this summary of the September 27, 1994, meeting of the CLIAC Subcommittee on Proficiency Testing, Quality Assurance and Quality Control is an accurate and correct representation of the meeting.

Wendell R. O'Neal, Ph.D.
Chairman