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Analysis of Rejection rates in a Clinical Biochemistry Laboratory in a Tertiary Care Hospital in Bathinda

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ABSTRACT

Background: Total testing process (TTP) in biochemistry laboratory is composed of 3 phases; pre-analytical, analytical and post-analytical. Errors in these phases can lead to erroneous results, hence, compromise the patient management. **Objective:** 1. To document the nature and determine the frequency of errors in all the three phases of TTP using quality indicators (QI). 2. Applying sigma metrics to data obtained. **Study Design:** Prospective cross-sectional study. **Settings:** Clinical Biochemistry Laboratory, at AIMSR, Bathinda, Punjab India. **Duration:** June 2023 to Nov 2023. **Methods:** Quality indicators were used to screen errors in requisition forms and samples received in clinical chemistry for analysis. **Results:** During analysis of 22320 samples, a total of 132 samples were unsuitable for testing and reporting, this resulted in 0.59% of rejection. Out of total 132 rejections, 99 (75%) were in pre-analytical phase, 11 (8.3%) in analytical phase and 22 (16%) in post-analytical phase. The Sigma score of 5 is seen which is acceptable. **Conclusion:** The preanalytical error is the most common error. Error is unacceptable in the medical field hence training program for the laboratory and non-laboratory personnel involved should be conducted.

Keywords: Rejection rates, Clinical Biochemistry Laboratory, quality indicators (QI), pre-analytical errors, and sigma metrics

INTRODUCTION

A high standard laboratory service means precise, accurate and timely delivery of results. This requires following the standard practices at all steps.[1,2] Quality Indicators (QI) are used to quantify laboratory performance.[3-5] Automation has reduced analytical error by tenfold. While pre-analytical and post-analytical errors occur due to physicians, staff nurses and phlebotomists, they can still be controlled.[6,7]

AIMS & OBJECTIVES

1. To estimate the prevalence of the type of error / rejection rate in the clinical laboratory.
2. To determine the reason for the type of error / rejection rate in the clinical laboratory.

METHODS

This study is a prospective observational study conducted in Laboratory for Clinical Biochemistry of Adesh Hospital, without involvement of the patients directly for June-Nov 2023. Approval from the institutional ethical committee, vide letter No. AU/DAA/06/2022/FA 125, was taken before the start of the project.

Data Collection: Quality indicators used were – [3]

Pre-analytical errors (QI -1-QI-16): Errors in requests forms concerning clinical information, Identification of the patient, data entry for the test request, billing mistake, identification of the sample, sample collection, sample storage and transportation, and sample suitability.

Analytical errors (QI-17-QI-20): Errors in instrument calibration, failure to perform daily IQC, reporting even when controls are out of range, instrument maintenance not done, dilution and pipetting error, specimen inconsistency, insufficiency, or presence of an interfering substance.

Post-analytical error (QI-21-QI-25): Transcriptional errors/amended reports, calculation errors, report released out of TAT, results with incorrect units.

All sample received during the period of study were included. Documentation for the type and frequency of the error and reviewing was done daily. Samples were followed from the moment of collection, separation and the analysis. Technicians checked the samples about volume, the label and clot and accepted accordingly. Calibrations and controls were run in analytical phase.

Sample size was calculated using formula:

$$\text{Sample size} = \frac{z^2 \times p \times (1-p)}{d^2}$$

- z= 1-96, it is the SD score for a 95 % set interval
- p = assumed prevalence (3.45%) [2]
- d= confidence interval (it should be 10% of p)
- $$\text{Sample size} = \frac{(1.96)^2 \times (3.45) \times (96.55)}{(0.345)^2} = 11194$$

Samples were followed and observed for a period of 6 months to cover the sample and to take care of any errors.

To display and evaluate the data, descriptive statistics like numbers, percentages, and sigma scores were employed.

RESULTS

Throughout the study period, a total of 22320 samples were received and examined. There were 132 errors in total, of which 99 occurred during the pre-analysis stage, 11 during the analytical phase, and 22 during the post-analytical phase.

The different types of errors and their frequency observed is during the study period is given in the table 1, 2, 3 & 4.

Table 1: Depicts the segregated frequency of various pre-analytical errors

Pre-analytical Error	Frequency	Percentage
Hemolyzed sample	30	22.7 %
Insufficient sample volume	23	17.4%
Inadequately labeled tube	18	13.6%
Lipemic samples	10	7.5%
Damaged sample tube	07	5.3%
Inappropriate temperature condition/sample not on ice	05	3.8%
Sample drawn from IV area	05	3.8%
Missing sample	01	0.75%
Total	99	75%

Table 2: Depicts the segregated frequency of various analytical errors

Analytical Error	Frequency	Percentage
Equipment failure	4	3.0%
Calibration out	3	2.2%
QC out of range	2	1.5%
The Nonlinear results released without retesting	2	1.5%
Total	11	8.3%

Table 3: Depicts the segregated frequency of various post-analytical errors

Post-analytical Error	Frequency	Percentage
Results released out of TAT	9	6.8%
Critical values not communicated immediately	6	4.5%
Transcriptional error	5	3.8%
Results reported with wrong units	2	1.5 %
Total	22	16%

Table 4: Frequency and percentage of errors in all three phases of the testing process

Type of Error	Frequency	Percentage
Pre-analytical error	99	75.0%
Analytical error	11	8.3%
Post-analytical error	22	16.7%
Total	132	100%

Table 5: Depicts the DPMO and sigma metrics

Sigma level	Defects per Million Opportunities	Percentage Yield
1 sigma	691,462	31%
2 sigma	308,537	69%
3 sigma	66,807	93.3%
4 sigma	6,210	99.38%
5 sigma	233	99.977%
6 sigma	3.4	99.9996%

DISCUSSION

The present study used QIs to find the rejection rates in the clinical chemistry laboratory.[8-10] The accuracy of reports is essential to prevent incorrect diagnosis and incorrect treatment of the patients. Hence standard protocol of performance should be followed and kept under vigilance using the quality indicators.[11,12]

Sigma concept can be used to describe error rates. Sigma (σ) is a Greek alphabet letter. The performance of a process is at its best levels when it is functioning at sigma score of 6.[13] The 6 sigma means no more than 3.4 defects per million opportunities. The sigma scale runs from 0 to 6.

Hemolysis (QI-10) was found to be the most frequent pre-analytical error resulting in 30% of the total rejection

rates, similar results were reported by H L Vishwanath et al (2021)[4] and Bhutani N et al (2020).[8] In vitro hemolysis results in release of contents of hemolyzed red blood cells into plasma causing inaccurate laboratory test results.[1] Few parameters like Lactate Dehydrogenase, Potassium and Aspartate transaminase (AST) are overestimated in a hemolyzed sample whereas other parameters like albumin, gamma-glutamyl-transferase (GGT), alkaline phosphatase (ALP), chloride, glucose and sodium are underestimated. The various causes for hemolysis are when venipuncture site is not allowed to dry app), lately (at least 30 sec) after cleaning the site by alcohol, using fine needle syringes, shaking of the vacutainers vigorously and centrifuging the sample specimen before clotting is complete.[7,9] Any phlebotomist, nurse or doctor should know the proper technique of phlebotomy to prevent hemolysis. Laboratory personnel must ask for new sample when hemolysis is detected.[16]

The second common error seen was inadequate sample (QI-12), accounting for 23 % sample rejection which is like the results found in studies done by H L Vishwanath et al (2021)[4] and Sushma BJ et al (2019).[7] A specified amount of serum/plasma is required for each analytical process. These tubes are marked to collect a predetermined quantity of blood to achieve correct blood to additive ratio. Inaccurate results can occur due to inappropriate blood to additive ratio. The primary causes of this error include challenging sampling in patients with long-term medical conditions, pediatric cases, patients with thin veins, and the phlebotomist's ignorance of the testing volume (inadequately reading the test requisition form to determine the number of tests requested).

Inadequately labeled samples (QI-15) contributed 18 % of rejection rates. Patient identification is the critical step in sample processing. Mislabeled, unlabeled or incompletely labeled specimens results in wrong patient management. This can occur in an environment of heavy workload where thousands of specimens are handled in a similar way.[16]

5.3% of samples with lipemic results were rejected. When samples are taken too soon (after meals), or when a patient is diagnosed with hyperlipoproteinemia, lipemic samples result. It is possible to prevent this by suggesting an overnight fast. When a patient is diagnosed with hyperlipoproteinemia, the doctor has a duty to notify the laboratory.[8,15]

Other errors accounting for rejection were the damaged sample tube (7%) during transportation or centrifugating without proper balancing, inappropriate temperature condition/sample not on ice (5%) usually when relatives of the patients were sent from wards to labs for delivering the samples in the absence of lab attendants, sample drawn from the IV area (5%) usually by new untrained interns and nurses and missing samples (1%) which could be attributed to excessive work-load due to a large number of patients or sampling done by an untrained staff.

Analytical errors[18] were 8.3% of total rejection rates. These were due to equipment failure (2.2%), calibration out (2.2%) and QC out of range (1.5%) and nonlinear results released without retesting (1.5%).

TAT (QI-21) was exceeded in total of 9 samples (6.8%). Errors in the pre-analytical and analytical phases may lead to performance redundancies and loss of precious time hence resulting in prolonged TAT. Automation in the pre-analytical phase (automated robotic workstations) helps to prevent the human error that occurs in sorting and labelling of samples. When internal and external quality controls are satisfactory, repeating the test is unnecessary. Repeating critical results is not recommended unless delta check fails.[8]

4.5% errors due to 6 reports with critical values being not conveyed immediately to the physician (QI-22). The entire testing process involves more than just processing samples and creating reports; it also actively involves informing clinicians about critical findings so that remedial action can be taken as soon as possible.

Transcriptional errors constituted 3.8% of errors (calculation errors for lipids and globulin fractions). These are due to the wrong entry of results, which can be eliminated by automation, use of barcodes and digitalization. 1.5% of rejection rates were contributed due to reporting with wrong units (CSF protein in gm/dl lead to rejection twice).

When evaluating laboratory errors, the sigma metric holds greater significance than the quantity of flaws on its own. The sigma metric can be used to evaluate the caliber of laboratory testing procedures and the quantity of quality controls required to guarantee the required caliber.[19]

The lowest acceptable quality for a process to be implemented is three sigma values, and achieving Six Sigma performance corresponds to 3.4 DPMO.[20]

Table 6: Shows the DPMO and sigma score of all the three phases of the TTP

Type of Error	DPMO	Sigma score
Preanalytical error	4435	5
Analytical error	492	5
Post analytical error	986	5
Total errors	5913	5

On applying sigma metrics for all the phases in our laboratory, sigma score of 5 was noted which is acceptable. All the three phases of analysis are having the

sigma score of 5. The highest performance sigma score is 6 (Table 6)

CONCLUSION

The reduction in these errors can be achieved by carrying out repeated trainings and continuing education programs. This can be accompanied by annual proficiency and competency assessment. Easily understandable policies can be formulated. Phlebotomy Standard Operating Procedures (SOPs) can be put into place; they include appropriate protocols for collecting specimens and general safety measures to be followed when discarding needles, syringes, and other items used in the specimen collection process.

LIMITATIONS

The study's limitations include its short duration and single-center setting, which may limit the generalizability of the findings.

SUGGESTIONS / RECOMMENDATIONS

To avoid the study's limitations, future research should be conducted over a longer period and across multiple centers to ensure broader applicability and more comprehensive data.

CONFLICT OF INTEREST / DISCLOSURE

Nil.

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REFERENCES

1. Hofer TP, Kerr EA, Hayward RA. What is an error? Eff Clin Pract. 2000 Nov-Dec;3(6):261-9.
2. Grober ED, Bohnen JM. Defining medical error. canadian Journal of Surgery. 2005 Feb;48(1):39.
3. Grecu DS, Vlad DC, Dumitrascu V. Quality indicators in the preanalytical phase of testing in a stat laboratory. Laboratory medicine. 2014 Feb 1;45(1):74-81.
4. Vishwanath HL, Vibha C, Krishna M, Sreeja Shanker J, A study of pre-analytical errors in the clinical biochemistry laboratory at Victoria hospital, BMCRI, Bangalore. Int J Clin Biochem Res. 2021;8(4):278-280.
5. Cornes MP, Atherton J, Pourmahram G, Borthwick H, Kyle B, West J, Costelloe SJ. Monitoring and reporting of preanalytical errors in laboratory medicine: the UK situation. Annals of clinical biochemistry. 2016 Mar;53(2):279-84.
6. Aggarwal K, Jhajharia S, Pradhan T, Acharya V, Patra S, Mahapatra SK. Analysis of Errors in a Clinical Laboratory of a Tertiary Care Hospital. Journal of Clinical & Diagnostic Research. 2021 Oct 1;15(10): 27-30.
7. Sushma B, Shrikant C. Study on "pre-analytical errors in a clinical biochemistry laboratory": the hidden flaws in total testing. Biochem Anal Biochem. 2019;8(374):2161-1009.
8. Bhutani N, Bhutani N. An Analysis of Preanalytical Errors and Turnaround Time in Emergency Biochemistry Laboratory in a Tertiary Care Hospital in New Delhi. Journal of Evolution of Medical and Dental Sciences. 2020 Mar 30;9(13):1065-9.
9. Panchbudhe S, Kumar S. Contribution to Lab errors as a healthcare Professional. Journal of Pharmaceutical Research International. 2021 Jul 3;33(34B):242-8.
10. Abdollahi A, Saffar H, Saffar H. Types and frequency of errors during different phases of testing at a clinical medical laboratory of a teaching hospital in Tehran, Iran. North American journal of medical sciences. 2014 May;6(5):224.
11. Jung K. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, Carl A. Burtis, Edward R. Ashwood, and David E. Bruns, editors. St. Louis, MO: Elsevier Saunders, 2006, 2448 pp., $229.00, hardcover. ISBN 0-7216-0189-8. Clinical Chemistry. 2006 Jun 1;52(6):1214-.
12. National Accreditation Board for Testing and Calibration Laboratories (NABL 112 Specific Criteria for Accreditation for Medical Laboratories. Issue No: 04 Issue Date 11 Feb. https://nabl-india.org/nabl/file_download1.php?filename=201905031045-NABL-112-effective-from-01.06.2019-doc.pdf
13. Harry MJ. Six Sigma: a breakthrough strategy for profitability. Quality progress. 1998 May 1;31(5):60.
14. Eichhorn JH. Prevention of intraoperative anesthesia accidents and related severe injury through safety monitoring. Anesthesiology. 1989 Apr 1;70(4):572-7.
15. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. Clinical chemistry. 2007 Jul 1;53(7):1338-42.
16. Faghih MM, Sharp MK. Modeling and prediction of flow-induced hemolysis: a review. Biomechanics and modeling in mechanobiology. 2019 Aug 15;18:845-81.
17. ATM VR, Sweta K, Shanmugasamy K, Sowmya S. Risk assessment of pre-analytical errors and their impact on patient safety in a tertiary care centre in South India. IP Journal of Diagnostic Pathology and Oncology. 2023 Jan 20;5(4):415-8.
18. Naphade M, Ankur PS, Rajendra SR. Quality Control in Clinical Biochemistry Laboratory-A Glance. Journal of Clinical & Diagnostic Research. 2023 Feb 1;17(2).
19. Westgard S, Westgard QC. Six Sigma metric analysis for analytical testing processes. Abbott Laboratories MS-09. 2009;4:7907.
20. Teshome M, Worede A, Asmelash D. Total clinical chemistry laboratory errors and evaluation of the analytical quality control using sigma metric for routine clinical chemistry tests. Journal of multidisciplinary healthcare. 2021 Jan 15:125-36.