

Preanalytical Errors and their Impact on Tests in Clinical Laboratory Practice

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Abstract

There are pre-analytical, analytical and post analytical factors that contribute to accurate test results in clinical laboratories. Pre-analytical variables account for 32-75% of laboratory errors, and encompass the time from when the test is ordered by the physician until the sample is ready for analysis. Most mistakes often occur before the samples are analysed. There is a need for stronger coordination between clinicians and personnel working outside the laboratory for improving the test quality.

Introduction

Advances in science and technology have led to transformation of laboratory diagnostics from manual, cumbersome testing methods to fully automated science, ensuring accuracy and speed. Advances in automation, sample collection, transportation, and dispatch of reports have led to a drastic improvement in the performance of laboratories. However, the laboratory cannot function in isolation and is dependent on other departments, mainly the clinical division for sending properly filled requisition slips and samples for analysis. Modern day diagnosis is heavily dependent upon reliable laboratory data. It is therefore, pertinent to ensure credibility of the results emanating from the clinical laboratories.

Quality is the core issue for all laboratories and this requires total quality management in the laboratory process in the pre-analytic, analytic, and post-analytic phases. The concept of total quality management encompasses all the steps involved in sample processing, beginning from test ordering to the final interpretation of results by the clinicians to reduce or eliminate the errors that may arise during the various steps. Promotion of ideal phlebotomy practices and sample transport procedures are a pre-requisite for the effective laboratory functioning. Dependence on accurate laboratory results for establishing diagnosis makes it mandatory for labs to ensure accountability and accuracy of results and negate incorrect diagnosis due to faulty report. Keeping record

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of the errors at all stages of analysis and devising corrective strategies for their future prevention can gradually free a laboratory from such errors.

The Total Testing Process

The total testing process is the entire process from ordering of a test to the interpretation of test result. It starts and ends with the patient, and can be subdivided into three phases i.e. pre-analytical step, analytical step and post-analytical step.

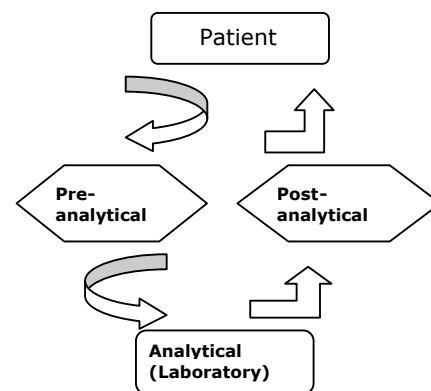


Figure 1: Total testing process starts and ends with patient

Pre-analytic Phase

This phase involves in the test request, patient and specimen identification, blood drawing sample collection, handling and the transportation of specimens to the laboratory.¹

Pre-analytic Errors

These include errors in specimen preparation which involves all activities to render a sample suitable for analysis. Log-in, centrifugation, aliquotting, pipetting,

dilution, and sorting specimens into batches for their introduction into automated analyzers are all included in pre analytical errors. Most studies demonstrated that a large percentage of laboratory errors occur in the pre and post analytical phases, with fewer mistakes occurring in analytical phase.²

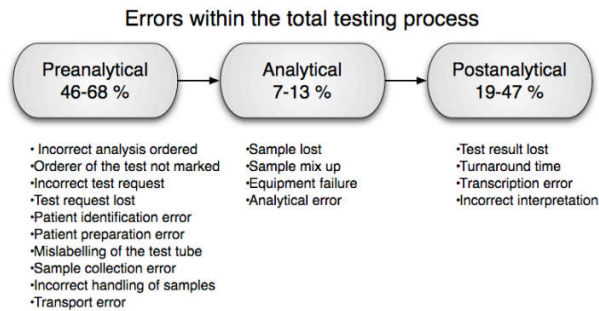


Figure 2: Distribution of errors within the total testing process. Included are the examples of errors in each step.

In the pre analytical phase, the important errors are as follows

a. Inappropriate Laboratory Test Requisition

Many studies indicate the importance of the pre-analytical phase. Misuse of laboratory services through requesting inappropriate laboratory test is under scrutiny worldwide because of its impact on total costs, and the inherent increased risk of medical errors and injury. The estimations of inappropriate laboratory tests vary from 11% to 70% for general biochemistry and hematology tests, 5% to 95% for urine screens and microbiology, and 17.4% to 55% for cardiac enzymes and thyroid tests.^{3,4}

b. Incomplete Laboratory Request Forms

One 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.⁵ Several other studies confirm that test requests can be a clinically important source of errors.⁶ Paper-based test requests are risky as they can be incompletely filled, placed in the wrong collection box, or simply be lost. Incomplete laboratory requests forms are rarely rejected at the service point and in many instances the reception staff in the laboratory may not know the significance of the missing data. Specific missing information included the physician's name, misidentification of patient and requested tests.⁷

c. Wrong Patient Identification

Correct patient identification is the most important task in all medical procedures, therefore,

efforts to ensure compliance with standardized identification routines should be prioritized.

Mistakes in patient identification before specimen collection is responsible for up to 25% of all pre-analytical errors⁸ while, critical patient identification errors occur in approximately 1 out of 1200 test requested.⁹ Mistakes in patient identification often occur during manual tasks which can be avoided using electronic technologies like barcodes, radiofrequency identification and wristbands.^{10,11} Wristbands have patient's name and identification number, and sometimes also have a barcode. Studies have reported error rates of 0.3–11% for identification wristbands mostly comprising of missing or incomplete wristbands, and wrong wristband on the patient.

d. Wrong Labeling of the Containers

Labeling of specimen containers should always be done immediately before sample collection while, labeling them after sample collection increases the risk of the specimen collection from the wrong patient. Mislabeling is responsible for 50% of all identification errors.¹²

e. Potential Outcomes of Collection Errors

Proper sample collection is an important part of good laboratory practice and improper collection can lead to delays in reporting, unnecessary re-draws/re-tests, decreased customer satisfaction, increased costs, incorrect diagnosis / treatment, injury and occasionally death.

Prescription practices: studies have shown the importance of checking for specimen adequacy as a critical factor in test result accuracy and usefulness.¹³ Samples that are missing, coagulated, hemolysed, insufficient or wrong due to inappropriate specimen collection and handling account for a large percentage of pre-analytical mistakes.

i. Inadequate Volume

Insufficient volume is a major factor leading to rejection of samples. The main reason for this anomaly is the ignorance of the phlebotomist, difficult sampling as in pediatric patients, debilitated cases, those on chemotherapy and those with difficult to localize veins. Insufficient sample constituted the most frequent cause of test rejection in a study done in out patients department (OPD).¹⁴

ii. Incorrect Phlebotomy Practices

Incorrect phlebotomy practices are also one of the main reason behind pre-analytical errors which occur due to lack of knowledge or heavy workload. Ideal

phlebotomy practices should be adopted by all health care workers.^{15,16}

iii. Lipemic Samples

Lipemic samples are often seen following collection after heavy meals or the due to pre existing metabolic disorder (hyperlipoproteinemias). Some of these errors can be avoided by collecting samples after an overnight fast or by mentioning the metabolic disorder in the requisition slip. Fat interferes with optical reading of the instrument and can affect electrolyte values.

Too many lipemic samples are often due to non-dissemination of information regarding patient preparation by the clinicians, non-compliance and/or miscomprehension by the patient.¹⁷ It is the responsibility of the clinicians and the phlebotomists to ensure that proper patient preparation is instituted before sample collection.

iv. Hemolysis

Hemolysis of samples occur when blood is forced through a fine needle, shaking the tubes vigorously, and centrifuging the sample specimens before clotting.¹³ Hemolysis accounts for the majority of rejections in specimen, received in the laboratory. The introduction of vacuum tubes along with the closed system of blood collection has made blood collection efficient and easy. But lack of staff training engaged in phlebotomy is an impediment for expediting sample collection and transport. Red top vacutainers without any anticoagulant should not be shaken after the sample has been collected, and vacutainers for plasma should be gently inverted a few times so the anticoagulant mixes with the blood. Freezing and thawing of blood specimens also causes massive hemolysis. A study reported that over 95% of the hemolysed samples were due to incorrect sampling procedure or transportation.¹⁸ Hemolysis leads to the extravasation of intracellular contents into the plasma, leading to false high values of potassium, aspartate amino transferase (AST) and lactate dehydrogenase (LDH).

f. Delayed Transport of Specimen

Transport delays to the laboratory can give rise to clinically important errors if transport conditions are not optimized.¹⁹

g. Errors in Specimen Preparation

The specimen preparation steps contribute to approximately 19% of the overall cost of analyzing a single specimen and are time-consuming (37% of time spent in producing result). Being infectious, manual handling of samples are a well-recognized hazard to laboratory staff.

Possible consequences of few of the above mentioned preanalytical errors are mentioned in the Table below. Patient identification is probably the most important task in sample collection and error in this crucial step could have mild to life threatening consequence. Therefore, efforts to ensure compliance with standard identification procedures should be prioritized. Similarly wrong container labeling could also result in mild to severe life threatening consequence.

Table: Possible consequences of preanalytical errors and their degree of seriousness.

S#	Preanalytical error	Possible consequence	Degree of seriousness
1	Patient identification	Sample collected from the wrong patient	Mild to Life threatening
2	Test tube labeling	Wrong patient's blood in the test tube	Mild to Life threatening
3	Test request management	Incomplete or erroneous test	Mild to Severe
4	Patient rest	Increased or decreased concentration of analysed substances	Mild to Moderate
5	Test tube inversion	No mixing of blood with additive	None to Moderate
6	Vertical test tube storage	Incorrect coagulation of serum samples	None to Mild

2. Biological Variations and Pre-analytical Errors

Other important sources of pre-analytical error not related to human mistakes include medications, which can cause errors through analytical (in vitro) or biological (in vivo) effects. Biological variation is the major source of variation for certain analyses.²⁰ It consists of two parts i.e. intra-individual part (normal variation of analyzed substance in each individual) or inter-individual part (normal variation of the analyzed substance between individuals). Other patient-related physical variables such as stress, diet and exercise can also affect test results.²¹

3. Rejection of Samples

The laboratory should establish rejection criteria and follow them closely. It is sometimes difficult to reject a sample, but it must be remembered that a poor sample will give poor results.

Management should regularly review the number of rejected samples and reasons for rejections by conducting audit and training on sample collection, and revising written procedures for sample management as and when needed. Always record the reason for rejection in the log book and include all pertinent information. Promptly inform the authorized person that the sample is unsuitable for testing and request for fresh sample. Retain the rejected sample till decision is finalized and in some circumstances it may be necessary to proceed with the testing of a sample that is not optimal.

To conclude, we as the laboratory workers need to adopt a holistic approach towards laboratory diagnosis and function in close coordination with the clinicians so as to provide effective diagnostic services to the patients. Adoption of quality control, not merely in the analytical processes, and regular appraisal and audits, but in all phases of diagnostic process is necessary to safeguard patient interests and to deliver quality services.

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