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Short Communication

PRE-ANALYTICAL ERRORS IN THE CLINICAL LABORATORY AND HOW TO MINIMIZE THEM

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Abstract: Since evidence based medicine (EBM) is now become the main principle guiding clinical practice and is being followed universally the role of laboratory medicine in EBM needs not to be over-emphasized. So it is the need of the hour to ensure that the best evidence on testing is made available through the help of the laboratory to the clinician. This would result in making the best decision based on test results which would lead to increased probability of improved health outcomes. So it is necessary for the laboratory to maintain the strictest quality possible. Here we would see the steps of pre-analytical phase and the various points at which error can arise and how to mitigate them. The present study was carried out in our hospital central laboratory and data were collected and analyzed. Pre-analytical phase is most important in testing process and involves variables that are not under the control of the laboratory. So much care needs to be taken to deeply scrutinize this step of analysis and keep a tab on errors arising in it.

Keywords: Errors, Pre-Analytical, Analytical, Post Analytical, Total Testing Process, Quality Improvement.

INTRODUCTION

Laboratory diagnostics is a fast-growing field, which provides a substantial contribution to the clinical decision making by supporting prevention, diagnosis, and therapeutic monitoring of most, if not all, human disorder. Quality and safety in diagnostic testing is, however, essential to furthering the goal of high-quality and safe healthcare, no other disciplines having such a prominent position in the patient safety solution than laboratory medicine.

The whole process of testing of a patient's blood from it's ordering to its testing and then to its reporting and ultimately reaching the treating doctor can be divided into three broad steps

1. Pre-analytical: specimen collection, transport and processing
2. Analytical: testing
3. Post-analytical: testing results transmission, interpretation, follow-up, retesting

Overall the three processes combined are called as 'total testing processes'. Errors can arise at any step and lead to a faulty report generation that can affect patient care like mis-diagnosis, improper treatment mismatched blood transfusion and so on can be sometimes be fatal.

Laboratory errors can be defined as "any defect from ordering tests to reporting results and appropriately interpreting and reacting on these".

Frequency of errors in clinical laboratories:

Most errors affecting laboratory test results occur in the pre - analytical phase (46–68.2% of total errors) while a high error rate (18.5–47% of total errors) has also been found in the post-analytical phase

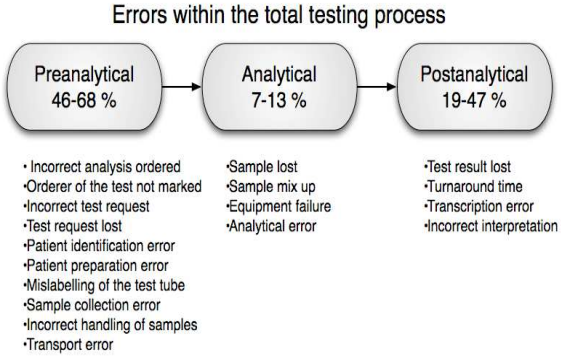

Figure: below shows the current stratification of errors in laboratory medicine and their distribution within the different phases of the testing processes

The traditional laboratory approach to correct pre analytical tasks has involved providing appropriate clinical history, proper patient preparation, proper collection of laboratory specimens (patient and specimen identification, appropriate sample collection containers), proper preparation of these samples (transportation, handling, accession), and assurance that the testing equipment was "in control" for testing. In a recent study by an ISO 9002:1994 certified clinical laboratory, 84.5% of errors detected in their laboratory occurred in the pre-analytical phase.

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Types of pre-analytical errors in laboratory testing

Type of error	Percent of pre-analytical errors
Inaccurate quality of specimen	47.0%
Wrong identification of the patient	26.8%
Missing physician order	14.0%
Inappropriate quantity of specimen	11.6%
Use of inappropriate container	0.6%

Various studies done have come out with different results regarding error rates per tests and their finding have been tabulated below

ERROR RATES IN CLINICAL LABORATORIES

ONE IDENTIFIED ERROR EVERY	
33 – 50 Events	Mcswiney and Woodrow
50 – 100 events	Souverijn *et al.*,
330 events	Chambers *et al.*,
1000 events	Boone
8300 laboratory results or 2000 patients	Lapworth and Teal
900 patients	Nutting *et al.*,
214 laboratory results	Plebani and Carraro
164 laboratory results	Stahl *et al.*,
283 laboratory results	Hofgartner and Tait

Pre-analytical errors should never be considered as inevitable as they can easily be prevented with the right training and the use of proper quality control procedures in all phases of the collection and testing process. All employees should be required to take continuing education classes to ensure that not only are they familiar with current procedures, but that they become aware of any changes that can serve to reduce the risk of this type of error occurring.

Order of draw of blood sample:

CLSI (former NCCLS) recently revised the specific order for collection of tubes and recommends this order:

1. Culture tubes (yellow top) or culture Non-additive or serum tubes (red top)
2. Citrate tubes (light top)
3. Gel separator tubes and clot activator tubes (in color top)
4. Heparin tubes (green top)
5. EDTA tubes (lavender top)
6. Other additive (color depends on manufacturer)

Scenario in the laboratory of KIM's hospital:

Sample collection: Outpatient samples are collected in the blood collection chamber by laboratory staff and since it is close to the laboratory sample are immediately transported to the laboratory for processing. Samples from inpatient are collected by the nursing staffs and transported to the laboratory through concerned personnel through proper manner taking special precaution were ever needed.

Color coded tubes are used to collect blood; urine and other biological fluid are collected in sterilized plastic collection bottles. Samples from IP are received by laboratory staff on duty after checking that the samples have been sent in appropriate vials, there is adequate sample volume, blood in anti-coagulants vials have not clotted, vials have been properly labeled and test requisition sheet are properly filled. The time when the sample is received is also noted. The patient sample is then given a number and then sent for sample analysis.

Errors arising in the pre analytical phase in our laboratory:

IP sample collection:

Wrong identification of patient at bedside
Duplicate test ordering
Patient not appropriately prepared for the test
Sample collection technique not proper
Wrong procedure of blood collection
Sample mismatch during blood withdrawal
Errors in specimen transport to the laboratory
Blood collection vials no properly labeled
Requisition form not properly filled – wrong patients name, wrong tests entered
Inadequate sample volume and clotted blood
Hemolysis of sample

Pre analytical in Errors OP sample:

Wrong patient identification while collection
Error in listing the prescribed tests
Sample mismatch during blood collection
Wrong numbering of patient's sample
Patient's not properly prepared for the test
Blood sample inadequate or clotted
Hemolysis of sample
Misplacing of sample
Delay in performing test

Frequency of error occurrence:

Data collection period	3 months (June 2012 – August 2012)
No. of tests	15000
No of patients	7000
No. of errors	120
Frequency	0.2% per 1000 patients
Pre analytical phase	46%
Analytical phase	20%
Post analytical phase	34%

Frequency of different types of errors that were registered:

Types of errors	Percentage of occurrence
Wrong identification of patient at bedside	10%
Duplicate test ordering	5%
Patient not appropriately prepared for the test	10%
Sample collection technique not proper	10 %
Wrong procedure of blood collection	10%
Sample mismatch during blood withdrawal	5%
Errors in specimen transport to the laboratory	5%
Blood collection vials no properly labeled	10%
Requisition form not properly filled – wrong patients name, wrong tests entered	15%
Inadequate sample volume and clotted blood	10%
Hemolysis of sample	10%

Error Prevention:

1. Phlebotomy Education
2. Continuing Education
3. Phlebotomy Staffing
4. Technology

CONCLUSION

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. The promotion of ideal phlebotomy practices and sample transport procedures is a pre-requisite for the efficacy of laboratory functioning. The dependence on accurate laboratory results for diagnostics makes it mandatory for labs to ensure accountability and accuracy of results to negate incorrect diagnosis as a consequence of faulty reporting. A practice of keeping a record of the errors at all stages of analysis and then devising corrective strategies for their prevention can gradually free a laboratory from such errors.

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