Modern Quality Management Misunderstood?

To the Editor:

Currently, there is a trend in clinical chemistry to assess laboratory quality by so-called "quality management techniques". These techniques enable managers to investigate the quality of complex processes and allow identification of weak points within these processes. In addition, they allow the investigation of patient-benefit-related outcome of testing. According to a recent editorial in this journal (1), the application of these techniques in the clinical laboratory are expected to yield "healthcare that is not only better but cheaper, and much more satisfying to practice." I agree with that statement, but I was somewhat surprised that it was evoked by two studies in the same issue of the journal (2,3) that, in my opinion, do not substantiate these expectations.

The studies that were cited, and nearly all studies of that kind, come down to the message that (a) the error frequency in the clinical laboratory is very low (2,3); (b) most errors occur in the pre- and postanalytical phases (2); and (c) the vast majority of analytical errors would not have caused severe patient management problems (2,3). In short, the reader is convinced that current analytical quality is excellent. On those grounds and considering the cost-pressure on the laboratory, nobody can take seriously such statements as "improvement (read: of analytical quality) should be possible" (3). I do not dispute the value of the cited studies, but their approach is limited. For analytical quality, they investigated only whether the process had been applied correctly, and they assessed, in fact, relative quality. For example, in one of the cited articles, results were classified as unacceptable on the basis of the imprecision of the analytical methods used (3). Whether the imprecision itself was questionable was not discussed. In the other study (2), clinicians were asked to identify suspect results. I assume that the clinicians reacted on the basis of their experience with the analytical quality that was available. Whether the intrinsic quality of the test was satisfactory was not discussed. Thus, the weakness of such studies is that they do not recognize that error-free operation is meaningless when the intrinsic quality is poor. The same holds true when the clinical accuracy of a test is poor or when the test had been inappropriately ordered.

The cited articles, indeed, showed that process performance was excellent. However, the laboratory should also feel responsible for the intrinsic analytical quality it offers and for the value that a certain test has for the patient. I see danger in the question of intrinsic analytical quality and test value will be pushed out of focus by such studies, and interest will be moved to the pre- and postanalytical phases. Indeed, the latter two might have been given too little attention in the past. Nevertheless, analytical quality should stay in focus, because it is the most important value the laboratory can offer. I feel it more urgent to locate the problem areas in the laboratory than to demonstrate that, in general, everything is perfect. Otherwise, old statements will come back in nice new clothes, such as the phrase: we were good, we are good, we will be even better in the future, and we only have to sell ourselves better.

Many of the problem areas are, in fact, known. Among them are measurements of free hormones or steroid hormones at low concentrations. In addition, many analytes are not unequivocally defined, and it is often not known what is really measured. Think, for example, of glycated polypeptides. Different tests give different answers, with the consequence that common reference intervals or cutoff values cannot be used. This will become a serious problem in the future because of the need for unified treatment strategies and the introduction of expert systems. For the same reason, standardization will become a major issue; in fact, it has not yet been achieved in many areas. Knowledge about internal quality control is still far from optimal and might even diminish in the future because of industry promises that the new systems have built-in quality control with no need for attention by the user. Reaction patterns when quality control rules are violated are often overly simplistic. For example, many people recommend remeasuring the control and, when it is "in again," continuing with patient specimens.

Modern quality management, on the other hand, goes far beyond assessment of whether current processes are correctly performed. Its strength is its ability to disclose the weak parts of the overall process and to estimate the value of the process itself. However, this can be effective only when all input elements are checked for validity. In this view, modern quality management should assess actual quality on the basis of specifications for desired quality. Furthermore, it should provide tools that allow practitioners to anticipate future quality needs in an early stage.

Modern quality management is much more than the investigation of error rates and the effects thereof. The latter is valuable, but nowadays the more important problem for laboratories is to demonstrate that their services are useful for patient management. The primary task is not to prove that the measurements do no harm (which directly provokes concern that they are of no use either) but to demonstrate their benefits for the patient. Modern quality management should, therefore, refocus the laboratory on, for example, test selection. This needs another way of thinking, one that is primarily focused on the clinical utility of measurements. An exemplary article that demonstrates this kind of thinking...
was recently published by Hammond (4). He applied utility analysis to the question of measuring (or not) glucose for the early identification of diabetes. The completeness of the input data in that article is striking. Among the data are knowledge of actual analytical quality, knowledge of the biological variation of glucose in healthy and diabetic subjects, knowledge of the prevalence of diabetes mellitus, and a decision threshold for glucose. On the basis of these data, a decision theoretical analysis is performed to answer the question of whether to test or not to test. I think that this kind of article is needed in Clinical Chemistry to demonstrate the real benefits of modern quality management for the laboratory and the patient.

References

Dietmar Stöckl
STT Consulting
Abraham Hansstraat 11
B-9667-Horebeke, Belgium
Fax 32 5549 8671

The authors of one of the articles referred to above reply:

To the Editor:
In response to Stöckl’s letter, we stress that the duties of the clinical laboratory are to provide information to assist in the diagnosis and monitoring of disease and to promote patient care. However, as yet, quality assessment programs in clinical laboratories have dealt with the integrity of the analytical process that produces laboratory test results without considering whether the tests enhance patient care. In the past, the main focus was on improving the analytical reliability of laboratory tests, but the new standard to be adopted should be to establish exactly how appropriate tests are for patient care. Patients cannot be safeguarded merely through accuracy and precision in the analytical phase of the testing process. Our recent paper (1) showed that mistakes in the preanalytical and postanalytical phases of testing seem to compromise the usefulness of laboratory results in patient care more often than poor performance in the analytical phase of testing, thus confirming the data previously reported by Ross and Boone (2).

These findings point to the need to evaluate all the steps in the entire testing process and to promote the quality of the entire process, including the pre- and postanalytical phases. Therefore, as stated by Stöckl in his letter to the editor, state-of-the-art laboratory competence calls for the ability to conduct test-ordering, specimen collection, transport, storage, analysis, and result-reporting in an accurate, timely, and cost-effective way. Of course, quality assurance schemes are necessary, but they do not sufficiently guarantee the quality of a clinical laboratory service. This does not mean that the analytical quality in clinical laboratories is excellent or that we should curtail efforts to improve the standardization of methods, the design of instruments, and technical performance in general. We stress that the results reported by us in the above paper were obtained in a stat laboratory that tests mainly for relatively simple and standardized analytes. We are aware of the pressing need to improve analytical quality for more sophisticated analytes (e.g., hormones, tumor markers, and special metabolites). However, any such improvement will be of value only if an effort is made to ensure that requests for tests and the interpretation of results are appropriate. Moreover, the error rates [447 parts per million (ppm) analyses] that Witte described (3) and the error rates that we described (4700 ppm) are quite different because of the different study designs, but they both indicate the need to evaluate the effect of all laboratory errors on patients’ outcomes, and to consider continuous quality improvement as the goal of our everyday activities.

Blumenthal’s well-written editorial (4) stressed the importance of collecting data on laboratory mistakes and working out new methods for preventing and minimizing nonconformities. Our paper, despite some weakness in its study design, is in line with this view.

Moreover, we believe that we must now demonstrate to customers and administrators the vital importance of laboratory medicine in patient care. Here it is crucial to communicate to clinicians the overall reliability of laboratory tests by considering analytical performance as well as other important variables. In other words, although we do not wish to undermine the great importance of analytical quality, which remains the core for total quality, we do wish to stress that it is risky to presume that good analytical data can be provided if specimens are unreliable and/or erroneous clinical requests are made. Modern quality management must be implemented on the basis of an overall view of laboratory medicine as a medical discipline. Clinical laboratories can no longer be considered “supermarkets”.

References

*Author for correspondence.

Mario Plebani*
Paolo Carraro
Servizio di Medicina di Laboratorio
Laboratorio Centrale
Azienda Ospedaliera di Padova
Via Giustiniani, 2
35128 Padova, Italy