



## Research Article

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## Preanalytical Variables: Role in laboratory testing

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### Abstract

**Introduction:** In present medical scenario diagnosis of various diseases largely depends on investigations performed at hospital laboratory and with the advancement of technology error rates in analytical phase reduced drastically but still preanalytical errors in laboratories are very common and play a very important role in patient care and treatment. **Objectives:** To identify the nature and frequency of pre-analytical factors responsible for sample rejection. **Methodology:** The study was conducted in Clinical Biochemistry laboratory of Department of Biochemistry, over a period of 6 months from October 2018- March 2019 on total 33,303 samples which include OPD samples (n=20040), IPD samples (n= 11488) and Emergency samples (n=1775) and in these samples different preanalytical variables were categorized separately. **Results and Conclusion:** Out of 33303 samples analysed over a period of 6 months pre-analytical errors were seen in 1.38% (n=461) samples, with the commonest error was incomplete requisition forms followed by hemolysis of sample.

**Keywords:** Preanalytical variables, Pre-analytical errors, Hospital laboratory services, Quality assurance.

### INTRODUCTION

In a hospital, laboratory services plays a very important role in diagnosis of disease, to monitor its progress and its response to treatment, and also in screening of disease in apparent healthy individuals so any error in laboratory part have serious consequences in terms of patient diagnosis, treatment and prognosis also. Total testing process of laboratory investigations depends on preanalytical, analytical and post analytical phases of investigation. In all these phases pre-analytical phase is mostly human dependant and out of laboratory control and any mistake in this phase will becomes apparent in analytical and post analytical phase. The pre-and post-analytical phases account for 93% of errors [1]. With the advancement in technology and focusing on quality, the error magnitude decreased in analytical phase, thus the preanalytical stage constituted the most error prone part with percentage of 46-71% [2,3]. The common preanalytical errors include inappropriate tests orders, improper sample collection, inadequate volume, transport delays, and illegible handwriting on requisition slips, sample collection in wrong vacutainer, missing samples etc. To avoid these errors several recommendations and standards have been developed for the preanalytical phase [4-6]. The working group on preanalytical variables of the German Society for Clinical Chemistry and the German Society for Laboratory Medicine proposed comprehensive recommendations on the quality of diagnostic samples [4] and more recently on the handling of hemolytic, icteric and lipemic samples [5].

Better control of these variables and to improve the analysis quality of laboratories various guidelines are given by the accreditation agencies [7,8]. The purpose of this study is to find out various preanalytical variables which may affects testing process in our set up at North India.

### MATERIAL AND METHODS

The study was conducted in Clinical Biochemistry laboratory of Department of Biochemistry at T.S.M. medical College and Hospital, Lucknow, over a period of 6 months from October 2018- March 2019 on total 33,303 samples which include OPD samples (n=20040), IPD samples (n=11488) and Emergency samples (n=1775) and in these samples different preanalytical variables were categorized separately.

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## RESULTS

In this we found that total number of samples from all department were 33303 and in them 20040 were from OPD, 11488 from IPD and 1775 were from Emergency. Total number of rejected samples from all departments were 461 with overall percentage of preanalytical error was 1.38%.

In this study we found that preanalytical errors were more in IPD and emergency patients as compared to OPD patients and possible cause

may be that in IPD and emergency patients samples were collected by nursing or other paramedical staff which are not in direct control of laboratory but in OPD sample collection and deposition was done by phlebotomists in laboratory itself where regular staff training is done regarding sample collection and processing that's why chances of errors are less. In this study we also found that maximum number of preanalytical error was in the form of incomplete filling of requisition form followed by hemolysis of samples.

**Table 1:** Total numbers of samples month wise and percentage of preanalytical errors

Month	OPD	IPD	Emergency	Total	Number of rejected samples	% of error
October,2018	2741	2106	300	5147	78	1.52%
November,2018	2282	1860	321	4463	69	1.55%
December,2018	2537	2017	334	4888	60	1.23%
January,2019	4589	2025	313	6927	87	1.26%
February,2019	4398	1699	263	6360	79	1.24%
March,2019	3493	1781	244	5518	88	1.59%
<b>Total</b>	<b>20040</b>	<b>11488</b>	<b>1775</b>	<b>33303</b>	<b>461</b>	<b>1.38%</b>

**Table 2:** Number of OPD samples and percentage of preanalytical errors

Month	OPD	Number of rejected samples	Percentage (%)of error
October,2018	2741	24	0.88%
November,2018	2282	19	0.83%
December,2018	2537	15	0.59%
January,2019	4589	21	0.46%
February,2019	4398	19	0.43%
March,2019	3493	23	0.65%
<b>Total</b>	<b>20040</b>	<b>121</b>	<b>0.60%</b>

**Table 3:** Number of IPD samples and percentage of preanalytical errors

Month	IPD	Number of rejected sample	Percentage(%) of error
October,2018	2106	40	1.89%
November,2018	1860	37	1.99%
December,2018	2017	26	1.29%
January,2019	2025	46	2.27%
February,2019	1699	50	2.94%
March,2019	1781	49	2.75%
<b>Total</b>	<b>11488</b>	<b>248</b>	<b>2.16%</b>

**Table 4:** Number of samples from Emergency and Percentage (%) of preanalytical errors

Month	Emergency	Number of rejected samples	Percentage(%) of error
October,2018	300	14	4.66%
November,2018	321	13	4.05%
December,2018	334	19	5.69%
January,2019	313	20	6.39%
February,2019	263	10	3.80%
March,2019	244	16	6.56%
<b>Total</b>	<b>1775</b>	<b>92</b>	<b>5.18%</b>

**Table 5:** Types of preanalytical errors

Types	Type of error in rejected samp (n=461)
Incomplete requisition form	159
Hemolysis of sample	98
Inadequate volume of blood	86
Collection in wrong vacuitainer	19
Clotted blood	11
Wrong labeling of sample	09
Others	79

## DISCUSSION

Laboratory plays a very important role in diagnosis and management of disease and in emergency unit management is mostly dependents on laboratory reports, but laboratory procedures are prone for errors specially in preanalytical phase of the testing process. [9] The advancement in the technology like automation and computerization of the tests reduces the error rates but whole process of testing is not free from error. The major contributors being the pre-analytical errors as it involve various steps and various levels of professionals [10]

In this study we found that commonest error in preanalytical phase was incorrect or incomplete filling of requisition forms. Other researchers also reported that important source of pre-analytical error is incorrect or incomplete information on the test request or labels which have been found in more than two thirds of all rejected samples in the laboratory. [11] Incomplete filling of requisition form was found to be the commonest cause of preanalytical error in our study with regard to patient age, confusion with same name, missing guardian's name, referring physician's name, provisional diagnosis etc. Munilaxmi et al, 2018 reported that around 0.63% (618) and 1.37% (559) samples received from inpatient and outpatients respectively had incomplete requisition forms.[12] Chawla R et al., 2010 and Nikolac N, 2014 reported that these errors affects the reporting system of the laboratory, unnecessary test repetition management of a case if a critical value for that particular analyte is observed. [13,14]

In this study haemolysis was the second commonest cause of sample rejection. Commonest causes of hemolysis are improper phlebotomy techniques, insufficient additive in blood collection tube, trauma during venipuncture or double puncture of veins, vigorous shaking of tubes after collection and forcefully transferring blood in collection tube after venipuncture through needle, use of antiseptics like alcohol as disinfectant if not dried properly, longer duration of tourniquet application. Periodic training of staff and following standard operating procedures for venipuncture are required to avoid hemolysis of the patient sample. [15,16]

Inadequate volume of sample is the another cause of sample rejection and in this study. The main reason for this is the ignorance by the phlebotomist, difficulty in sampling as in pediatric patients, anemic patients, debilitated cases, patients on chemotherapy and in obese patients with difficult to localize veins or in cases of shock. Hollensead SC et al in their study reported that in OPD patients insufficient sample constituted the most frequent cause of test rejection. [17]

## CONCLUSION

In hospitals laboratory services plays a very important role in the diagnosis of a disease, its management as well as prognosis. In spite of rapid advancement in laboratory care services still various manual and systemic errors are reported. Most of the errors occur in the preanalytical phase because of the involvement of various personnel other than laboratory staff. To prevent these error periodic training of staff involved in sample collection, labeling, transport is necessary.

Laboratories should implement strict quality assurance programmes to provide quality laboratory services.

**Conflicts of interest:** Nil.

**Authors' Contribution:** All three authors have involved in planning project, implementing, data collection and analysis.

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