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EVALUATION OF THE QUALITY INDICATORS IN HEMATOLOGY LABORATORY – GCRI STUDY

Oncology

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ABSTRACT

Introduction: Quality indicators in a clinical laboratory are considered as useful tools for continual improvement of the laboratory services.
Aim: The aim of this study was to assess timely performance of the Gujarat Cancer & Research Institute (GCRI) service laboratories in three phases of testing – pre-analytical, analytical and post-analytical, in an effort to improve their performance.
Methodology: The study included an assessment of different quality indicators from central laboratory - Hematology, at GCRI which provide service for the patient care.
Results: Data obtained from a total of 490349 samples collected over a period of three years was used in the study. The overall error rate was found to be 2.72%. The commonly observed indicators were clotted sample (3.62%) followed by low quantity (0.99%) of samples during the pre-analytical phase. In the analytical phase, IQC failure (0.27%) was the most common in the three years study period, TAT outlier was 1.2%, during the post- analytical phase.
Conclusions: Quality indicators are important tools in improving the quality system in a clinical laboratory and patient care.

KEYWORDS

Quality indicators, pre-analytical, analytical, post-analytical, quality control

INTRODUCTION

Clinical laboratories play vital role in prevention and control of infectious diseases by providing timely test results which help in the patient management and disease surveillance[1]. In an era of medical diagnostics, around 80% of decisions depend on the medical laboratory services and thus the quality of laboratory tests has a huge impact on the diagnosis and treatment planning[2]. This highlights the significance of carrying out tests on correct samples (pre-analytical phase) using accurate and precise techniques (analytical phase) at the earliest (post-analytical phase). The pre-analytical phase comprises the procedures before processing the sample. Studies indicate that approximately 40% to 70% of errors occur in the pre-analytical phase, most of which arise from problems in patient preparation, sample collection, transportation and storage. Errors in this phase generally occur due to high patient turn over, negligence, lack of understanding about good laboratory practices and ineffective training [3, 4, 5, 6,7]. The analytical phase involves actual performance of assays on the samples and interpretation of investigations. Establishing and verifying test method performance to assess accuracy, precision, sensitivity, specificity, and linearity is utmost important in reducing the errors occurring during this phase. Even though automation, standardization and technological advances have significantly improved the analytical reliability of the laboratory tests, analytical errors still continue to occur[6, 7]. The post-analytical phase deals with providing accurate and reliable test reports to the clinicians and subsequently to the patients within the TAT time. The procedures performed in this phase include verifying laboratory results, entering data into the laboratory information system, communicating results to the clinicians using different methods like by generating reports and verbal communications, especially in case of the "alert" or panic values[5,6,7].

With the advent of technology, the automated tools, database and computers have significantly improved the rate of the analytical errors, however errors pertaining to the pre- and post- analytical phases are still a source of concern indicating the need of adapting defined Quality indicators (QI) to assess and monitor continuous improvement in these phases[8]. It is essential that each laboratory establishes its own quality management system (QMS) to control and monitor the quality in the overall testing process. This promotes and encourages investigations when errors occur, their root cause analysis leading to the identification of strategies and procedures for improvement. 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[9]. In India, the policy of continual improvement for medical laboratories has been laid by the Bureau of Indian standards [10]. 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 critical phases associated with the testing (pre -analytical, analytical and post-analytical) in the central laboratory (Clinical Hematology) at the Gujarat Cancer and Research Institute (GCRI), Gujarat, India.

METHODOLOGY

Study site: The data collection was carried out by the Quality Management (QM) at GCRI, Gujarat, India over a period of three years (January 2016 to December 2018) as a strategy for continuous quality improvement. The QM cell monitors processes related to sample collection, handling and transportation, performance of the tests and participation in the quality assurance program. In addition to this, it monitors regularity of the technical training of the laboratory staff pertaining to the institutional policies and procedures, their implementation and documentation. To ensure implementation of these policies and continuity of the quality improvement, the QM cell continuously reviews performance of the laboratory during the pre-analytic, analytic and post-analytic phases.

Sample collection and transportation to the Central laboratory: For obtaining the data, the clinical samples in the present study were collected from GCRI collection center which is situated in different locations of the Hospital. The specimens were collected in suitable containers at this collection center and transported to the central laboratory at appropriate temperature along with the test requisition forms (TRFs). The samples and TRFs were received at the GCRI central laboratory. The data obtained in this study were from the samples collected under various institutional projects approved by institutional ethics committee.

Pre-analytical procedures followed in the laboratories:
The indicators during the pre-analytical phase included the TRF and the quality of the sample. The completeness of the TRFs was checked and verified for essential entries by the concerned laboratory staff. The quality of the samples (haemolysed/clotted/lipemic/quantity not sufficient) was checked in the laboratory in and the sample was categorized as "accepted or rejected". In case of rejection of any sample, the respective doctor was informed and a rejection note was sent to the respective center.

Facilities available in the laboratory: In the GCRI central laboratory where the processing and testing of specimens is carried out are well equipped with equipment like Beckman Coulter LH 750 hematology analyzer. The assays performed in these laboratories include Complete blood count (CBC), Peripheral blood smear (PBS), Differential count, retic count etc. The laboratory staffs carrying out these tests are well trained in respective tests and undergo external as well as internal competency assessment regularly.

Analytical and post- analytical procedures followed in the laboratories: After reaching to the GCRI central laboratory, the samples and TRFs are distributed to the respective laboratories, where entries are made in the sample receiving register and verified following institutional policies. The samples are further processed according to the standard operating procedures for each assay with quality control procedures and wherever applicable, Levy –Jennings chart are plotted for quality control checks. All protocols, kits, reagents and the assay procedures are reviewed by the Supervisor/ Lab-in-Charges. The results are entered in the electronic software and verified by the supervisor. After verification and obtaining signature of the authorized signatory, the reports are sent. The indicators during the analytical phase included routine equipment maintenance, equipment down time, processing of the specimens as per the standard operating procedures, inter-laboratory comparison, reagent stability, parallel testing, validation of method, validation of instrument, inter instrument comparison, quality control (QC) assessment, internal quality controls (IQC) and external quality assessment (EQAS). The post-analytical indicators considered for analysis include quality control of the report, maintenance of the turnaround time (TAT, time between receiving and reporting of the sample) specific for each test, generation of the revised reports in the laboratories.

RESULTS

During the period of three years (January 2016-December 2018), data from a total of 490349 samples received in the central laboratory of GCRI were analyzed. During the year of 2016 total, 142790 samples were received and analyzed. Total error during the year 2016 was 4.15%. During the year of 2017, total 156070 samples were received and analyzed. Total error during the year of 2017 was 1.02%. During the year of 2018, 191489 samples were received and analyzed. Total error during the year 2018 was 3.18%. Error rate was further analyzed considering QIs categorized into the three phases: pre-analytical, analytical and post analytical. The average error rate of three years during the analytical phase was highest (1.03%) followed by pre-analytical error rate (0.77%) followed by post-analytical errors (0.11%). The data was further analyzed considering various QI under each of the three phases. Figure:1 show the pre-analytical error indicators during the year 2016-2018. In the year of 2016,2017 and 2018, Clotted sample (3.8%,5.4% and 1.67%) was the most common indicator observed in pre-analytical errors. Table:1 show the average error rate during the three years for 4,90,349 samples.

Figure:1- Pre-analytical errors in the year of 2015-2018

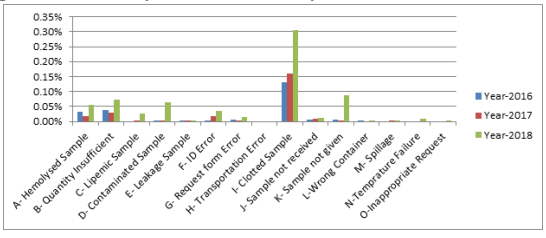

Figure:2- Analytical errors in the year of 2015-2018

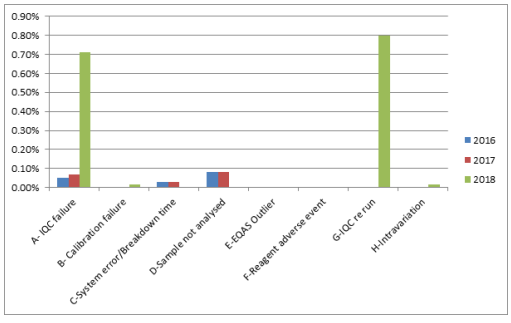

Figure 2 show the analytical errors from 2015-2018 years. In the analytical phase, sample not analyzed was the most common indicator due to various errors in pre-analytical phase in the year of 2016 (4.1%) and 2017 (3.46%). In the year of 2018, IQC Re-run (4.3%) was the most common indicator in the analytical phase. In the year of 2016 and 2017, second most common indicator was IQC failure, followed by system breakdown. In the year of 2018 second most common indicator was IQC failure, followed by system breakdown.

Figure:3-Post-analtical errors in year 2015-2018

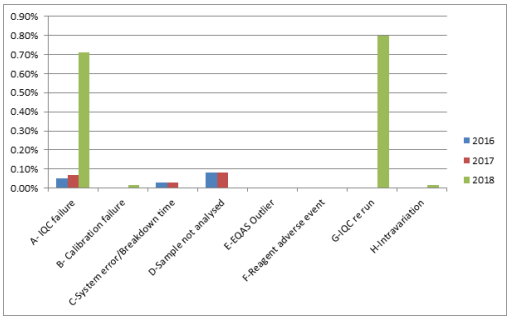

Figure:3 show the post analytical errors in year of 2015-2018. In Post analytical errors TAT outlier was the most common indicator in 2016(0.16%), 2017(0.26%), 2018(2.58%). The reasons for not maintaining the TAT were mainly unavailability of the Kit; break down of the equipment or transcriptional error in reports.

Table:1: Total error during three years. (January 2016-December 2018)

Year	No. of samples	Total Error
2016	1,42,790	4.15%
2017	1,56,070	1.02%
2018	1,91,489	3.18%
Total	4,90,349	2.78%

DISCUSSION

In today's world of medical diagnostics, ensuring high standards of quality rendered by any service provider is a top priority because it has great impact on the outcomes delivered by the health systems. The concept of QI as a part of the QMS has emerged over the past few years for the fulfillment of quality work as it indicates the performance of the health system which leads to improved care. Based on the identified quality indicators in the three phase of testing (pre-analytical, analytical and post-analytical), we assessed performance of our central laboratory located at GCRI, Ahmedabad, Gujarat, India over a period of 3 years. The errors observed in pre-analytical phase were found to be 0.77%. Of these, the Clotted sample (3.62%) was the common quality indicator followed by low quantity (0.99%) of samples. In our study, the sample rejection was 1.15% as compared to that reported in other studies conducted in India[11,12,13 14,15,16] and other parts of the world[3,4,5,17,18,19,20]. We have assessed the frequency of rejection due to insufficient quantity and quality (hemolysis, lipemic, blood clotting) due to wrong phlebotomy technique, incorrect transportation or centrifugation. A clotted sample was the common quality indicator observed during the evaluation of pre-analytical indicator followed by insufficient quantity followed by lipemic samples. Insufficient sample quantity may be due to wrong phlebotomy technique. The analysis of pre-analytical errors in our laboratory revealed low frequency of rejection due to quality of sample, i.e. lipemic (0.01%), hemolytic (0.03%) and insufficient quantity (0.02%) as compared to other studies[2, 7, 11,12, 20]. The error due to insufficient quantity could be due to lack of knowledge on the required sample quantity for a particular project or technical difficulty while sample collection.

In the analytical phase, the error rate in our study was 1.03%. Of these errors, IQC failure (0.27%) was the most common in three years. As compared to other studies the error rate due to failure of internal QC in our study was found to be low [2, 11, 20]. This could be due to frequent and stringent hands on practical training of the laboratory staff, continuous monitoring as well as timely competency assessment to monitor their performance. Another important reason could be regular monitoring of quality indicators by our QM cell and creating awareness about the same to the concerned individuals. We found 0.5% of samples which remained untested during this phase while other studies have reported missed test ranging from 0.74% to 1.4% [2,4,11,15,18,19,20]. As compared to the

pre-analytical and analytical phases, the rates of overall errors observed in the post-analytical phase were comparatively lower (0.11%). The data was analyzed for maintaining the TAT of a particular test report as provision of test results in timely manner is important for patient care and clinician's satisfaction. In our study, the TAT outlier was 1.2%, which was mainly due to unavailability of the kits (shortage in kit supply from the manufacturer) and intranet failure. The delay in pre-analytical and analytical phases also affects the TAT of a particular test; however, it was not noticed in our study.

To summarize, the assessment of the quality indicators in our laboratories indicated that the error during the analytical phase was higher as compared to the pre-analytical and analytical phases.

CONCLUSION

Quality indicators play a key role in reducing the risk of errors in clinical diagnostics. Thus, the use of quality indicators to assess and monitor the quality system is an extremely valuable tool for improving the quality of laboratory services and patient care.

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