

# Emerging Concepts of Quality Assurance in Clinical Laboratories

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## Abstract

Quality Assurance is a management system designed to achieve an acceptable level of quality services, prevent poor quality and in laboratories is intended to ensure reliability of results. It comprehensively includes controlling the quality of procedures at each and every step including Pre-analytical (specimen collection and transport), Analytical (specimen processing in the lab) and Post-analytical (reporting and interpretation of results).

Concept of total quality management (TQM) is closely interlinked with good laboratory practices and goes far beyond the widely practiced conventional Quality Control (QC) procedures. TQM includes Technical accuracy and precision, equipment and supplies, staff training and skill, financial management (cost effectiveness), lab safety, communication etc.

Recent pressures on pathology laboratories have meant that laboratories no longer have the numbers of scientists and pathologists they had in the past. This has resulted in more questions being asked of the QA staff with a steady increase in the number of scientists employed to address this demand. Quality improvement in the modern clinical laboratory environment entails the continuous inspection and refinement of processes to ensure the efficient delivery of services that meet the needs and expectations of those who use them.

## Introduction

For a clinical laboratory to serve any real purpose the results of the tests from that laboratory must be correct, the tests themselves must be relevant for diagnosis, clinical care of patients, for health care screening and for epidemiological studies, and the laboratory must be efficient, effective and as economical as possible without sacrificing its standards.<sup>1</sup> To achieve these objectives of Good Laboratory Practices (GLP) requires skilled management with critical supervision of the work of

laboratory, which must include the Quality Assurance Programme.

Clinical chemistry is the area of laboratory medicine where since the mid-1960s quality assurance has progressed from a need to define and improve precision and accuracy in analytical test procedures to an all-embracing process of assuring that the whole process of pre-analytical, analytical and post-analytical phases of handling patient samples is managed effectively and efficiently.<sup>2</sup> Automated and computer-controlled equipment has reduced many of the analytical errors, in particular in imprecision that were present in manual analysis. New management techniques have been developed to control the quality and appropriateness of results.<sup>3</sup> Developments in internal quality control and external quality assessment procedures have enabled laboratories to continually improve the quality of assays. Laboratory accreditation and external quality assessment scheme accreditation have ensured that peer review and peer pressure have been applied to both laboratory and external quality assessment scheme performance.<sup>4</sup>

Quality assurance in histopathology and cytopathology is underestimated and it is not well established in Pakistan but the quality assurance scheme in histopathology and cytopathology started in late 1970s as slide circulation scheme.

## Types of QA system

**Internal QA:** Internal quality assurance covers all stages of lab procedures right from the collection of specimen to the issuance of final report. The term is sometimes used synonymously with quality control (QC)

Quality Control is an operational procedure for the continuous monitoring of tests and results in order to satisfy given requirements. It includes day-to-day monitoring of reproducibility or precision and design to detect any serious error.

**External Quality Assessment:** An independent organization or agency at national or international level monitors the performance of laboratories by distributing a panel of specimens and evaluating the results with their own known results.<sup>5</sup>

## Laboratory Accreditation

A national or international organization of standardization accredits the laboratory both in managerial and technical aspects and evaluates that whether it meets the international standards or not. There are different codes for different aspects of laboratory working. ISO 15189 of the Pakistan national accreditation council (PNAC) provides a framework for the design and improvement of process-based quality management systems by medical laboratories. It is based on the new standard is intended to promote a common approach to the quality management of medical laboratories and to all aspects of its operation, from patient preparation and identification to the collection and examination of clinical samples.<sup>6</sup>

## Elements of QA system

### 1. Quality manual

The quality manual is the definitive working guide to laboratory function and is issued by the chief executive or designated quality officer. The size of the quality manual will depend on the size and complexity of the laboratory concerned and may vary in content from facility to facility. The manual should be written in plain easy to understand language and contain no jargon that can confuse staff or an external auditor. The use of flow charts can often be used to demonstrate practices and procedures in a clear and concise manner.

### 2. Standard Operating Procedures (SOPs)

Standard operating procedures (SOPs) are an essential part of good laboratory practice. Using SOPs is the best way to maintain the optimal quality of performance in the laboratory by providing a stable pattern of function for laboratory staff. By enabling everyone working in the laboratory to understand the various procedures, SOPs ensure consistent quality of work with appropriate quality assurance procedures and provide guidance for solving problems when results fail to meet the expected quality standards.

By definition, an SOP is a written standard procedure that has been approved by the person in charge. Any subsequent change must be authenticated and authorized so that the precise procedure used on any day is always documented. SOPs should be prepared for every analytic test undertaken and for all significant activities relating to the practice of the laboratory. Thus, some are

intended primarily for test procedures, whilst other documents should be prepared for specimen collection, specimen storage, laboratory safety, data processing, record storage, handling of urgent requests, and even for a telephone-answering policy. SOPs should accurately reflect good laboratory practice and be sufficiently practical to be useable in a routine service laboratory.

### 3. Control of Nonconforming Testing

A nonconformance is any variation from the normal or accepted process, procedure or protocol. This can cover any abnormalities in test results discovered by way of examination of quality control material, both internal and external, or by regular audits of laboratory processes and protocols. In terms of the quality system there can only be a nonconformance if there is a variation from stated quality system information in the quality manual.

The laboratory should have documented policies and procedures to deal with nonconformance of test results and all associated practices. The protocols for handling nonconformance should indicate all staff responsible for identifying and evaluating the significance of the episode and dealing with the situation.<sup>7</sup>

### 4. Corrective Action

The laboratory should have documented policies and procedures to implement corrective actions when nonconformance is detected. Corrective actions are not only associated with failures in the quality of test results, but may also be required when problems in the quality system are identified following reviews, audits, complaints or other events affecting laboratory function are observed or recorded.<sup>8</sup>

Immediate corrective action may be necessary in order to rectify situations with immediate impact upon patient care and treatment. These types of incidents also require a process or procedure, which details personnel authorized to take immediate corrective action and the mechanism for recording the incident.

### 5. Record

The laboratory should maintain a comprehensive record keeping system. Records should include written or electronic material relating to test outputs of the laboratory. The material must be accessible and stored in a suitable environment. Both quality and technical records should be kept in accordance with required standards.

Records may include Request for tests, patients result, Workbooks and instrument printouts, Calibrations and calculations, Critical reagent details such as kit numbers, batch numbers, expiry dates, date received, Quality control records, external proficiency programs record, review of records (QC/QA) and proof of scrutiny by

authorized, personnel, equipment maintenance records, complaints and corrective actions, audit reports, both internal and external, incident or accident records.

## Modes of Internal Quality Control

Three modes include:

1. Using Control Material (Commercial or locally prepared)
2. Random Duplicate Sampling
3. Retesting of randomly selected samples from a previous day's run<sup>9</sup>

### 1. Using Control Material (Commercial or locally prepared)

QC material usually consists of a serum pool either prepared locally or as more often the case, purchased commercially. The target values of the QC serum pool are the estimated concentrations of each analyte within the pool. The manufacturers for their products usually give mean values along with the estimated higher and lower limits. However, each laboratory must establish its own values for each analyte under its own laboratory conditions, by the procedures and the instruments routinely being used by that laboratory.

The target average plus and minus 2SDs is the control limit for each pool sample. These are also the 95% confidence limits based on parametric statistics

Frequency of QC analysis varies according to different lab protocols. QC analysis may be run the first thing in the morning before starting regular routine analysis. If values are found to be within limits the entire day's results are taken as valid. Those labs that work in shifts, QC may be run at the start of each shift. More common practice, especially where large multi channel analysers are used, is to include controls after every 20 samples.

When the control values are within the acceptable range then these values should be recorded in the proper log sheet. Plot the control values in Quality Control Chart i.e. Levey Jennings quality control charts and interpretation is done according to Westgard Multirules.<sup>10</sup>

### 2. Random Duplicate Sampling

It is a measure of reproducibility of results and is a useful indicator of accuracy. After every 5 - 10 samples, a randomly selected duplicate aliquot of any of the samples

being tested is included and the two results are compared. The percentage variation is calculated. A record of daily readings is kept and cumulative reproducibility observed.

### 3. Retesting of randomly selected samples from a previous day's run<sup>9</sup>

It is a measure of reproducibility of results of the same sample tested under the same experimental conditions on two different occasions. The percentage variations are calculated and a record maintained.

## Conclusion

The concept of total quality control emphasized that quality assurance must be a way of life for laboratorians, and concerns about growing laboratory volume led to the idea that managing laboratory utilization is also a component of quality assurance. It is now universally recognized by professional bodies, government, health care administrators and other interested parties that quality assurance of clinical/medical laboratories is essential in order to ensure the high standards of services which patients and clinicians should be able to take for granted.

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