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QUALITY CONTROL

by

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The purpose of a system of quality control in clinical laboratories is to assure the laboratorian and the physician that the data provided by the laboratory are reliable, are not (even potentially) misleading to the physician, and also provide for documentation of the quality of the laboratory's performance. In the application of quality control programmes, laboratories should direct their efforts towards achieving a level of performance where the results from one laboratory have the same significance in another.

It is not the intent of this paper to present a detailed and specific approach to quality control programmes for each clinical laboratory discipline or test procedure. There are many excellent publications available which offer adequate guidelines for implementing quality control programmes in the various specialties of clinical laboratory practice (see references). Since there are several ways of accomplishing the purpose of quality control programmes, the structure may differ from one laboratory to another. However, there are certain fundamental issues such as the components of a quality control system, good laboratory practices, surveillance, use of consensus standards, and use of reference laboratories and cost, which should be considered under any circumstances. It is the purpose of this paper to discuss these issues.

Components of a quality control system

The quality control system for a clinical laboratory is dependent on the supporting activities and elements which are organized and maintained by national and international efforts and are covered in detail in other working papers for this conference. In implementing a clinical laboratory quality control programme the organization of laboratory services at the national level (centralized, decentralized, regionalized) must be taken into consideration, as well as whether or not the operation of clinical laboratories is subject to national regulation. The national capability to evaluate laboratory technology and to standardize and/or control laboratory procedures and the quality of diagnostic materials are major factors in determining the type of quality control programme to be utilized. If that national capability is lacking, there should be ready access to such capability on an international basis.

The clinical laboratory director must select methods (test systems) providing the most appropriate combination of desirable qualities such as dependability, accuracy, precision, sensitivity, speed, freedom from interferences, cost, etc., which are appropriate to the purpose of the laboratory.

The quality of test results will depend greatly upon the capability of the laboratory to assure a continuous supply of defined, reliable, and stable reagents; the continuous maintenance of the integrity of the laboratory instruments including a system of repair, supply of parts, and a preventive maintenance programme; the capability of the laboratory to provide and maintain appropriate test conditions such as temperature, pH, timing, volume measurements, etc.; and to provide a system for initial and periodic retraining of personnel performing test procedures.

Each test procedure should provide, as an integral part of the system, a reliable system for local laboratory calibration traceable to national or international standards of accuracy (where available), with periodic checks to assure maintenance of accuracy. Accuracy of results and inter-laboratory comparability is dependent upon the inherent accuracy of the test system and the materials used for initial calibration and periodic maintenance. In many cases, accuracy can be maintained only by carrying out the calibration process for each test run.

The quality of test performance should be assessed routinely using quality control reference materials each day the test system is used. The parameters of performance are usually measured in terms of precision (variability of results) and accuracy (differences from expected results). Dependability is measured in terms of frequency of breakdowns for which action limits should be established. Action limits should be set for each control material as used in each test system which indicates that the test system may be giving unacceptable results. These action limits represent the antecedent judgment of the laboratory director about the testing process and its expected behaviour, and his directions to the person performing the test when the action limit is reached.

Good laboratory practice

There are a number of specific rules which should be observed in the implementation of a clinical laboratory quality control programme in the preanalytical as well as the analytical stages. In the preanalytical stage, the laboratory director should select a test system appropriate to his needs and validate it to assure himself as to its accuracy and precision. This step includes, as well, a training period for those performing the test. All personnel who are to be assigned to perform the test should be trained and observed to assure their familiarity with the procedure and to measure their competency. The specifications for reagents, their supply and formulation, and performance checks should be met, as should the specifications for the performance of the necessary equipment, glassware and other supplies. The specific ambient conditions for the performance of tests (temperature, pH, etc.) should be assured. Provision should be made for recording the results of the testing procedures on speciments, calibration and control materials, as well as for other relevant control data.

In the analytical stage, written procedures for each test system should be available to guide the person performing the test, not only as to the details of the procedure, but also for the calibration process, the use of control materials, and the designated responses associated with specific action limits. The calibration process and the use of associated materials should be carried out initially, and periodically as the protocol requires. Records of calibration results should be maintained. Appropriate reference and control materials should be included in the test run, and records made of the results. Patient specimen identification, including date, and other test identifiers should be recorded along with primary data, as well as the final calculated results of the test.

Surveillance

This step should be regarded as entirely separate from the process of calibration. The information collected by surveillance should not be used to "correct" patient test results. Any such corrections, if made, should be carried out as a part of the calibration process and on the basis of data derived from reference materials, other than those used for surveillance. The surveillance system should assess both precision and accuracy. If no definitive accuracy base has been established, each test system should be evaluated for "relative accuracy" by establishing a local temporary "expected value" for the reference control materials used.

External quality control or proficiency testing is an extension of the local laboratory's system of quality control. It adds the dimension of a larger consensus of an accuracy base and allows a comparison between methods as well as between laboratories. Proficiency testing programmes usually consist of, but are not confined to, the processing of "unknown" specimens which have been characterized by a group of reference or referee laboratories, and provided by mail from a central source. Results are analysed at the central source to determine and compare levels of performance of participant laboratories, and to evaluate the test methods used. There are several good proficiency testing programmes which are operated on a national or international basis to which laboratories may subscribe as an external mechanism of surveillance of the quality of their performance, or as an effective educational tool. Other, less frequently used types of proficiency testing programmes, include "blind" proficiency testing, on-site proficiency testing, and retrospective sample of product proficiency testing.

Use of consensus standards

Consensus standards for clinical laboratories are agreements among professionals as to good laboratory practice. Such standards, once established, generally provide the basis for standardization of the basic elements of a test system, or of quality control needed for clinically useful results. Some standards may be made mandatory by law or regulation, and may specify minimal qualifications for personnel, for quality control and for participation in proficiency testing as well as for appropriate record keeping. Compliance with such regulations in many cases will incur costs both to the laboratory and for the actual compliance process.

Use of reference laboratories

Reference laboratories are important reservoirs of back-up diagnostic services and consultative assistance for the clinical laboratory. They should be used for the less frequent, complex test procedures which are difficult to maintain. While there is a tendency to use commercial test kits to provide such services, unless the requisite degree of familiarity and proficiency can be assured, it is better to allow such services to be provided by laboratories having larger workloads for such tests. Reference laboratories also fulfil a quality control function to the extent that they can be used to verify results obtained by the clinical laboratory or to provide validated reference control materials. Reference laboratories also provide an essential component of quality control by their participation in proficiency testing programmes. Their results, together with many similar reference laboratories, can provide a consensus accuracy base where no more objective basis exists.

International co-operation in quality control

Laboratory quality control, as a primary responsibility, should be exercised in the individual laboratory by assuring good laboratory practices, supply of reliable reagents, and a system of internal quality control for continual surveillance of results. Such practices are strongly supported by systems which permit comparisons to be made with other laboratories. This can be done by informal arrangements to exchange specimens with one or a few other laboratories, by more formal proficiency testing programmes, many of which are available to laboratories around the world, and by the use of reference laboratories to confirm results obtained locally. The use of calibrator and control materials can be used to periodically or routinely establish the accuracy of local values or test results.

For certain test procedures, international programmes of standardization or international reference materials are available, which can be used to check individual laboratory results.

Cost of quality control

Quality control costs are difficult to measure or even to define; the costs of not having adequate quality control may be even greater.

The national and international system of reagent and instrument supply is not usually regarded as quality control. However, without such a system, maintained by the commercial self interest and by government control, the difficulties of the task of the laboratory director would be greatly multiplied. In some parts of the world, climatic and other conditions make the provision of stable, long lived reagents and instruments extremely difficult. The World Health Organization is directly addressing this problem by devising instruments and test systems especially designed to withstand these strains.

The cost of appropriately training persons to carry out clinical laboratory tests is a long-term investment in quality control. It has been shown that an investment in basic laboratory orientation is essential to provide the necessary knowledge to make their further training in specific skills more effective.

Costs involved in record keeping are essential to a quality control programme. Only if records are kept well and displayed appropriately can trends and sudden subtle changes in laboratory quality be detected. In laboratories without such record keeping, there can be no supervisory review of the quality control system.

Surveillance costs are unavoidably greater if the test workload is small, and becomes proportionately smaller as the number of tests increases. This is not a reason for slighting quality control in the smaller laboratories. It may serve, however, to indicate that reference laboratories should be used. Surveillance serves to protect the laboratory director from legal suits as well as the physician and patient from suffering the results of incorrect and possibly misleading results.

The costs of laboratory errors are seldom appreciated. Although a laboratory error may be recognized by a physician who may request a repeat test, the consequences of a laboratory error not detected and compensated for by the physician may be serious. Mechanisms have been developed to calculate the costs of laboratory errors and they may be several times as great as the costs associated with the test itself as well as the costs of appropriate quality control procedures which would have prevented, or at least identified, the error at the time the test was performed.

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