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Original article

Study of Quality Indicators (QIs) of Clinical Biochemistry Laboratory in rural hospital, Loni

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ABSTRACT:

Background: Quality Indicators are utilized globally to collect data from its documentation, to identify the recent most effective performance criteria as well as to reduce errors in the total testing process. However, it is essential to maintain the credibility of the tools by close monitoring with effective and correct record keeping. The Quality Indicators monitors and controls the total testing process which includes the Pre-analytical, Analytical and Post-Analytical Phases. The present study is necessary to study the status of quality of testing processes and to set quality goals and to achieve those goals by monitoring and assessing those quality indicators.

Aims and Objective: To study the Quality Indicators of Clinical Biochemistry Laboratory.

Material & Methods: The Quality Indicators were studied and analyzed post-recording and monitoring on daily basis from August 2019 to December 2019 in Clinical Biochemistry Laboratory.

Result: The present study indicates significant occurrence of errors in Pre-analytical phase Quality Indicators as compared to Post-Analytical and Analytical Phases. The major challenge for the documentation of Quality Indicators indicate a requirement for round-the-clock basis monitoring to record the deviations in the total testing process as observed in the present study.

Conclusion: The present study emphasizes upon the necessity of monitoring the Quality Indicators in clinical laboratories. The selected Quality Indicators should be specific, sensitive and diagnostically appropriate and relevant to the various test profiles utilized in clinical laboratories. The Quality Indicators improve accuracy and precision, sets benchmark for laboratory performance for both within and inter-laboratory comparisons which enables decision making and set priorities post-corrective actions which supports accountability, quality improvement and accreditation.

KEYWORDS: Pre-analytical, Analytical, Post-analytical, Quality, Quality Indicators

Introduction:

The quality of the laboratory services should be maintained throughout the total testing process by correct performance assuring and emphasizing upon valuable clinical decisions and effective patient management (1). Previously a ten-fold decrease in the analytical error rate have been achieved due to improved maintenance of precision and standardization of analytical techniques, reagents and instrumentation (2). With an aim to decrease the occurrence of errors , the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) launched a working group named " Laboratory errors and patient safety " (WG-LEPS) with the emphasis upon identifying and evaluating valuable Quality Indicators (QI) and the associated quality specifications in order to monitor all the stages of the total testing process (TTP). This project was also responsible to define the usage of QIs for their usage in all laboratories globally, collect data from its documentation, identify the recent state-of-art and effective performance criteria to ensure improvements in the activities, reduce errors rates and suggest actions to further improve the total testing process (3,4,5).

A quality clinical laboratory service might be simply described as performing the right test on the right person at the right time and interpreting that test correctly. This would be reflected as a service that provides quality in the preanalytical, analytical and postanalytical phases (6).

The total testing process includes all the three stages such as: (a) Pre-analytical (Pre-examination processes). This is the initial stage, which includes the clinician's request, requisition form, preparation and registration of the patient, collection of primary samples (s), transportation to and within the laboratory and ends where the next stage of analysis begins. (b) Analytical Phase (Examination process) includes the analysis of the patient's sample with effective processing of quality control samples simultaneously. (c) Post-Analytical Phase (Post-examination processes). Progressive post-analysis which includes review of results, retention and storage of clinical specimens, samples, biomedical waste disposal, formatting, reporting, verification and retention of examination results (7) (8).

There are approximately 16 QIs in pre-examination process, approximately 3-5 in the analytical process and approximately 4-5 in the post-analytical processes which can be defined in order to monitor the quality of the total testing process of the clinical laboratories (9).The basic necessity to monitor the QIs is to reduce the occurrence of the rates of errors in the total testing process. This is based on standardized data collection and definitive state-of-art facilities, quality specification for each monitored QIs; which are independent of a) the organizational size of the clinical laboratory and its activities performed, b) intra and interrelationships of the test processes, c) the competency and training of the laboratory personnel (4). Hence, QIs provides information in terms of qualitative or quantitative associated to an event (test process or test results) under the scrutiny with the target to changes periodically and to record the quality achievements and targets by comparison with the criterions required (10,11).

Much attention is paid to analytical phase though wealth of evidence pointing to the predominance of errors in the pre- and postanalytical phase is there. So, the present study was done with the aim to study QIs and improve laboratory performance by monitoring the less attended extra-laboratory factors in preanalytical & postanalytical phases. The present study is necessary to study the status of quality of testing processes and to set quality goals and to achieve those goals by monitoring and assessing those quality indicators.

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Aims and Objectives: To study the Quality Indicators (QIs) of Clinical Biochemistry Laboratory.

Materials And Methods:

Clinical Biochemistry Laboratory is a section of Central Clinical Laboratory, Pravara Rural Hospital and Rural Medical College. In accordance with ISO 15189 the Clinical Biochemistry Laboratory monitors the total testing processes to meet and maintain the quality standards. The monitoring of Quality Indicators (QIs) is one such criterion to assess the quality of the overall functioning of the clinical laboratory.

In the present study only the data pertaini 19 Clinical Biochemistry Laboratory is incl Data pertaining to Clinical Microbiology and Clinical Pathology was excluded.

The Quality Indicators (QI) pertaining to Pre-Analytical, Analytical and Post-Analytical Processes were recorded on daily basis in Clinical Biochemistry Laboratory. The quality indicators used in study are given in table no. 1- Preanalytical QI, Table no. 2- Analytical QI and Table no. 3- Postanalytical QI.

Table no.1- PREANALYTICAL QUALITY INDICATORS

SN	PREANALYTICAL QI	SN	PREANALYTICAL QI
1	Requests without clinical diagnosis/question	8	Samples collected in inappropriate containers
2	Unintelligible requests	9	Samples clotted
3	Requests with Erroneous Identification of Physician	10	Samples with inadequate sample anticoagulant ratio
4	Requests with errors concerning test inputs	11	Samples Damaged in Transport
5	Samples lost /not received	12	Improperly stored samples
6	Samples hemolyzed	13	Inappropriate tests
			with respect to the clinical question
7	Samples with insufficient volumes	14	Requests with erroneous identification of patients

Table no.2- ANALYTICAL QUALITY INDICATORS

SN	ANALYTICAL QUALITY INDICATORS
1	Test with inappropriate Internal Quality Control performance
2	Tests uncovered by External Quality Assurance
3	Tests with unacceptable performances in External quality Assurance

Table no.3- POSTANALYTICAL QUALITY INDICATORS

SN	POSTANALYTICAL QUALITY INDICATORS
1	Tests with inappropriate turnaround time
2	Tests with Incorrect Laboratory Reports
3	Failure or delay in reporting Critical alert Value
4	Tests with Transcription errors
5	Failure in reporting results

In the present study, the documented data of the period August 2019 to December 2019 was collected and analyzed.

Ethics: The study benefits the user needs of the Clinical Biochemistry Laboratory which included both clinicians and patients, the ethical clearance of the research study was sought, and, approval and clearance was received from Institutional Ethical Clearance Committee (IEC) with Registration No. PIMS/DR/RMC/ 2020/317.

Statistical Analysis: The data pertaining to the period of the present study was analyzed and percentage of errors in quality indicators was calculated for each month. Then represented graphically on GraphPad of Microsoft Excel 2010.

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Results:

Figure 1 shows the percent errors in preanalytical phase, n denotes number of samples in each month. The percent preanalytical error for August, September, October, November & December 2019 was 27.2±0.32, 30.9±0.35, 32.6±0.68, 28.8±0.35 & 39±0.42 respectively and average percent preanalytical error was 31.7. Out of which more than 25% errors were in three QI which were i) Requests without clinical diagnosis/question, ii) Requests with Erroneous Identification of Physician & iii) Samples with insufficient volumes.

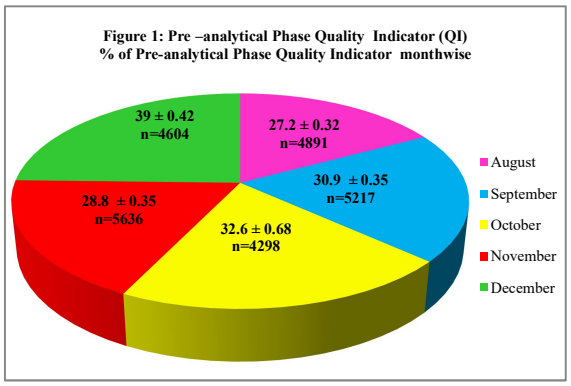


Figure 2 shows the percent errors in analytical phase, n denotes number of samples in each month. The percent analytical error for August, September, October, November & December 2019 was 0.6±0.01, 0.3±0.01, 0.07±0.02, 0.21±0.04 & 0.3±0.02 respectively and average percent analytical error was 0.29.

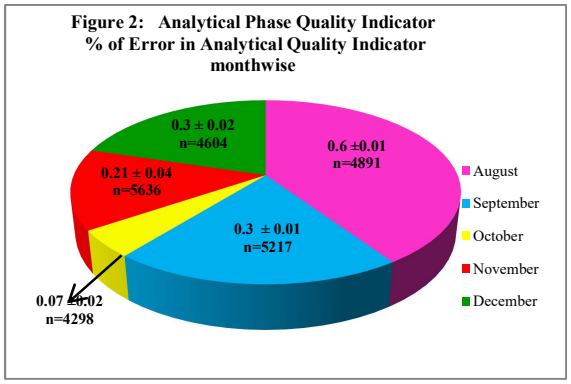
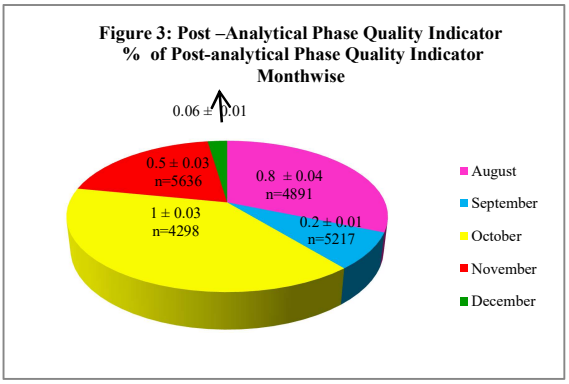


Figure 3 shows the percent errors in Post-analytical phase, n denotes number of samples in each month. The percent Post-analytical error for August, September, October, November & December 2019 was 0.8±0.04, 0.2±0.01, 1.0±0.03, 0.5±0.03 & 0.06±0.01 respectively and average percent post-analytical error was 0.51.



Discussion:

In the present study, it was observed that the occurrence of errors in QIs of the Pre-analytical phase exceeded significantly as compared to occurrence of errors in QIs of Analytical Phase and Post-analytical Phase respectively (Figure 1,2 and 3).

Total Quality Management System (TQMS) based on ISO 15189 requirements are used in the total testing process in clinical laboratory of the present study; the monitoring of the same was initiated by the usage of Quality Indicators (QIs). The biggest challenge for the documentation of the QIs is that the monitoring should be done round the clock basis to record the deviation in the total testing process as observed in the present study.

Time is an important factor with respect to all the pre-analytical, analytical and post-analytical processes. Some of the tasks involving the real-time factors are the right diagnostic test ordered, analyzed, promptly viewed and reported. Thus, will effectively benefit in the patient care

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avoiding the unnecessary delays. Kurec and Wyche et al described the timeliness of tests performed in the laboratories as the "within laboratory turnaround time", included the transport time of the sample to the laboratory (12). In our study we noted no delay in the reporting of samples. All results were reported within laboratory turnaround times. A further consideration of the report delivery to the clinicians as reported by a study by Singh et al that clinicians received reports with abnormal flags; 10% were not electronically read and 7% did not follow the real time of total testing process and even 17% of the critical alert values were not repetitive (13). Results in our study were in contrast to Singh et al, critical results were informed to respective personnel within time.

Our results are in consensus with Cigdem Sonmez et al findings which confirms the relative occurrence of errors in preanalytical phase & emphasizes training of laboratory staff, quality indicator monitoring & periodic auditing of the total quality processes (14)

The clinical laboratories objective is to satisfy the user needs eg patients and clinicians and requirements to benefit clinically and exhibit analytical accuracy. The pre-requisites of QIs, should be timely and satisfy the thresholds of analytical total testing process. Thus, QIs are the measure and means of the quality improvement hence should not be treated leniently. Once the QIs are selected they should be specific, sensitive and be diagnostically useful parallel to the various test-profiles executed in the clinical laboratories (6). The evolution of QIs is from the process of audit. Our findings and results support the Plebani et al views, that monitoring of QIs will aid the management decisions for improvement of quality and forms the vital fundamental components of a continuous maintenance of total quality management system (15).

Conclusion:

The errors in the QIs of the Pre-analytical phase were significantly higher as compared to the Post-analytical phase and Analytical Phase respectively. The occurrences of Post analytical and Analytical QIs are comparatively less. The present study has emphasized upon the necessity of measurement and monitoring of QIs in clinical laboratory. Inaccurate results can result in additional and unnecessary diagnostic testing, wrong diagnosis or failure in diagnosis, unnecessary treatment, treatment complications and failure to provide the proper treatment. All this result in increased wastage of money, time, personnel efforts and in poor patient outcomes. All this can be prevented with good clinical laboratory practices and good quality of laboratory services monitored with quality indicators on daily basis. So the benefits of monitoring quality indicators are improved accuracy and precision, ensuring patient safety, setting benchmarks of laboratory performance for within and inter- laboratory comparisons, make judgments and set priorities of performance in the form of corrective actions and support accountability, quality improvement and accreditation.

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