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Evaluation of Quality Indicators in the Laboratory: A Three Year Experience

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ABSTRACT

INTRODUCTION - Quality indicators (QIs) are important tool for the monitoring and evaluation of laboratory performance at pre-analytical, analytical and post-analytical phases. Aim of this study was to analyze total testing process (TTP) and QIs for the period of three years, to evaluate the laboratory performance in all three phases. **Materials and methods-** A retrospective study was conducted for the period of three years from Jan 2017 to Dec 2019. All sections of the laboratory were included in this study to analyze the QIs at pre-analytical, analytical and post-analytical phases. The laboratory followed the guidelines specified by International Organization for Standardization (ISO) 15189:2012 to identify errors in all processes. **Results-** laboratory received a total of542885 samples during the study period. The overall error rate was 0.33%, these results were consistent for the three years. In pre-analytical phase most common cause of sample rejection was errors in registration (0.13/1000) followed by hemolysis (0.32/1000). In analytical phase the incidence of error was very minimal (0.4/1000). In the post analytical phases light improvement in TAT (2.0/1000) and reduction in amended reports (0.09/1000) were seen over the three years. **Conclusion-**Monitoring and evaluation of QIs identify problematic area in the processes and hence, helps in formulating the strategies for improving the quality of laboratory services and patient safety.

INTRODUCTION:

The clinical laboratory plays a vital role in management and control of diseases by providing timely test results which help in patient management.[1] 'Quality' in Laboratory means 'doing the right test at the right time for the right person'. Almost 80% of all diagnosis are made on the basis of laboratory test results.[1,2,3] So the quality of laboratory results have a huge impact on the patient outcome.

However, the problems in laboratory arise more frequently before and after the analysis of submitted samples. That's why the Total Testing Process (TTP) needs to be managed properly in Pre-Analytical, Analytical and Post-Analytical phases.[4]

The broad definition of all three phases can be given as the journey of the sample from the patient to the dispatch of report back to the patient/clinician. The pre-analytical phase includes the procedures before processing the sample like patient preparation, sample collection, transport and storage. Actual performance of assays on the samples and interpretation of investigations comprise the analytical phase. The post-analytical phase deals with delivering reliable and accurate reports to the patients/clinicians.[4]

In a large clinical laboratory, errors are bound to happen due to volume of samples, the number of individuals handling these samples and number of steps involved in the testing process. These errors can be minimized by appropriate training, quality control measures and timely review of protocols. [5,6,7] International organization for standardization 15189:2012 and NABL provide guidelines for quality management system (QMS) for the medical laboratory.

According to the international standard for clinical laboratory accreditation (ISO 15189: 2012) clause 3.19, "quality indicators (QIs) can measure how well an organization meets the needs and requirements of users and the quality of all operational processes." Clause 4.14.7 specifies that "the laboratory shall establish QIs to monitor and evaluate performance throughout critical aspects of preexamination, examination, and post examination processes.[5]QIs are qualitative as well as quantitative measures; provide information about the TTP of the laboratory. So these measures must be good enough to monitor critical aspect of TTP and enable quantitative evaluation of the performance of a laboratory.

The aim of this study was to analyze Total Testing processes (TTP) and QIs in order to evaluate laboratory quality performance at Pre-Analytical, Analytical and Post-Analytical phases for the data collected over the period of three years.

MATERIALS AND METHODS:

This retrospective study was conducted for a period of 3 years during 2017 to 2019 following institute's ethics committee permission at Dr. Hedgewar Rugnalaya, which is a tertiary care hospital in Aurangabad. The hospital has 300 beds and includes specialty &superspeciality departments. The medical laboratory involves the disciplines of biochemistry, hematology & clinical pathology, microbiology & serology and histopathology. The laboratory is well equipped and has NABL accreditation in all the sections since 2005.

The clinical chemistry lab is equipped with auto analyzers DXC AU 700 and AU 480 (BECKMAN) for routine biochemistry investigations, Image 800 for special proteins and Access 2I and Architect 1000 iSR for hormones, tumor markers and vitamins, Biorad D10 for Glycated hemoglobin and abnormal hemoglobin analysis. The hematology and clinical pathology departments use the DHX800 automated cell count analyzers (BECKMAN), and iQ200 ELITE and iChem VELOCITY for urine analysis (Beckman). The Stago STA Compact and Stago STart automated and semiautomated hemostasis workstations. For blood cultures, the microbiology section uses the BacT/ALERT and VITEK automated systems (by bioMérieux SA) for identifying bacteria and typing their antimicrobial resistance levels and also uses Biosafety Cabinet class 2 (KIM microsystems). The surgical pathology section is supported by the Leica TP1020 automated tissue processor. All instruments are validated by vendors before clinical use and are calibrated at regular interval according to defined schedule of maintenance; laboratory technician documents daily maintenance.

Samples collected from outpatient and inpatient departments were labeled with a unique barcode generated by the laboratory information system (LIS). System recorded the data such as name, age, sex of patient, full name of referring consultant, specimen type, date and time of collection and tests to be done. The samples were screened for pre-analytical errors before processing according to acceptance and rejection criteria. When sample was rejected based on the criteria, repeat sample was requested and reason for rejection documented. Samples marked 'urgent'

were processed immediately and informed to respective consultants. Critical laboratory findings were conveyed immediately to treating Physician by verbal communication followed by printed report dispatch. All reports were reviewed by Consultants of respective discipline from laboratory before release.

In the laboratory, internal and EQA/proficiency testing (PT) programs are actively used to identify analytical phase accuracy. The laboratory conducts daily internal quality control (IQC) and EQA/PT on a regular basis (monthly). The EQA specimens are processed in the same manner as routine specimens. In case of unavailability of EQA/PT for a particular test, the laboratory performs interlab comparison for accuracy of results. Documentation of all steps in the analytical process was done for reducing errors. The laboratory made mandatory staff training at regular intervals so that they should have current knowledge of techniques and technologies used in the laboratory.[5,6]

A representative range of Turnaround time (TAT) for different sections is given in the following table, which vary from test to test.

Table No. 1: Turnaround Time (TAT) for different sections

Section	TAT
Biochemistry	2 – 24 Hrs
Hematology & Clinical Pathology	2 – 48 Hrs
Microbiology & Serology	24 Hrs – 7 Days
Histopathology Pathology	4– 8 Days

The QIs were calculated every month based on all of these criteria and expressed as percentages. The samples were drawn with routine venipuncture according to the guidelines suggested by the Clinical and Laboratory Standards Institute.[8]The samples then transferred to the laboratory for processing. At the time of sample acquisition, technicians visually checked the samples in terms of volume, labeling, clotting, and simultaneously matched the label with the requisition form. Any fault or mistake was recorded in the laboratory information system. The samples were

allowed to clot and centrifuged at 3000g for 15 minutes, and then brought to the analyzers. To evaluate the occurrence of post-analytical errors, the laboratory maintains a record of amended reports issued. The Laboratory manager analyzes the records monthly and undertakes corrective or preventive actions to reduce or eliminate the errors.

RESULTS:

Table No. 2: Pre-Analytical Errors

Types of Pre-Analytical Errors		**Years Percentage (%)**			**Total No. (No. per 1000 of samples)**
		2017	**2018**	**2019**	
Errors in registration of patient		83 (0.041)	82 (0.039)	16 (0.008)	181 (0.33)
Sample Rejection	Hemolysed	28 (0.012)	28 (0.013)	18 (0.012)	74 (0.13)
	Wrongly Labeled/Lipemic	15 (0.007)	28 (0.013)	11 (0.010)	54 (0.10)
	Wrong container	20 (0.010)	21 (0.012)	8 (0.005)	49 (0.09)
	Inadequate Sample	15 (0.007)	11 (0.004)	10 (0.007)	36 (0.06)
	Clotted	12 (0.006)	11 (0.005)	8 (0.002)	31 (0.05)
Total no. of errors		**173 (0.087)**	**181 (0.087)**	**71 (0.051)**	**425 (0.75)**

Table No. 3: Analytical Errors

Analytical Errors in three years	2017	2018	2019	**Total No. (No. per 1000 of samples)**
Internal QC Failure	18 (0.009)	12 (0.005)	10 (0.007)	40 (0.07)
Unacceptable Performance inEQAS	67 (0.033)	59 (0.028)	52 (0.037)	178 (0.32)
Total no. of errors	**85 (0.043)**	**71 (0.034)**	**62 (0.044)**	**218 (0.40)**

Table No. 4: Post Analytical Errors

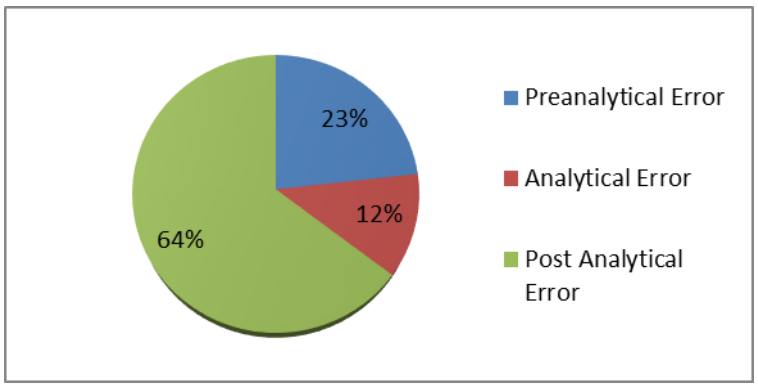
	2017	2018	2019	**Total No. (No. per 1000 of samples)**
Prolonged TAT	432 (0.21)	397 (0.19)	290 (0.20)	1119 (2.06)
Amended reports	35 (0.017)	11 (0.005)	7 (0.005)	53 (0.09)
Total no. of errors	**467 (0.23)**	**408 (0.19)**	**297 (0.21)**	**1172 (2.15)**
Overall error rate (%)	**0.36 %**	**0.32%**	**0.30%**	**0.33%**

Table No.5: Comparison with other studies

		Chawla et al	**S. Kumar et al**	**Sakyi et al**	**Present study**
Pre-analytical	0.3-0.8% **Dale & Colleague**	1.5%	0.61%	3.7%	0.2%
Analytical	0.8% **Jesus & Colleague**	1.3%	0.09%	0.1%	0.1%
Post-analytical	1.6% **Alsian & Colleague**	2.5%	0.46%	0.9%	0.63%

Table No. 6: Overall error rate

	Lippi et al	**Plebani &carraro et al**	**Present study**
Overall error rate	0.1% - 3.0%	0.33 - 0.47%	0.30 – 0.34 %



Graph 1 : Errors in three phases over the period of 3 years:

The laboratory received a total of 5, 42,885 samples during three year period of study. The year wise samples were 197692, 206146, and 139047 respectively. The overall error rate was calculated by dividing the total number of errors by the total number of samples; the result was 0.33%. Errors were most common in the post-analytical phase in all the years of the study.

Pre-analytical variables included registration errors, rejection of samples due to hemolysis, clotted samples, wrongly labeled/lipemic samples, samples in wrong containers etc. These are described in table 1. Most common cause of sample rejection was registration errors (0.33 per 1000), followed by others which included hemolysis (0.13 per 1000), and wrong labeling/lipemia (0.10 per 1000). Low frequency of errors was shown by other pre-analytical variables such as insufficient samples (0.06 per 1000) and clotted samples (0.05 per 1000).

Table 2 shows the prevalence of certain QIs for the analytical processes used in the laboratory. The laboratory included IQC failure; unacceptable performances in EQA are measures for the analytical processes as an indicator of the performance. EQA/PT performance, which compares the analytical results in our laboratory to peer laboratories, appeared to be the major source of analytical errors (0.3 per 1000). The post-analytical variables that we used to measure the quality of our laboratory services are listed in Table 3. Analysis showed that Turn Around Time (TAT) was prolonged for 1119samples (2.0 per 1000), whereas we gave out a total of 53 amended reports (0.03 per 1000).

The laboratory followed the guidelines specified by ISO 15189:2012 for laboratory quality and competence. According to the guidelines, the laboratory performed internal audit quarterly to

monitor the laboratory performance and NCs were recorded of all three phases for three years. The number of NCs was highest in pre-analytical phase.

DISCUSSION:

The patient care of highest standard demands healthcare professionals to provide quality laboratory services. Each and every step in Total Testing Process (TTP) should be correctly performed. The best laboratory practices include achieving highest level of accuracy and reliability. In this study there was improvement in the TTP of laboratory. And the results were consistent for the 3 years.

The overall error rate of laboratory over a 3-years period was 0.34%; this figure is within the range of 0.1% to 3.0% that had been published by Lippi et al in a summary of data from a number of studies.[9] Plebani and carraro et al reported decline in laboratory error rates over 10 years from 0.47% in 1977 to 0.33% in 2007 in their studies.[10]

In recent years, automation and technological advances have significantly improved the analytical reliability of the laboratory results and decreased the error rate. Quality assurance is one of the most important tools for impact on laboratory testing. It ensures both precision and accuracy of laboratory test results. We observed an analytical error rate of 0.4 (per 1000samples) in this study. Our results are observed to be within range as compared with the study of Jesus and colleagues[11]and many other Indian studies.[13,14,15,16]

The results were found similar to the results of earlier studies in that the prevalence of errors occurred in the pre-analytical and post-analytical phases. [13,14,15,16] Pre-analytical phase starts with the test request, patient and specimen identification, sample collection, handling and ends with the transportation of specimen to the laboratory.

In this study, all the pre-analytical variables mainly dealt with the specimen quality. It was found that, errors in registration were the most frequent cause of sample rejection. The next variables causing pre-analytical error were hemolysis and mistakes in sample labeling. These results are consistent with studies of Savitha Kumar et al.[13] and Chawla et al. [14]

Our error rate in the pre-analytical phase was lower as compared with earlier studies[13,14,15,16] pertaining to well trained staff & phlebotomist, a high end collection center infra-structure and bar coding system in our hospital minimizing personal handling of specimens.

Post-analytical errors can happen during the process of report verification, transcription & dispatch of test results to the health care person. In this study, prolonged TAT and amended reports were considered as post-analytical errors. Our results are within range with the studies done by Savitha Kumar et al.[13] Chawla et al, [14]and Sakyi et al.[16]TAT is the measure of the number of tests that do not meet a reporting deadline. No guidelines are available for determination of ideal TAT goals. However, Ricos and colleagues have suggested that 11% is an acceptable fraction of laboratory reports that may exceed the stipulated TAT.[17]The preponderance of prolonged TAT in our study is more, owing mainly to transcriptional errors in reports and rejection of samples. The delay in pre-analytical and analytical phase also contributes to prolonged TAT. The rate of amended reports was comparable to those reported by Savitha Kumar et al[13] and Sakyi et al.[16]

CONCLUSION:

The present study showed steady improvement in all three phases of laboratory. To achieve the requirement of ISO 15189 guidelines Quality indicators play important role. Monitoring and evaluation of QIs identify problematic area in the laboratory processes and hence, helps in formulating the strategies for improving the quality of laboratory services and patient safety.

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ABBREVIATIONS:

EQA-external quality assessment

ISO-international organization for standardization

IQC-internal quality control

NABL-national accreditation board for testing and calibration laboratories

NC-non compliance

PT- proficiency resting

QMS-quality management system

QI-quality indicators

TAT - turnaround time

TTP-total testing process

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