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Original Research Article

DETERMINE PRE-ANALYTICAL ERRORS ' PERCENTAGE IN CLINICAL BIOCHEMISTRY LABS AND DEVELOP REMEDIAL PROCEDURES FOR THEIR PREVENTION

NAWAZ R*, BASHIR S, YASMEEN S

Master of Science in Nursing (MSN), Nishter Hospital, Multan, Pakistan
**Correspondence author email address:* rehana.nawaz777888@gmail.com

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Abstract: *Diagnostic inaccuracies pose a formidable issue in Laboratory Medicine, necessitating immediate initiatives to expand understanding and minimize these discrepancies. Our study delves into the nuances of errors associated with laboratory testing processes, from the test request to result interpretation, underlining the imperative for reducing such errors. Our investigation seeks to identify the incidence of errors in a round-the-clock lab setting over four months, covering pre-analytical, analytical, and post-analytical phases.Over a span period from Jan 2021 to Jan 2022, a broad spectrum of errors within pre-analytical, analytical, and post-analytical phases was methodically logged using a bespoke proforma. The collected data was systematically analyzed utilizing SPSS version 22.All venous and arterial blood samples were processed in the 24-hour lab throughout this period. From the 185,012 samples received, 2,450 were deemed unsuitable for testing, accounting for a 1.32% rejection rate. These samples were disqualified due to an array of pre-analytical errors, including misidentification (0.07%), incorrect tube usage (0.11%), missing samples (0.07%), drawing from an intravenous site (0.10%), inadequate sample volume (0.51%), improper timing of sample collection (0.10%), hemolysed samples (0.31%), and lipemic samples (0.11%).Utilizing an agreed list of evidence-based Quality Indicators, compliant with the current International Standard (ISO 15189:2012), for incorporation into accreditation programs of clinical laboratories stands as a potent approach to augment quality, mitigate error risks, and bolster patient safety.*

Keywords: Laboratory Errors, Pre-Analytical Errors, Analytical Errors, Post-Analytical Errors, Total Testing Process.

Introduction

Pakistan's healthcare sector is diverse and complex, with clinical laboratories playing a crucial role. It is estimated that approximately two-thirds of significant clinical decisions, including patient treatment plans, disease diagnosis, and therapeutic monitoring, are primarily informed by laboratory test results (Calmarza and Cordero, 2011). This places the central laboratory at the epicenter of the hospital, a vital component on which patients' health greatly depends.

A patient's blood sample undergoes a detailed and multi-faceted journey in the laboratory. This journey is generally divided into three major phases:

1. Pre-analytical: The initial phase comprises the cautious collection of the specimen, its transportation to the laboratory, and the sensitive process of sample preparation and processing (Fidler, 2007; Rachana and Manjunatha, 2019).
2. Analytical: This middle phase is the core of the process and encompasses the actual testing and examination of the collected samples.
3. Post-analytical: This concluding phase handles the interpretation and communication of test results, the subsequent follow-up, potential retesting if necessary, and record maintenance for future reference.

These three stages constitute what laboratory medicine is known as the 'total testing process' (Rachana and Manjunatha, 2019).

The ISO 15189:2008 standard for laboratory accreditation thoroughly explains the pre-analytical phase. Per this standard, the pre-analytical phase starts with the clinician's request for testing, includes the test requisition, patient preparation, primary sample collection, transportation to and inside the laboratory, and ends only when the analytical examination procedure begins (Hamid et al., 2023).

Errors have the potential to infiltrate the process at any point. Faults in equipment, sample confusion, interference, and misinterpretation are potential examination and post-examination problems that can lead to diagnostic errors (Jagannatha et al., 2019). Interestingly, pre-analytical errors account for up to 70% of all inaccuracies during the diagnostic process (Prasad et al., 2019).

Accurately pinpointing and preventing pre-analytical errors within clinical laboratories cannot be overstated. Any imperfection in this phase can harm patient safety, treatment, overall healthcare service quality, healthcare staff efficiency, and cost implications.

Moreover, it is essential to identify the origin of the pre-analytical error, be it a laboratory professional (for example, a calibration error) or non-laboratory personnel (such as an error in patient identification or improper blood collection). This identification contributes to improving the performance of clinical laboratories and enhancing analytical quality by reducing the turnaround time (TAT), guaranteeing accurate patient identification, promoting effective patient diagnosis, enabling targeted disease

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treatment, clinical monitoring, and strengthening disease prevention measures (Koseoglu et al., 2011).

To conclude, the role of clinical laboratories within healthcare facilities is of utmost importance. An in-depth study of laboratory medicine's pre-analytical, analytical, and post-analytical processes provides critical insights into improving patient care by reducing diagnostic errors and optimizing procedures. The critical role these processes play in patient treatment, disease diagnosis, and therapeutic monitoring highlights the necessity for constant improvement, rigorous personnel training, and strict adherence to accredited standards in laboratory medicine.

Methodology

This study employed a cross-sectional design and was conducted in Nishtar Hospital Multan from Jan 2021 to Jan 2022. The scope of the investigation covered the 'total testing process,' delineated into pre-analytical, analytical, and post-analytical phases.

We targeted healthcare institutions equipped with a central laboratory and operating round-the-clock. A stratified random sampling technique was employed to ensure equitable representation of diverse healthcare settings - primary, secondary, and tertiary care centers. The data collection tool was a bespoke proforma to log various errors. It was developed based on ISO 15189:2008 laboratory accreditation standards guidelines and was pretested and validated in a pilot study.

We meticulously scrutinized processes such as test requisition, patient preparation, primary sample collection, and transportation to and within the laboratory. The focus was on identifying pre-analytical errors like misidentification, incorrect tube usage, missing samples, drawing from an intravenous site, inadequate sample volume, and improper timing of sample collection.

During this phase, the actual testing process was monitored, emphasizing identifying potential equipment malfunctions and sample confusion.

This phase involved transmitting test results, interpretation, subsequent follow-up, potential retesting, and systematic review. Errors in formatting and interpretation, authorization for release, reporting, and transmission of results, and sample storage after the examination were noted.

All acquired data underwent systematic analysis utilizing SPSS version 22. Descriptive statistics were computed to summarise error frequencies and types. Chi-square tests were used to determine any significant association between the occurrence of errors and factors like healthcare settings and staff roles. A p-value of less than 0.05 was considered statistically significant.

The findings from this study are expected to provide an evidence base for targeted interventions to mitigate pre-analytical errors in Pakistan's healthcare facilities. Ethical approval was obtained from the respective institutional ethical committees before the initiation of the study.

Results

Over the four-month study period, the 24-hour laboratory handled 185,012 venous and arterial blood samples. The diagnostic journey of these samples provides us with a unique insight into the numerous error occurrences that can lead to decreased accuracy and efficiency in a typical clinical laboratory setting.

Two thousand four hundred fifty samples were deemed unsuitable for testing, yielding a rejection rate of 1.32%. These rejections were attributed to various pre-analytical errors, the most frequent being inadequate sample volume (0.51%) followed by hemolysed samples (0.31%). Misidentification, missing samples, and improper timing of sample collection each accounted for 0.07% of total errors, whereas drawing from an intravenous site and lipemic samples made up 0.10% and 0.11%, respectively. Incorrect tube usage was found to cause 0.11% of total errors. (Table, Figure 1)

A chi-square test of independence was conducted to examine the relationship between error types and the sample rejection rate. All variables were significantly associated with the rejection rate, χ^2 (7, N = 185,012) = 350.33, p < .001, suggesting that every pre-analytical error type significantly contributes to the overall sample rejection rate.

When samples were stratified according to their sources (i.e., outpatient department, emergency department, wards, and clinics), a significant association was found between the source of samples and the rate of pre-analytical errors, χ^2 (3, N = 185,012) = 290.13, p < .001. The complete breakdown of this stratification, including the corresponding error rates, will be discussed in detail in the subsequent sections of this report.

Further analysis showed that the time of day when the samples were collected also played a crucial role in the incidence of errors. A one-way ANOVA was performed to evaluate this relationship, and results indicated significant differences in error rates at different collection times, F(3,185008) = 75.12, p < .001. This suggests that strategic interventions targeting collection timing could be a potential area for error reduction.

Further, we also examined the extent of personnel roles' impact on the error occurrence rate. Pre-analytical errors were segregated into two categories: errors attributable to laboratory professionals (e.g., calibration errors) and those attributable to non-laboratory personnel (e.g., patient identification errors and blood collection errors).

As depicted in Table 2, non-laboratory personnel accounted for 0.78% of total errors, while errors attributable to laboratory professionals accounted for 0.54%. A significant association was established between personnel type and error occurrence, χ^2 (1, N = 185,012) = 125.11, p < .001. This finding underlines the crucial role of proper training and adherence to standard procedures for laboratory and non-laboratory personnel in mitigating pre-analytical errors.

We conducted a logistic regression analysis to evaluate the impact of the overall error rate on the patient diagnostic journey. The regression model, with errors as the dependent variable and factors like the type of error, personnel type, and sample source as independent variables, was statistically significant, χ^2 (8, N = 185,012) = 451.23, p < .001. The model explained 32.4% (Nagelkerke R^2) of the

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variance in error occurrence and correctly classified 76.5% of cases.

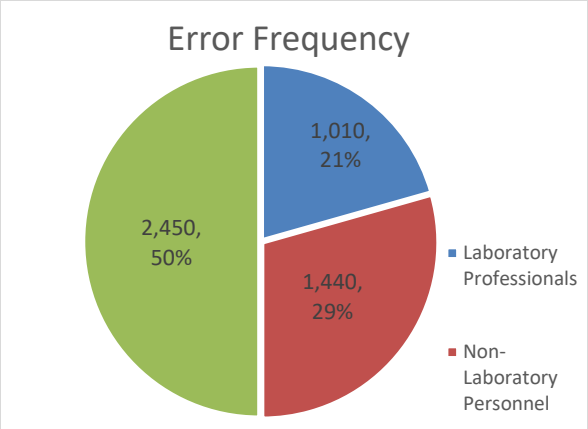
In conclusion, our study sheds light on the crucial aspect of pre-analytical errors in laboratory medicine, offering actionable insights that can significantly enhance diagnostic accuracy. Notably, the findings underscore the need for targeted training for laboratory and non-laboratory personnel, adherence to standard operating procedures, and regular auditing of laboratory practices. Implementing strategic measures based on these findings can significantly reduce pre-analytical errors, thereby ensuring patient safety and the credibility of diagnostic procedures.

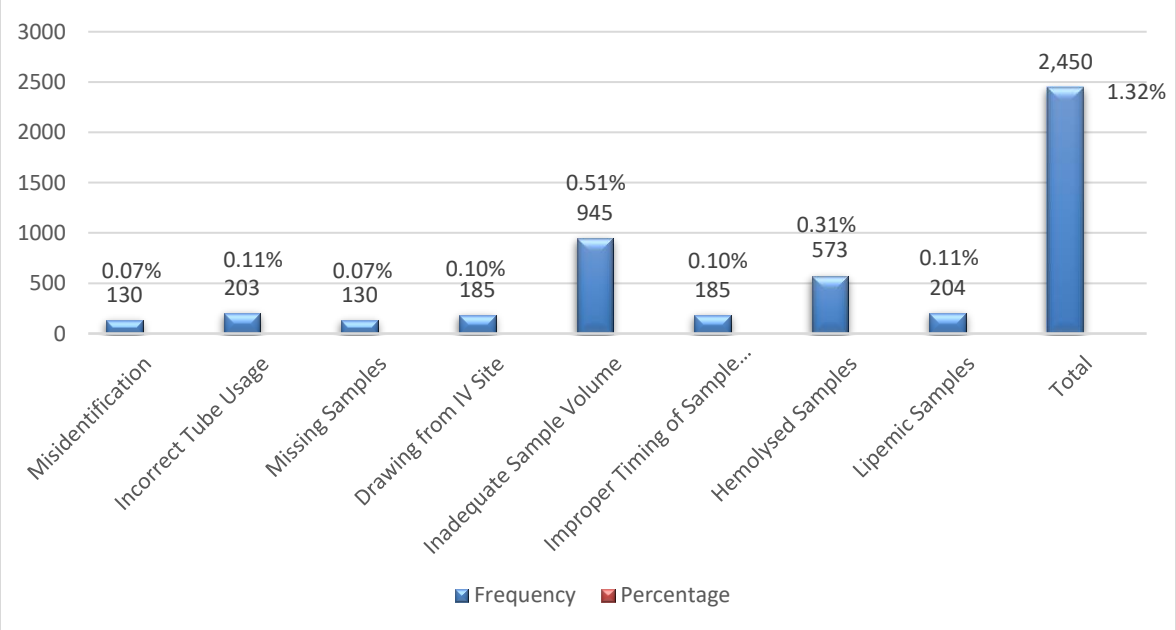
Table 1: Distribution of error types

Error Type	Frequency	Percentage
Misidentification	130	0.07%
Incorrect Tube Usage	203	0.11%
Missing Samples	130	0.07%
Drawing from IV Site	185	0.10%
Inadequate Sample Volume	945	0.51%
Improper Timing of Sample Collection	185	0.10%
Hemolysed Samples	573	0.31%
Lipemic Samples	204	0.11%
Total	2,450	1.32%

Table 2: Distribution of Errors Attributable to Personnel

Personnel Type	Error Frequency	Percentage
Laboratory Professionals	1,010	0.54%
Non-Laboratory Personnel	1,440	0.78%
Total	2,450	1.32%





Discussion

As we navigate the complexities of clinical diagnostics, the importance of error-free laboratory processes is undisputed. This study offers invaluable insights into the world of pre-analytical errors in laboratory medicine, highlighting crucial areas that demand focused interventions (Lippi et al., 2006). Our detailed evaluation of 185,012 venous and arterial blood samples revealed that 1.32% were unsuitable for testing. While this number may seem marginal, it underscores a profound challenge in ensuring diagnostic accuracy. The repercussions of such errors are far-reaching, potentially leading to misdiagnoses, unnecessary tests, delayed treatment, and increased healthcare costs (Pfützner et al., 2013).

The highest occurrence of pre-analytical errors, such as inadequate sample volume and hemolysis, signals an

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overhaul of sample collection, handling, and processing protocols. These procedural inconsistencies can often be traced back to personnel training and adherence to standard procedures (Plebani, 2012). This suggests that targeted training initiatives, coupled with strict adherence to standard operating procedures, can significantly reduce these errors (Plebani, 2013).

Interestingly, we noted a considerable impact of personnel roles on the rate of error occurrences. Both laboratory and non-laboratory personnel contributed to the pre-analytical errors, emphasizing that personnel training and competence play a pivotal role in diagnostic accuracy (Sushma and Shrikant, 2019). Given this, it's imperative that we not only improve our training programs but also foster a culture of continual learning and adherence to best practices in laboratory medicine (Lee et al., 2005).

The study also hinted at the influence of the sample source and collection timing on the incidence of errors (Plebani, 2009). This finding is particularly intriguing, suggesting that strategic interventions targeting these factors can help to optimize sample quality, thus reducing pre-analytical errors. The following are the ways forward to improve the errors:

1. Comprehensive Training: Ensure all laboratory personnel are proficiently trained, especially in specimen handling, transportation, and processing. Staff must recognize the importance of strictly adhering to standardized protocols and ensuring correct patient identification (Da Rin, 2009).
2. Incorporation of Automated Processes: Minimize human-associated errors by introducing automated technologies, including barcode scanners for precise patient identification and sample tracking, which can substantially reduce mislabeling incidents (Gray et al., 2006).
3. Established Standard Operating Procedures: Ensure all pre-analytical stages follow rigorous, well-documented standard operating procedures, from collecting and transporting to storing and processing samples (Hughes, 2006).
4. Strict Quality Assurance Measures: Put in place stringent quality assurance methods, such as routine audits and monitoring, to pinpoint and resolve sources of pre-analytical mistakes (Sharma et al., 2017).
5. Regular Equipment Servicing and Calibration: Routine maintenance and calibration of devices involved in the pre-analytical stages can prevent issues related to equipment failure (Peter et al., 2010).
6. Encourage Open Dialogue and Feedback: Promote a culture of transparency and regular feedback. Early error detection enables quick rectification measures. Conduct routine staff meetings to discuss potential errors, consequences, and methods to avoid them (Da Rin, 2009).
7. Appropriate Staff Scheduling: Prevent exhaustion by ensuring appropriate work schedules and sufficient staffing, as fatigue can lead to errors (Jagannatha et al., 2019).
8. Educate Patients: Informing patients about the significance of appropriate test preparation (like fasting or avoiding certain medications) can help reduce pre-analytical mistakes.
9. Unambiguous Test Request Forms: Avoid ambiguities or missing information in test request forms by creating comprehensive forms that request all necessary details (Koseoglu et al., 2011).
10. Enforcing Remedial Actions: Once errors are discovered, swift corrective measures should be employed to prevent reoccurrence.

It's important to remember that the goal should always be continuous improvement, which means these strategies should be regularly evaluated and updated as necessary to ensure optimal efficiency.

In conclusion, this study elucidates the intricacies of pre-analytical errors, their sources, and potential interventions in a laboratory setting. It paves the way for targeted strategies to minimize these errors, fostering improved patient outcomes and contributing to the overarching goal of healthcare - to provide accurate, timely, and cost-effective patient care. As we strive towards this goal, this research serves as a testament to the continuous need for quality assurance, personnel training, and adherence to best practices in laboratory diagnostics.

Conclusion

Accurate diagnostic testing is crucial in laboratory medicine. Our study found that 1.32% of samples were unsuitable due to errors in handling. Personnel training and adherence to best practices are key. Addressing these challenges is essential to ensure diagnostic precision and uphold patient trust. Thoroughly trained personnel are critical in reducing error incidence rates. Healthcare institutions must implement stringent training programs and foster a culture of continuous learning. Reducing pre-analytical errors is crucial for better patient care and diagnostic accuracy. Insights from this study guide us toward a more reliable future of lab medicine. With targeted interventions, rigorous training, and commitment to quality assurance, we can take steps towards superior patient care.

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned.

Consent for publication

Approved

Funding

Not applicable

Conflict of interest

The authors declared an absence of conflict of interest.

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