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# Errors in comprehensive testing regime of a clinical biochemistry research facility

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## ABSTRACT

**Objectives:** To document and determine the nature the prevalence of errors in the testing regime using quality index (QI). Applying sigma metrics to data obtained.

**Material and Methods:** This was a cross-sectional academic work carried out from June 2023 to November 2023 in the Clinical Biochemistry research facility at Adesh Institute of Medical Science and Research, Bathinda, Punjab. QI was used to screen inaccuracy in request forms and samples received in clinical chemistry for analysis.

**Results:** During the analysis of 22320 samples, a total of 132 samples were unsuitable for testing and reporting; this resulted in 0.59% rejection. Out of a total of 132 rejections, 99 (75%) were in the pre-testing stage, 11 (8.3%) in assay related stage, and 22 (16%) in the post-analytical stage. The sigma score of 5 is seen, which is acceptable.

**Conclusion:** The pre-testing error is the most common fallacy. Error is unacceptable in the medical field; hence training program for the research facility workforce involved should be conducted.

**Keywords:** Analytical errors, Post analytical errors, Pre analytical errors

## INTRODUCTION

A comprehensive testing regime in a biochemistry research facility is composed of three aspects: Analytical, pre-analytical, and post-analytical. The fallacy in these parts can lead to wrong outcomes and, hence, compromise the management of the sick. A high-standard laboratory facility means precise, accurate, and timely delivery of outcome. This requires following a standard practice at all steps.[1,2] Quality indicators (QIs)/Quality index (QI) are used to quantify laboratory performance.[3-5] Automation has reduced analytical error by tenfold. While pre-analytical and post-analytical mistakes happen 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 in the research facility
2. To determine the reason for the type of error in the research facility.

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## MATERIAL AND METHODS

### Research plan

Prospective observational research was conducted in the Clinical Biochemistry Laboratory of Adesh Hospital, June–November 2023, without direct interaction with the patients.

### Data acquisition

QI used were[3] pre-analytical errors (QI-1–QI-16): Errors in request forms concerning clinical information, patient identification, data entry of requisition form, billing error, sample identification, sample acquisition, storage and transport of sample, and suitability of samples.

Analytical errors (QI-17–QI-20): Errors in instrument calibration, failure to perform daily internal quality control (IQC), reporting even when controls are out of range, instrument maintenance not done, specimen mix-up, dilution and pipetting error, inadequate specimen, presence of the interfering substance.

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

### Sampling procedure

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

### Size of the sample

Following formula was used to calculate the sample size:

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

- $z = 1.96$, it is the SD score for a 95% set interval
- $p$ = Assumed prevalence (3.45%)[2]
- $d$ = Confidence interval (it should be 10% of $p$)

$$Sample\ size = \frac{(1.96)^2 \times (3.45) \times (96.55)}{(0.345)^2}$$

$$= 11194$$

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

### Analysis of statistical data

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

## RESULTS

Out of 22320 samples observed during the period of study, the total number of fallacies was 132, out of which 99 were in the pre-testing stage, 11 in the assay-related stage, and 22 in the post-analytical stage.

The varied types of fallacies and their prevalence observed during the study period are given in Tables 1-4.

**Table 1:** Depicts the segregated prevalence of various pre-analytical errors.

| S. No. | Pre-analytical error | Total frequency | Percentage |
|---|---|---|---|
| 1. | Hemolyzed 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 |

IV: Intravenous

**Table 2:** Depicts the segregated frequency of various analytical errors.

| 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 non-linear results released without retesting | 2 | 1.5 |
| | Total | 11 | 8.3 |

QC: Quality control

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

| 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 |

TAT: Turn around time

**Table 4:** The frequency and percentage of errors in all three phases of the testing process.

| 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 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 |

DPMO: Defects per million opportunities

**Table 6:** The DPMO and sigma score of all three phases of the TTP.

| Type of error | DPMO | Sigma score |
|---|---|---|
| Pre-analytical error | 4435 | 5 |
| Analytical error | 492 | 5 |
| Post-analytical error | 986 | 5 |
| Total errors | 5913 | 5 |

DPMO: Defects per million opportunities, TTP: Total testing process

## DISCUSSION

The present study used QIs to find the rejection rates/fallacies in the clinical research facility.[8-10] The accuracy of reports is essential to prevent incorrect interpretation or management of the patients. Hence, the standard protocol of performance should be followed and kept under vigilance using the quality indicators.[11,12]

The Sigma concept can be used to describe flaw rates. Sigma (σ) is a Greek alphabet letter. The performance of a process is at its best when functioning at a 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 [Table 5].

Hemolysis (QI-10) was found to be the most frequent pre-analytical flaw, resulting in 22.7% (30 out of 132) of the total error rates, and similar results were reported by Vishwanath *et al.*[4] and Bhutani *et al.*[8] *In vitro* hemolysis results in the release of contents of hemolyzed red blood cells into plasma, causing inaccurate outcomes.[1] Few parameters, such as lactate dehydrogenase, potassium, and aspartate transaminase are overestimated in a hemolyzed sample whereas other parameters, such as alkaline phosphatase, albumin, gamma-glutamyl-transferase, chloride, glucose, sodium, are underestimated. Various causes for hemolysis are when venipuncture site is not allowed to dry appropriately (at least 30 s) after cleaning the site with alcohol, using fine needle syringes, shaking the vacutainers vigorously, and centrifuging the sample before completion of clotting.[7,9] Any phlebotomist, nurse, or doctor should know the proper technique of phlebotomy to prevent hemolysis. Laboratory personnel must ask for new specimens when hemolysis is detected.[14]

The second common flaw seen was inadequate sample (QI-12), accounting for 17.4% (23 out of 132) sample rejection which is similar to the reports found in studies done by Vishwanath *et al.*[4] and Sushma and Shrikant.[7] A specified amount of serum/plasma is required for each analytical process. These tubes are marked to collect a fixed volume of blood so as to obtain the correct blood-to-additive ratio. Inaccurate results may occur because of an inappropriate blood-to-additive ratio. The main reasons behind this error are complications in sampling in patients having thin veins, chronic diseases, pediatric cases, and the phlebotomist not reading the test requisition form properly about the number of examinations requested in the requisition form.[15]

Inadequately labeled samples (QI-15) contributed 13.6% (18/132) of rejection rates. Patient recognition is the most important 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.[14]

Lipemic samples resulted in 7.5% of rejections. Lipemic samples arise due to post-meal sampling and a patient suffering from hyperlipoproteinemia. This can be corrected by an overnight fasting sample. In case a patient is diagnosed with hyprlipoproteinemias, it is the responsibility of the doctor to intimate it to the research facility.[8,16]

Other errors were the damaged sample tube (5.3%) during transportation or centrifugating without proper balancing, inappropriate temperature condition/sample not on the ice (3.8%), usually when relatives of the patients were sent from wards to laboratories for delivering the samples in the absence of laboratory attendants, sample drawn from the IV area (3.8%) usually by new untrained interns and nurses and missing samples (1%) which could be due to excessive workload (large number of patients) or sampling done by untrained workforce.

Analytical errors[17] were 8.3% of total rejection rates. These were due to equipment failure (2.2%), calibration out (2.2%),

Quality control (QC) out of range (1.5%), and non-linear results released without retesting (1.5%).

TAT (QI-21) was exceeded in total of 9 samples (6.8%). Protesting and sample handling mistakes may lead to performance redundancies and loss of precious time hence resulting in prolonged TAT. Automated robotic workstations in the pre-testing phase helps to prevent the human error during sorting and labeling of samples. Repeating critical outcomes 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 the generation of the reports but is actively involved in conveying critical outcomes to clinicians so that management can be initiated at the earliest.

Transcriptional errors constituted 3.8% of fallacies (calculation mistakes for lipids and globulin fractions). These are due to the erroneous entry of the outcomes that may be eliminated by research facility information system, use of barcodes as well as digitalization. 1.5% of rejection rates were contributed due to reporting with wrong units (cerebrospinal fluid protein in g/dL led to rejection twice).

The sigma metric is more meaningful than the number of defects alone in the evaluation of laboratory fallacies. It is possible to assess the quality of research facility testing processes.[18]

Attainment of Six Sigma performance represents 3.4 defects per million opportunities (DPMO) and the achievement of 3 sigma values is the minimum acceptable quality for a process to be applied.[19]

All the three phases of analysis have the sigma score of 5 [Table 6]. The highest performance sigma score is 6.

## CONCLUSION

The scaling down of these fallacies can be attained by carrying out repeated trainings and education programs. This can be accompanied by annual proficiency and competency assessments. Easily understandable policies can be formulated. Standard operating procedures can be implemented for phlebotomy, which includes proper method for specimen collection, universal precautions to be taken for disposal of syringes, needles, and other materials.

### Authors' contributions

PK: Designed the study, retrieved the literature, extracted data and wrote article; SS: Conceptualization.

### Ethical approval

The research/study was approved by the Institutional Review Board at Adesh Institute of Medical Sciences and research, Bathinda, number 125, dated 20th June 2022.

### Declaration of patient consent

Patient's consent is not required as there are no patients in this study.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

### Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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