

Quality Assurance and Quality Control in Clinical Laboratories

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Abstract

Health care delivery is no longer a simple process of examining the patient and giving him a prescription. Over the years there has been rapid expansion in the various branches of health care services. As part of this expansion process and explosion of scientific medical knowledge, laboratory diagnosis has gained tremendous importance in today's practice. Especially in our country since the beginning of 80's we have been witnessing significant growth in laboratory services. Through quality management process the laboratory can ensure that the result being issued by the laboratory is reliable to allow decisions to be taken with confidence. Quality control and quality assurance are parts of quality management. Quality control is focused on fulfilling quality requirements, whereas quality assurance is focused on providing confidence that quality requirements are fulfilled. By utilizing quality control practices, a laboratory is able to find and correct flaws in the analytical processes of a lab before potentially incorrect patient results are released.

Key words

Quality assurance, quality control, quality management

“Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives.”

The issue of Laboratory quality has evolved over more than 4 decades since the 1st recommendation for quality control was published in 1965.¹ Now Quality Control is seen as only one part of a total laboratory program. Government of Bangladesh has recently approved a draft on National Health Policy with an aim to reach the minimum Health care facility (MDG) by 2015.²

The purpose of the health care system in a country is to correctly diagnose the disease,

identify the factors responsible for the disease and take appropriate preventive and curative measures to control the disease. The pathologists and laboratory people are very much involved in the correct diagnosis, effective treatment and follow up of the patients. For correct diagnosis quality assurance and quality control are very important. Laboratory quality control is designed to detect, reduce and correct deficiencies in laboratories analytical process to release patient results and improve the quality of test result.³

Quality assurance (QA) is aimed at ensuring quality test results. The purpose of quality assurance is to give relevant, reliable, timely test

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results which are interpreted correctly. Quality assurance involves activities both inside and outside laboratory, good laboratory practice and proper management skill. The WHO definition of quality assurance is a total process whereby the quality of lab reports can be guaranteed.⁴

It has been summarized as the

- right result, at the
- right time, on the
- right specimen, from the
- right patient, with result/interpretation based on correct reference date, and at the
- right place

Quality control (QC) on the other hand covers the part of quality assurance which primarily concerns the control of errors in the performance

of tests and verification of test results. Quality control must be practical, achievable and affordable. The primary aim of quality control is to do the test reliably. The broad aim of quality control is that results from one lab should be comparable with that from any lab in the world provided the same method is followed.³

The fundamentals of Quality control include:

- i. Total quality management of clinical laboratory
- ii. Control of pre-analytical variable
- iii. Control of analytical variable
- iv. External quality assessment and proficiency testing programs

Many international agencies supervise quality assurance namely ISO, ioQA, intertek and Quality assurance program run by different

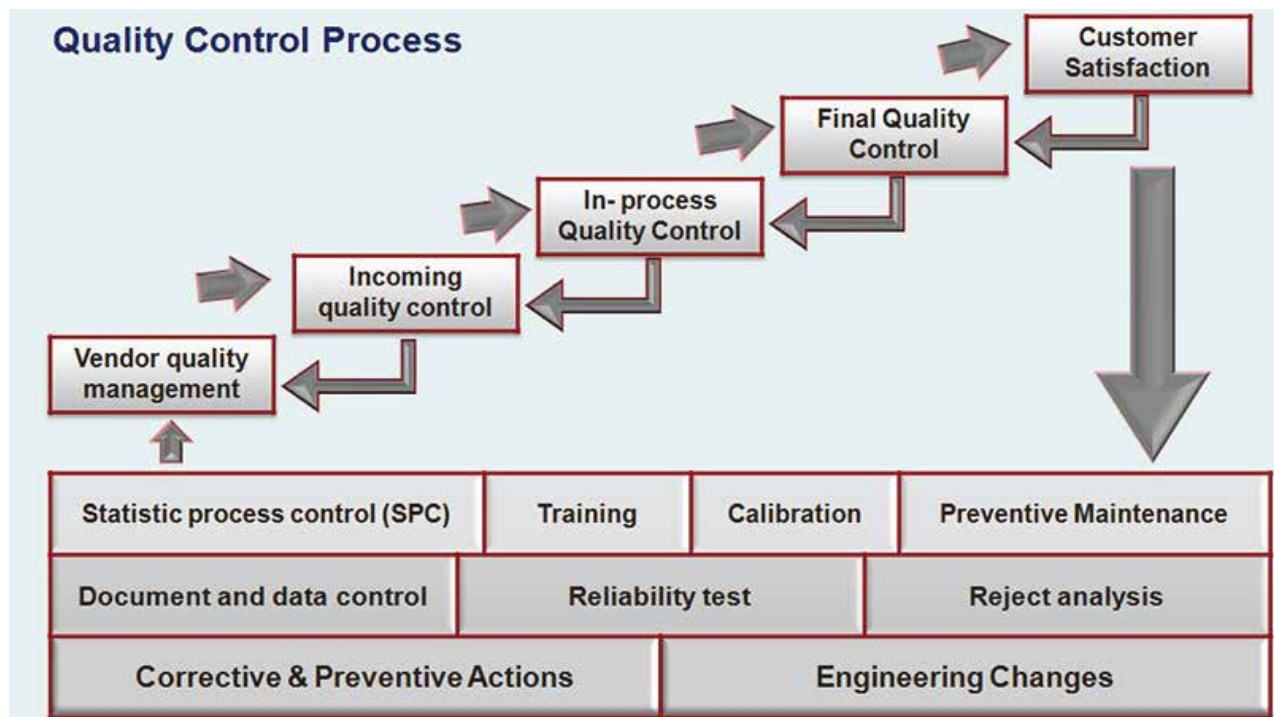


Fig. 1: Quality control process

reputed laboratories aboard. Proper QA dramatically improves the effectiveness of QC program of a laboratory.^{5,6,7}

For biochemistry quality control involves optimum condition variance (OCV), routine condition variance known value (RCVK), composite and long term assay, and computer aided check, accuracy and precision tests. Accuracy is defined as closeness of the test result and accepted true value, whereas precision is a measure of reproducibility. Daily QC chart preparation is mandatory. Control value within $\pm 2SD$ is good sign and patient's results obtained are reliable and can be reported. If control value is beyond $\pm 2SD$ the result must not be reported and fresh control serum should be measured together with few patients sample. If the result is now within $\pm 2SD$, the result can be reported. The type of material used for QC is frozen, pooled serum; commercially available lyophilized freeze dried pool serum; commercially available low temperature liquid serum pools.⁷

For histo and cytopathology, quality control involves intra departmental consultation, random case review, intra departmental and inter departmental conference, inter institutional review, specimen adequacy record, lost specimen record, turn around times, techniques i.e staining, proper sectioning, embedding, fixation, re and dehydration of samples, clearing, mounting, labelling etc.^{8,9}

For microbiology, quality control involves use of ATCC strains of organisms for standardization, measuring the disc potency, MIC, media contamination, standardization of staining procedures, autoclaving and sterilization of

media, safe disposal of infected materials is also an important procedure to maintain standard lab practice.

For hematology, standardization of staining procedures, preparation of proper blood film, bone marrow smear, special staining techniques flow cytometry, chromosome analysis are the mainstay of quality control.

Wrong test results are caused by faults on the part of the clinicians like sending sample without identification number and name of the test, collection date, appropriate container, sending specimens divided in several parts to different labs; without clinical history, provisional diagnosis, other relevant test results, radiology/imaging reports/etc.

Wrong results are also caused by the faults of laboratory and the pathologists which can be divided into pre-analytical stage faults, analytical stage faults and post analytical stage faults. In the pre-analytical stage the faults are misidentification of patients due to incomplete ID, incorrectly labeled specimen container, partly erased or illegible label and disparity between request form and specimen.

Faults may also be with the specimen. A faulty specimen is one which is inadequate, collected at incorrect time in dirty and contaminated container, in a container without proper anticoagulant and stored incorrectly or in hemolysed status. These are known as pre analytical faults. In the analytical stage the faults resulting in wrong findings if the principle and procedure of the test is not strictly followed; reagents, standards, QC materials are not prepared, mixed, processed properly and performance standards are not followed strictly.

In the post analytical stage the faults may occur if reporting, checking and verifications are not done properly, interpretation of test results are not considered seriously, and abnormal/unexpected result is not taken seriously and not reviewed and or performed again.



Fig. 2: Factors influencing Quality Control Process

Quality control is a part of total laboratory control program which can be achieved through proper documented and validated interventions at pre-analytical, analytical and post-analytical stages. Implementing quality does not guarantee an error free laboratory but it detects errors that may occur and prevents them from recurring.

To monitor QA and QC, minimize errors establishment of a Central Reference Laboratory and Institute of Pathology is a must and need of the hour. The sooner the Government, people's representatives, Medical professionals, Social workers, Journalists, Patients and their relative understand this, the better is the outcome. Bangladesh Society of Pathologists should come

up with concrete proposals for this and talk to the Government and other appropriate agencies for its early implementation. The good news is that Government has accepted in principle the concept of a Central reference laboratory, allocated budget for this project and preliminary baseline work has been done.² Now the society of Pathologists should work shoulder to shoulder with Ministry of Health for quick implementation of the project.

It is very important to maintain QA and QC for reliable, quick and dependable results in shortest possible time. This will help the clinicians to come to a correct diagnosis and treat the patient early. This will lead to early recovery and save working time, money for the patient and the nation.

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