

**Clinical
Laboratory
Improvement
Advisory
Committee**

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

March 23, 1994

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



Subcommittee Meeting on Proficiency Testing,
Quality Assurance and Quality Control

March 23, 1994

Summary

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

Committee Members

Ms. Lynne Garcia
(for Dr. Ronald Zabransky)
Dr. Brenda McCurdy
Dr. Wendell O'Neal
Dr. Robert Pierre
Dr. Charles Ray
Dr. Morton Schwartz

Consultants

Dr. James MacLowry (CAP)
Mr. Nicholas Serafy (AAB)

Ex Officio Members

Dr. Carlyn Collins, CDC
Dr. Steve Gutman, FDA
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. James Bloom
Dr. Joe Boone
Ms. Genoria Bridgeman
Ms. Cheryl Coble
Ms. Crystal Frazier
Ms. Clio Friedewald
Dr. Edwin Holmes
Dr. Katherine (Kati) Kelley
Dr. John Ridderhof
Ms. Julie Wasil
Ms. Rhonda Whalen

Welcome and Announcements

The meeting was called to order by Dr. Wendell O'Neal, who introduced the subcommittee members, resource persons, and consultants in attendance, and acknowledged that Ms. Garcia was sitting in for Dr. Zabransky.

Dr. Schwartz welcomed those attending the first meeting of this subcommittee, and stated that the purpose of the subcommittee was to advise and make recommendations to CLIAC on proficiency testing (PT), quality assurance (QA) and quality control (QC) issues.

Issues

Introduction of CLIA PT Issues

Appendix A

Dr. Carlyn Collins opened the discussion by stating that PT is a key element in the CLIA process, and, whereas the law may appear straightforward in this regard, the implementation of the law is complex. She said that as a result of HCFA and CDC working closely with the PT providers, and through public comment, several PT issues have been identified. The two primary issues targeted for discussion at this meeting require regulatory changes. Dr. Collins then introduced Ms. Rosemary Bakes-Martin, Health Scientist in charge of PT for the Division.

Ms. Bakes-Martin presented to the subcommittee an update of PT activities at CDC, and outlined the specific PT changes proposed by CDC.

Ms. Bakes-Martin stated that during the phase-in of the PT requirements, the PT providers held several meetings. These meetings were initiated by providers in an effort to promote consistency in serving the increased number of laboratories enrolling in PT programs. In reviewing the PT results for 1993, a large number of ungraded PT samples were noted. For the most part, these samples were ungraded due to lack of consensus in the PT results reported. The smallest number of ungraded samples occurred with automated test systems and test systems that require limited interpretive skill, while the greatest number of ungraded samples occurred with tests that require more judgment and interpretation, e.g., immunohematology, blood cell identification, and microbiological testing. Under the current regulation, there are two factors that determine whether a sample is graded: (1) consensus based on either results from a group of referee laboratories or results from laboratories in a peer group, and (2) the minimum percent consensus needed to determine whether a sample is to be graded.

Ms. Bakes-Martin explained that a referee laboratory is a laboratory with one year of satisfactory PT performance, i.e., a laboratory that is considered to be a top performer; a peer group consists of laboratories that test for an analyte using the same or similar methodologies. The use of a peer group will account for random variability within comparative method groups. Currently, for all specialties except immunohematology, a sample must be graded if consensus is achieved by either 90% of ten or more referee laboratories or 90% or more of the participant laboratories in a peer group. For immunohematology, samples for ABO group, D typing, and compatibility testing must be graded if consensus is achieved by either 100% of ten or more referee laboratories or 95% or more of peer group participants. Samples for unexpected antibody detection and antibody identification must be graded if consensus is achieved by either 95% of ten or more referee laboratories or 95% or more of all peer group participants. Under the current regulations, providers may determine the gradability of a sample based on the consensus of either referee or peer group laboratories.

Ms. Bakes-Martin said that the reason for the consensus requirement was to adjust for samples in which uniform, correct results cannot be obtained due to a variety of problems such as matrix inconsistencies. A laboratory is not penalized for attempting to analyze such samples because the participant, in effect, receives a score of 100% on a sample that is deemed to be ungradable. This approach would be valid if the levels for consensus would ensure that most of the samples that were determined to be ungradable actually were "problem" samples. With that in mind, it was anticipated that the number of ungraded samples would be small; however, this has not proven to be the case. Analysis of the ungraded samples for 1993, in fact, showed that most of these samples should not have been identified as "problem" samples. Ms. Bakes-Martin explained that having a large number of ungraded samples where no real sample problems exist means that poor performance may be masked.

Ms. Bakes-Martin then outlined the CDC proposal for regulation changes designed to decrease the number of ungraded samples. One proposed change was to base the consensus requirement on referee laboratories' performance for all testing in immunohematology, hematology blood cell identification, organism identification and stain reactions in the microbiology subspecialties. She also stated that referee grading had been considered for microbiology direct antigen and antimicrobial susceptibility testing, but she suggested that this proposal be discussed by the subcommittee. For all other tests, consensus could be based on either referee or peer group laboratories' performance; however, the percent consensus for peer group laboratories would be changed to 80%, with the consensus requirement for referee laboratories remaining at 90%. Providers would continue to choose peer group laboratories or referee laboratories at their own discretion.

Dr. Edwin Holmes gave a presentation summarizing the information received from PT providers on the 1993 ungraded PT samples. The total number of ungraded samples by specialty/subspecialty and by analyte or test system was detailed, along with the percent consensus obtained for each sample. Of special interest was the large number of ungraded samples reported for immunohematology, blood cell identification, and microbiology, i.e., tests which require interpretive skills.

Dr. Holmes observed that if the consensus requirement for peer group laboratories was changed to 80%, there would continue to be many ungraded microbiology samples. However, all of the ungraded samples in immunology, except for HIV and anti-HBc, would be gradable using an 80% consensus, as would many of the ungraded samples in the other areas. In one sample testing event, a matrix problem occurred, or was associated with, cholesterol, and in toxicology and endocrinology, some samples were ungraded because there were less than 10 participants in the peer groups. Ms. Bakes-Martin said that with the large number of ungraded samples in all areas, it is difficult to detect problems. Therefore, CDC is suggesting changes in the regulations in an effort to increase the number of gradable samples, and thus make it easier to identify true performance problems.

Subcommittee Discussion

The subcommittee asked for reiteration and clarification of some of the data presented, including a definition of matrix effect. Ms. Bakes-Martin explained that matrix effects occur when PT samples differ in composition from patient samples.

Following additional general discussion, Dr. O'Neal summarized by stating that there are two main issues at hand: (1) the make-up of the reference base, i.e., referee laboratories or peer group laboratories, and (2) the percent consensus requirement. He further indicated that CDC was presenting specific proposed regulatory changes regarding these two issues, and suggested that the subcommittee focus its attention on these proposed changes.

CDC Recommendation 1:

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

Discussion ensued and a subcommittee member asked for input from Ms. Kay McCurdy, an AABB representative who was in the audience. Ms. McCurdy expressed concern about the method for selecting referee laboratories and indicated that referee laboratories should be representative of all of a provider's participant laboratories. She stated that guidelines are needed for the selection of referee laboratories. She pointed out that it is difficult to develop a good PT sample that maintains stability during shipping.

Dr. O'Neal asked if there was consensus to agree with the CDC recommendation and the Subcommittee voted to recommend the proposed change to the full CLIAC.

CDC Recommendation 2:

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

A subcommittee member asked if the recommendation was for morphology only and not for automated differentials. Ms. Bakes-Martin said that the recommendation was for morphology only. Discussion then focused on the differentiation of the band and segmented neutrophil and it was suggested that CDC specify the types of cells a physician office laboratory (POL) should be able to identify. Another subcommittee member commented that some data indicates that even referee laboratories do not achieve 90% consensus in cell identification when distinguishing between band and segmented neutrophils. Ms. Bakes-Martin acknowledged that fact, but said that CDC feels that referee laboratory consensus is appropriate for this area.

Dr. O'Neal asked if the subcommittee agreed with CDC's proposed change, and the Subcommittee voted to recommend the proposed change to the full CLIAC.

CDC Recommendation 3:

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

The subcommittee was asked also to consider making the same change for microbiology direct antigen testing and antimicrobial susceptibility testing.

The subcommittee discussed several problems associated with PT samples in

microbiology, such as the difficulty of producing thousands of good slides for Gram stain, and the instability of urine samples for culture. However, the subcommittee concluded that requiring consensus of referee laboratories for scoring PT results for organism identification and stain reactions could be workable. Microbiology direct antigen testing and antimicrobial susceptibility testing was also discussed but no consensus was reached on recommending that these tests be included in the proposed change in the PT requirements. The subcommittee voted that the CDC proposed change for organism identification and stain reactions in microbiology be recommended to the full CLIAC.

CDC Recommendation 4:

For all other tests not included in the previous three recommendations, change the regulations so that the consensus requirements for PT grading when based on peer group results would be 80%, instead of the currently required 90%.

A subcommittee member asked for an estimation of the expected number of PT failures if the change to 80% was made. Ms. Bakes-Martin said that, with the change, most of the samples discussed in the CDC presentation would be graded, and that there would be some failures in chemistry, HIV and hepatitis testing.

Dr. Robert Rej, a representative from New York State who was in the audience, presented and discussed three overheads [See Appendix B]. Using triglycerides as an example, he said that at least for certain analytes, the criteria for acceptable performance currently included in the regulations need to be evaluated before considering any changes in the consensus requirements. He said that the acceptable limits for PT samples are so wide that only a few laboratories fail when target values are established using 90% consensus. He thinks that there would be essentially no difference if the consensus requirement was changed from 90% to 80%. Dr. Lasky, a non-voting liaison to CLIAC who represented a group of manufacturers, pointed out that not all quantitative analytes perform as well as triglycerides and there are significant differences between PT samples and patient specimens. Ms. Bakes-Martin said CDC plans to evaluate the limits for PT samples as more data on PT performance is received.

One member asked if the 80% would apply to all tests not specifically mentioned in the previous three recommendations. Ms. Bakes-Martin responded yes and said that the 80% consensus would allow more samples to be graded. Some members felt that the change from 90% to 80% should not apply to microbiology direct antigen testing and antimicrobial susceptibility testing, but Mr. Serafy, a

consultant to the committee, disagreed, saying that he would prefer requiring less than 90% consensus for these tests. Another member said that we need to consider the impact of any changes that are made. Dr. Collins responded that if the consensus requirement for peer groups remains at 90%, the large number of ungraded samples would continue resulting in many undetected poorly performing laboratories failing to take the corrective action necessary to improve performance. She said that if the consensus requirement is changed to 80%, more samples would be graded and it would be easier to detect the laboratories that have problems. One subcommittee member asked what happens to laboratories that fail. Dr. Collins replied that the sanctions are outlined in the regulations. She said that since we are still in the phase-in period, PT is still educational for previously unregulated laboratories, but that we should move toward ensuring that PT performance problems are identified. A subcommittee member said that sanctions and the punitive aspects of PT are separate from this discussion and noted that laboratories could use PT for educational purposes when samples are ungraded. Another member pointed out that laboratories would take the educational component more seriously and focus on correcting the problems if failures are identified rather than having ungraded samples.

Dr. Verlin Janzen, speaking from the audience as a representative of the American Academy of Family Physicians, said that many of the laboratories having problems are the smaller laboratories, primarily the POLs. He predicted that a learning curve would occur in the POLs as was seen previously in hospital laboratories. Since POLs were not required to be enrolled in PT until January 1994, we can expect that many of the performance problems identified through PT will be resolved as the laboratories gain experience in testing PT samples. He said that performance in a PT program may not be a good way to differentiate "good" and "bad" laboratories. He does not believe there is enough data available on POLs to determine whether a problem really exists.

After further subcommittee discussion of the proposed change to 80% consensus, it was determined that additional information was needed on the number of laboratories that would pass or fail before making the proposed change. The subcommittee then voted to further consider CDC's fourth proposed change following the provision of more information on the impact of the proposed change on the laboratory community; this information is to be provided to the subcommittee at its next meeting.

Public Comments

Dr. Paul Bachner presented data from the New York State PT program indicating that in January 1993 in one immunohematology testing cycle, almost 13% of 290 laboratories failed PT. Some of the failures were due to technical problems, but the

majority of laboratories failed because of clerical problems, such as filling out the report form inappropriately, transposing numbers, or returning the results after the required timeframe. He said that under the Clinical Laboratory Improvement Amendments, all types of errors are treated in the same manner, but that previously New York State imposed less stringent penalties for clerical and administrative errors. Dr. Bachner made a plea for a sanction mechanism which would allow clerical and administrative errors to be dealt with less stringently than technical errors.

Ms. Bakes-Martin responded that a laboratory is not required to stop testing unless there are failures on two consecutive or two out of three consecutive events. Ms. Yost added that if a laboratory is flagged for unsuccessful participation, prior to any adverse action, the laboratory surveyor first requests the actual data in order to review the situation in detail. Dr. Bachner stated that his impression from New York State was that all failures had to be reported to HCFA, and Dr. Rej, from the audience, agreed with that impression. Ms. Yost responded that surveyors should fully investigate a situation before any sanction is issued, and HCFA can communicate with the surveyors if such investigations are not occurring.

Ms. Yost then pointed out that, for 1994, there are no sanctions for previously unregulated laboratories but that these laboratories should obtain technical assistance, if needed, to improve their performance. Ms. Bakes-Martin said that the PT providers may be willing to offer their assistance to resolve testing problems.

Ms. Bakes-Martin further stated that CDC will be presenting a proposal at the upcoming PT provider meeting that would standardize the reporting of PT data, and would include evaluation of data from each provider and across programs, following each PT event.

Dr. Schwartz suggested that efforts be made to shorten the process of recertification for laboratories that have failed PT and that he hopes that this issue will be dealt with in the "final-final" regulation.

The subcommittee meeting was then adjourned by Dr. O'Neal.

I certify that this summary of the March 23, 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

Addendum A

Addendum B