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A Study of Pre-Analytical Errors in a Chemical Pathology Laboratory

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Abstract

Clinical chemistry laboratory plays a crucial role in clinical decision-making, yet it is not immune to human errors. While scientific innovations like automation have significantly improved laboratory science, avoidable errors still happen. A major example of this is the high prevalence of errors occurring in the pre-analytical phase of the total testing phase. The objective of this study was to evaluate the pre-analytical phase of laboratory testing in a Clinical Chemistry Laboratory, identify the types of errors occurring, and determine specific steps where these errors arise to formulate corrective measures. This prospective observational study was conducted in the Chemical Pathology Laboratory of Osun State University Teaching Hospital over six months, from April to September 2024. We reviewed all samples and accompanying request forms for pre-analytical errors, systematically recording daily errors and their types. Data analysis was performed using Microsoft Excel software. Out of 10,136 forms reviewed, 5,575 forms (55%) included an identifying hospital number, while diagnosis was provided in 6,690 forms (66%). Doctors' handwriting was legible in 7,703 forms (76%), and the type of specimen was specified in 7,501 forms (74%). The date of sample collection was recorded in 2,027 forms (20%), while only 507 forms (5%) indicated the time of collection. Sample mix-ups occurred 253 times (2.5%), and wrong numbering of samples was noted in 111 instances (1.1%). Insufficient samples led to rejection in 426 cases (4.2%), and lipaemic samples were identified in 81 instances (0.8%). Haemolyzed samples were observed 314 times (3.1%), while clotted samples and incorrect times of sample collection were reported 172 (1.7%) and 111 (1.1%) times respectively. Continuous evaluation of the pre-analytical phase, along with identifying the causes of errors and implementing corrective measures, is essential to minimize these errors.

Keywords: Pre-analytical error, clinical chemistry, total testing process, insufficient samples

Introduction

Medical laboratories are integral to the diagnosis and treatment of patients, making the precision and accuracy of generated results crucial (Plebani, 2010). Diagnostic errors are leading cause of medical malpractice claims, as reported by Green (2013), and they rank as the most common source of medical mistakes. Recent literature highlights the prevalence of these errors, emphasizing the need for thorough examination and effective mitigation strategies (Green,).

A laboratory error is defined as any mistake occurring before, during, or after the testing process that can affect the accuracy, reliability, or timeliness of test results (Lippi *et al.,* 2009; Kalra *et al.,* 2013). Errors can occur at any stage of the testing process pre-analytical, analytical, or post-analytical and can severely compromise test reliability (Lippi *et al.,* 2009; Kalra *et al.,* 2013). However, pre-analytical phase, which encompasses sample collection, handling, and transportation, is particularly vulnerable, accounting for approximately 70% of laboratory errors (Šimundić, 2015; Šimundić and Lippi,2012).

The pre-analytical phase can be further categorized into two stages: the first involves test ordering based on clinician knowledge and experience, while the second encompasses patient identification, selection of appropriate specimen containers, sample collection, transportation, and storage. Each of these steps is susceptible to error, often due to miscommunication or procedural inconsistencies.

Advancements in automation have significantly simplified many laborious laboratory procedures, shifting the focus from analytical errors as the primary influence on diagnostic reliability (Lippi & Šimundić, 2010; Ashakiran *et al.,* 2011). A greater proportion of missed or delayed diagnoses arises from failures in requesting appropriate laboratory tests (Plebani, 2010; Plebani *et al.,* 2011). Despite the prevalence of diagnostic errors, this topic remains underexplored in the broader context of patient safety (Kalra, 2004; Bonini, 2009; Plebani & Piva, 2010). Increasingly, literature reflects concerns about the implications of such errors on patient care and outcomes (Binita *et al.,* 2010; Adegoke *et al.,* 2011; Agarwal,). This study aims to enumerate the various errors occurring in the pre-analytical phase, emphasizing the importance of understanding and addressing these issues to ensure the accuracy and reliability of laboratory results.

Materials and Methods

This was a prospective observational study that was done in the Chemical Pathology Laboratory of Osun State University Teaching Hospital, Osogbo for a period of 6 months. Tests done are routine biochemical tests, hormonal assay, lipid profiles and drug screening. The hospital is a tertiary health center serving a population of about 200,000 in south western Nigeria. The sample size was a total of 10,136 laboratory request forms and specimen received from April to September 2024. All samples and their accompanying request forms were reviewed for pre-analytical errors, with daily errors and their types systematically recorded. Test request forms were assessed for: (a) Patient Information e.g age, gender, hospital number, location (b) Clinical Information, and (c) Sample Information e.g nature of the sample, date and time of collection. Specimens collection procedures for in-patient, out-patient and NHIS patient (patient and specimen identification, sample container, labelling, transportation, storage and documentation), identification of types and frequencies of pre-analytical errors were also critically examined. Patient confidentiality was prioritized; names and hospital numbers were not included on the data sheets for analysis. Data analysis was by metrics, facts and figures with representation of analytics in tables to illustrate data generated and trends in pre-analytical errors. Data analysis was performed using Microsoft Excel software.

This study was conducted with the following objectives:

1. Identify and quantify the various errors occurring in the pre-analytical phase.
2. Determine the specific steps where errors occurred
3. Formulate corrective measures and ensure the entire process is error-free.

Ethical Approval

Ethical approval was obtained from the Ethical Review Committee of UNIOSUN Teaching Hospital, Osogbo.

Results

A total of 10,136 request forms were reviewed, and the results are summarized in table 1 and 2. Among these, 5,575 forms (55%) included an identifying hospital number, while the age of patients was documented in 8,920 forms (88%). All forms recorded patients' names, and the consultant in charge was identified in 9,933 forms (98%). Details of the requesting physician were also noted in 9,933 forms (98%). A diagnosis was provided in 6,690 forms (66%), but no information regarding current therapy was included. Doctors' handwriting was legible in 7,703 forms (76%), and the type of specimen was specified in 7,501 forms (74%). The date of sample collection was recorded in 2,027 forms (20%), while only 507 forms (5%) indicated the time of collection.

Table 3 shows the errors identified in the second phase of the pre-analytical process; missing forms accounted for 1.4% (142) of errors, while incorrect sample specimens were noted 122

times, representing 1.2% of errors. Sample mix-ups occurred 253 times (2.5%), and wrong numbering of samples was noted in 111 instances (1.1%). Insufficient samples led to rejection in 426 cases (4.2%), and lipaemic samples were identified in 81 instances (%). Haemolyzed samples were observed 314 times (3.1%), while clotted samples and incorrect times of sample collection were reported 172 (1.7%) and 111 (1.1%) times respectively.

Table 1: Forms received from different sections of the hospital

Months	In-Patient	Out-Patient	Nhis	Total
April	917	433	291	1641
May	847	720	348	1915
June	702	647	289	1638
July	819	735	351	1905
August	540	655	246	1441
September	597	708	291	1596
Total	**4422**	**3898**	**1816**	**10136**

Table 2: Types and frequencies of pre-analytical errors in phase 1

S/No	Well documented	Frequency	Percentage (%)
1	Patient name	10136	100
2	Ward / clinic name	8920	88
3	Illegible handwriting	7703	76
4	Consultant in-charge	9933	98
5	Hospital number	5575	55
6	Physician name	9933	98
7	Diagnosis	6690	66
8	Specimen type	7501	74
9	Age	8920	88
10	Date of collection	2027	20
11	Time of collection	507	5

Table 3: Types and frequencies of pre-analytical errors in phase 2

S/No	Pre-analytical errors	Frequency	Percentage
1	Missing requestion form	142	1.4
2	Incorrect sample specimen	122	1.2
3	Sample mix up	253	2.5
4	Wrong Numbering of samples	111	1.1
5	Insufficient Sample	426	4.2
6	Lipaemic sample	81	0.8
7	Haemolysed sample	314	3.1
8	Clotted sample	172	1.7
9	Wrong Timing of sample collection	111	1.1

Discussion

In medical practice, 70% of critical clinical decisions rely on laboratory test results, underscoring the laboratory's role as the backbone of healthcare (Plebani, 2004). Therefore, errors within the laboratory can significantly impact the cost and outcome of patient treatment. Most mistakes in medical laboratory are as a result of pre-analytical errors, this must be minimized to guarantee a better quality of care in accordance with latest approach to provision of quality health care, which centered on patients' need and satisfaction.

Our findings revealed that no request form included medication history, and provisional diagnoses were often incomplete. In many cases, the accurate interpretation of results hinges on the provisional diagnosis provided. Additionally, the time of specimen collection was frequently not recorded. This oversight is crucial, as delays between collection and analysis can lead to falsely low results for parameters such as bicarbonate and bilirubin. The type of specimen collected is also vital; for instance, a bloody tap from pleural or cerebrospinal fluid could be misidentified as blood, resulting in inappropriate reference ranges and misleading interpretations. Improving laboratory forms to be more user-friendly could help reduce errors and unnecessary tests (Adegoke *et al.,* 2011). The observed frequency of legible handwriting in our study was 76%, which can be improved, as reported by Chawla and Mallika (2010), who noted a legibility rate of 99.9%. Names of the attending consultant and requesting physicians were recorded in 98% of forms reviewed, reflecting an improvement over Khoury *et al.,* (996). The absence of clinicians' names on request forms can lead to delays in results and therapy commencement, unclaimed reports, and increased costs due to repeated tests. We found that only 88% of patients had their age documented, presenting a challenge for proper research and epidemiological studies, given the relationship between clinical chemistry and age. An attitudinal change is necessary on both sides to maximize patient benefits from healthcare services, starting with accurate completion of laboratory forms. Enhancing the quality of information received in the laboratory largely depends on requesting physicians ensuring all relevant fields are diligently filled out.

The most common error recorded in the second phase of the pre-analytical process was insufficient sample volume, noted in 426 cases (4.2%). Each analysis requires a fixed volume, and inadequate samples can stem from phlebotomist ignorance or difficult collections, such as in pediatric patients or those with challenging veins due to chronic conditions or chemotherapy (Koseoglu *et al.,*). The second most frequent error was haemolyzed samples, identified in 314 cases (3.1%). Haemolysis can release intracellular contents into the plasma, resulting in falsely elevated potassium and intracellular enzyme levels, while analytes like albumin and bilirubin may be underestimated. Common causes of hemolysis include difficult venipunctures, improper site preparation, and excessive force when transferring samples (Fidler, 2007). Haemolysis also prolongs turnaround times due to the need for fresh samples. Missing forms accounted for 142 instances (1.4%), often leading to misdiagnosis and poor clinical outcomes. This may be attributed to heavy workloads, emphasizing the importance of correctly filling out forms before sample collection. Incorrect sample collection was reported in 122 instances (1.2%), often due to using the wrong containers or lack of knowledge about proper collection techniques, which can increase turnaround times and lead to misdiagnosis (Golla and Manjunatha, 2019). Lipaemic samples were observed in 81 cases (0.8%), typically resulting from postprandial collections or patients diagnosed with hyperlipoproteinemia. This can be mitigated by advising overnight fasting and requesting clinicians to indicate hyperlipoproteinemia on the forms. The interference of lipaemia in spectrophotometric assays varies with the wavelength used (Calmarza and Cordero, 2011). Clotted samples were reported in 172 instances (1.7%), often due to improper collection techniques or delays in placing blood into tubes. Also, not allowing the serum specimen to clot for the recommended amount of time can result in fibrin formation in the serum (Fidler, 2007). It also prolongs turnaround time due to the need for

a fresh sample for processing the request. In this phase, missing forms were reported 142(1.4) times. Errors associated with this mistake are usually responsible for the worst clinical outcomes because of the possibility of misdiagnosis. This may probably be due to heavy workload, and it is important to fill forms correctly before sample collection. Incorrect sample collection was reported in 122 (1.2%) times, collecting sample in a wrong container, using unsterile container for sample collection, lack of knowledge about collecting tubes and its order of draw can increase TAT, request for repeat sample, misdiagnosis and wrong treatment. Copy of standard operating procedure for order of draw has to be pasted on walls right above the sample collection tray in wards to reduce this type of error (Golla and Manjunatha, 2019).

In conclusion, pre-analytical errors can lead to misinterpretation of results and hinder meaningful laboratory insights. While this study was limited to one hospital, it is likely that similar issues exist in other facilities across the country. To address pre-analytical errors, we recommend the following corrective measures:

1. Maintain a register to track errors
2. Develop corrective strategies tailored to the errors noted
3. Establish standardized phlebotomy practices and sample transport procedures in each institution
4. Implement continuing medical education programs for all laboratory staff to enhance expertise
5. Conduct competency assessments for both new and experienced personnel to identify and manage errors effectively.
6. Embrace the latest technologies to reduce error margins in the laboratory.

Identifying errors, ensuring proper form completion, and adhering strictly to sample collection protocols are essential for accurate testing and quality performance in medical laboratories.

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