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Analytical Quality, Test Quality and Quality Costs

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ABSTRACT

This paper discusses briefly

analytical quality and its determinants

design of quality assurance procedures on the basis of quality specifications and quality-cost models

test quality and medical costs

external quality assessment and harmonization of clinical chemical test results

the potential role of computers, database and knowledge-based systems in achieving quality goals in decentralized analytical activities.

ANALYTICAL QUALITY

The analytical quality of a laboratory test result is determined not only by the quality of the analytical method proper, but also by the calibration procedure and the control procedure. The saying that 'A chain is no stronger than the weakest link', applies also here, and it is necessary to consider all three links when attempling to optimize the performance of the total analytical procedure. Analytical quality is generally expressed in terms of analytical imprecision and analytical bias. This may be appropriate during stable analytical performance. However, the existence of analytical disturbances resulting in e.g. systematic shifts in baseline and increases in the inherent random error, also influences on the analytical quality of reported test results. The need of a quality control procedure depends on the frequency of occurence and the magnitude of these disturbances (11). For instance, if analytical disturbances occur very seldom or never at all, or if the magnitude is negligible compared to allowable analytical errors, we do not actually need a quality control system. On the other hand, if we do not know the nature of analytical disturbances we require an effective quality control procedure to find out.

DESIGN OF QUALITY ASSURANCE PROCEDURES

Given the limits for allowable analytical errors we can estimate critically sized analytical disturbances, i.e. how large systematic shifts and how large increases in the inherent random error we can accept without jeopardizing the quality goal. Recommendations of allowable analytical errors in various clinical situations have been published (cf. 5,6), but much work still remains to be done to assess the quality requirements in primary care. Such quality goals derived from medical needs form a rational starting point for a quantitative design of quality assurance procedures (8). Computer simulation techniques are then very helpful to evaluate various statistical control rules and to determine the optimal number of controls and calibration standards for a particular analytical method (1). A suitable optimization criterion would be to minimize the quality-costs of the procedure (12). This formulation of the problem considers costs related to reruns caused by true and false rejects of analytical runs, requests for reruns in connection with false (and true) accepts, in additon to costs for calibration and control material, training of personnel etc. The multi-rule Shewhart procedure published as a "proposed selected method" in clinical chemistry (9), was designed to be applicable also in small laboratories without computer support. It is not very likely, however, that primary care doctors will plot these types of control charts manually. Microcomputers are required for implementation of working quality control procedures in these settings (10). More complex trend analysis techniques could also be easily applied for continuous monitoring of critical changes in accuracy and imprecision. Colour-coded displays would fascilitate the interpretation and communication of actual control status to non-laboratory personnel.

TEST QUALITY AND MEDICAL COSTS

A clinical chemistry test is not only an analytical determination but also a decision criterion. The quality of a test therefore also depends on the choice of the discriminatory limit. It should be realised that the conventional reference limits for healthy individuals provided by most central laboratories do not generally constitute optimal discriminatory limits. Such limits can only be calculated after specification of the relative importance to avoid misclassification of different types (falsely positive and falsely negative outcomes) in order to minimize costs for misclassification. Costs and inconveniences related to misclassification may, to the extent they are quantifiable, be used as measures of the importance to avoid misclassification. These costs include "financial cost" for personnel, investigations and care etc., "health costs" related to mortality, morbidity, pain and anxiety in connection with diagnostic investigations and therapy.

The optimal value of the discriminatory limit and the predictive value of a test also critically depends on the prevalence of disease in the situation the test is applied. The analytical quality may also influence on the usefulness of the test. Computer simulation is a powerful technique for studying this problem complex. This is illustrated in ref. (3) as applied to screening of patients with hyperparathyroidism with use of serum calcium determinations. The same technique can also be applied to assess quality requirements in connection with diagnosis and patient monitoring.

HARMONIZATION OF TEST RESULTS

An external quality assessment program should lead to some concrete measures to decrease the variation between various laboratories and differences between single instruments within a laboratory. This problem of "harmonization" of reported test results could be approached by correction of systemic differences as estimated from analyses of "accuracy assessment standards" and comparison with definitive or reference methods. This problem will grow in importance with the increased decentralisation of laboratory services. The conditions for a successful implementation of such a "harmonization program" has been investigated by computer simulation (4), and is practiced in full scale in connection, with health screening in France (P. Valdiquié, personal communication). Database management systems (2) and data communication technology (7) are necessary prerequisites for a successful achievement.

TOOLS FOR IMPLEMENTATION OF QUALITY ASSURANCE PROCEDURES

As mentioned above microcomputers are necessary for implementation of working quality assurance procedures in decentralized laboratory activities. Computers will probably be commonly available in primary care centers and the doctor's office for word processing, patient administration etc., so there should be no severe economical constraints. First generation quality control packages have been commercially available for some years (10). The next generation of these packages will provide powerful database management facilities, advanced colour graphics and sophisticated reasoning mechanisms providing advice on how to do in various situations to assure the specified quality. Transmission of quality control data between laboratories for external quality assessment and harmonization programs is another important facility of such a workstation. Knowledge-based systems are also of great interest for supporting proper test selection and interpretation of test results, considering knowledge on age-, sex- and disease related reference values, optimal discriminatory limits, and the influence of drugs on analytical determinations.

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