

Preanalytical Errors in Laboratory - Their Consequences and Measures to Reduce Them

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ABSTRACT

Laboratory process is a highly complex process and the problem of laboratory errors has recently received great attentions, which will perhaps increase. The quality of the pre-analytical phase plays a crucial role in obtaining trustworthy test results, thus promoting patients' health, diagnostics and facilitating analysis of the effectiveness of the treatment.

Laboratory data are broadly used in medical practice thus laboratory errors have a great impact on patient safety. Studies indicate that pre-analytical errors contribute a major proportion of errors in laboratory processes and contribute to a number of risks related to the patient safety. Therefore, laboratory services are designed to identify and minimize these errors and improve patient safety.

The studies conducted in the area indicate that laboratory errors in pre-analytical phase are significant and health care facilities focus on handling them in a way that ultimately reduces those errors. From the secondary data, it was found out that in laboratory processes the most common errors are- patient misidentification, mislabeled or unlabelled containers, inappropriate storage conditions, inappropriate transportation etc.

The purpose of this paper is to identify the frequently encountered laboratory errors at pre-analytical phase, their hazards on patients' health and consequences in managing the healthcare organizations, and some measures to minimize or to remove these errors.

Keywords:

Pre-analytical errors, Patient safety, Consequences of pre-analytical errors.

INTRODUCTION

Medical errors described as human errors in healthcare. Medical errors defined as, it occurs when a healthcare provider chooses an inappropriate method of care or improperly executes a proper method of care. A medical error is an avoidable adverse effect of care, whether or not it is harmful to the patient.

A Harvard study by Prof. Jha indicates that 5.2 million medical errors occur in India annually.

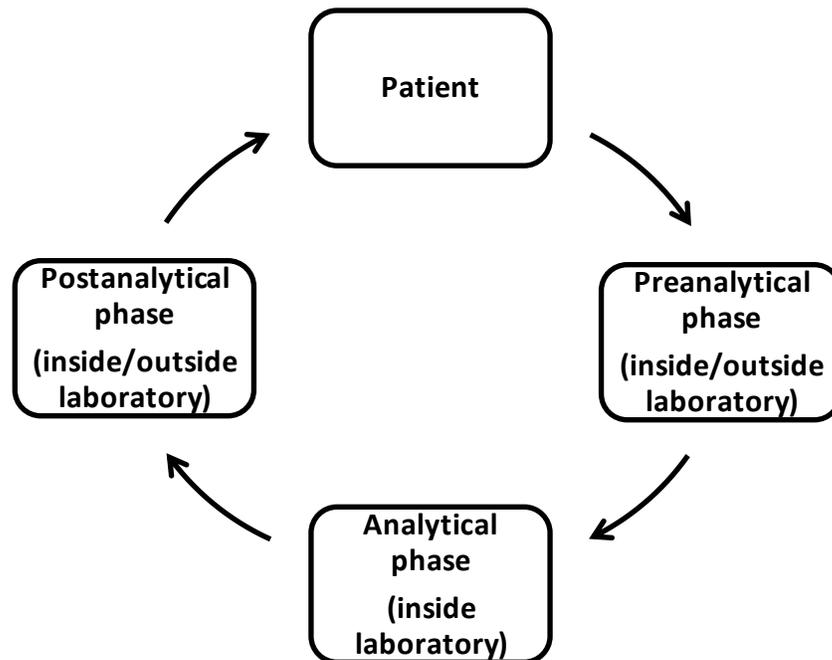
Laboratory error is any error made by the workforce in a medical laboratory in performing a test, interpreting data, or reporting the results. The accuracy of any laboratory test depends upon numerous factors like the collection of sample at the proper time, collection of specimen in a specific container, storage & transportation of sample, technique/methods used for testing etc.

Laboratory errors occur mainly at 3 phases- pre-analytical phase, analytical phase and post-analytical phase. A common assumption is that errors are probably occurring in the analytical phase. The recent surveys on laboratory errors say that in the delivery of laboratory testing, errors occur more frequently in pre-analytical and post-analytical phases. Studies indicate that the total errors that occur at the pre-analytical phase range between 45 to 70% of the total laboratory errors. These errors are related to manual activities during this phase. However, 18-47% of the total errors have also been found in the post-analytical phase. With the standardization, automation, and better awareness, errors due to analytical factors have been significantly reduced over time.

The pre-analytical phase occurs outside the laboratory away from its control, consisting of the selection of appropriate tests, ordering, collection and handling, transportation and preparation of samples to make them suitable for analysis.

The second phase is the analytic phases. This phase includes what is generally considered the "actual" laboratory testing. The analytical phase of laboratory testing begins when the patient specimen is prepared in the laboratory for testing, and it ends when the test result is interpreted and confirmed by the technicians in the laboratory. Not processing a specimen properly prior to analysis can affect test results in the analytical phase.

The post-analytic phase is the final phase of the laboratory processes. In this phase of the testing process, results are released to the clinicians. This phase conclude the production of a final result, or in the case of histology, a diagnostic pathology report.



There are some variables that can cause errors in the pre-analytical phase of the laboratory testing. These variables are patient variables (age, gender, diet, medication, body mass etc.), specimen collection variables (time of collection, fasting status, posture etc) and specimen handling variables (temperature, sunlight, evaporation, labeling, transportation condition etc.). The laboratory staff should aware of all these variables to reduce the errors.

The pre-analytical phase of the testing process has an important effect on the reliability of patients' laboratory results and consequently, on the quality of patient care and on patient safety. Hence, identification of these factors is a challenge to nurses and to the quality of nursing care. Nurses play a vital role in taking and handling samples and in providing patients with accurate information prior to the tests.

OBJECTIVES

- To study the major errors those occur in pre-analytical phase of laboratory testing.
- To study the main reasons of the pre-analytical errors.
- To study the consequences of these pre-analytical errors.
- To identify the system/mechanism to minimize the effect of these errors.

METHODOLOGY

This research paper is based on secondary data. The information gathered through the various sources like-

- Books
- Journals
- Websites related with the healthcare management
- Newspapers
- Previous studies which held in healthcare setups (national & international)

DISCUSSION

This study shows that pre-analytical errors in laboratory testing processes are very serious problem. Pre-analytical phase has a significant effect on the reliability of laboratory results and on patients' safety. Focus on patient safety calls for increased attention to this issue and highlights the need to develop a new mode of action to avoid errors in laboratory testing.

To synthesize the data from the previous studies, pre-analytical errors occurred during three phases- before, during and after sample collection.

Before Collection

- **Inappropriate test request-** Inappropriate laboratory test over requesting is very frequent. This can result not only in a problem of cost but also in a problem regarding patient safety.
- **Failure to use guidelines-** It is a problem for the standardization of this critical part of the laboratory testing process. It is expected that all medical staff should follow all procedures to reduce risks.
- **Improper time of collection-** When advising patients how to prepare for tests it is necessary that nurses know when samples should be taken, the timing of the last meal, the time after taking any medicine and how long the patient has to wait before taking the sample.
- **Patient misidentification-** Several reviews reported that it is a serious error in the pre-analytical phase that can be related with high risk to the patient. Accuracy of patient identification is the most essential goal in improving patient safety.
- **Adaptation of patient-focus view-** Focusing on the sources of errors that could transform into harm and adverse events for the patient would encourage nursing staff to adopt a patient-focus view.

During Collection

- **Use of inappropriate container-** Some studies revealed that samples were collected in inappropriate containers preventing their analysis as a result need for re-call the patient for re-collection.
- **Contaminated sample-** Contamination from infusion route is most common error. Contaminated sample is not suitable for test which leads to rejection of the sample.
- **Variation in tube filling-** There were also problems related with filling of test tubes, both over filling and under filling, lead to unpredictable laboratory results.

- **Mislabeled specimens**- Mislabeled and unlabelled samples were also common errors in the pre-analytical phase.

After Collection

- **Inappropriate handling and storage conditions**- The studies also showed that handling and storage of samples outside the laboratory both have an impact on the quality of samples. Wrong storage conditions can cause errors in laboratory results.
- **Delayed processing samples**-After collection of the sample, it should be transported as quickly as possible to the laboratory.

FINDINGS

Reasons of Pre-analytical Errors

It is found that there are some major reasons that cause errors in pre-analytical phase of laboratory testing like unawareness among healthcare professionals, do not follow the guidelines, carelessness during the sample collection, handling, storage and transportation.

It is also noticed that the variables that impact pre-analytical errors can be classified as Patient variables, Specimen collection variables and Specimen handling variables. The below list depicts these variables -

Patient Variables	Specimen Collection Variables	Specimen Handling Variables
Age	Time of collection	Haemolysis

Gender	Posture	Temperature
Diet	Diurnal variation	Processing time
Body mass	Fasting status	Centrifugation
Medications	Tourniquet	Labeling
Smoking	Presence of IVs	Sunlight
Pregnancy	Capillary vs venous	Evaporation
Exercise	Anticoagulants	Lipemia
Dehydration	Order of draw	Transport conditions

Patient Variables-

Specimen composition is influenced by any of the patient variables listed in Table. In this, some are controllable, some are not. The laboratory staff must be aware of these influences and try to reduce the effects when possible.

Specimen Collection-

Specimen collection is perhaps the most critical among the controllable pre-analytic phase variables. Unacceptable specimens due to misidentification, inadequate volume to perform the test, or specimen quality issues (haemolyzed, clotted, contaminated, or collected in the wrong container) account for the majority of pre-analytic errors.

Specimen Handling-

From patient to laboratory, how a specimen is handled is an area of potential error and mostly outside control of the laboratory. Careful handling of the specimen during transport and processing is very important in maintaining the quality of collected specimen. The means of transport, exposure to heat and cold, vibration, position of specimen tubes and overall time to delivery can notably affect test results.

Major Pre-analytical Errors

- Missing sample and inappropriate test request
- Wrong or missing identification
- Contaminated samples
- Clotted, haemolysed, and insufficient samples
- Inappropriate containers
- Inappropriate blood to anticoagulant ratio
- Improper transport and storage conditions

Consequences of Pre-analytical Errors

- Time loss
- Delay in report
- Increased intra-laboratory activity
- Patient inconvenience
- Physician inconvenience
- Wrong medication
- Wrong further investigations & procedures
- May lead to death sometimes
- Poor quality impacts
- Reputation impact
- Cost impact

Measures to Reduce Pre-Analytical Errors

- Interdepartmental cooperation to improve the quality of test request
- Developing clear written procedures
- Checklist for all procedures in pre-analytical phase
- Enhancing health care professional training
- Requisition form should be randomly reviewed by doctors
- To check that requisition form sent to the laboratory along with the same specimen

- Labeling the syringe with patient ID to reduce the chance of misidentification
- Use barcode system for appropriate labeling
- Ensuring strict adherence to the handling and storage guidelines
- Quick transportation of sample
- Maintaining accession list at the time of specimen received
- Maintaining specimen rejected record
- Improving communication among health care professional
- Awareness programs for patients
- Accreditation of laboratories
- Internal laboratory audit at regular intervals
- External laboratory audit
- Quality audits
- Monitoring quality indicators

CONCLUSION

This study revealed that the pre-analytical errors can have a significant effect on reliable laboratory results and thus on patient safety.

Healthcare professionals play an important role in sample collection and in advising the patients on how to prepare for this. Awareness of quality failures in the pre-analytical phase and cooperation with personnel outside the laboratory are key factors for improving the quality of laboratory procedures and producing reliable results, thus enhancing patient safety.

Quality audits in laboratory should be used as a tool to detect errors caused by organizational problems outside the laboratory. More than half of the laboratory errors are related to pre-analytical phase; therefore, proper training and knowledge of intervening factors are important for reducing errors and optimizing the quality.

Besides carrying serious harms to patients' health, medical errors translate into a huge amount of money wiped out of the national and international economy.

Prevention of pre-analytical errors requires excellent communication and cooperation among all members of the health care team, from the phlebotomist who collects the sample, to the courier who picks up the samples for transport to the laboratory, to the personnel receiving the sample.

A practice of keeping records of the errors at all stages of analysis and then develops corrective strategies for their prevention can gradually free a laboratory from such errors.

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