QUALITY CONTROL AND QUALITY ASSURANCE IN LABORATORY RESEARCH

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Quality Control (QC) and Quality Assurance (QA) are integral part of laboratory medicine. Quality control is clinical chemistry denotes the reliability of the information provided by the results regarding the patients.

"The primary aim of the laboratory is to produce correct results, not by chance, but at all times and it uses quality control methods to achieve and demonstrate this."

P.M.G. BROUGHTON

In other words, QC measures form the basis for quality assurance. Two yardsticks are used in QA viz. Accuracy and Precision. Accuracy denotes the agreements between the estimated value and the true value. Precision denotes the agreement between the replicate values or it is a measure or variability. In order to ensure accuracy and precision, the method used should be specific and sensitive. Specificity is the ability to measure the analyte only and sensitivity is the ability to measure small quantities.

QA is thus by choosing an appropriate specific, sensitive and accurate procedure with precision which involves consideration of several other practical aspects such as the speed, economy and the skill required. The present day modern methods have been widely tested and certified by international body such as IFCC. Such tests assure both accuracy and precision and should be used by the laboratories aiming QA and Qc. For special reasons, if a laboratory choose to use a less costly procedure, it should standardise its own normal values and mention it in the reports. However, it is mandatory that some of the old non-specific chemical methods should be given up. For e.g. the Folin-Wu or Somogyi-Nelson methods for blood glucose which have poor rates of specificity and sensitivity.

In research laboratories, no compromise can be made on QA as today's is the trendsetter for tomorrow's clinical diagnosis. Comparison of data between laboratories, both the national and international level is possible by use of standardized procedures.

In laboratories involved in epidemiological research, it is essential that standard methods recommended by the WHO are used so as to enable comparisons with data from other countries. If tests like blood glucose are done at the survey sites, the quality of the results need to be counter checked by testing a batch of same samples in the laboratory also. Variations in temperature, humidity and the mode of storage of glucose test strips can effect the reading taken by reflectance meter and appropriate measure are to be taken to avoid the errors.

Analytical errors, but not biological variations are the causes of intra and intra-laboratory variations. Internal and external quality control measures should be adopted and recorded by each laboratory.

Measure to ensure precision

1. Replication of tests with calculation of coefficient of variation (CV).
2. Good quality of control materials (with known values of analytes)
3. Goods selection of calibrators (standards), controls of appropriate matrix.
4. Ensure proper methods of storage.
5. Check within batch variations, day to day variations and reagent variations.

Assessment of Accuracy

1. Check of linearity of the reaction
2. Recovery experiments.
3. Use controls with known values
4. Compare the method with a definitive method with no known source of inaccuracy and determine the correlation coefficient.
5. Drug interference should be checked.

Internal quality control measures by using controls, replications and random sample check determine the drifts occurring in the daily tests. Appropriate remedies to correct any large deviation should be implemented immediately.

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External quality control methods: Periodic analysis of unknown samples from reputed QC programmes (e.g. Welcome, Bird) can be done. The variance index scores are the measure of the performance. Performance comparisons with other laboratories are provided. These measures help to assess the quality of work in comparison with international laboratories and also to implement corrective procedures if the performance is not upto standard.

With automated analytical system, several personal errors are minimised. It is also possible to check daily and cumulative drift in the results by QC programmes. However, it must be remembered that the instrument is capable of doing only what is programmed. The system also should be maintained well.

Sources of error: - A large number of steps are involved from the sample collection to the despatch of reports and at each step precautions are to be taken to assure quality. It starts with properly identified, instructed and prepared patients, appropriate collection procedure with proper use of anticoagulant, storage and labelling, use of good quality reagents and equipments, skill of the laboratory technicians, proper calculation of results, print out of results without errors and despatch of the results without delay.

A standardized system involving a laboratory manager, supervisor, technicians and assistants, well trained and motivated to maintain high quality review of the performance with the involvement of the medical personnel is also required. Laboratory safety also has to be considered. In 1994, the International Organisation for standardization (ISO) working with the committee on clinical laboratory standards (NCCLS) recognized the need for an internationally accepted set of guidelines and standards for the international laboratory community and a technical committee 212 was formed, with a view to develop world wide standards for clinical laboratories.

The quest for excellence is an achievable goal and should be pursued by every laboratory.