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Evaluation of quality management systems implementation in medical diagnostic laboratories benchmarked for accreditation

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Accreditation is the process which ensures that certification practices are implemented in laboratories to enhance their quality and efficiency. It in turn helps laboratories to improve technical processes, achieve competitive advantage and increase market share. To achieve accreditation, successful implementation of the laboratory quality management system (LQMS) is a requisite. In this study, evaluation of quality system implementation in small, medium and large sized laboratories, covering management and technical requirements were carried out. The study analysis was carried out by scoring the implementation of quality system in various operational activities of laboratory system. Data was gathered by auditing the laboratories using check list for the purpose of International Organization for Standardization (ISO) quality management system implementation. This study, emphasize that training should be an essential element, and can play a major role in creating awareness and understanding to implement quality system in medical testing laboratory. There should be real time training on various aspects of laboratory activities. The training needs should be evidence based and assess the competency of laboratory staff, and evaluate staff performance in order to maintain world class service of the laboratory. The quality indicators can be used for benchmarking and improving services. The study conclude that LQMS in medical testing laboratories explicate the need for understanding current standard requirements of quality system implementation and maintenance to improve the quality of service of the laboratories and facilitate accreditation. A break down in implementation of quality systems can cause a decline in quality services and hence accreditation.

Key words: Laboratory quality management systems, accreditation, quality indicators, implementation, training.

INTRODUCTION

Accreditation is a procedure by which medical testing laboratories are approved for their demonstrated capability and competence in executing each and every process of operation. The major gain of accreditation in medical testing laboratories is quality test reports which are accepted internationally. Quality of laboratory reports is always maintained when quality systems are established and followed by the laboratory personnel

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which in turn leads to customer satisfaction and confidence leading to increase in performance and productivity. Accreditation also offers a change in total operational process for implementing standards. Other advantages of accreditation are having accessibility, affordability, scalability and sustainability.

To implement uniformity/harmonization in laboratory testing process, international organization for standardization (ISO) is a worldwide federation, which publishes guidelines as international standards. The other agencies are International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). By following the guidelines of these agencies, the laboratory releases the test results and is certified to be standard, unique and accepted all over the world. At national level, National Accreditation Board for Laboratories (NABL) is an autonomous accreditation body, acting under the Department of Science and Technology, Government of India and its objective is to provide third party assessment of quality and technical competence for medical testing laboratories.

NABL promotes development and maintenance of good clinical and laboratory practices (GCP, GLP) in compliance with existing standard practices in testing and calibration, that is, technical and management requirements and competencies. It is also involved in establishing and maintaining international standard of identification for national program. GLP issued by Department of Science and Technology (also helps to get more structured approach to achieve quality in the laboratory along with ISO standard (OECD, 1999).

Laboratories are the core function in the health quality system. The result of a test is an essential and life-saving support within the health care system and ensures accurate and reliable test results. Therefore, quality-assured testing of patient samples is vital (WHO, 2006). Implementing quality in laboratories is in a better position to meet the requirements of international standards. Accreditation is most effective when it is rooted in a policy framework for evaluating laboratory quality and patient safety (Trevor et al., 2010). Accreditation will build trust with the consumer in all of the sectors. Furthermore, accreditation will raise the medical testing to internationally acceptable and comparable levels.

The laboratory quality management system (LQMS) has not received its full attention in the areas of medical testing laboratory operations. As per the current revised standard (ISO 15189:2012) every laboratory should have the quality system to manage all the technical and management process and the process flow of the Quality Management System (QMS) as shown in Figure 1. Implementing quality system in the laboratory not only provides certification but also credibility to the competency among the laboratories. Accreditation process will ensure the quality of the test results and in turn assures quality. The present study was undertaken to follow up of implementation of current regulatory compliance related to quality systems in medical testing laboratories.

The study analysis was done to identify, improve and maintain the implementation of quality system standard in the laboratory process. The measures to improve and achieve the current requirement of quality system in the testing laboratories are discussed.

MATERIALS AND METHODS

Methodology

This study was conducted in several medical testing laboratories as well as standalone laboratories. The study conducted existing system study analysis in the context of implementation of quality system according to NABL 15189: 2012 standard (WHO, 2006) and GLP guidelines (OECD 1999). This study context is regional. Real time study analysis was conducted as per the existing WHO scores based on the pre developed check list.

Study selection

Systematic study analysis was done on implementation of quality system, and for its potential relevance to improving the quality of medical testing in laboratories. The study evaluated in depth according to the standard requirements (ISO 15189:2012).

Studies included:

(1) Laboratory specified valid criteria for quality system improvement and appropriate to laboratory as per published guidelines.
(2) Implementation of these criteria in all its testing process.
(3) The scope of testing in which the laboratory specified for accreditation.
(4) Laboratory quality control issues appropriate to testing.

The study, studied existing condition in implementing quality system by personnel for specific activities. The study included qualified, trained key personnel laboratory director, quality manager, technical manager and senior laboratory technician in this study. The study was done in small, medium and large sized laboratory with score sections on document and records, organization and personnel, equipment, purchasing and inventory, process control internal/external quality assessment and facilities and safety. This study was carried out to investigate implementation of quality system and its maintenance as per ISO 15189.

RESULTS AND DISCUSSION

Quality system audit

A quality system implementation audit was done in small, medium and large sized laboratories, which do or do not have awareness of basic quality system in its operation and applying or renewing accreditation. As per World Health Organization checklist, top scores of the clauses are given in the Table 1. The study analysis was done on the represented parameters in the X axis and the points were given based on the implementation of existing

Table 1. WHO score data as per ISO 15189:2012 standards in laboratories.

S/N	Sections	Points
1.	Process control and internal/external quality assessment	43
2.	Facilities and safety	40
3.	Purchasing and inventory	30
4.	Equipment	30
5.	Documents and records	25
6.	Organization and personnel	20

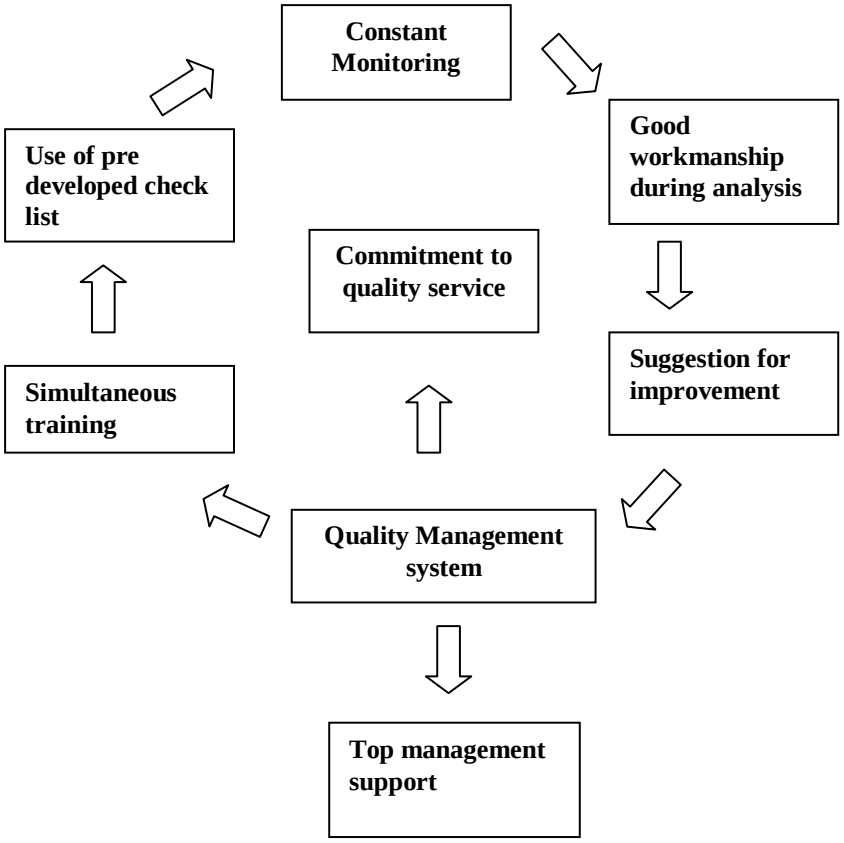

Figure 1. Process flow of quality management system.

quality system. The data is represented in a 100% stacked horizontal bar graph. The study analysis reveals that the laboratories are implementing and practicing quality system in its operation irrespective to the size of the laboratory (Figure 2). However, there were differences in terms of facilities and safety aspect when small laboratories are compared with medium and large size laboratories.

Ignorance in quality Implementation

To achieve laboratory effort on its measurable objectives implementation of QMS facilities is essential. In this system study, the study found that the quality system management implementation process was not practiced effectively in the laboratories. A manual of procedure was not developed to support efficient, effective, high quality operation and appropriate laboratory services irrespective of the size of the laboratory. A brief written statement describing the Laboratory's intended action with respect to attain a specific requirement of the standard (ISO 15189:2012) was not implemented in the laboratories. Quality standards were not implemented in the laboratory processes or series of inter-related steps involved in examination that uses instruments, reagents, staff and

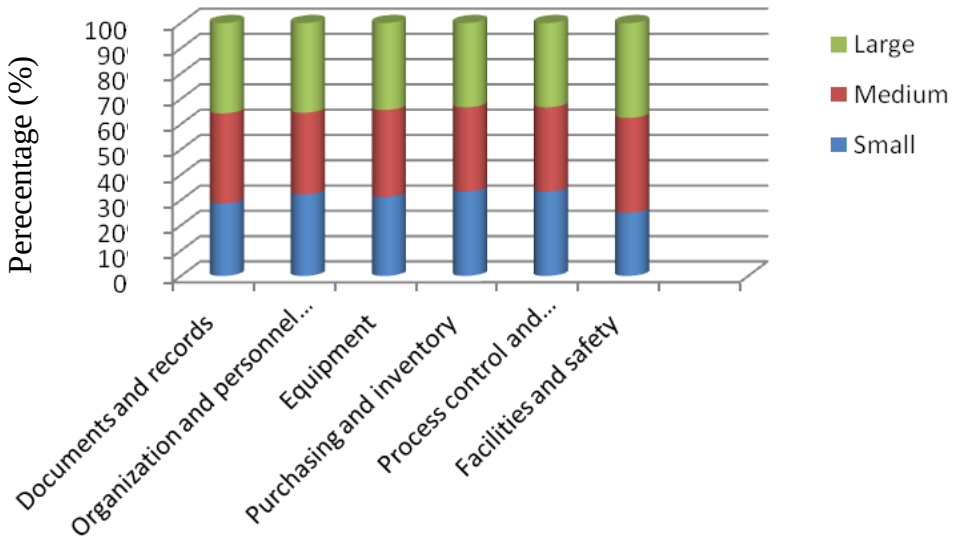

Figure 2. Comparison of quality system implementation in small, medium and large sized laboratories.

other related resources to get the test results efficiently.

A written test procedure was not prepared in most of the laboratories. Technician does the test by using kit instructions as a routine practice. Other staff also learned the same practice and followed without proper documentation. Awareness among the staff is very poor regarding implementation of quality standards. Internal audits were not done to see the progress and performance of the laboratory. Non-conformities observed during audit were not discussed with the management in Management Review Meeting (MRM) to improve the overall quality standards in its entire operational process.

Deficiency in personnel training

A good quality system is developed by scheduled training program implemented and ensuring that each staff of the laboratory is suitably trained to meet the skills required for undertaking job responsibilities. In this study, it is found that training of the personnel was not effectively done in the laboratories. Awareness of quality system implementation in operational process was lacking among the personnel. Training on test procedures is insufficient in the staff. Based on survey of training records and audits training on safety process especially handling the infectious samples was deficient in the laboratories. General training on how to write the standard operation procedure, and maintain documentation in all laboratory process was not given to the personnel. Training on biological waste management is poor. Training of personnel was not consistent. Training on mentioned subjects, its effective implementation and evaluation is given as a pie chart representation in Figure 3. By implementing all the mentioned training to the laboratory proves 100% performance compliance.

Inadequate quality assurance

The laboratories are required to have adequate quality service (QA) personnel in place. It is important that records are kept of all control and standard results which help the assessor to overview the laboratory performance. In this study, it is found that laboratories are not having adequate QA personnel in place. Records are not kept updated. QA is not given priority at the laboratory. There is negligence in evaluation of personnel performance and insufficient coordination with the quality system implementation. The administrator is poor in management and skills. There was no simultaneous training which can help and improve personnel performance to solve troubleshooting.

Need for quality service

In recent decades, due to the competitiveness, worldwide laboratories have realized that a good quality service is a key area for the commercial success and its development. Quality is essential where the measure of performance and satisfaction of the client or customer is to be placed foremost. Quality management is to assess the level of quality in operational process and to improve it. Accreditation reassures quality by giving an opportunity for laboratory to function in a highly organized way to

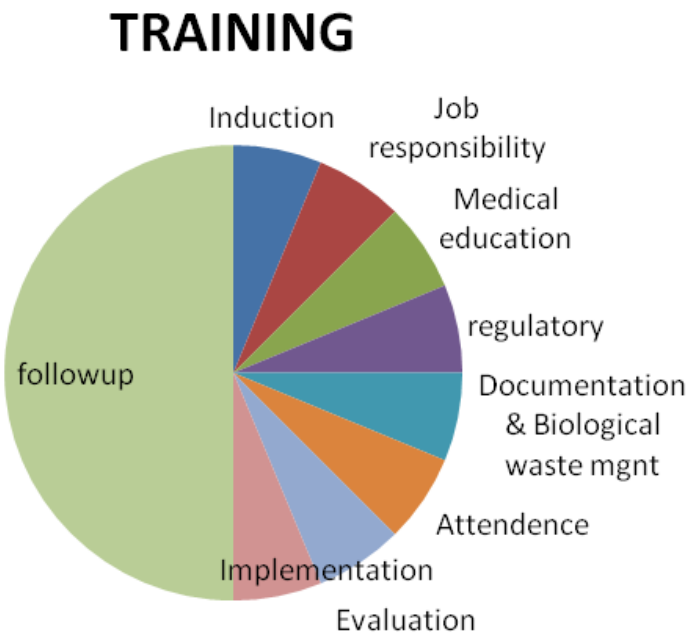

Figure 3. Various training aspects, its evaluation and output analysis of quality implementation in medical testing laboratories. Training input: Induction, job responsibility, medical education, regulatory, documentation and biological waste management; Training evaluation: Attendance and implementation, training output, follow-up for the effective implementation.

achieve the quality in its operations.

Measures for implementing quality

Laboratories should standardize and implement quality improvement process, from lot to lot reagent verification, external quality assurance services (EQAS), inter laboratory comparison (ILC), equipment calibration, instrument comparison of methods to the control of records and documentation. Errors can be prevented and arrested by preventive action and root cause analysis for nonconformities. Real time process of quality management in laboratory need to be followed and comply with the standards (ISO 15189:2012) and can lead to quality achievement. Quality system procedures (QSPs) meant to execute policies can serve as guide to streamline laboratory work. The most important step towards the process of achieving quality is to follow the pyramid structured documentation process which includes QSM, QSP, dept manual and all the forms and records used in laboratory operational process (Figure 4).

Quality manager (QM) in the laboratory needs to be cautious in addressing training needs of new and existing staff. Training can play a major role in creating awareness and understanding to implement quality system in medical testing laboratory. There should be real time training on various aspects of laboratory activities. The training needs should be evidence based and assess the competency of laboratory staff and evaluate staff performance in order to maintain world class service of the laboratory. The QM holds the key to sustain quality by remaining vigilant and creating a system for routine audit to monitor all the activities and a continuous training on relevant medical education for all the laboratory staff. Quality is a philosophy and by implementing the principles of quality system in day to day operation of laboratory is vital to sustain quality (Burke, 2014). In order to maintain the quality standard of the laboratory, understanding the quality concept, terms and definitions of Quality Management System (QMS) is a key aspect of improving quality. The laboratory staff and management should understand the importance of audits and QMS.

Implementation process of quality system ensures that customer requirements are achieved consistently. Quality management system will also define time scales and internal review mechanisms to implement quality in laboratory process. Awareness raising sessions for staff should be conducted on the implementation of the system. Maintenance of quality needs full support and commitment of the entire laboratory. Evaluation process of internal audit, corrective action on findings,

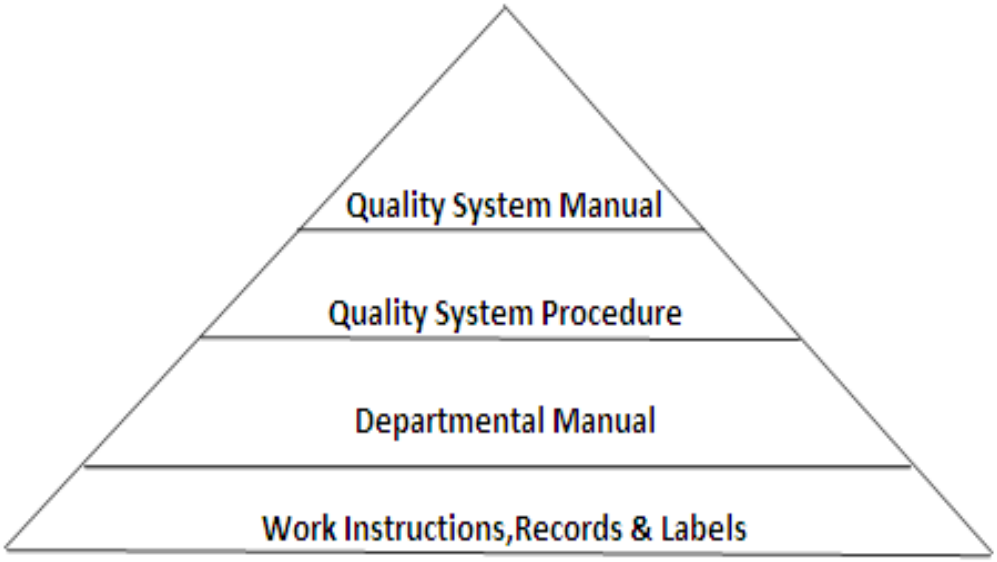

Figure 4. Quality system documentation in medical testing laboratories.

management review meetings and ongoing internal audits provides an opportunity to refine the quality management system policies and procedures by Framework for Assessment of Environmental Impact (FASSET, 2004).

To achieve laboratory effort on its measurable objectives and implementation of QMS facilitates, a manual of procedure must be developed to support efficient, effective, high quality of operation and appropriate to the laboratory services. It should also include accurate and precise test results, appropriate test selection, timely reporting, and correct interpretation of test results, and recommendations for further investigations. Written instructions/standard operating procedures (SOP), describing the way to carry out a step in the process of an examination, how one should perform an activity should be designed to meet quality policy and objectives and to direct and control an organization with regard to quality should be the precedence to achieve implementation of quality in the laboratories.

The laboratory is providing the information for the diagnosis, prevention, or treatment of any disease to assess the health of, human beings, therefore implementation of quality system is one of the essential requirement in order to maintain quality standard in the performance of all activities from sample collection to release of reports. Audit findings should be addressed along with its corrective action and preventive action. In case of any major non conformities root cause, analysis must be done along with investigation for complete closure of the addressed findings (Burke, 2014). Laboratory should conduct internal audit as per the standard (ISO 15189:2012). Good laboratory practice entails planning, conducting and reporting the entire laboratory operation. It also includes personnel training, job responsibilities of laboratory personnel including key personnel, examination, data collection, quality system for continual improvement (Burke, 2014). If any aspect GLP is not followed, yet the same should be addressed with sound reasoning for the occurred deviation and it does not necessarily invalidate the process. The study director must explain why the deviation occurred and assess its impact on data integrity as per 21 CFR 58 subpart j (Shahram and Susan, 2009).

The most relevant subjects to be audited in the laboratory are quality system, personnel, documentation and records, laboratory controls, validation, change control and complaints. The checklist that was used during the initial laboratory evaluation should also be verified during the audit. A qualified quality auditor, from quality assurance (QA) and/or a quality control (QC) expert would be the recommended to do the audit. The auditors should focus on the effectiveness of the laboratory controls for the procedures: form test process and all its related process (APIC, 2012). Internal quality control procedures must be practiced for all testing methods used by the laboratory and quality control data sheets and summaries of corrective action should be retained for documentation (Gershy-Darnet et al., 2010; Shahangian and Snyder, 2009)

Medical laboratory diagnostic testing services have an important role in the human health care. Assessing the quality of laboratory services using quality indicators requires a systematic, transparent, and consistency in analysis, since the analysis is considered one of the important consequences on patient care and health. Laboratory quality indicators are identified as one of the

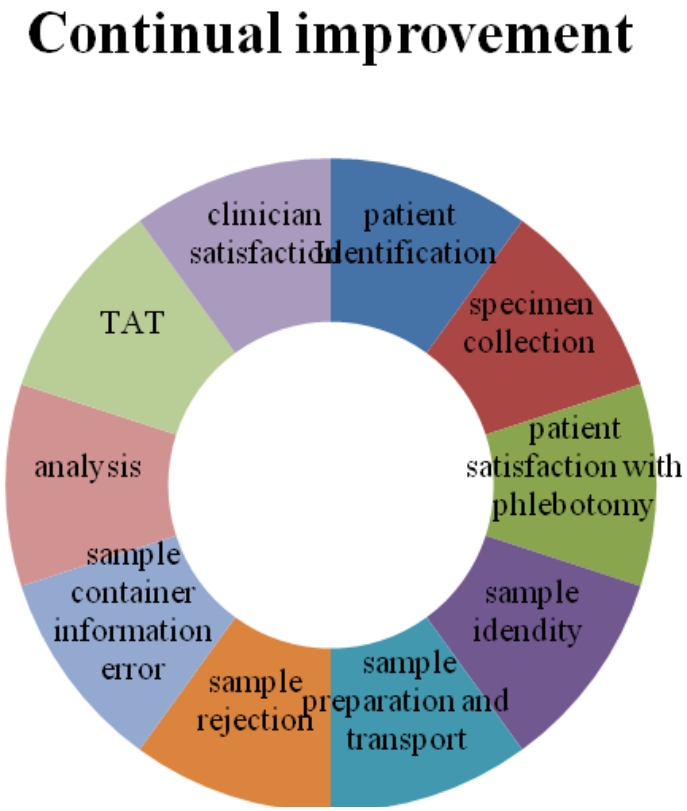

Figure 5. Laboratory process for continual improvement in quality implementation.

continual improvement in laboratory testing process. The general awareness of the standard (ISO 15189:2012) among the laboratory personnel may result in excellence in monitoring of the total testing process. Test order appropriateness, patient identification and specimen collection, patient satisfaction with phlebotomy, sample Identity, sample preparation and transport, specimen Inadequacy and rejection, blood culture contamination, sample container information error, analysis, proficiency testing performance, result reporting, inpatient laboratory result availability, turn around time, clinician satisfaction with laboratory services are the areas of work where the laboratory can constantly monitor the performance to customize the quality of services Shahram and Susan (2009) and the QM has to give equal importance to all the addressed parameters includes from patient identification to analysis, turnaround time (TAT) and clinician satisfaction (Figure 5). Total TAT is considered as one of the critical aspect of quality indicator. TAT is established in the laboratory in consultation with its clients. At least 80% of specimens received must be processed within the stated TATs to receive an accreditation rating. TATs will be interpreted as the time from receipt of the specimen in the laboratory until the reporting of results.

Customer satisfaction is generally considered as one of the quality indicator of laboratory services and related to null test report errors or no delays in release of reports and appropriate utilization of laboratory services and its associated costs. Laboratory administrator being the immediate person to know for most laboratory services including timely reporting, communication of relevant information, and notification of significant abnormal results to any outcomes, laboratories can carry out their quality system development on a sustainable basis by using the existing checklist prepared until all areas of quality are fully developed (Kusum and Silva, 2005). Assessing the effectiveness of quality system by anticipating errors, developing clear systems and procedures, ensuring that staff is trained for the tasks they perform and validate all operations, follow SOP and its amendments Pereira (2015).

Agreement with contract service providers, and where after satisfactory quality assessment done by the QM, the signed documents of both parties should be maintained. Laboratory confidentiality agreement should be signed by all the laboratory staff to assure patient safety, patient confidentiality, data integrity and compliance with good clinical practice (GCP). Laboratory facilities, system, equipment, examination procedures, QC, data recording,

personnel records, report of all documents should be done at intervals as per the audit plan. Performance measures of the laboratory-related quality are very important in case of any nonconformity which is beyond the acceptable range for which laboratory is responsible to comply with the requirements of standard (ISO 15189:2012).

Laboratory testing and its related process of improvements certainly have the potential to improve outcomes of interest and consequences in the laboratory quality systems. Medical testing is often the principal basis for more costly downstream care. It also features prominently pay-for-performance guidelines and compliance standards, making it a potential target for cost savings under global payment plans (Song et al., 2011). Other areas that have not been adequately monitored are corrective and preventive actions and their effective implementation in which they have been shown to improve the provision of service. Because there are so many processes involved in laboratory testing, there is considerable challenge in identifying, defining, and, ultimately, implementing indicators that cover the various stages of the total laboratory testing process (Chopra et al., 2012).

In medical diagnostic laboratory, the challenge will be to continue to improve quality practices and to continue to support laboratories in achieving accreditation. Laboratory personnel must have knowledge of the ISO requirements for medical testing laboratories as well as expertise in the area of work and to increase awareness of EQAS. Thus, both accreditation and participation in EQAS are accepted as effective and important tools to improve the accuracy and reliability of quality standards in testing process. During recent decades, quality management sciences have advanced dramatically in many industries, operational standards are defined, and the information technology revolution has opened up new possibilities for highly reliable service. Nevertheless, experience suggests that the application of these sciences, standards and information technologies in health care seems to advance slow and unevenly (Schneider, 2014).

Laboratory testing is the single highest volume of medical activity and drives clinical decision-making across medicine. Thus, overall quality system improvement of a diagnostic laboratory at present condition depends on understanding of standard compliance of the personnel involved. Medical testing is considered appropriately if it supports the standard of care, which in turn is defined according to patient outcomes, improving laboratory utilization (Alexander, 2012) when it follows standard compliance. Therefore, laboratory professionals should comply with the NABL 15189:2012 standards to achieve major harmonization of laboratory test results (individual results, reference- and decision levels). NABL 15189:2012 standardization of all the mentioned aspects helps to improve the overall quality of service and will have an enormous economic impact, and will contribute to uniform test results over time and space (Müller, 2000, 2010) and customer satisfaction. A well defined documented process provides perfect evidence to the assessors that the system is suitable for its intended use.

CONCLUSION

Overall, the present study focused on the quality system implementation in the laboratories, and the study discussed the measures that could be taken to improve and implement quality system in its practice. A more detailed evaluation of documentation in quality system and the quality indicators should be done. Considerable variation and inconsistency in key terms, definitions, implementation, measurement and reporting practices should be solved in order to improve subjective evidence and its importance. The study, recommend that there should be a regular training for all the staff in order to create awareness and interest to implement quality in laboratory process. The quality indicators should be used for benchmarking and improving services. LQMS in medical testing laboratories explicate the need for understanding current standard requirements of quality system implementation and maintenance to improve the quality of service of the laboratories and facilitate accreditation. A break down in implementation of quality systems can cause a decline in the quality services and hence accreditation.

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Conflict of Interest

The authors have none to declare.

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