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Original Research Paper

Pathology

AN ANALYSIS OF QUALITY INDICATORS IN HEMATOLOGY LABORATORY AT TERTIARY CARE CENTER.

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ABSTRACT **Introduction:** In health care centers, quality indicators in a clinical laboratory are considered as very impactful tools for constant improvement of the laboratory services. **Aim:** The aim of this study was to monitor and assess periodic performance of laboratory in three phases of testing – pre-analytical, analytical and post-analytical phase and to analyze and timely review quality indicators in an effort to continual improvement. **Methodology:** This retrospective cross-sectional study included an assessment of different quality indicators from NABL accredited Hematology laboratory at tertiary health care center, South Gujarat. **Results:** Data obtained from a total of 4,94,184 samples collected over a period of January - December, 2022 year was used in the study. In pre-analytical phase, total error due to sample rejection was 1408 (0.2%) in a year. From them commonly observed errors were clotted sample (82.8%) followed by hemolyzed samples (8.8%). In analytical phase, 1 (2.5%) unacceptable CBC parameter from EQAS, 3 times (0.8%) IQC failure and 5 times instrument breakdown were noted. In post analytical phase, TAT outlier was 18024 (3.6%) and critical value reporting was 16444 (3.3%) in a year. Total 19,441 error were recorded. Out of them post analytical phase is most common with 92.72% followed by pre-analytical (7.24%) and analytical phase (0.04%). **Conclusions:** Quality indicators are important tools in improving the quality system in a clinical laboratory and patient care. Constantly improve the services to provide the highest quality at the minimum cost.

KEYWORDS : Quality indicator, Pre-analytical phase, analytical phase, post analytical phase

INTRODUCTION:

The medical laboratory is essential to patient care; activities are provided within an ethical and governance framework, that recognizes the obligations of healthcare providers to the patient. These activities are undertaken in a timely manner to meet the needs of all patients and the personnel responsible for the care of those patients (ISO 15189:2012.).

With approximately 60–70% of medical decisions related to diagnosis and treatment involving the laboratory, no other discipline is better positioned to the pivotal to the patient safety solution (Agarwal et al., 2012). The dependence of patient management on laboratory data highlights the need for ensuring the quality of these services. The Joint Commission has underlined this fact by stating that the laboratory is required to "systematically assess and improve important functions and work processes and their outcomes." It is essential to identify certain determinants for the assessment of the quality in laboratory functioning. The term quality indicators is used for these determinants (Chawla et al., 2010).

A quality indicator is defined as an objective measure evaluating critical health care domains as defined by the Institute of Medicine (IOM) (patient safety, effectiveness, equity, patient centeredness, timeliness, and efficiency) (IOM, 2000). The International Organization for Standardization-Medical Laboratories (ISO 15189:2012) specify continuous monitoring of testing process, improvement using QI and measurement of the efficacy of specific interventions as the key measures for improving the laboratory services (ISO 15189:2012). The identification of vulnerable areas is achieved by implementation of error detecting systems specifically developed to target all three phases of total testing process, i.e., pre-analytical, analytical and post-analytical phases (Agarwal et al., 2012).

Updating the knowledge on laboratory services, adequate training of the staff and sensitization about the importance of the quality indicators in all the three phases will help in minimizing errors. Only few studies on the quality indicators have been reported from India. Hence in the present study, we assessed the quality indicators covering three phases- pre - analytical, analytical and post-analytical associated with the testing.

Methodology

Study setting: This was an institution based observational retrospective cross-sectional study which will be conducted at pathology department of tertiary health care center, South Gujarat with a capacity of 1230 beds and catering upto 3000 outdoor patients and 200 indoor patients daily. Data collection period for study was over a period of 1 year from January - December 2022. Our laboratory is NABL accredited since 2011 and all the samples are processed according to Standard Operating Procedure (SOP).

Retrospective data collection: The sample data is retrieved from Laboratory Information System (LIS) and records from hematology lab (QC records, NC records, Training records, TAT records, instrumental breakdown records, sample rejection records, reagent records).

Considering possible lab errors generated at each step of lab process, taking reference of ISO 15189:2012 and various literature available, quality indicators were established for monitoring quality at pre-analytic, analytic and post analytic phases of lab process. The common **pre-analytical phase** variables include wrong identification, incomplete forms,

haemolysed sample, clotted sample, inappropriate vial, lipemic sample, sample not received and insufficient quantity. Based on these parameters the samples are categorized as "accepted or rejected". The quality control measures of **analytical phase** include Our lab's proficiency testing, which was done at national level by EQAS at AIIMS for CBC, PS and reticulocyte count (3 monthly) & CMC Vellore for coagulation profile (4 monthly), inter laboratory comparison, IQC failure, calibration failure, system error/instrumental break down and reagent adverse event. The **post analytical** variables include TAT and critical value reporting. Quality indicators will be maintained and reviewed as per their frequencies on daily, weekly and monthly basis. Quality manager analyzed these records periodically and suggested and undertook corrective actions to reduce the future occurrence of such errors. In addition to this, laboratory staff undergoes regular training pertaining to these policies and procedures, their implementation and documentation.

Inclusion criteria- all samples data for routine and specialized hematology tests analyzed using- automated hematology analyzer, coagulometer and reporting of results done via Laboratory Information System (LIS)

Exclusion criteria- HPLC samples data

Table 1: The various quality indicators of hematology, their calculation and frequency of data analysis.

Sr. No.	Name of quality indicator	Calculation	Frequency of data analysis
	Pre-analytical phase		
1.	Sample rejection	No. of sample rejection X 100/Total no. of sample received in a month	Monthly
	Analytical phase		
2.	EQAS (CBC, PSCM, Reticulocyte count, PT, APTT)	EQAS outlier X 100/Total tests received	As per EQAS cycle
3.	Inter laboratory comparison (ILC)	ILC outlier X 100/Total no. of sample received	Monthly
4.	IQC failure	No. of IQC failed X 100/ Total IQC run in a month	Monthly
5.	Calibration failure/ Instrumental breakdown	No. of calibration failure or instrumental breakdown	Monthly
	Post Analytical phase		
6.	TAT outlier	No. of TAT outlier X 100/ Total no. of sample received in a month	Monthly
7.	Critical value reporting	No. of critical value reporting X 100/ Total no. of sample received in a month	Monthly

RESULTS:

Our hematology laboratory is a very large laboratory in a tertiary health care center and is operational 24x7. During 12 months period from January 2022 to December 2022. 4,94,184 samples were received for hematological test.

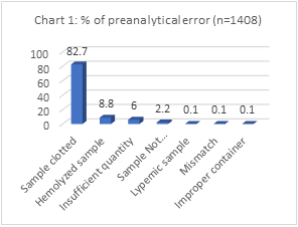
On periodic reviewing the quality indicators, following observations were made:

Pre Analytical QI:

Monitoring specimen acceptability may facilitate identification of quality improvement opportunities that could reduce rejection rates and improve patient care. Maximum sample rejection rate of the year was 0.6%, which was declining trend in following months. But overall sample rejection rate of a year was 1408 (0.2%), which is within laboratory's acceptable limits (as per Table 2). In our study we found that, most common reason for preanalytical error was found to be sample clotted (82.8%) (Chart 1).

Table 2: Pre-Analytical error- monthly sample rejection rate

Months	%
January	0.6
February	0.3
March	0.3
April	0.4
May	0.3
June	0.2
July	0.2
August	0.3
September	0.3
October	0.3
November	0.2
December	0.3



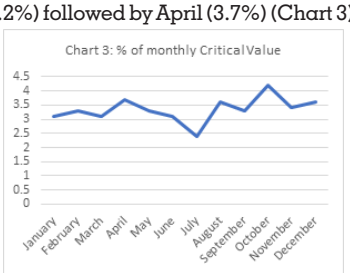
Analytical QI

External quality was checked by EQAS and interlaboratory comparison. 1 (2.5%) outlier of CBC parameter (MCHC) from EQAS cycle was noted. Otherwise 97.5% for CBC and PS morphology and 100% for coagulation parameters were concordance with our lab results. The cause of error was due to random error or human error. Monthly one sample was sent for interlaboratory comparison for PSMP and ESR and 6 monthly one bone marrow smear was sent for interlaboratory comparison. All interlaboratory comparison results are concordance with our laboratory results.

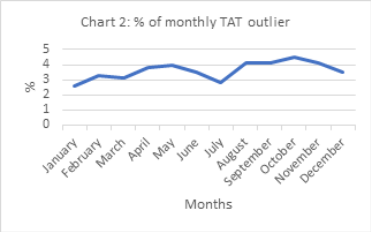
In this year, 3 times (0.8%) IQC failure were noted. This type of error detected by continuous monitoring of Levy Jenings charts for each parameter. Instrument breakdown was 5 times in a period of one year which was dealt immediately. Our AMC and CMC facilities have worked promptly to avoid any inconvenience in the patient care and we also had backup instruments to prevent any mismanagement.

Post Analytical QI :

Critical value reporting is an important for excellence in patient care ((Lundberg, 1981). After a thorough screening, critical samples were separated, analysed and reported at priority basis and these reports were conveyed to the treating clinician immediately. Overall Critical values of a year were 16444 (3.3%). Highest number of critical values were reported in October (4.2%) followed by April (3.7%) (Chart 3).



Overall TAT outlier of reports of a year was 18024 (3.6%). Delay in turnaround time was highest in October (4.5%) (Chart 2). This could have been due to more work load because of increased critical cases and instrument breakdown.



Here, total 19,441 error were recorded from pre-analytical, analytical and post analytical phase in a year. Out of them post analytical phase is most common with 92.72% followed by pre-analytical (7.24%) and analytical phase (0.04%).

DISCUSSION:

The hematology laboratory plays crucial role in diagnosing and managing patients. It requires high standards of quality by service provider which is foremost priority for better outcome. We assessed performance of our hematology lab for one year from January to December 2022.

In pre-analytical phase, a total of 0.2 % of the total 4,94184 was rejected over a period of 1 year. Dale at al (Dale & Novis, 2002) and stark et al reported a rejection rate of o.3% and 0.74% respectively. The most common error observed for sample rejection was sample clotted (82.8%) which is also common in a study performed by Guimaraes et al (43.5%) and Kouser et al (79%) (Guimarães et al., 2012). There is low frequency of rejection due to quality of sample, i.e. hemolyzed sample (8.8 %), insufficient quantity of sample (6%), sample not received (2.2%), lipemic sample (0.1%), incorrect identification (0.1%) as compared to other studies (Codagnone et al., 2014 & Goswami et al., 2010). So, overall rejection rate was within limits because of periodic training for the correct techniques and our protocols and an induction training for new residents, interns and technical staff. Moreover, there are SOPs in place for every step to reduce any fallacies. Laboratory staff members periodically review and perform root cause analysis of specimen-rejection trends to identify frequent preanalytical errors.

In the analytical phase, EQAS concordance for CBC and PS morphology (97.5%) and coagulation parameters (100%) were almost similar to study done by Akriti Kashyap et al. It was 99% for CBC and PS morphology and 97% for coagulation profile ((Kashyap et al., 2020). 3 times IQC failure were noted. The main cause of error was observed to be due to random errors, for which corrective actions were taken and precision checking was done. As compared to other studies the error rate due to internal QC failure in this study was low, which are 14 times and 6 times respectively (Agarwal et al., 2012,Goswami et al., 2010 & Kouser, S et al, 2023). This could be due to periodic sensitization of staff members for managing such issues by training programs and continuous monitoring of their performance so that frequency of IQC failures can be reduced. Instrument breakdown was 5 times in a period of one year which was dealt immediately. Our AMC and CMC facilities have worked promptly to avoid any inconvenience in the patient care and we also had backup instruments to prevent any mismanagement which is lower than study done by Goswami et al, which is 36 times Goswami et al., 2010.

In postanalytical Phase, average critical value is 3.3% in a year. It is an indicator of awareness to alert clinician of the report bordering danger mark. This helps decision making for the institution of corrective measures that might prove to be lifesaving in certain cases (Chawla et al., 2010). This is similar with study done by Kouser et al (3.7%)(Kouser, S et al, 2023) but higher than Agarwal et al (0.11%) (Agarwal et al., 2012)). Our TAT was 3.6% for period of a year. Rico's and colleagues have suggested that 11% is an acceptable fraction of laboratory reports that may exceed the stipulated TAT (Ricós et al., 2004). Our Delayed TAT was well with in this limit.

In present study, we summarize that though there is our TAT outlier is within expected limit, postanalytical error (92.72%) was higher than pre-analytical (7.24%) and analytical error (0.04%) due to high delayed TAT. Apart from delayed in release and dispatch of reposts, increased critical value reports, instrument breakdown, and error in internet connection for online LIS were major contributing factors for prolong TAT. To reduce our TAT, we have appointed dispatch persons and update of LIS with new software, which have helped in bring down the turnaround time. Timely reporting may augment patient care and clinicians' satisfaction.

CONCLUSION

The function of hematology laboratory in diagnostic side is unaltered. Thus, a systemic approach to assess and monitor the quality system of the clinical laboratory services via quality indicators is an extremely valuable tool in keeping the total testing process under control in a systematic and transparent way leading to improvement of work place culture. We observed that with appropriate and conscientious corrective and preventive actions can address failures within the system and help laboratory staff to achieve the goals of a patient-centered laboratory service.

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