



## Small Steps for a Big Change: Attention towards Preanalytical Error

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### Authors' contributions

*This work was carried out in collaboration among all authors. Author SDS designed the study, performed the statistical analysis. Author AAP wrote the protocol and wrote the first draft of the manuscript. Author AAB managed the analyses of the study. Author SV managed the literature searches. All authors read and approved the final manuscript.*

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### ABSTRACT

**Aims:** The study aimed to evaluate the preanalytical errors in the Indoor patient department in tertiary care Hospital. To calculate the percentage of preanalytical errors in the Indoor patient department in our Hospital and to recommend standard operative interventions to improve quality of results. To test the effectiveness of attention by continuous educational action at reducing preanalytical errors and improving patient care.

**Study Design:** An observational study.

**Place and Duration of Study:** The work was done from July 2014 to July 2015 at a tertiary care Hospital India.

**Methodology:** We retrospectively reviewed the samples and test request forms received at Biochemistry laboratory for one month. The outcome measures were incomplete laboratory forms, mislabeling samples, inappropriate tests, wrong container, poor quality of samples and

transportation problems. Two weeks of interventions in the form of continuous educational training and education regarding standard operative procedures were given to stakeholders to raise awareness towards the preanalytical phase. Two weeks later, data was monitored again for one month.

**Results:** 2330 and 2130 samples and request forms were monitored before-after intervention respectively from wards for one month each. Of the total chances of preanalytical errors, 22.17% were due to inappropriate tests, 81.5% were related to incomplete patient information, 97% lacking clinical information, 18.8% errors related to specimen information, 3.5% errors were of the deranged quality of the specimen, and in 4.5% transportation problems were observed. Subsequently, these were reduced to 10%, 20%, 16.4%, 7.5%, 2.3%, 3.1% respectively. A significant difference in percentage change was observed in all the above errors after the one-month interventions for the reduction in preanalytical errors.

**Conclusion:** The results of the present study revealed that taking small steps in the form of implementing standard operative procedures for collection, storage and transport facilities and continuous educational training of stakeholders would reduce big errors occurring due to human factors in preanalytical phase. We need good interdepartmental communication and cooperation to achieve good laboratory results and patient well being. This study improved the quality of test results and patient care.

*Keywords: Preanalytical error; indoor patient; standard operative interventions; patient care.*

## 1. INTRODUCTION

The three main phases in laboratory testing are preanalytical, analytical and post-analytical. Of these, the preanalytical phase is the major source of error, accounting for 81% of all the errors in lab tests. Pre-analytical errors occurring in each laboratory have to be checked. Such errors are not inevitable and can be avoided with a diligent application of quality control, continuing education and effective collection systems to ensure total quality patient care [1].

The last few decades have seen a significant decrease in the rates of analytical errors in clinical laboratories, and currently, the available evidence demonstrates that the pre- and post-analytical steps of the total testing process are more error-prone than the analytical phase [2]. The increasing attention paid to patient safety and the awareness that the information provided by clinical laboratories impacts directly on the treatment received by patients has made it a priority for clinical laboratories to reduce their error rates and promote an excellent level of quality [3]. The errors in health care can be prevented if we understand the human factors causing them [4]. The surgical specialties, emergency rooms and intensive care units have been previously identified as areas of risk for patient safety. The nature of work in these specialties and their interdependence on clinical diagnostic laboratories presents abundant opportunities for error-generating behaviour. However many of these errors can be prevented.

Appropriate attention to system factors involved in these errors and designing intelligent system approaches may help in controlling and eliminating many of these errors in health care [5]. From both the clinical and laboratory sides, there is a widespread perception that errors prevalently occur in the analytical phase which is due to instrument malfunctions, however, the great majority of laboratory flaws occur in the extra analytical phases of the total testing process [6].

In the performance of any laboratory tests, Lundberg described the brain-to-brain turnaround time as a series of nine steps consisting of ordering, collection, identification, transportation, preparation, analysis, reporting, interpretation and action [7].

The present study focuses on the pre-analytical stage intending to calculate the percentage of these errors in the Indoor and at the outdoor patient department of Hospital and to recommend some standard interventions to improve quality of results and patients welfare.

Our study shows the importance of standard blood collection procedures, proper storage and transport techniques and correct transcription of requisition form for laboratory analytical data for precise and accurate reporting of results to clinicians. We require urgent attention towards preanalytical errors and need close inter-departmental cooperation to meet the goal of ensuring patient well being.

## 2. MATERIALS AND METHODS

We retrospectively reviewed the samples and test request forms received at Central Biochemistry laboratory for one month. The study was conducted from July 2014 to July 2015 at tertiary care Hospital, India. Results obtained in the study were evaluated using Stat Pac calculator.

The outcome measures were incomplete laboratory forms, mislabeled samples, inappropriate tests, wrong container, quality of samples and transport problems. One month interventions in the form of various informative instructions & continuous technical education regarding outcome measures were given to stakeholders. By introducing various programmes awareness was created regarding standard operative procedures for taking attention towards the preanalytical phase. One month later, data was monitored again for similar outcome measures for one month.

An error is defined as a rejected specimen; any blood or urine sample which cannot be successfully tested as it does not meet the acceptability criteria of the laboratory or if the sample is not received [8].

**Some Do's and Don'ts are followed:** [9]

1. The vein to be punctured should be localized and the area should be cleaned with 70% alcohol or chlorhexidine. It should be allowed to air dry before venipuncture.
2. The tourniquet should not be applied for more than 1-2 minutes and the patient's fist should not be clenched repeatedly to visualize the vein.
3. Do not collect the blood from the vein or even from the arm which is receiving an infusion.
4. Avoid blood collection from an IV catheter.
5. If the needle slips after venipuncture, then it should be taken out and it should not be manipulated. A fresh prick should be made by using a fresh needle and syringe, even if there is no visible blood in the previous syringe.
6. Blood should not be poured into the vial/tube through the needle and with great pressure.
7. The amount of blood to be taken into an additive tube/vial should be exactly as is required for that tube/vial.
8. Do not shake the vial/tube vigorously after pouring the blood into it.

9. When collecting blood into containers, follow the following sequence: plain tube (no additive) – citrated tube – heparin tube – EDTA tube – fluoride tube.

## 3. RESULTS

2330 and 2130 samples and request forms were monitored before and after intervention respectively from wards for one month each. Of the total chances of preanalytical errors, 22.1% were due to inappropriate tests, 81.5% were related to incomplete patient information, 97% due to lacking clinical information, 18.8 % errors related to specimen information. Subsequently, these chances of errors were reduced to 10%, 20%, 16.4%, and 7.5% respectively. We analyzed the data using two-sample t-test between two percentages with the help of Stat Pac calculator.

Significant difference in percentage change was observed in many errors ( Table 1) after the one month interventions; however no statistically significant difference had been observed in errors such as wrong data collection time (  $p=0.400$ ), order entry error ( $p=1$ ), error in unique identification number ( $p=0.293$ ), hemolysis sample ( $p=0.523$ ), error in fluoride and sample volume ratio ( $p=0.652$ ), error as mislabeled sample ( $p=0.215$ ), diagnosis not written ( $p=1$ ), delayed transportation ( $p=0.070$ ) ( Table 1).

In our study, Inappropriate test request was found to be 22.17% before intervention which has decreased to 10 % after the intervention (Fig.1). The error due to the wrong bulb found to be decreased significantly after the intervention (4%) as compared with data before intervention (11.86%) (Fig. 2).

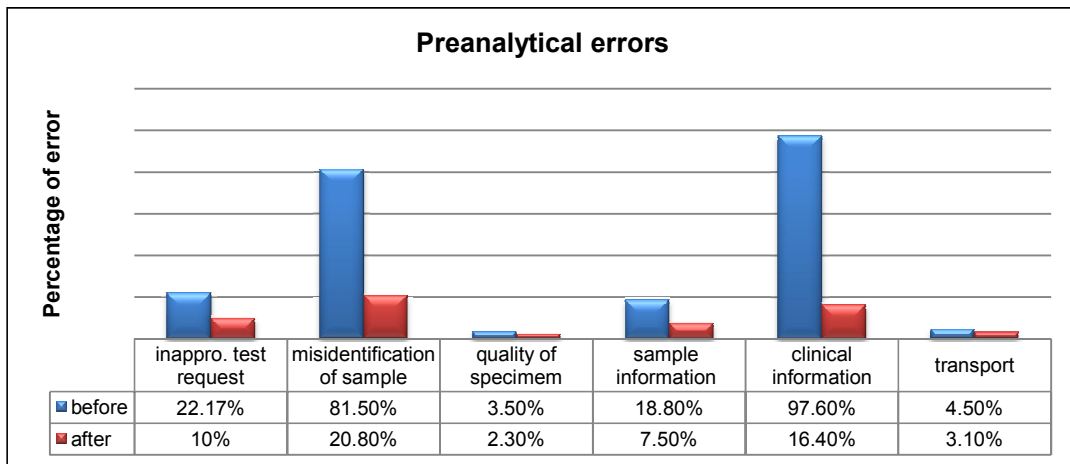
As per Fig. 3, more than 50% reduction in chances of misidentification of the patient has occurred after giving instructions for writing the full name of patients.

There was less reduction in the chances of errors that would be occurred due to the quality of the specimen (Fig. 4). These parameters require intensive attention to prevent such kind of errors which involves good collection practices & training of stakeholders.

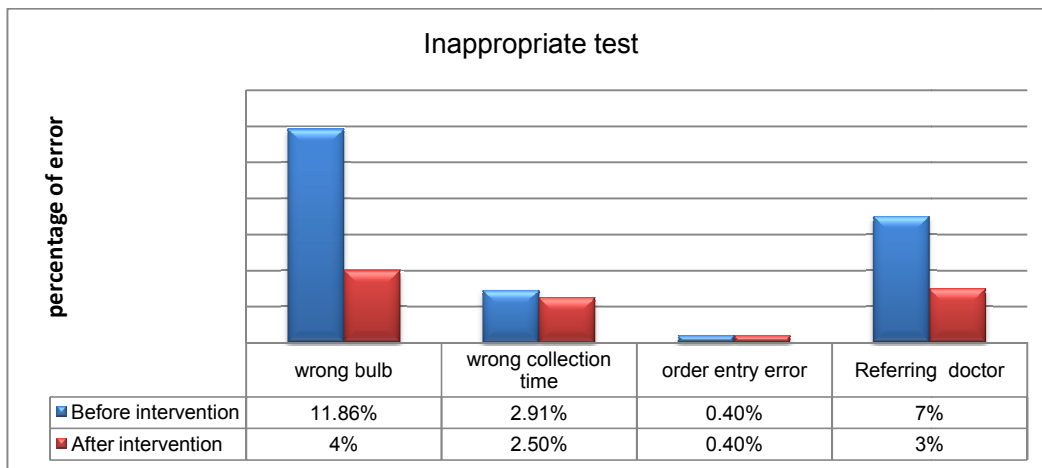
After the intervention, sample information observed to be written on requisition forms with the reduction in chances of the percentage of errors due to mislabeled sample, collection time and date and type of specimen (Fig.5).

Table 1. Preanalytical errors

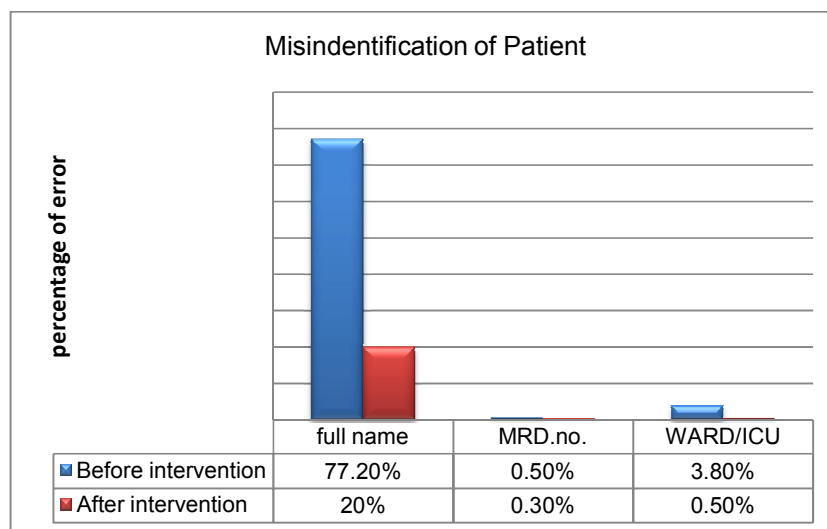
Preanalytical errors		Before intervention		After intervention		p-value
		No. of samples	Percentage	No. of samples	percentage	
Inappropriate test request	1.wrong bulb	276	11.86 %	85	4 %	p< 0.05
	2.wrong collection time	68	2.91 %	53	2.5%	p=0.40
	3.order entry error	8	0.4%	8	0.4%	p=1.0
	4.Referring doctor	164	7%	63	3%	p< 0.05
	Total	516	22.17 %	209	10 %	p< 0.05
Misidentification of patient	1.full name	1800	77.2%	426	20%	p< 0.05
	2. Unique identification no.	12	0.5%	6	0.3%	p=0.293
	3.WARD/ICU	90	3.8%	10	0.5%	p< 0.05
	Total	1902	81.5%	442	20.8%	p< 0.05
Quality of Specimen	1.Hemolysed sample	28	1.2%	21	1%	p=0.523
	2.fluoride:sample volume ratio	15	0.6%	10	0.5%	p=0.652
	3.Quantity insufficient	40	1.7%	17	0.8%	p< 0.05
	Total	83	3.5%	48	2.3%	p< 0.05
Sample information	1.Mislabelled sample	20	0.8%	10	0.5%	p=0.215
	2.Collection time & date	68	3%	21	1%	p< 0.05
	3.Type of specimen	344	15%	127	6%	p< 0.05
	Total	432	18.8%	158	7.5%	p< 0.05
Clinical information	1.Prov.diagnosis+Age+sex +Ref. doctor Not written	2256	96.8%	340	16%	p< 0.05
	Only sex not written	20	0.8%	10	0.3%	p< 0.05
	The only diagnosis not written	4	0.1%	4	0.1%	p=1.0
	Total	2280	97.7%	354	16.4%	p< 0.05
Transport	1.Transport delayed	96	4%	63	3%	p=0.07
	2.Misplaced samples	12	0.5%	2	0.1%	p< 0.05
	Total	108	4.5%	65	3.1%	p< 0.05



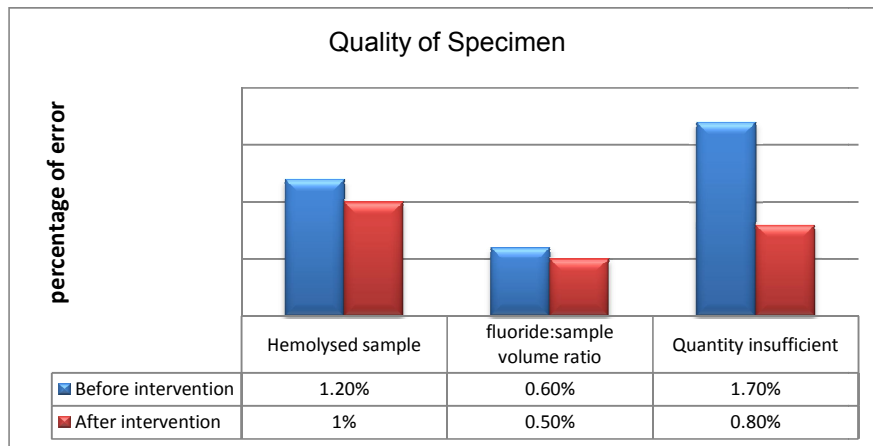
**Fig. 1. Preanalytical errors**



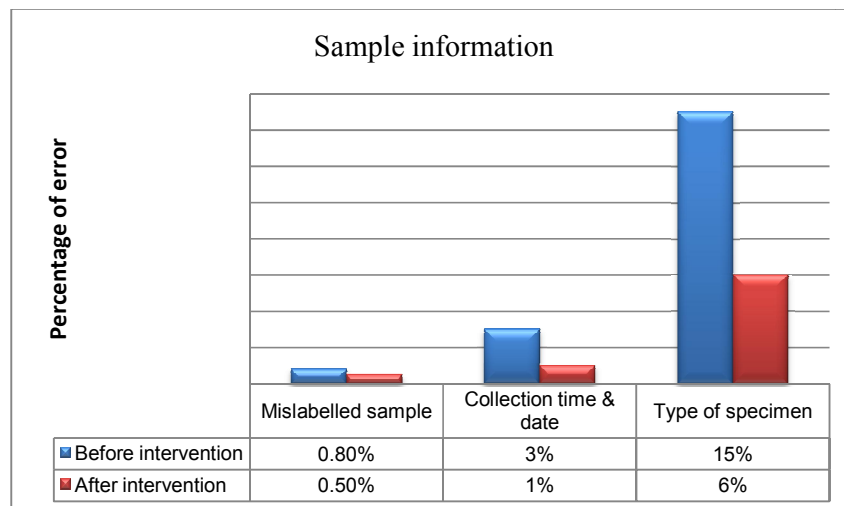
**Fig. 2. Inappropriate test request**



**Fig. 3. Misidentification of patient**



**Fig. 4. Quality of Specimen**



**Fig. 5. Sample information**

As per Fig. 6, Clinical information is seen to be written on more than 80% of requisition forms that would help in the clinical correlation of reports and improving the quality of laboratory services.

Percentage of error due to transport delay was 4% before the intervention and 3% after intervention. There was not more reduction in chances of errors due to transport facilities. For the emergency test, we would have to establish good Point of test caring units under Central Biochemistry laboratory to avoid errors due to transport delayed (Fig. 7).

#### 4. DISCUSSION

A study by Salinas M *et al* showed that there is a high incidence of preanalytical errors and

variability between health departments which suggests that there is a need to standardize the drawing practice [10].

Stankovic Ana K, et al. study showed that the preanalytical phase of the testing process is complex and labour intensive. The more steps involved in a process more likely will be errors committed. The author stated that Between 32 and 75% of all test errors occur in the preanalytical phase [11].

A Study by Dr Nigam states that Preanalytical process involves patient, physician, resident doctor, nurse, technician, laboratory personnel and the transport service. Therefore, all of them are required to know about the preanalytical variables, their possible sources and their effects

on the test results. Moreover, since the resident doctors have direct interaction with the paramedical staff, it is very important for them to understand the preanalytical variables so that they could instruct the paramedical staff accordingly [9]. Thus, by following standard operating procedures vigorously from patient preparation to sample processing, the laboratory results can be significantly improved without any extra cost. But the extra-analytical phase (preanalytical and the post-analytical stage) is still the source of concern as they can lead to an unpredictable and unfavourable impact on the well being of patients. Various researchers have reported that 46-68.2% of laboratory errors occur in the pre-analytical phase which is mainly due to

lack of standardized protocols for defining and measuring pre-analytical variables [12,13].

A similar study done by Nutt *et al* reported that the information regarding the details of treating physician was missing in 61.2%, the details of diagnosis was not indicated in 19.1% whereas in 80.9% where the only provisional diagnosis was mentioned. In a total of 151 Critical results encountered in their study, 19.9% were not communicated to physicians [14].

Misinterpretation of laboratory test results or ineffectiveness in their notification can lead to diagnostic errors or errors in identifying patients' critical condition. Incorrect interpretation of tests

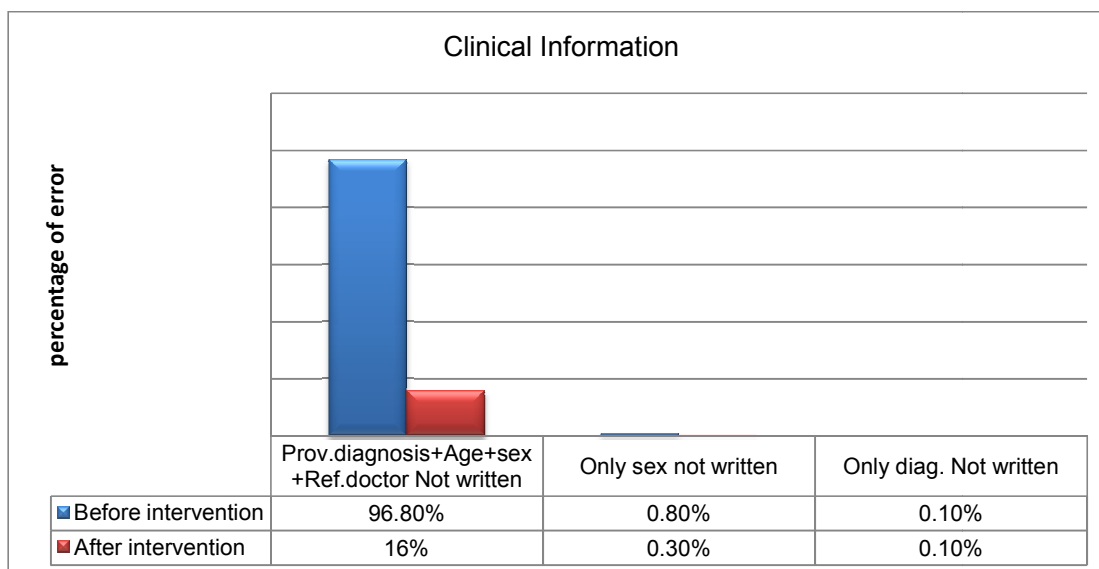


Fig. 6. Clinical Information not written

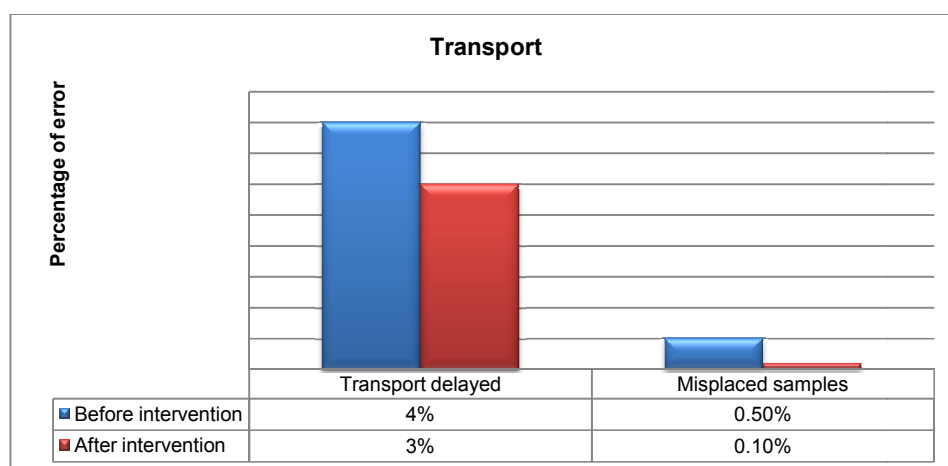


Fig. 7. Transport

and the breakdown in the communication of critical values are preventable errors; hence every effort should be made to prevent the types of errors that potentially harm patients. Clinical laboratories can, therefore, work to improve clinical effectiveness, without forgetting that everything should be designed to provide the best outcomes for patients [15].

The major contributors of the pre-analytical errors are complex as they involve numerous steps and various levels of professionals. Since the majority of the errors in the total testing phase originate in the preanalytical phase, these errors can be minimized by ensuring that the specimens are obtained from the right patient [16].

A study by Kemp et al. proved that despite enthusiasm on the part of the ward-based staff, both short-term interventions had no significant impact on preanalytical error rates. Most errors are due to human factors. These may be reduced with the introduction of an electronic ordering system [17].

Another study by Da Rin developed a comprehensive plan to prevent pre-analytic errors which have five interrelated steps: [18-20]

1. Developing clear written procedures.
2. Enhancing healthcare professional training.
3. Automating functions, both for support operations and for executive operations.
4. Monitoring quality indicators.
5. Improving communication among healthcare professionals and fostering interdepartmental cooperation.

According to Simundic et al., Continuous educational action is needed for all stakeholders involved in laboratory testing to improve the quality of the preanalytical phase of the total testing process. Properly collected blood samples will lead to the patient being correctly diagnosed [21].

A study by Green et al. stated that errors that occur in the preanalytical phase of testing may account for up to 75% of total laboratory errors; 26% of these may have detrimental effects on patient care, which contribute to unnecessary investigations or inappropriate treatment, increase in lengths of hospital stay, as well as dissatisfaction with healthcare services [22].

## 5. CONCLUSION

Our study demonstrated that chances of percentage-wise errors occurring in the preanalytical stages are more common and could be avoided by implementing small steps to deliver accurate results in analytical stages.

The combined decrease of errors after intervention in preanalytical stages such as of inappropriate test requests, quality of the specimen, misidentification of patients, clinical information and transport would be of immense help to increase the accuracy of reports and helping in clinical diagnosis. Thus, the results of the present study revealed that taking small steps in the form of implementing standard operative procedures for collection, storage and transport facilities and continuous educational training of stakeholders would reduce big errors occurring due to human factors in preanalytical phase. We need good interdepartmental communication and cooperation to achieve good laboratory results and patient well being. This study improved the quality of test results and patient care.

Further studies involving large scale sample size are needed to elucidate and to confirm the findings of the present study.

## CONSENT

All authors declare that 'written informed consent was obtained from the Patients'

## ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the institutional ethics committee and have therefore been performed following the ethical standards laid down in the 1964 declaration of Helsinki.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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