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A Review On: Quality Assurance and Quality Control in Clinical Laboratories

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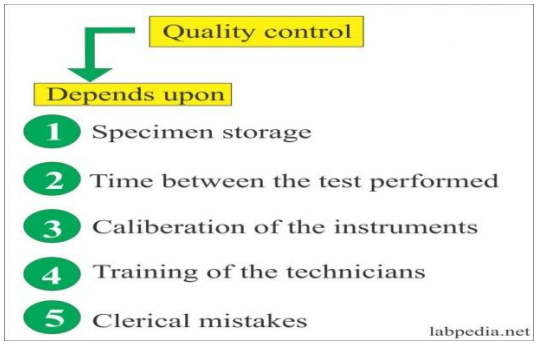
ABSTRACT: Health care delivery is no longer a simple process of examining the patient and giving him a prescription. Over the years there has been rapid expansion in the various branches of health care services. As part of this expansion process and explosion of scientific medical knowledge,
laboratory 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

I. INTRODUCTION

"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. Thepathologists and laboratory people are very much involved in the correct diagnosis, effectivetreatment and follow up of the patients. Forcorrect diagnosis quality assurance and quality control are very important. Laboratory quality control is designed to detect, reduce and correctdeficiencies 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 testresults which are interpreted correctly. Quality assurance involves activities both inside and outside laboratory, good laboratory practice and proper management skill. The WHO definition ofquality 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



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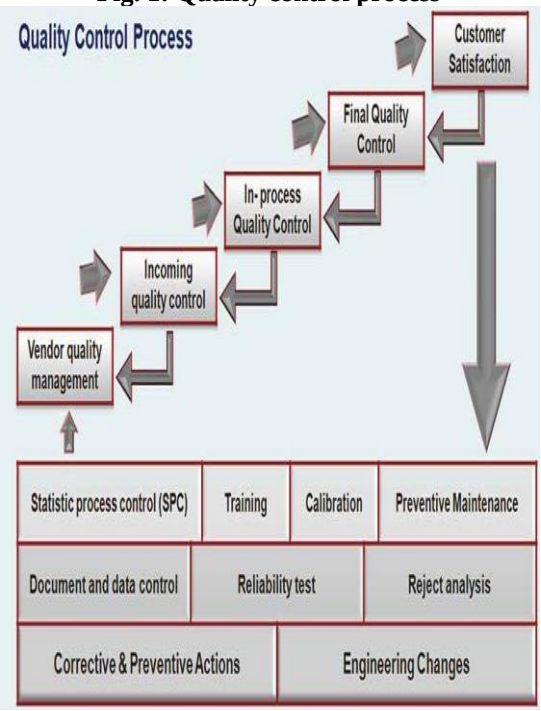
Quality control (QC) on the other hand covers the part of quality assurance which primarily concerns the control of errors in the performanceof tests and verification of test results. Quality control must be practical, achievable and affordable. The primary aim of quality control is to do the test reliably. 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 ± 2SD is good sign and patient's results obtained are reliable and can be reported. If control value is beyond ± 2SD the result must not be reportedand fresh control serum should be measured together with few patients sample. If the result is now within ± 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 lowtemperature 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 aroundtimes,

techniques i.e staining, proper sectioning, embedding, fixation, re and dehydration of samples, clearing, mounting, labelling etc.8,9For 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 sterilizationofmedia, safe disposal of infected materials is also an important procedure to maintain standard lab practice. For hematology, standardization of staining procedures, preparation ofproper 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 time in dirty and contaminated container, in a container without proper anticoagulant and stored incorrectly or in hemolysed status. These are

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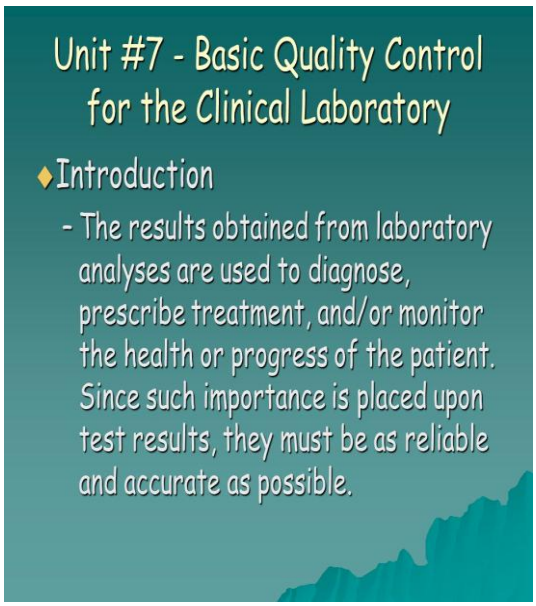
known as pre analytical faults. In the analytical stage the faults resulting in wrong findings if the principle and procedure of the test is not strictly followed; reagents, standards, QC materials are notprepared, mixed, processed properly andperformance standards are not followed strictly. In the post 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 thatmay 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, Socialworkers, Journalists, Patients and their relativeunderstand this, the better is the outcome.Bangladesh Society of Pathologists should comeup with concrete proposals for this and talk to the Government and other appropriate agencies for its early implementation. The good news is thatGovernment 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 implementationof the project. It is very important to maintain QA and QC forreliable, quick and dependable results in shortestpossible time. This will help the clinicians tocome to a correct diagnosis and treat the patientearly. This will lead to early recovery and saveworking time, money for the patient and thenation.



Laboratory testing of patient samples can be a complex procedure, depending on clinical analysis, microbiological study, or blood banking testing among other facets of the clinical laboratory. Quality control (QC) is one of the most important impacts on laboratory testing—it ensures both precision and accuracy of patient sample results. The integrity of quality controlsamples is important to both management of overall quality as well as to meeting requirements of proficiency testing. Addressing QC issues is critical to the identification of potential errors with patient results, including reagent matrix effects as well as calibration misalignment of testing function. Maintaining accurate and frequent checks of laboratory sample testing through quality control is vital to ensuring that patient testing is done right and that it produces accurate results

QC samples are expected to be identical and tested identically to patient samples.[2]The purpose of repeated quality control testing is to validate precision and accuracy of the results of patient sample testing. Precision is the "degree of agreement among repeated measurements of the same characteristic on thesame sample,"[3] while accuracy is how close results are to what is

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expected from a test. For example, a glucose quality control reagent is expected to produce results on average of 100 mg/dL. Ten repeats of that same agent produce resultsof 96, 98, 101, 92, 93, 88, 92, 93, 91, 90, and 98 mg/dL. These results would indicate a low bias result in the instrument.

Many laboratories utilize L-J charts for 14- or 30-day reviews of QC testing. While daily identification of QC deviations from normal ranges ensures accuracy of sample testing, longer-term reviews are more beneficial to diagnose trends and biases in tests which could be missed on a daily basis. An additional use of the L-J chart without quality control samples is to utilize patient samples as their own controls.[6]By tracking the running averages of the patient results, a laboratorian can identify drift or problems with analyzer function that are not captured by quality control testing. Addressing concerns with QC materials as well as recall issues are common challenges for laboratory managers.

Failure to integrate quality control in a laboratory can lead to several negative consequences, including the following:

- Time wastage, as experiments and tests are repeated.
- Budget implications, as more reagents are needed to carry out repeat tests and experiments.
- Unreliable results, which will impact the integrity of the lab and consequently any funding options and certification/accreditation process.
- Loss of customer loyalty and satisfaction.
- Safety concerns due to non-compliance in the absence of quality control mechanisms.

Objective :

A **clinical laboratory** is a **laboratory** where tests are done on **clinical** specimens in order to get information about the health of a patient as pertaining to the diagnosis, treatment, and prevention of disease.

Establishing a Laboratory Quality Management System

- A laboratory quality management system (QMS) streamlines and coordinates all the processes and operations within the lab, ensuring that each step is well planned, controlled, and correctly performed. It encompasses both the managerial and technical aspects of the lab procedures. The goal of a laboratory QMS is to ensure that results are accurate, reliable, and obtained under a traceable process that can easily detect errors.
- To establish a proper quality management system, several widely used systems essential have been developed and are discussed separately below;

Organization

- The laboratory should have an outlined hierarchical chart showing how management, supervisory roles, and authority flows. In addition, there should be documentation showing the functions and duties of every lab member, their competencies, experience, training attended and training required.
- The appointment of individuals to integral positions like lab manager (for operational supervision), safety officer, and quality control officer is necessary.

Personnel

- The effective management of laboratory staff is crucial because they are the most important lab resource. Capacity building by ensuring they undergo regular training and motivation, as well as proper handling of staff concern ensures optimal performance. There should be regular meetings between the management and all staff to disseminate information and discuss issues of concern.
- To ensure conformity to SOPs, performance appraisal and proficiency tests should be part of quality assessment.

Equipment

- All laboratory equipment should be documented with an inventory on maintenance and occurrences. After its installation, members should be properly trained on the use of the new equipment. Equipment manuals should be easily accessible in the laboratory area for easy reference.

Purchasing and Inventory

- The buying of reagents, media, and supplies should be centralized, with one individual tasked with that responsibility. The procedures should be written and implemented to ensure that all supplies are correctly selected.

Process Control

The process control refers to the management of all the activities employed in the handling of samples. This involves all the pre-

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analytical, analytical, and post-analytical stages. Due to the wide range of processes and individuals involved, including processes/persons that are outside of the laboratory premises like sample collection and transportation, adherence to standard best practices should be enforced for all handlers of the sample or test material. Documentation should be availed for all parties and a coordination person or team in place to ensure a smooth workflow.

Documents and Records

The laboratory documentation and records include SOPs, good laboratory practices (GLPs), equipment maintenance logs, occurrence books, etc. The documents provide information about the laboratory's policies, processes, and testing procedures and should be stored in the laboratory quality manual for each laboratory. An SOP should be written for all procedures in the laboratory, including specimen collection, transport, storage, and waste disposal.

Occurrence Management

Occurrence management ensures quality control by identification of errors or non-conformance, recording them and putting in place corrective measures such as retraining programs, equipment servicing, or replacements. The laboratory must have provision for documentation of such errors and occurrences that may interfere with proper laboratory operations.

Assessment

This involves investigations to verify process compliance and reliability of results. It can be either internal or external assessment and audit. The internal assessment is done by members of the lab and makes use of test controls like standards to validate the testing process and equipment.

The external assessment and audit involve the use of persons or agencies outside of the lab premises. This is done through lab visits by the assessors to observe processes, validating tests by sending aliquots of test materials to the external assessment agency or having the assessing agency send in unknown material for testing in the lab.

Process Improvement

This process follows assessment and auditing. It involves all the corrective efforts made after the identification of points of errors and non-compliance. All actions should be documented, SOPs and QMS should be updated, and the changes in process and procedures should be communicated to the lab members.

Customer Service

It is important for laboratories offering services to maintain open communication channels with clients. Ensure that the customer is able to freely give feedback through interviews, questionnaires or meetings and have access to a complaints medium. All customer feedback should be documented, analyzed, and used for process improvement.

Facilities and Safety

A laboratory contains potentially harmful chemicals and infective material and therefore several safety protocols should be in place to protect the staff, environment, and the community. The laboratory management should ensure that all lab members are well-trained in safety requirements, SOPs, emergency response, and waste management. Different guidelines exist depending on the risk level of the lab.

Emergency response aids such as showers, fire blankets and extinguishers, first aid kits, should be easily accessible within the lab and the members effectively trained on their use. Detailed information on laboratory safety

Importance Of Quality Control In Laboratory:

Quality control (QC) is one of the most important impacts on laboratory testing—it ensures both precision and accuracy of patient sample results. ... When quality control works effectively, it is able to find and correct flaws in the analytical processes of a lab before potentially incorrect patient results are released

II. CONCLUSION:

Although the implementation of comprehensive QA and QC programmes in the andrology laboratory will certainly be aided by the revised QA and QC chapter in the 5th edition, other factors will also be important in this endeavour. First, there must be a general realization within the profession that QA and QC are not optional parts of the laboratory repertoire but inherent parts of the modern medical laboratory, as they are in other disciplines [14]. This may be achieved by the publication of the revised manual itself, but also through articles, such as this one, that raise awareness of the issue and promote debate. Second, there must be increasing emphasis on investigating QA and QC by accrediting bodies and regulatory authorities as part of their surveillance of andrology

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laboratories. In countries where such organizations do not exist, they need to be developed. Finally, and crucially, appropriate and accessible basic training and continuing professional development must be available for laboratory scientists engaged in andrology to allow them to develop and maintain their skills. It has been shown that attending training courses can significantly improve the performance of individual scientists [32, 33]; yet, a common complaint is that too few such courses exist. Moreover, there is no consensus as to which teaching methods are the most effective. These aspects, too, warrant our attention.

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