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

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Abstracts: 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. AIMS AND OBJECTIVES: 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. MATERIAL AND METHODS: A prospective cross-sectional study was conducted from June 2022 to Nov 2022 in the Clinical Biochemistry Laboratory, at AIMSR, Bathinda, Punjab. 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.

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 and 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.

Material And Methods:

Study design:

The present study was a prospective observational study conducted in Clinical Biochemistry Laboratory of Adesh Hospital, without direct interaction with the patients for June-Nov 2022.

Data collection:

Quality indicators used were –[3]

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

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 mix-up, inadequate specimen, presence of the interfering substance.

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

Sampling procedure:

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 with regard to volume, the label and clot and accepted accordingly. Calibrations and controls were run in analytical phase.

Size of the sample was calculated using formula:

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

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

$= 11194$

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

Statistical analysis:

Descriptive statistics such as number, percentages and sigma score were used to present and analyze the data.

Results:

A total of 22320 samples were received and observed during the period of study. The total number of errors were 132 out of which 99 were in pre-analytical phase, 11 in the analytical phase and 22 in the post-analytical phase.

The different types of errors and their frequency observed is during the study period is given in the table I, II, II and IV.

Table I: depicts the segregated frequency of various pre-analytical errors.

TABLE I			
S.no.	**Pre-analytical Error**	**Total frequency**	**Percentage**
1.	Hemolysed sample	30	22.7 %
2.	Insufficient sample volume	23	17.4%
3.	Inadequately labeled tube	18	13.6%
4.	Lipemic samples	10	7.5%
5.	Damaged sample tube	07	5.3%

6.	Inappropriate temperature condition/sample not on ice	05	3.8%
7.	Sample drawn from IV area	05	3.8%
8.	Missing sample	01	0.75%
Total		99	75%

Table II : depicts the segregated frequency of various analytical errors.

TABLE II –			
S.no.	**Analytical Error**	Frequency	Percentage
1.	Equipment failure	4	3.0%
2.	Calibration out	3	2.2%
3.	QC out of range	2	1.5%
4.	The Nonlinear results released without retesting	2	1.5%
	Total	11	8.3%

Table III : depicts the segregated frequency of various post-analytical errors.

TABLE III			
S.no.	**Post-analytical Error**	Frequency	Percentage
1.	Results released out of TAT	9	6.8%
2.	Critical values not communicated immediately	6	4.5%
3.	Transcriptional error	5	3.8%
4.	Results reported with wrong units	2	1.5 %
	Total	22	16%

Table IV: shows the frequency and percentage of errors in all three phases of the testing process.

TABLE IV			
S.no.	**Type of Error**	Frequency	Percentage
1.	Pre-analytical error	99	75.0%
2.	Analytical error	11	8.3%
3.	Post-analytical error	22	16.7%
	Total	132	

Table V. 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 hemolysed 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 appropriately (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 similar to 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 so as to achieve correct blood to additive ratio. Inaccurate results can occur due to inappropriate blood to additive ratio. The main reasons behind this error are difficult sampling as in patients with chronic diseases, pediatric cases, patients having thin veins, the phlebotomist lacking knowledge about the testing volume (not reading the test requisition form properly about the number of tests requested in requisition form).

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]

Lipemic samples resulted for 5.3% of rejection. Lipemic samples arise due to the wrong timing of sample collection (post meals) and if a patient is diagnosed to have hyperlipoproteinemia. This can

be avoided by advising for overnight fasting. In case of patient diagnosed to have hyprlipoproteinemias, it is responsilbility of physician to intimate it to 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 total testing process is not merely sample processing and preparation of reports but is actively involved in disseminating information about critical results to clinicians so that corrective measures can be initiated at the earliest.

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).

The sigma metric is more meaningful than the number of defects alone in evaluation of laboratory errors. It is possible to assess the quality of laboratory testing processes and the number of quality controls needed to ensure the desired quality by using sigma metric. [19]

Attainment of Six Sigma performance represents 3.4 DPMO and the achievement of 3 sigma values is the minimum acceptable quality for a process to be applied. [20]

Table VI shows the DPMO and sigma score of all the three phases of the TTP.

TABLE VI		
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 IV)

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. Standard Operating Procedures (SOPs) can be implemented for phlebotomy, which include proper procedures for specimen collection, universal precautions to be taken for disposal of syringes, needles and other materials used during the specimen collection process.

Ethical clearance: Approval from the institutional ethical committee was taken before the start of the project.

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Conflict of interest: Nil

Data Availability: Data included within this article.

Authors' Contributions: Dr Premjeet Kaur: Designed the study, retrieved the literature, extracted data and wrote article.

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