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**Original Research Article** 

### Study of Pre-Analytical Errors in Laboratory & Steps to Improve

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### Abstract

**Objectives:** Pre-analytical errors decisively influence the total laboratory errors and consequently the diagnostic accuracy. The following were the objectives of the study. 1) To detect the percentage of pre-analytical errors in venous specimens in Laboratory. 2) To categorize these pre-analytical errors. 3) To formulate steps of corrective measures to avoid such type of errors. *Study Design and Result*: Type of Study - Retrospective study. Study period - 12 months (June 2015 to May 2016), documenting the frequency and type of pre-analytical errors. *Results*: Total number of pre-analytical errors detected in the period of 12 months' study were 180. Improper timing of specimens, hemolyzed & clotted specimens and improper requests were the major concerns followed by delay in specimen transport. *Conclusion*: Pre-analytical phase is an important component of Total Laboratory Quality. Pre-analytical errors are not inevitable and can be avoided or minimized with diligent application of quality control, continuing education, effective protocols, and standardized procedures for effective blood collection systems to ensure total Quality patient care.

**Keywords:** Laboratory quality, Pre analytical error, Specimen handling, Patient misidentification, Blood Collection Tubes, Hemolysis, Lipemic specimens, Clotted specimens, Standardization, Technology, Quality Indicators.

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### **1. INTRODUCTION**

Laboratory diagnostics, a pivotal part of clinical decision-making is no safer than other areas of healthcare. Remarkable advances in instrument technology, automation and computer science have greatly simplified many aspects of laboratory diagnostics & Analytical errors are no longer the main factor influencing the reliability and clinical utilization of laboratory diagnostics. Therefore, the additional sources of variations like pre-analytical errors became the focus for further quality improvement.

Laboratory processing consists of a sequence of procedures that begins with the ordering of tests by physicians and ends with the interpretation also by physicians of the test results. The three phases of this cycle pre-analytical, analytical and post-analytical are subject to possibilities of error that affect quality and reliability of laboratory results (Figure 1). Out of all errors, pre-analytical errors decisively influence the total errors & consequently the diagnostic accuracy and accounts for an important phase of laboratory medicine & total laboratory quality management [1].

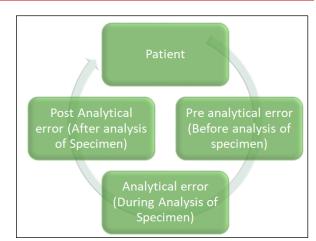


Figure 1: Phases of specimen processing cycle and errors

Preanalytical errors can be further subdivided in to three phases according to the time of specimen collection (Table 1). Most of the pre-analytical errors encountered within the entire preanalytical process is largely due to lack of standardized processes for specimen collection including patient preparation, specimen acquisition, handling & storage. This highlights the importance of good laboratory practice & compliance with the new accreditation standards. Hence it is necessary to adopt the suitable strategies for error prevention, including process redesign, the use of extraanalytical specification & improved communication among other clinical departments [2].

Table 1: Types	of pre analytical	errors in specimen	processing
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Sr. No	Time	Error
1	Before	Inappropriate test request or Incorrect test order
	specimen	Patient identification error
	collection	Inadequate patient preparation
		Inadequate collection of patient information e.g. Medications, smoking, heavy exercise, etc.
2	During	Inadequate specimen volume / inappropriate blood to anticoagulant ratio
	specimen	Clotting or hemolysis of specimen due to inappropriate tube mixing
	collection	Inappropriate specimen container
		Contamination from infusion route
		Incorrect order of draw
3	After	Specimen labeling error
	specimen	Improper specimen transport and storage conditions (time and temperature)
	collection	Improper centrifugation time or speed

### 2. STUDY TYPE AND OBJECTIVES

A Retrospective study was conducted for a period of 12 months (June 2015 to May 2016) in Aster Medical Center Plus Laboratory, Al-Hilal, Doha, Qatar. We monitored the type & frequency of pre-analytical errors in all the venous specimens collected.

The objectives of the study were as follows:

- 1) To detect the percentage of pre-analytical errors in venous specimens in Laboratory.
- 2) To categorize these pre-analytical errors and compare it to previous studies.
- 3) To formulate steps of corrective measures to avoid such type of errors.

### **3. MATERIALS AND METHODS**

All types of pre-analytical errors documented by technical staff & verified by Pathologist for final decision-making. Pre-analytical errors were recorded systematically under the following categories.

- 1) Improper Request
- 2) Incorrect identification/ Improper labelling
- 3) Improper timing of specimens
- 4) Inadequate/Insufficient specimens
- 5) Improper tube collection
- 6) Hemolyzed/Clotted specimens
- 7) Specimen handling & transport

The analysis of such errors done by calculating the percentage of errors occurring every month and type of each category.

Review of literature and international guidelines used to establish and implement recommendations and steps to improve.

### 4. OBSERVATIONS & RESULTS

During the 12-month study period, a total of 180 pre-analytical errors were identified. The distribution of these errors at different phases of specimen handling is presented in Table 2.

## Table 2: Pre analytical errors at different pre-analytical level identified in Aster Medical Centre Plus, Laboratory, Doha, Qatar

Error Level	Error Type	Mor	Months						%					
		Jun 15	Jul 15	Aug 15	Sep 15	Oct 15	Nov 15	Dec 15	Jan 16	Feb 16	Mar 16	Apr 16	May 16	Nos of Error & 9
1)	a.	2	0	3	2	4	2	3	4	3	3	2	6	34
Errors at the level of Patient	Improper Request	5.88	0	8.82	5.88	11.76	5.88	8.82	11.76	8.82	8.82	5.88	17.65	18.90 %
Identification	b.	2	0	1	1	2	1	3	0	0	2	1	0	13

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Error Level	Error Type	Months						%						
		Jun 15	Jul 15	Aug 15	Sep 15	Oct 15	Nov 15	Dec 15	Jan 16	Feb 16	Mar 16	Apr 16	May 16	Nos of Error & 9
	Incorrect Identification/ Improper labeling	15.38	0	7.69	7.69	15.38	7.69	23.08	0	0	15.38	7.69	0	7.20%
2)	a.	10	5	2	5	4	2	3	7	3	6	4	3	54
Errors at the Level of Specimen	Improper timing of specimens	18.52	9.26	3.7	9.26	7.41	3.7	5.56	12.96	5.56	11.11	7.41	5.56	30.00 %
Collection	b.	1	4	2	1	0	1	0	2	1	0	1	0	13
	Inadequate/ Insufficient specimen	7.69	30.7	15.38	7.69	0	7.69	0	15.38	7.69	0	7.69	0	7.20 %
	c.	1	2	1	0	0	1	0	1	2	0	0	1	9
	Improper tube collection	11.11	22.22	11.11	0	0	11.11	0	11.11	22.22	0	0	11.11	5%
	d. Hemolyzed and	1	6	5	5	6	5	0	4	3	4	2	2	43
	clotted specimens	2.33	13.9	11.6	11.6	13.9	11.6	0	9.3	7	9.3	4.65	4.65	23.90 %
3)	Delay in specimen	0	1	2	1	3	3	1	0	0	1	1	1	14
Errorshandlingduring& transportSpecimentransport		0	7.14	14.29	7.14	21.43	21.43	7.14	0	0	7.14	7.14	7.14	7.80 %
4)		17	18	16	15	19	15	10	18	12	16	11	13	180
Total Pre-analytical errors		9.4	10	8.89	8.33	10.56	8.33	5.56	10	6.67	8.89	6.11	7.22	100 %

During our study, several important errors were identified. These errors can be categorized as follows:

Approximately 30% of the total pre-analytical errors were attributed to the improper timing of specimen collection. This included instances where non-fasting specimens were collected or when patients did not fast properly before specimen collection. Errors also occurred when specimens were collected after heavy meals or strenuous exercises. Additionally, preexisting metabolic disorders such as Hyperlipoproteinemia contributed to these errors.

Around 24% of the errors were related to hemolyzed and clotted specimens, particularly in the processing of hematology and coagulation tests. These errors occurred during the handling and preparation of the specimens.

Approximately 19% of the errors were due to improper request forms. This included instances where manual test requests were made without providing appropriate clinical details and basic information. Common issues included missing age data and a lack of information regarding the specific tests to be performed. About 8% of the errors were documented because of delays in specimen handling and transport. These delays could lead to compromised specimen integrity and inaccurate test results.

Around 7% of the errors were attributed to incorrect patient identification and improper labeling of specimens. These errors can lead to mix-ups and confusion in the laboratory, potentially resulting in incorrect test results being reported.

Another 7% of the errors were caused by inadequate or insufficient specimens, particularly in cases involving pediatric and debilitated patients. Difficulties in locating veins for specimen collection contributed to this error category.

Finally, 5% of the errors encountered were due to improper or wrong tube collection. This refers to instances where the wrong type of tube was used for specimen collection, leading to potential issues during analysis.

### **5. DISCUSSION**

In present study, significant observation is that small percentage of errors attributed to the factors like improper labelling, insufficient specimen volume, and delays in specimen handling and transport. These errors were effectively minimized by the presence of skilled lab technicians and licensed staff members who were exclusively responsible for collecting and processing specimens from patients, following the guidelines outlined by the Ministry of Public Health (MOPH) in Qatar.

Previous study conducted in Denmark by Pal Bela Szecsi *et al.*, [3] found that pre-analytical errors accounted for a substantial 81% of all errors observed throughout the entire laboratory testing process and errors related to specimen identification were commonly observed when non-technical staff members were involved in the collection process.

The findings from our study indicate that most errors encountered can be attributed to improper timing (30%), hemolyzed and clotted specimens (24%), and improper request forms (19%). These results are aligned with previous research findings [4-12].

In a study conducted by Ashkiran S *et al.*, [4], it was noted that most errors were attributed to improper requests, incorrect timing of specimen collection, incorrect tube collection, and in-vitro hemolysis of specimens which are in line with our studies. Improper timing and Improper request forms are mainly noted due to process of paper based manual request forms and, in some instances, inadequate information provided to patients e.g., Fasting specimen requirements or avoiding some foods and drugs etc. LIS and HIS ordering and SMS systems to patients can reduce these errors.

Lippi G *et al.*, [5] noted that incorrect procedures for specimen collection, such as hemolysis and clotting, can be identified as the primary sources of the common errors and use of inappropriate containers was notably high for outpatient specimens. In a study conducted by Dale JC *et al.*, [6] regarding the success of outpatient phlebotomy, it was found that most unsuitable specimens were attributed to hemolysis (18.1%), insufficient quantity (16.0%), and clotting (13.4%).

Previous studies [5-12] also highlight that issues directly associated with specimen collection are the primary contributors to preanalytical errors specifically hemolyzed, clotted and incorrect specimens are frequently encountered problems in preanalytical errors which is mainly caused by improper collection techniques e.g., applying torniquet for a long time and difficult vein collection especially by non-experienced staff.

Hemolysis is responsible for rejection of countless tests like lactate dehydrogenase (LDH), Acid phosphatase, Potassium, aspartate transaminase (AST), alanine transaminase (ALT), Prothrombin time (PT), Activated partial thromboplastin time (aPTT) [13-15].

The findings of a study conducted by Fabio *et al.*, [9] and Guimaraes *et al.*, [16] in a hospital laboratory in Brazil showed that inadequate specimen volume was a major cause of pre-analytical errors. Specifically, 18.49% and 24% of total pre-analytical errors were attributed to this cause respectively, making it one of the most common reasons for such errors. However, our study found that Insufficient volume of specimen was responsible for only 7% of preanalytical errors, ranking as one of the least common errors. This could be attributed to the fact that our clinic employs licensed lab technicians for blood collection and uses the vacutainers blood collection tubes system.

In conclusion, our study identified various important errors in the pre-analytical phase of specimen collection and processing. These errors highlight the need for improved protocols, training, and attention to detail in order to minimize their occurrence and ensure accurate laboratory test results.

# 6. STEPS TO IMPROVE & RECOMMENDATIONS:

In recent years several recommendations & standards developed for the pre- analytical phase [17-19]. The working group on pre-analytical errors of the German Society for Laboratory Medicine proposed comprehensive recommendations on the quality of diagnostic specimens and more recently on the handling of hemolytic, icteric & lipemic specimens [17, 18].

International Standardization bodies such as ISO:6710 have issued the standards for type & concentration of anticoagulants to be used for venous blood specimens [19].

The Clinical and Laboratory Standards Institute (CLSI) publishes their guidelines on aspects of the preanalytical phase to comply need for quality control and standardization in laboratory testing [20].

Table 3 provides an overview of the most frequently encountered pre-analytical errors, potential causes and consequences associated with these errors, and effective measures to reduce their occurrence.

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	Table 3: Common pre-analytical errors, its consequences, and practices to minimize									
Sr. No	Type of preanalytical error	Most common causes	Possible consequences	Best practices to minimize these errors						
1	Patient misidentification e.g. incorrectly labeled tubes or incorrectly filled forms	Inadequate data on test requisition form. Missing patient identifiers. Labeling specimen container away from specimen collection site.	Wrong diagnosis or delayed diagnosis due to specimen collection from wrong patient or wrong labeling of specimen container. Wrong Treatment e.g. wrong blood transfusion leading to acute hemolytic reaction.	Label the specimen container immediately after specimen collection. Use barcoded wristbands data, biometric information e.g. fingerprints, iris scanning [14] Use at least two patient identifiers while taking specimens [17]						
2	Lipemic specimens	Test collection after heavy meals. Preexisting metabolic disorder.	Interference of fat with optical reading of instrument leading to wrong result reporting e.g. wrong electrolyte values [17, 18].	Provide proper patient instructions during test ordering to prepare patient before specimen collection (overnight fasting). Specify patient's pre-existing conditions on test requisition form e.g. hyperlipoproteinemia [18]						
3	Homolysis	Forcing blood through needle of syringe, Collecting blood through intravenous line. Vigorous shaking of specimen. Centrifuging specimen before clotting.	Falsely high values of some Laboratory tests e.g. AST, Potassium and LDH. Interference with spectrophotometric assays [15].	Avoid vigorous mixing/agitation of blood specimen. Do not apply tourniquet for more than one minute since this can cause localized stasis and rupture of red blood cells. Prefer closed system for blood collection. [15, 16] Use transfer devices to transfer blood from syringe. Use luer-lok access device and discard tube when drawing from line [19].						
4	Incorrect Specimen volume	Incorrect phlebotomy technique. Difficult venous access (pediatric patients, debilitated patients).	Erroneous lab result duo to improper additive to blood ratio [17, 18]. Specimen rejection. Redraws.	Use vacutainer tubes for collection / closed system for blood collection [15, 16]. Fill evacuated blood collection tubes to the stated draw volume [17].						
5	Clotted specimen	Inappropriate mixing of tubes	Pseudo thrombocytopenia, False leucopenia, Aberrant red cell indices [12]. Erroneous low chemistry results, Instrument downtime duo to probe clogging.	Follow standard guidelines for tube mixing and order of draw.						

### Steps to improve pre-analytical errors:

1. Firstly, it is essential to establish clear and standardized protocols for specimen collection, handling, and transportation in specimen collection manual. This manual serves as a foundation for implementing strategies to identify and manage this critical aspect of laboratory quality in preanalytical phase of laboratory testing. Laboratory personnel must adhere to the standardized protocols outlined in the specimen collection manual to comprehend the significance of these procedures for

maintaining the quality of the laboratory and ensuring the safety of patients.

- 2. Provide clear instructions to the patients regarding preparation for specimen collection including fasting overnight, refraining from exercise & stressful activity the night before & just prior to the blood collection, foods, and medications to be avoided [20].
- 3. The posture during blood collection, the duration of tourniquet application, the time of blood collection to minimize diurnal effects and the order of specimen collection should all be

addressed in the pre-analytical Quality manual [20, 21].

- 4. Specimen Processing, transportation & storage conditions should be clearly delineated as per international guidelines [21].
- 5. Continuing Education Laboratory staff should participate in regular educational Competency assessments both written & observational, which give them an opportunity to recognize & overcome errors [22].
- 6. Vacutainers & use of Evacuated tube system will overcome the errors pertaining to specimen volume & use of anticoagulants [23].
- Prompt Transport Education given to transport personnel to transport the specimens promptly to the respective lab soon after collection, taking care of ideal temperature requirements, to avoid the errors related to delay.
- 8. Technology Incorporation of Barcode scanners for patient identification will recognize their identity accurately by avoiding possible human errors [24].
- 9. Implementing and monitoring preanalytical quality indicators and regular clinical audits can serve as effective mechanism for identification and correction of preanalytical errors [25].

### 7. CONCLUSION

The preanalytical phase plays a crucial role in patient care, and errors occurring during this phase can have a profound impact on the overall outcome of Laboratory reports and Diagnosis of disease. This phase is particularly vulnerable in most laboratories due to the presence of uncertainties and incidents, lack of standard guidelines and staff trainings. The evaluation and management of pre-analytical errors in the clinical laboratory is a complex process that requires rigorous approach to detecting and categorizing errors as well as the adoption of appropriate technologies and guidelines to minimize the occurrence of errors.

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