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Total Quality Management in Pathological Laboratories: An Overview with Emphasis on Need for Structured National Policy

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Abstract: ***The last decade has witnessed tremendous growth in healthcare sector. Pathological laboratories plays central role in decision making of clinicians to start proper procedure to cure disease or abnormality in patient. Continuous Total Quality management practice in pathological laboratories is mandatorily to be adopted in order to deliver error free services. It cannot be achieved simply through the control of accuracy in analytical testing phase alone. In analysis of Clinical specimen there are many possible pre analytical errors also. The quality system for pathological laboratories must include promotion of accuracy in analytical phase as well as quality assurance in the reliability of pre analytical and post analytical activities. Active monitoring and feedback control of all potential defects generated by laboratory personnel as well as non laboratory personnel is necessary part of quality improvement. In present study authors strongly recommends that Pathological laboratories should strive to produce high quality result to its customers by utilizing up to date scientifically proved methodology employing competent staff, monitoring process to control internal and external quality control and participation in external quality assurance assessment schemes.***

Keywords: Total Quality Management, Pathological Laboratory, Quality assurance assessment Schemes

1. Introduction

Direction and skillful execution, it represents the wise choice of many executives." **-William A. Foster**

Pathology is unique in medical profession functioning as a bridge between clinical medicine and basic science. In clinical practice, pathology report based on tissue or body fluid analysis determines clinical diagnosis and shows the path of treatment of patient. Pathology laboratory plays central role in delivery of health care services as 70% clinical decisions are taken on the based on pathology report. Remarkable advances in instrument technology, automation, computer science has indeed simplified task of laboratory but reliability in pathology laboratory cannot be achieved without quality, accuracy at all levels including pre analytical, analytical and post analytical phase in testing process [1]. Quality is the heart in management of all laboratories. Quality implies that work being performed meets or exceeds some defined standards which can be measured or whose performance can be monitored. For an individual, quality is way of life but for an organization it is culture. Quality management is a system for agreeing and documenting policies, responsibilities and procedures which need for agreed customers requirement accrediting body requirement both external and internal. Quality management focuses on detection of errors in the individual laboratory operations through pre and post service inspection and review. It is concerned with adherence to standards and scrutinizing mistakes and errors [2-4].

2. Total Quality Management

Total quality management has been extensively used in developed countries but its use in developing countries like India is limited because lack of knowledge and its benefits. Total quality management is a philosophy embracing all activities through which the need and expectations of the customers are satisfied in most efficient and cost effective manner by maximizing the potential of all employers in a continuing drive for improvement. TQM essentially generates reliability and efficiency, profits by increasing revenues also increase profit by cutting costs [5]. For successful implementation of TQM organizing must concentrate on ethics, integrity, trust, training, teamwork, leadership, recognition and communication. TQM in pathological practices comprises quality laboratory process, quality control, quality assessment, quality improvement, quality planning and quality goals. TQM benefits are as:

"Quality is never an accident; it is always the result of high intention, sincere effort, intelligent

- Ensure quality in overall process.
- Curtail costs.
- Encourages active and effective leadership and involvement by top management.
- Involves and empowers staff.
- Attempting to solve problems by band aid fixes for individual mistakes as they occur drastically reduced.
- Reduces errors by doing thing right and ensures consistency.
- Staff will have greater confidence that that the system will catch mistakes before the patient report.
- All operations are transparent to both staff and clients and staff will clearly understood their responsibility
- Improves consistency within and between laboratories.

3. Infrastructure

Total quality management focuses on the need of adequate infrastructure including proper space, separate laboratory for each division, technologically highly accurate and sensitive instrument and connectivity through Laboratory information system. Infrastructure of laboratories should be planned

according to the services provided by the laboratory and as per guidelines of accreditation agency [6]. The basic infrastructure facilities include:

- Reception room/area where requisition forms are received and reports disbursed
- Specimen collection room/area, toilets, privacy for special purposes e.g. Semen collection, facilities for disabled persons, toilet for staff
- Quality water supply for analytical purpose
- Uninterrupted power supply
- Analytical work area
- Specimen/Sample/slide storage facility including cold storage where applicable
- Record room/area
- Facility for cleaning of glassware, sterilization /disinfection
- Waste disposal facility including biomedical wastes
- Fire-safety equipment
- Ventilation, climate control and lighting arrangements
- Separate room/area for meetings/administrative work
- Separate facilities/area for staff for hand washing, eating and storing food, drinks etc.
- Communication facility with referral centers
- Transport of specimen/samples to referral centers
- Additional infrastructure facilities may be added for special tasks as and when needed.

4. Human Resource

In the changing scenario of the twenty first century, the laboratory assessment and their upgradation agenda will be based upon intangible assets also. With this view, the role of intellectual pathologist and technologist should fully understand. Pathology laboratories should make appropriate investment in human resource to produce quality outcome. Pathologist and technologist in pathology laboratories are key asset who can play crucial role to achieve and set goals. Superlative performance can be achieved provided that organizational goal are linked to individual goals and their needs as well as aspirations. The organizations have everything to gain by turning its employees into assets-good performance, motivational atmosphere and higher productivity [7-8]. Technology is developing so fast that it frequently necessitates exposure of pathologist to new technological advancement taking place in elsewhere in scientific world.

5. Compliance of Accreditation

Accreditation is a voluntary process by which the organization introduces quality system according to specific requirement and certified by an independent quality monitoring institute. The National Accreditation Board for Testing and Calibration Laboratories (NABL) is the sole accreditation body in India with the criteria assuring accuracy, reliability and conformity of the tests results. Through accreditation, organization gets formal recognition from accreditation body that organization is competent to carry out certain test and process adopted is valid and technologically competent. Accreditation is a seal of competence, accuracy and quality. Benefits of accreditation in pathological practices are as:

- Demonstrates compliance with international standards
- It improves patient care
- Strengthens confidence in analytical results
- It provides continuous staff education, and attracts professional reference due to accuracy and competence
- It meets the requirements of Insurance companies and third party requirement
- In case of a discrepancy the Accreditation stands as a proof of competence of the laboratory, which can be verified
- Improves liability insurance coverage and provides a competitive edge in the market.
- Provides professional advice

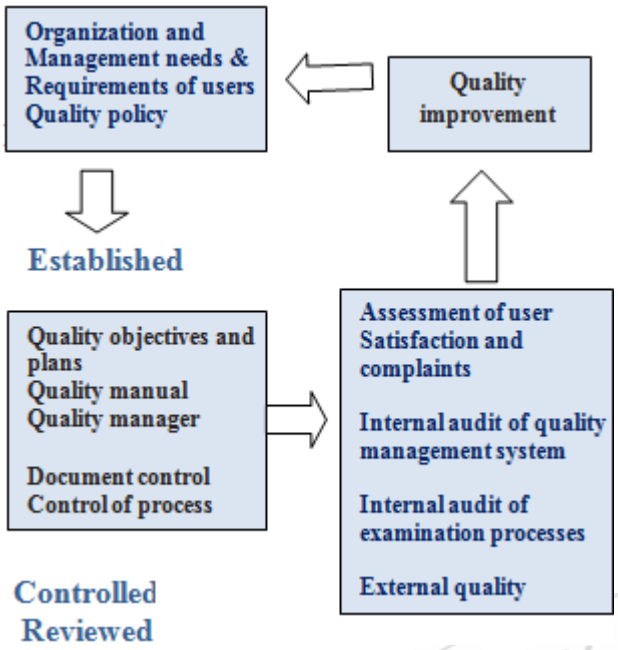
ISO15189 (3) is the international standard for quality management in the medical laboratory. To set up laboratory for accreditation based on ISO15189, it is necessary that pathology laboratory prepare quality manual point out lacunae's within. There should be clarity between policy and procedure. Thus laboratory analyze its policies, procedures and processes. A quality manager may play crucial role to evaluate the laboratory existing status and to determine whether laboratory is competent for accreditation. The quality manager in laboratory will be responsible to maintain quality system integrity, ensure staff commitment to the organization. The ISO 15189 standard also provides two important annexes the Laboratory Information System and Ethics in laboratory practices.

6. Laboratory Information System (LIS)

Informatics provides solutions in every aspect of pathology operation in pre analytic, analytic, post analytic stages of sample evaluation. Pathology laboratories are most data intensive and Laboratory information system plays crucial role in patient registration, patient management, billing system, bidirectional flow of information from key authorities to grass root level, results, report management, review of reports. Laboratory information system also provides details time stamped processing trial of specimen at each level. It can track clinical or internal laboratory problem and generate data by test, shift, technologist, location. Data from LIS can be used to analyze productivity, workflow, performance, optimization, management index reporting. The staff responsible for LIS implementation should have adequate knowledge of policies, procedures, workflow and technicalities of database to achieve optimal performance [9].

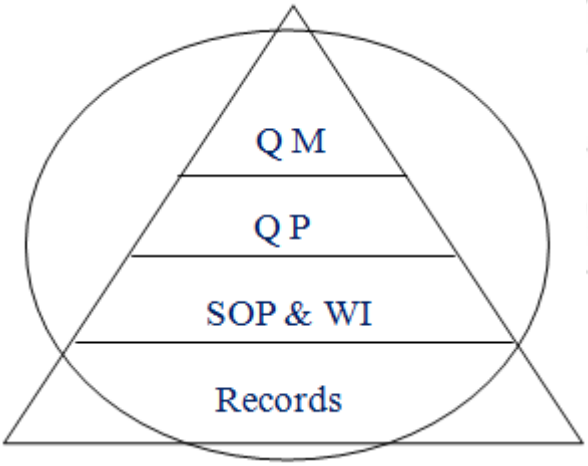
6.1 Quality Improvement Circle

The quality management system for pathology laboratories should strive for continual quality improvement through quality improvement circles. The Quality improvement Circles Can be explained as



6.2 Quality documentation

Pathology organization adopting TQM should also create and maintain quality documentation as per ISO15189(3) guidelines.TQM practices in pathology laboratory require quality manual which includes vision, policy, mission of laboratory. Quality manual make reference to quality procedures and procedure for corrective action. The next document to be essentially maintained is standard operating procedure and written instruction(SPO&WI).At the base is record which comprises technical and managerial record i.e. forms, reference, standards, equipment/instrument manual, results, reports, safety data sheets, research paper, journal article etc..



QM- Quality Manual
(Policy, Vision, Mission, Objectives & Commitment to Quality) Structure, Responsibility & Authority
Q P- Quality Procedure
(Guidelines to perform Quality related activities)
SOP & WI- Standard Operating procedure & Written Instructions
Records- Forms, Results, Reference Standards & Equipment Manuals

7. Error Control in Laboratory Operations

TQM emphasizes error control in pathology practices through good governance, use of reference procedures and use of highly accurate instrument. Pre analytical and post analytical error can be controlled through enhanced cooperation among pathologist and technologists as they are key to improvement of laboratory quality. In order to reduce pre analytical errors a regular feedback system from pathologist, technologist and personnel outside the laboratory should also be adopted. Pathology laboratory should focus on promotion of accuracy in analytical phase as well as in pre analytical and post analytical activity through process control.

8. Need of structured National policies in Pathological Practices

In such situation, Government of India should frame adequate monitoring policies mandatorily to be followed by pathology laboratories as per international standards. Authors strongly recommends Structured National Quality Assurance program for pathology laboratories. Central coordinating bodies like NABL, QCI should be equipped with more power to monitor activities and quality of pathology laboratories across country [10].

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