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## Original Research Article

# Risk assessment of pre-analytical errors and their impact on patient safety in a tertiary care centre in South India

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## ABSTRACT

**Aims and Objectives:** To identify the different preanalytical errors encountered in the central laboratory and to adopt the corrective measures to overcome them. To identify the cause of the preanalytical errors. To evaluate the impact of corrective measures and their role on patients safety

**Materials and Methods:** The study comprised of 500 samples over a period of one year in Central Laboratory, Mahatma Gandhi Medical College and Research Institute, Pondicherry. The study included all the samples collected from the patients that are sent to the Central laboratory, Mahatma Gandhi Medical College and Research Institute, departments like Pathology, Biochemistry and Microbiology. The samples were received along with the patients request form which included the patients details like name, age, sex, treating clinician, place of admission or where from the sample was collected, nature of the sample, the name of the test, clinical diagnosis etc.

**Results:** Amongst 500 samples received, preanalytical errors were detected in 263(52.6%) samples. Majority 83.6% were from inpatient wards, whereas 16.4% samples were from outpatient departments. 58.1% of samples were from Hematology, 21.6% of samples were from Biochemistry and 20.1% of samples were from Microbiology. 54.3% of samples were blood samples, 42.9% of were serum samples and 2.6% of were urine samples. The most common pre-analytical error encountered was insufficient volume accounting to 27.7% and least encountered pre-analytical error was Lipemic sample accounting to 7.2%. Failure Mode and Effects Analysis(FMEA) was applied and insufficient volume, diluted sample, mismatch name, clotted sample and lipemic sample were graded as very high with scale of 8. Insufficient information alone was graded as high grade with scale 7.

**Conclusion:** It is the need of the hour to adopt adequate, effective corrective strategies to curb the pre-analytical errors in the laboratory, thereby ensuring safety and satisfaction to the patients and clinicians, which would pave the way for an efficient health care system.

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## 1. Introduction

The clinical laboratory plays an increasingly pivotal role in the patient-care services. Physicians depend on accurate laboratory test results for proper disease diagnosis and for establishment of exact therapy.<sup>1</sup> Clinical laboratory errors can reflect on increased healthcare costs and decreased patient satisfaction. Laboratory errors can happen

at any of the three stages, studies show that the pre-analytical phase accounts for 46% to 68.2%.<sup>2</sup> However, with recent improvements in pre-analytical automation, the pre-analytical phase is still the most error-prone phase in a laboratory.<sup>2</sup> Thus, this study is done to identify the different preanalytical errors in the central laboratory and corrective strategies taken to overcome them.

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## 2. Material and Methods

Current study was a descriptive one and it was carried out in the Central Laboratory, Mahatma Gandhi Medical College and Research Institute, Pondicherry. Duration of study was one year from September 2018 to August 2019. The study included all the samples collected from the Central laboratory, Mahatma Gandhi Medical College and Research Institute, which included departments like Pathology, Biochemistry and Microbiology. The samples were received along with the patients request form which included the necessary and mandatory patients details. The errors in the preanalytical phase were noted as per the ISO 15189: 2012 in a separate register and risk on the patient safety was assessed based on Failure model and effects analysis (FMEA) and categorised into various grades of severity like highly hazardous, hazardous, very high, high, moderate and low.<sup>3</sup> Necessary corrective measures were implemented and pre-analytical errors were reassessed. A total of 500 samples were studied in this study period. Amongst 500 samples received, preanalytical errors were detected in 263 samples. The study and data accumulation were carried out with approval from the Institutional Human Ethics Committee. Z-test was applied to compare the results pre and post intervention of corrective measures.

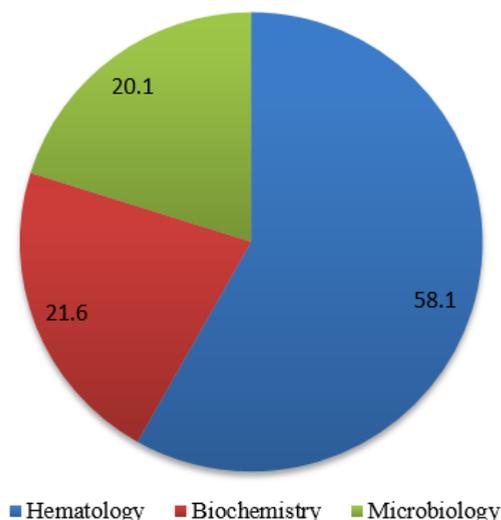
## 3. Results

Amongst 263 samples that had pre-analytical errors, Majority 83.6% were from inpatient wards, whereas 16.4% samples were from outpatient departments, 58.1% samples that had pre-analytical errors, were from Hematology, 21.6% samples were from Biochemistry and 20.1% samples were from Microbiology. Refer to Figure 1. for the frequency of pre-analytical errors department wise.

167(63.4 %) samples were blood samples, 89(33.8%) were serum samples and 7(2.6%) were urine samples. The pre-analytical errors detected were Insufficient volume (27.7%), Diluted sample (14.8%), Insufficient information (wrong vial/wrong slip) (14.4%), Mismatch name (8.3%), Clotted sample (15.2%), Lipemic sample (7.2%) and Hemolysed sample (12.16%). The most common pre-analytical error encountered was insufficient volume accounting to 27.7% and least encountered pre-analytical error was Lipemic sample accounting to 7.2%. The causes for the pre-analytical errors were evaluated, and the most common cause was lack of proper technique of phlebotomy by the nurses and phlebotomists, which was overcome by providing necessary training programmes and revision of Standard Operating Protocol(SOP). Table 1: percentage of pre-analytical errors and nature of sample.

Failure Mode and Effects Analysis (FMEA) was applied to assess the severity of risk of pre-analytical error on patients safety. Out of all the pre-analytical errors, insufficient volume, diluted sample, mismatch name, clotted

## Frequency of pre-analytical errors department wise



**Fig. 1:** Frequency of pre-analytical errors department wise

sample and lipemic sample were graded as very high with scale of 8, as lipemic sample can seriously interfere in patients value interpretation and can also affect in clinical management of the patient. Insufficient information alone was graded as high grade with scale 7. Table 2: severity of risk assessment of pre-analytical errors.

A total of 500 samples were studied again, after implementation of the above corrective strategies in the laboratory. Amongst 500 samples, 87(17.4%) samples had pre-analytical errors. Out of 87 samples that had pre-analytical errors, 53(60%) samples that had pre-analytical errors, were from inpatient and 34(39%) samples were from out-patient. Refer to table 3: corrective strategies in reducing pre-analytical errors in central laboratory. Z-test was calculated, on comparing the results of pre and post intervention, which showed  $z=11.6$  and  $p=0.001$ . Thus, showing statistical significance.

## 4. Discussion

In the present study, out of 263 samples that had pre-analytical errors, majority 83.6 % were from inpatient wards and 16.4 % were from outpatient departments. Study conducted by Pavani B et al also showed majority of percentage from inpatient departments.<sup>4</sup> Our study coincides with the above mentioned study. In the present study, out of 263 samples that had pre-analytical errors, 58.1 % were from Hematology, 21.6 % were from Biochemistry and 20.1 % were from Microbiology. This is the only study which included samples from Hematology, Biochemistry and Microbiology. Other studies conducted by Shashi Upreti et al, Shukla et al, Narang et al and Pavani B

**Table 1:** Percentage of pre-analytical errors and nature of sample

Type of pre-analytical error	Blood sample n(%)	Serum sample n(%)	Urine sample n(%)	Total number of errors n(%)
Insufficient volume	52(36.3%)	17(15%)	4(57.1%)	73(27.7%)
Diluted sample	39(27.2%)	0	0	39(14.8%)
Insufficient information (wrong vial/wrong slip)	20(13.9%)	15(13.2%)	3(42.8%)	38(14.4%)
Mismatch name	16(11.1%)	6(5.3%)	0	22(8.3%)
Clotted sample	40(15.2%)	0	0	40(15.2%)
Lipemic sample	0	19(16.8%)	0	19(7.2%)
Hemolysed sample	0	32(28.3%)	0	32(12.16%)
				263(100%)

**Table 2:** Severity of risk assessment of pre-analytical errors

Type of pre-analytical error	Degree of severity	Scale
Insufficient volume	Very high	8
Diluted sample	Very high	8
Insufficient information (wrong vial/wrong slip)	High	7
Mismatch name	Very high	8
Clotted sample	Very high	8
Lipemic sample	Very high	8

**Table 3:** Corrective strategies in reducing pre-analytical errors in central laboratory

Insufficient volume	<ul style="list-style-type: none"> <li>● Request for repeat sample</li> <li>● Maintenance of register for sample rejection</li> <li>● Training programme given to nurses and phlebotomists about proper collection of samples for a period of three months</li> </ul>
Diluted sample	<ul style="list-style-type: none"> <li>● Request for repeat sample</li> <li>● Maintenance of register for sample rejection</li> <li>● Training programme given to nurses and phlebotomists about proper collection of samples for a period of three months</li> </ul>
Insufficient information (wrong vial/wrong slip)	<ul style="list-style-type: none"> <li>● Request for Repeat sample if sent in wrong vial or request for the correct vial</li> <li>● Request for adequate details in the request form</li> <li>● Training programme given to nurses about proper collection of samples for a period of three months</li> </ul>
Mismatch name	<ul style="list-style-type: none"> <li>● Maintenance of register for sample rejection</li> <li>● Request for correct details on the vial or container and the form</li> <li>● Training programme given to nurses about proper collection of samples for a period of three months</li> </ul>
Clotted sample	<ul style="list-style-type: none"> <li>● Maintenance of register for sample rejection</li> <li>● Request for repeat sample</li> <li>● Training programme given to nurses and phlebotomists about proper collection of samples for a period of three months</li> </ul>
Lipemic sample	<ul style="list-style-type: none"> <li>● Maintenance of register for sample rejection</li> <li>● Request for repeat sample</li> <li>● Training programme given to nurses and phlebotomists about proper collection of samples</li> <li>● Provide proper instructions to the patients before collection of samples</li> </ul>

et al included samples from Hematology, whereas study conducted by Sumera Naz et al included samples from Biochemistry.<sup>4-8</sup> Out of 263 samples that had pre-analytical errors, 54.3 % samples were blood samples, 42.9% were serum samples and 2.6% were urine samples. Whereas, studies conducted by Shashi Upreti et al, Shukla et al, Narang et al and Pavani B et al involved blood samples, and study conducted by Sumera Naz et al. involved serological samples.<sup>4-8</sup> No study showed pre-analytical errors of urine samples. Our study more or less correlates with the above studies.

In the present study, the most common cause of pre-analytical error in blood and urine samples was insufficient volume, which accounted to 36.3 % and 57.1 %, whereas the most common cause of pre-analytical error in serological samples was hemolysis. which accounted to 28.3 %. Studies conducted by Shukla et al, Narang et al and Sumera Naz et al showed the most common cause of pre-analytical error was clotted sample, whereas study conducted by Pavani B et al showed the most common cause of pre-analytical error was mismatch sample.<sup>4-8</sup> This is because the nursing staff didn't draw enough volume of blood and few samples were hemolysed on transportation.

Although, there are many articles on pre-analytical errors and their corrective actions in a laboratory, there are very few articles with risk assessment of safety on patient and implementation of FMEA( Failure model and effects analysis).So, in order to bring such pre-analytical errors under control, regular training programmes for the laboratory technicians and diagnosticians should be implemented as a hospital policy, followed by assessment of the knowledge and skills in the quality management system of laboratory.

## 5. Conclusion

Although there are lots of development in analytical phase of testing in clinical labs, many errors still occur and they will continue to occur in pre-analytical phase.<sup>9</sup> Such pre-analytical errors can be overcome by better coordination between labs and wards, continuing medical education programmes of laboratory staff, computerization of the labs and competency check of staff.<sup>10</sup>

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## 7. Conflict of Interest

The authors declare they have no conflict of interest.

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