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Total Quality Management (TQM) of the Clinical Laboratory; Improving Patient Care

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Author's contribution

The sole author designed, analyzed and interpreted and prepared the manuscript.

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Short Communication

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ABSTRACT

Background: Public and private pressures to contain cost and improvement of test result require that the clinical laboratories adopt new systems for managing quality.
Objectives: To review the management process for improving the quality of all aspects of laboratory operations.
Method: Application of the concept and principles of total quality management.
Result: The users of health care laboratories are satisfied with the quality of laboratory service and their expectations are met by the laboratory performance. This enables faster and more accurate diagnoses and in turn, faster recovery of patients and shortened hospital stay.
Conclusion: Total quality management of the Clinical laboratories is an absolute necessity for monitoring performance that satisfies the needs and expectations of users and patients.

Keywords: Total quality management; laboratory; patient and quality assurance program.

1. INTRODUCTION

The principles of quality management, assurance and control have become the foundation by which clinical laboratories are managed and operated. Quality systems in healthcare organizations continue to evolve [1,2,3]. Publicand private pressures to contain cost are

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now accompanied by pressures to improve quality. The seemingly contradictory pressure for both cost reduction and quality improvement (Q1) require that healthcare organization adopt new systems for managing quality [4,5]. Total quality management provides both management philosophy for organizational development and a management process for improving the quality of all aspect of work. Many healthcare organizations have adopted the concepts and principles of TQM [6] According to Edwards Deming, quality improvement reduces waste and leads to improved productivity, which in turn reduces cost and provides a competitive advantage [7]. As a result, the organization stays in business and is able to continue providing jobs for the employees. Quality improvement occur when problems are eliminated permanently. Problems arise primarily from imperfect processes not from imperfect people. Industrial experience has shown that 85% of all problems are problems that are solvable only by managers, with the remaining 15% being problems requiring action and improvement of performance of individual workers. These quality problems are primarily management problems because only management has the power to change processes [8,9,10,11,12].

This paper discussed the framework for managing quality in healthcare laboratory and an outline of a quality control programme.

2. TQM FRAMEWORK

The principles and concepts of Total Quality Management have been formalized into a quality management process (Fig. 1). The traditional framework for managing quality in a healthcare laboratory has emphasized the establishment of quality laboratory process (QLPs), Quality Control (QC) and Quality assessment (QA).

A QLP includes analytical processes and the general policies, practices and procedures that define how all aspects of the work get done. Quality Control emphasizes statistical control procedures but also includes non-statistical check procedures, such as linearity checks, reagent and standards checks and temperature monitors. Quality Assurance, as currently applied is primary concerned with broader measures and monitor of laboratory performance, such as turnaround time, specimen identification, patient identification, and test utility.

Quality assurance requires either that causes of problems be identified through QI and eliminated through quality planning (QP) or that Quality Control be able to detect the problems early enough to prevent their consequences.

To provide a fully developed system and framework for managing quality, the QI and QP component must be established [14,15,16]. QI provides a structured problem-solving process for identifying the root cause of a problem and also for identifying a remedy for the problem. Quality Planning is necessary to (1) standardize the remedy, (2) establish measures for monitoring performance, (3) ensure that the performance achieved satisfies quality requirements and (4) document the new QLP. The new process is implemented through QLP, measured and monitored through QC and QA, improved through QI, and re-planned through QP. These five components working together in a feedback loop, illustrate how continuous QI is accomplished and how quality assurance is built into laboratory processes. The “five-Q” framework also defines how quality can be managed objectively using “Scientific method” or the PDCA cycle (plan, do, check, act). QP provides the planning step, QLP establishes standard processes for doing things, QC and QA provide measures for checking how well things are done, and QI provides a mechanism for acting on these measures. For objective management decisions, we apply methodology we use in scientific experiments.

3. QUALITY REQUIREMENT

Laboratories must define their service goals and objectives and establish clinical and analytical quality requirements for testing process. Quality goals cannot be set on an absolute basis. They vary from laboratory to laboratory, depending on the medical missions of the healthcare facilities and professional interests of the physicians using the laboratory tests.

Quality goals must also be considered in relation to cost. A goal of achieving the higher possible quality is not appropriate or practical when costs are being curtailed. In establishing quality goals, it is therefore more realistic to specify the quality that is necessary or adequate for the medical applications of the laboratory test results to be provided. The focus on users and customers is important, particularly in-service industries such as healthcare. The users of the healthcare laboratories are often physicians and nurses;

their customers are the patients and other parties who pay bills.

Cost must be understood in the context of quality. If quality means conformance to requirements, others "quality cost" must be understood in terms of "costs of conformance" and "cost of non-conformance" [17,18].

4. QUALITY ASSURANCE PROGRAM

A quality assurance program involves virtually everything and everybody in the clinical laboratory. An error in anyone step during the acquisition processing, and analysis of a specimen and the reporting of a laboratory test result in validating the quality of the analysis and cause the laboratory to fall short of its quality goals.

There are several essential elements of a quality assurance program including (1) dedication to quality service which must be central and a team effort driven. A true commitment is required by laboratory direction, managers and supervisors if the efforts of their laboratory personnel are to be successful; (2) laboratories must have the administrative support necessary to provide the quality services desired. This means having adequate space, equipment, materials, supplies, staffing, supervision and budgeting resources; (3) High quality personnel and essential for high-quality services; (4) High-quality technical procedures are necessary to provide quality laboratory services. These groups of procedures include the control of preanalytical conditions or variables [19].

The control of preanalytical variables and the monitoring of analytical quality by the use of statistical methods and control charts [20,21].

5. BENEFITS OF TQM

The rewards of a good quality control program are many. The clinical staff, the patients, the laboratory personnel, and whole medical profession benefit from a good quality control program in clinical laboratories. Such a program can produce more reliable test results. Physicians can then make faster and more accurate diagnosis; in turn, patients recover faster and their hospital stays are shortened. Quality in laboratory service and test results can create a good reputation for the laboratory among the clinical staff. Moreover, the pride and morale of laboratory workers increase with the quality of their services. In external surveys, laboratories with good quality control programs perform better consistently.

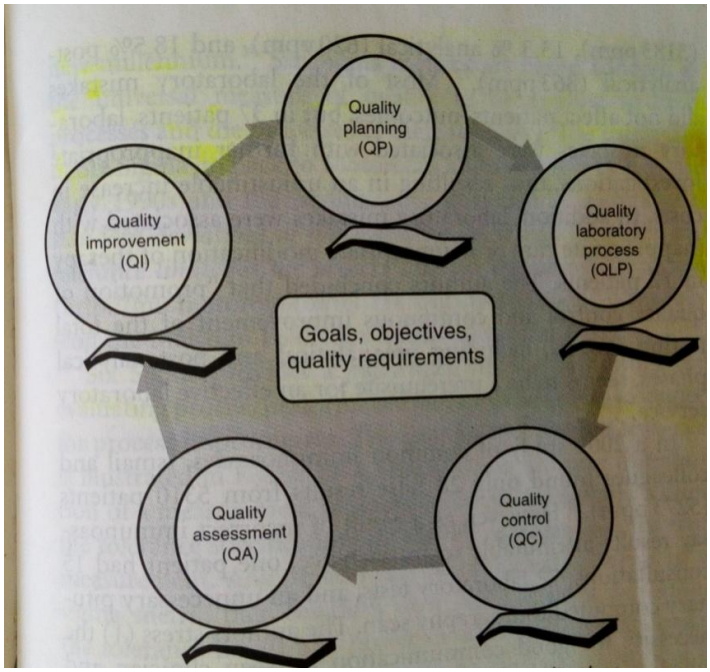

Fig. 1. Framework for managing quality in a healthcare Laboratory (Adapted from [13])

The fact that a laboratory has a quality control program may also be beneficial when one is dealing with the law and the government. With the increasing number of malpractice cases in the medical profession, laboratories with good quality control program can expect to have less trouble with the courts. A good quality control program is also an absolute necessity for laboratory accreditation and licencing by the CDC, CAP, Food and Drug Administration (FDA), or state agencies [22,23].

6. RECOMMENDATION

To provide the best possible test results, a total quality control program must include various aspects of proper laboratory operation. Such a program has 10 principal ingredients according to expert opinion [13,24,25]. They are summarized as follows:

1. Proper pre-analytical and post analytical processing of samples and test results
2. Acquisition and preparation of laboratory supplies of good quality
3. Maintenance of good accuracy and precision in all analyses.
4. Methods for error detection such as the analysis of normal and abnormal control seen everyday
5. Action to be taken when analyses appear to go out of control
6. Participation in external survey program
7. Preventive maintenance of instruments and equipment
8. Training and continuing education programs for the laboratory personnel
9. Documentation of the execution and the results of the quality control program
10. Coordination of the various individual functions of the quality control program

The ten-point plan can be applied to all clinical laboratory irrespective of their size. The only difference between laboratories in carrying out this plan would be in the nature of execution of the individual function.

7. CONCLUSION

Total quality management of the clinical laboratories is an absolute necessity for monitoring performance to ensure that the laboratory report provider to physician continuously improve the quality of patient care.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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