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Examination Of Pre-Testing Errors In A Newly Established Clinical Biochemistry Lab

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Abstract:
Background: *The pre-analytical phase in laboratory diagnostics remains a significant source of errors, directly impacting patient care. This study aimed to investigate the prevalence and types of pre-analytical errors at a tertiary care hospital.*
Methods: *A total of 5345 samples were evaluated over two months. Errors were categorized into types, and their distribution across various departments was assessed.*
Results: *The overall error rate was 9.7%. Mismatched or wrong vials emerged as the most frequent error at 25%. Hemolysed samples accounted for 17.3%, and inadequate samples contributed to 16.3% of the errors. Significant variability in error rates was observed across departments, with Medicine and Surgery departments showing the highest frequencies at 23.1% and 21.2%, respectively.*
Conclusion: *Our findings underscore the pressing need for targeted interventions in the pre-analytical phase, especially concerning sample collection and handling procedures. Department-specific strategies, ongoing training, and monitoring are crucial for minimizing errors and ensuring patient safety.*
Keywords: *Pre-analytical errors, Laboratory diagnostics, Mismatched vials, Hemolysed samples, Tertiary care hospital.*

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I. Introduction:

Clinical laboratories are essential entities in the healthcare system, facilitating timely and accurate diagnosis, guiding therapeutic decisions, and promoting medical research. The role of Central Clinical Laboratory (CCL) in such systems is unparalleled. Given its pivotal role in diagnostic services, understanding and managing errors, especially in the pre-analytical phase, becomes crucial for patient care, research outcomes, and overall system efficacy.

The Clinical Laboratory Workflow comprises three main phases: the pre-analytical, analytical, and post-analytical stages[1]. The pre-analytical phase is perhaps the most vulnerable to errors, encompassing activities from test order to sample processing. Studies have shown that pre-analytical errors can account for up to 70% of all mistakes in laboratory medicine, influencing the reliability and accuracy of diagnostic results[2].

The Central Clinical Laboratory serves multiple essential functions. Not only does it act as the frontline of diagnosis for various diseases and conditions, but it also offers a wealth of information that helps guide clinicians' treatment decisions. Moreover, as a nexus of diagnostic services, the CCL accelerates the medical research arena, offering data and insights that pave the way for innovative treatments and methodologies[3].

In the labyrinth of clinical diagnostics, the journey from sample collection to analysis is fraught with potential pitfalls. Patient misidentification, incorrect tube selection, hemolysis, inadequate sample volume, and prolonged transportation times are among the myriad challenges faced in the pre-analytical phase[4]. Given the CCL's role in critical decision-making processes, understanding, identifying, and rectifying these errors becomes paramount.

The recent study conducted at a tertiary care centre offers insights into the prevalence and nature of these errors in a newly established CCL. As healthcare leans more on central laboratories, ensuring the robustness and accuracy of this initial phase is not just a matter of operational efficiency, but a critical factor influencing patient outcomes.

II. Aim:

To comprehensively examine the prevalence and types of pre-analytical errors in a newly established Central Clinical Laboratory (CCL) at a Tertiary care centre of Assam.

III. Materials And Methods:

Study Design and Setting:

A prospective study was conducted at the Department of Biochemistry in a tertiary care hospital. The hospital also functions as a medical college and boasts state-of-the-art facilities. The Central Clinical Laboratory (CCL) under investigation was newly established, having commenced operations on the 26th of June 2023.

Study Period:

The research was carried out over a span of two months, beginning on the 1st of July and concluding on the 1st of September 2023.

Sample Size:

A total of 5,345 samples were meticulously assessed during the course of the study, ensuring a broad and comprehensive evaluation of pre-analytical errors within the stated period.

Identification of Pre-analytical Errors:

All samples that were submitted to the CCL during the study period underwent a systematic review. This review aimed to recognize any discrepancies or errors in test requests, sample collection, labeling, documentation, and transportation. Each identified error was logged with pertinent details for further classification.

Categorization and Quantification of Errors:

Upon identification, the errors were systematically categorized based on their type and origin. Categories were defined based on common laboratory practices and potential challenges specific to the CCL. The frequency and prevalence of each error type were then quantitatively determined, providing a clear picture of the predominant challenges faced by the laboratory.

Data Collection:

A standardized data collection form was employed to ensure uniformity in the information captured. The form encompassed fields for patient details, nature of the test, description of the error, the individual responsible (if identifiable), and the potential impact of the error on the diagnostic outcome.

Quality Control and Validation:

To maintain the integrity and accuracy of the study, regular quality control checks were instituted. These checks ensured that the instruments used for analysis were calibrated and that the procedures for error identification were consistently applied. All findings underwent a validation process wherein a subset of identified errors was reviewed by a separate team to confirm their classification and implications.

Statistical Analysis:

Data compiled were analyzed using statistical software. Descriptive statistics were employed to quantify the types and frequencies of errors. Further, inferential statistics were applied, where necessary, to discern patterns or significant factors contributing to the errors.

Ethical Considerations:

Given the nature of the study, it was paramount to ensure patient confidentiality. All data used were anonymized, and any identifiers that could trace back to individual patients were omitted or encrypted. The study was conducted with the approval of the hospital's ethical committee, adhering to all guidelines laid out for clinical research.

IV. Results

The data obtained through this research predominantly elucidated the distribution of various demographic samples and the nature and frequency of pre-analytical errors. Our investigation further shed light on the distribution of these errors based on the different departments/wards of the tertiary care hospital.

Demographic Distribution of Samples

A total of 5345 samples were analyzed in this study. From the age distribution perspective, the majority of samples were from the age group 20-40 years, comprising 37.5% (2005/5345) of the total samples. Those aged between 41 and 60 constituted the second-highest age group with 33.1% (1770/5345) of the total. The elderly age group (61 and above) represented 19.2% (1025/5345), and the youngest age group (<20) accounted for 10.2% (545/5345).

In terms of gender distribution, males had a slightly higher representation with 54.3% (2900/5345) of the samples, while females constituted 45.7% (2445/5345). When we analyzed the samples based on patient status, outpatients represented a more significant percentage with 59.9% (3200/5345), whereas inpatients accounted for 40.1% (2145/5345) of the total.

Nature and Distribution of Pre-analytical Errors

Out of the 5345 samples, a total of 520 samples exhibited pre-analytical errors, translating to an error rate of 9.7%. Delving into the specifics of the errors, the highest error frequency was observed with mismatched vials/wrong vials with a prevalence of 25% (130/520) among the errors. Hemolysed samples followed closely with a 17.3% (90/520) error rate. Other prevalent errors included inadequate samples at 16.3% (85/520), improper sampling techniques at 13.5% (70/520), lipemic samples constituting 11.5% (60/520), and issues with improper requisition forms, which accounted for 10.6% (55/520) of the errors. A smaller percentage, 5.8% (30/520), encompassed a category named "Others," which included errors not fitting into the mentioned categories.

Errors based on Departments/Wards

Our analysis extended to understanding the distribution of errors across various departments. The Medicine department had the highest error frequency with 23.1% (120/520) of the total errors. The Surgery department had the second-highest frequency of errors at 21.2% (110/520). Pediatric samples had a 15.4% (80/520) error rate, followed closely by the Cardiology department at 13.5% (70/520). The Orthopedics department accounted for 9.6% (50/520) of the errors. The remaining departments, clubbed under "Others," contributed to 17.3% (90/520) of the total errors.

Table 1: Demographic Distribution of Samples

Criteria	Frequency	Percentage (%)
Age (<20)	545	10.2
Age (20-40)	2005	37.5
Age (41-60)	1770	33.1
Age (61 and above)	1025	19.2
Male	2900	54.3
Female	2445	45.7
Outpatient	3200	59.9
Inpatient	2145	40.1

Table 2: Frequency and Categorization of Pre-analytical Errors

Criteria / Types of Errors	Frequency	Percentage (%)
Total errors	520	9.7
Mismatched Vials/Wrong vials	130	25
Hemolysed sample	90	17.3
Inadequate sample	85	16.3
Improper sampling techniques	70	13.5
Lipemic sample	60	11.5
Improper requisition forms	55	10.6
Others	30	5.8

Table 3: Distribution of Errors Based on Departments/Wards

Department	Frequency	Percentage (%)
Medicine	120	23.1
Surgery	110	21.2
Pediatrics	80	15.4
Cardiology	70	13.5
Orthopedics	50	9.6
Others	90	17.3

V. Discussion

The pre-analytical phase in laboratory testing is of paramount significance and can be the source of a significant proportion of errors[5]. Our study, performed at a tertiary care hospital, has provided a detailed insight into the prevalence and categorization of such pre-analytical errors. When compared with previous research, there are areas of convergence and divergence that warrant discussion.

The observed error rate in our study was 9.7%, with mismatched or wrong vials being the most frequent error. This error rate is slightly higher than the 7.3% reported by Lippi et al. in 2011[6]. However, similar to our findings, their study also found that the most common pre-analytical error was the utilization of mismatched vials. This consistency underscores the recurrent challenges associated with sample collection and labeling procedures.

Hemolysed samples, with an error rate of 17.3% in our study, is an area of concern. Such errors can significantly impair the accuracy of numerous biochemical parameters, leading to potential misdiagnoses[7]. Interestingly, a study by Carraro and Plebani reported an even higher error rate for hemolysed samples at 22.5%[4], emphasizing that this is a pervasive issue across multiple laboratory settings.

Another notable observation was the error rate associated with inadequate samples (16.3%). This mirrors findings from a study by Saleem et al., where 14.8% of errors were due to insufficient sample volume[8]. Their research stressed the need for establishing stringent protocols for sample collection to minimize such errors.

We noted a significant association between the departments/wards and the nature of pre-analytical errors ($p < 0.05$). This is a pivotal finding and aligns with the conclusions of another study by Astion et al., which similarly reported variability in error rates across different departments[9]. Such department-specific discrepancies might be attributed to varying levels of staff training, patient populations, or logistical challenges inherent to certain departments.

However, our study is not without limitations. Conducted over a span of two months, the timeframe could be a potential limitation. Long-term analysis might provide a more comprehensive picture of pre-analytical errors. Additionally, being a single-center study, the results might not be universally applicable.

In summary, while our study adds to the growing body of literature emphasizing the importance of quality assurance in the pre-analytical phase, it also beckons the need for continued research in this domain. The recurring errors across studies underscore the necessity of regular training, standardized procedures, and continuous monitoring for healthcare professionals involved in sample collection and handling.

VI. Conclusion:

Our study carried out at a tertiary care hospital underscores the critical significance of the pre-analytical phase in laboratory testing, presenting an error rate of 9.7%. While some of our findings align with prior research, such as the recurrent challenge of mismatched vials and the incidence of hemolysed samples, others offer novel insights. Notably, the correlation between error rates and specific departments/wards necessitates tailored interventions for enhanced accuracy. Regular training, the implementation of standardized procedures, and ongoing monitoring are imperative. These measures, coupled with a comprehensive understanding of the specific challenges faced in each department, can drastically reduce pre-analytical errors, ensuring higher patient safety and improved diagnostic outcomes.

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