

## Evaluation of Implementing Quality Management System and Accreditation Standards in Medical Laboratory for Quality of Services

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**Received:** 23 Nov 2018

**Revised:** 04 Dec 2018

**Accepted:** 22 Dec 2018



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### ABSTRACT

**Background and Objectives:** Implementing quality management system (QMS) in medical laboratories improves quality of procedures and enhances the staff's skill development. It prevents frequent inaccuracies in both clinical and laboratory procedures caused by lack of regulatory compliance, safety precautions and inadequate facilities. The purpose of this study is to evaluate effect of implementing QMS based on essential standards NABH (MLP) and NABL (ISO 15189:2012) in a medical laboratory on quality of services.

**Methods:** Important quality indicators such as external quality assurance services (EQAS), rework, turnaround time (TAT) and feedback were monitored for four months, following implementing the QMS standards in a medical laboratory.

**Results:** We found that implementation of the QMS program improved the tested indicators of quality. Overall percentage of rework reduced significantly.

**Conclusion:** Implementation of QMS improves overall quality of laboratory procedures. It significantly reduces laboratory errors and progressively improves quality, efficiency, and outcomes, thus enabling delivery of timely and accurate services for patients.

**Keywords:** ISO 15189, Quality Assurance, Quality Improvement, Accreditation, Clinical Chemistry, India.

This paper should be cited as: Tamil Selvi M, Ankanagari S[Evaluation of Implementing Quality Management System and Accreditation Standards in Medical Laboratory for Quality of Services]. mljgoums. 2019; 13(1):37-41

## INTRODUCTION

Present trend in developing and implementing quality management system (QMS) for improving quality of services in medical laboratories includes improving customer satisfaction and reduction of management costs. QMS implementation aims to guarantee clients, i.e. physicians and patients receive high quality medical laboratory services (1). Implementation of quality assurance system can directly help laboratories achieve quality objectives. In India, the voluntary quality accreditation system exists for all diagnostic laboratories, which is offered by two certification agencies: National Accreditation Board for Testing and Calibration Laboratories (NABL) and National Accreditation Board for Hospitals and Healthcare (NABH). NABL accreditation ensures meeting of international standards ISO/IEC 17025 and ISO 15189:2012 by the laboratory (2). NABH certification is the initial step of implementing quality services in the laboratory and aims for NABL accreditation (3). Under NABH medical laboratory program (MLP), laboratories can get certified as part of a healthcare institution or standalone laboratory. As per MLP, the idea of a QMS in medical laboratories influence the attitude, skills and motivation of staff, as well as organizational background, contexts, values and structure. Quality assurance (QA) program includes coordinating and supervising clinical activities as well as monitoring day to day laboratory processes. To improve and sustain continual improvement of quality services, laboratory personnel must comply with the procedures and ensure fulfilling the standard requirements for all laboratory activities. Staff should perform duties with precision and accuracy as the job requires. Laboratory errors directly affect patients in terms of treatment time and satisfaction. Thus, laboratories should have proper QMS in place to ensure quality of all laboratory services.

Laboratory quality program is managed by a multidisciplinary QA team. QMS achieves continual quality improvement by adhering to the procedures, work authorization, maintenance of quality laboratory work and compliance with the established standards. QMS is the total activities and information an organization uses to deliver quality services that fulfill the needs and expectations of

customers. QMS implementation reduces error rates and enhances quality (4, 5). Common nonconformities found in the laboratories include inadequate preparation of internal quality control (IQC), poor storage condition, non-calibration of critical instruments, inadequate training, and improper biological waste disposal, risk management and documentation. The recent results of laboratory audit highlighted inadequate preparation and inaccurate records as the most common errors. A large number of studies have investigated the impact of quality management practices on organizational performance, while fewer studies have focused on the efficiency of QMS in small laboratories. Thus, our study was carried out to investigate the influence of QMS in receiving certification and maintaining quality in laboratory for reducing errors. The outcome clearly indicates that QMS implementation in the laboratory improves the quality of laboratory services.

## MATERIALS AND METHODS

Before implementing quality program, all supervising QA personnel in the laboratory participated in a four-day training program on IQA by the NABL or any other agencies, which is mandatory for QA personnel in the laboratory. In the beginning, sessions were held in-house to improve the knowledge of all laboratory staff on essential standards for medical laboratories and the NABL (ISO 15189:2012) standard. Both standards were instructed as a course material. Emphasis was given to the continual improvement of EQAS, sample rework, customer feedback and total turnaround time (TAT). The trained IQA team in each department reviewed whether everyday activities are performed according to the standards and SOPs. All evaluations were made using a standard checklist based on the existing standards (NABL & NABH). The QA ensured that all procedures and reports are done perfectly prior to release of results. If the QA identified any deviation, the work or report was returned to laboratory staff/manager with specific feedback for modification and resubmission. The amended work was reassessed by the QA. If quality standards are not met, the work was returned to the laboratory, and QA corresponded with an acceptable method for resolution. All cases involving corrections were documented on a

CAPA form. The form lists the most common inadequacies encountered from collection of samples to the release of results, so that the issues are identified after the QA verification. In such instances, the supervisor marks the appropriate box corresponding to the issue encountered, and the relevant data are entered. The time required for laboratories to complete the requested rework is equal to the any everyday procedure. Total TAT was monitored by the QA personnel and instructions for TAT reduction were given to the personnel when necessary. The percentage of rework associated with both internal and external factors were closely monitored and reported. Data related to the study period (January to May 2017) were used to evaluate effects of QMS implementation. Total rework percentage before and after the active QMS implementation was compared.

**RESULTS**

We found that the rework percentage decreased with the continued implementation of active QMS. EQAS was also performed to ensure the instrument calibration and quality control validity.

In January, four biochemical parameters were out of the target range (Figure 1a).

In February, nine parameters were out of the target range (Figure 1b). Root cause analysis was performed for cases that required immediate action. Identification was done for sample dilution, instrument calibration and maintenance, IQC, and the person who was involved in the activity. In March, seven parameters were out of the targeted visual index score (Figure 1c). In April and May, four parameters were out of the target range for internal calibration of the instrument (Figure 1d). It was addressed, and IQC was within the limits, and the results were reviewed once the next cycle of EQAS results was received. Since the EQAS sample was from outside the laboratory, in-house samples with the mentioned parameters were rechecked to ensure they are within the limit.

The laboratory received good feedback from the customers. Implementing QMS promoted quality of service and fulfilled customers' needs. Figure 2 illustrates the amount of rework was less than one percent in the laboratory between January and May 2017, indicating that the laboratory was effectively implementing the QMS to maintain its quality of services. Figure 3 show that the laboratory was releasing the reports within the defined period of 2 hours.

Figure 1- (a), (b), (c), (d). EQAS of clinical biochemistry parameters measured during January-May 2017.

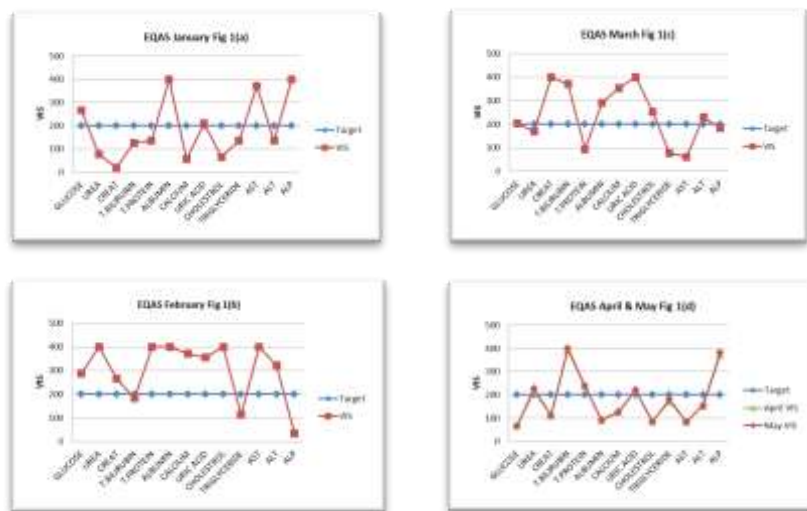


Figure 2- Percentage of samples reworked in the laboratory during January-May 2017.

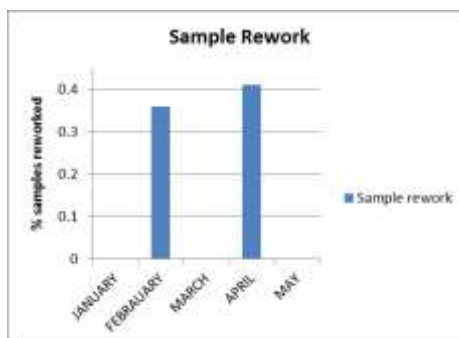
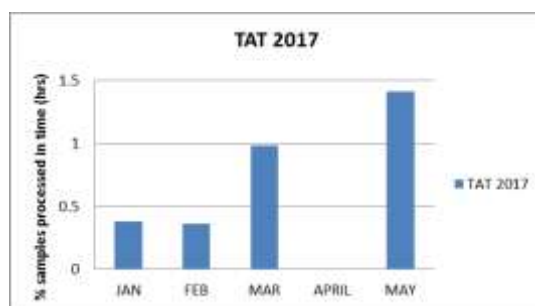


Figure 3- TAT for the samples processed in the five-month study period.



## DISCUSSION

QMS is a structured internal control system for improvement of the quality of services through customer feedback and continuous improvement. ISO 15189:2012 is the quality system for medical laboratories, which emphasizes on performance of medical testing according to a process-based QMS (6). In this regard, medical laboratories are certified by NABH that improves safety and accuracy of test results and patient care. This program is for small laboratories that cannot afford applying for ISO 15189:2012 (7) and intend to adhere to quality norms. In both NABH and NABL, patient safety is the basis of healthcare discipline that focuses on limiting any medical errors (8). The quality of laboratory results is extremely critical in 70% of diagnostic tests (9).

Implementing laboratory QMS program in all diagnostic laboratories is a good initiative for improving the healthcare system. Each laboratory has its own review process to audit laboratory procedures. Our quality strategy is to establish a concise, reproducible, verified review process that ensures continual improvement and patient satisfaction. QMS maintains continuous monitoring in the following processes: internal audit, management review, personnel, equipment, laboratory space, document control, procurement, external services, pre-examination, examination and post-examination process, reporting and continual improvement. Trend analysis was used to evaluate, plan and review the common laboratory mistakes in the laboratory. The aim of our study was to evaluate processes such as EQAS, TAT, rework and feedback in a five-month period and compare data before and

after implementing QMS as per MLP compliances. Prior to implementation of the QMS, internal audit was carried out and the findings showed some shortcoming in terms of calibration prior to sample analysis.

The staff knowledge, skills and common sense are essential for assuring quality in the laboratory (10). Quality assurance and quality control are vital for correct diagnosis. To achieve this, a successful implementation of the QMS is crucial (11). Quality control aims to make the results from one laboratory identical to any other laboratory. IQC ensures that quality control and test samples are within the accepted range (12,13). EQAS assists identification and tracking of IQC, to ensure the validity of test reports in the laboratory (14).

Customers expect the tests to be accurate, cost-effective and reported within a reasonable time. To achieve this, complying with ISO 15189 standards is an ideal approach to assure quality in medical testing. Implementation of a QMS includes the key aspects of document control, external quality assessment, internal quality control, internal audit, management review, staff management and validation. Implementing a QMS starts with the decision of the management and is followed by delegating responsibilities and collecting information through formalizing SOPs, offering training and performing validation and audits since it is an internal control which in turn complies the standard. Seminar and workshops are also effective for implementing QMS, and encourage laboratory staff to participate in EQAS and accreditation (15). The accreditation process ensures commitment of the staff and management to perform

laboratory activities according to the standard policies and procedures. Nevertheless, accreditation is a long-term process directly linked to quality (16). Quality is achieved only when the written principles are followed as routine practice throughout the laboratory activities (17).

## CONCLUSION

Implementation of QMS improves overall quality of laboratory procedures. It significantly reduces laboratory errors and progressively improves quality, efficiency, and outcomes, thus enabling delivery of timely and

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accurate services for patients. However, extensive follow-up, monitoring, and continued documentation are necessary to ensure the long-term success of implementing QMS programs.

## ACKNOWLEDGMENTS

We acknowledge the personnel who helped us throughout the project.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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