# "Evaluation & Control of Pre Analytical Errors in Required Quality Variables of Clinical Lab Services –"

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**Abstract:** Since the beginning of modern clinical labs in 1950s in West and early 1970s in Pakistan, quality assurances (QA) become the prime area of concern as well as of utmost priority. Regarding QA, the most important criterion or the category that the labs always cater to manage and evaluate most often are "Errors" in lab services, which is divided into three parts, Pre-analytical, analytical and post-analytical. These are the commonly accepted criteria's regarding lab working and services and thus regarded as back-bone of any management of Lab. Proper laboratory management system, whether part of the pre-analytical hierarchy, analytical labs or post-analytical arrangements, always keeps evaluating the categories, through continual assessments, working, estimating the possibilities and supervising the lab components, to avoid errors in labs and proving quality assured services to its patients.

# I. Introduction

In past, clinical laboratories emphasized on analytical errors and mistakes resulting in adverse event, but overlooked errors in the pre and post analytical steps. It is a fact, that laboratory errors may be defined as "any defect from ordering steps to reporting result" comprises on three phase:

Pre analytical - Specimen collection, transport, processing..

Analytical - Lab testing

**Post analytical** - testing results, transmission, interpretation, follow up, retesting.

Advances in science and technology have led to numerous pioneering innovations that have transformed the diagnostic laboratory manuals , bulky test methods for fully automated science, ensuring accuracy and speed. However, the laboratory can not function in isolation. It is dependent on other departments, including clinical division of slides and samples completed requisition for analysis. Accumulating evidence indicates that reliability can not be performed in a clinical laboratory by simply promoting accuracy in the analytical phase of the testing process. The phases before the sample reaches the laboratory ( pre analytical ) and the phase after the sample is analyzed (analytical post-) are equally important.

Generally Pre-analytical errors are those that occur during patient assessment; test ordering, request compilation and data, identification of samples, tests of patients, sample collection, labeling, transport or storage. Not processing the sample properly, sometimes also falls in this category. This is the one error that occurs most frequently and identified as the "obvious error" that can occur in clinical lab system. Error in this phase is mainly due to lack of knowledge, negligence, untrained staff, deficiency in lab good practices. Various researchers have reported that 46-62.8% of laboratory errors in the pre analytical phase which is mainly due to lack of standardization protocols for defining and measuring pre-analytical variables [1] Neelam ,C. (2011).

A proper procedure pre analytical phase is crucial to get the appropriate sample and therefore to achieve the most reliable laboratory results, the promotion of patient safety. Continuous laboratory personnel changes create the need to develop strategies to improve to reduce the risk of errors.

Laboratory is a key partner in patient health safety so their reliability and quality of test is the area of main focus. Considering the laboratory work flow is a chain process ,each phase is interconnected with another phase directly or indirectly any mistake at pre analytical phase lead error till the last phase. Laboratory manager should implement quality indicators for the systematic monitoring and evaluation of the laboratory's contribution to patient care.[2]. Angeles, G. (2014)

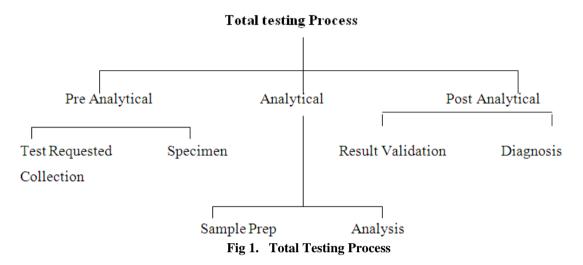
The second phase is the analysis phase. This phase includes what is "real " as one usually laboratory or diagnostic procedures, processes and products that ultimately results.

Analytical error, although known as minimal to occur, especially in advanced level labs where staff, management, and equipments are upgraded routinely and integrated through electronic or hierarchal system, but still counts as crucial. Analytical errors are basically those that occur during processing (labeling, centrifugation, aliquots' making, non-recognition of sample-type etc), actual analysis (incorrect test codes, critical values, non-

calibrated equipments) and incorrect data/result transfer or logging. However, the analytical errors are easy to handle within the lab, even before dispatching of results, due to multi-level check and balance system.

Post analytical are very few, but sometimes become critical, when its error components such as incorrect result reporting, delays in reporting or errors in tests requests timings (morning samples, evening samples, post-treatment samples) can hinder important clinical decisions.

To evaluate errors in pre analytical, analytical and post analytical phases require better understanding of the important steps of total lab testing process as it is a multistep process and each has its own significance.



**Tests Requested by Clinicians:** It is the first step when a clinician or physicians prescribed lab test and ends with the generation of requisition for sample collection.

## Phlebotomy

Phlebotomy is a highly complex skill requiring expert knowledge and critical judgment . Phlebotomy errors may cause harm to patients or result in needle stick injury to the phlebotomist. Specimen collection starts with the requisition slip from the lab receptionist arranging tubes according to the requested tests , collecting blood from patients, , labeling, entering and dispatching of sample to the analytical labs . 32-75% of all lab errors occur at this stage. **[3]** Howanitz ,(1983)

**Sample Preparation:** It is the first step of second phase , before start the testing prepare sample like serum separation , aliquot ting, if needed make dilutions and then perform testing . Any negligence or mistake at this step affects test result reliability.

Analysis: Perform test and examinations of the samples as per clinician prescription.

Validation of Result: It includes generation of reports, result interpretation and issuance of report to the patients or clinicians

**Diagnosis:** It is the post analytical activity done by clinicians, treat patients on the basis of laboratory test report. Laboratory test result play an important role in diagnostic decision making . More than 60-70 % of the most important decision on admission , discharge , treatment are based on lab test result. Due to this critical impact on physicians' decision , the quality of lab testing and reporting is a great matter of importance.

## **Evaluation Of Lab Errors: Pre Analytical Phase**

**Pre analytical Process:** As we described earlier, pre analytical phase is a first step in total lab testing process so we start our discussion on evaluating and controlling lab errors by list down all the steps include in this phase.

## **1.Test Ordered by Physicians / Clinicians:**

Transcriptionist errors are the most common errors in this stage as it involves processing orders trial of the doctor in formal work orders for phlebotomists.

- Oral or hand written prescription by doctors.
- Generation of requisition

# 2. Sample Collection

This phase begins with picking phlebotomist work orders from lab clerk and ends when allegations of patient samples to the analytical part of the laboratory for testing. It has been shown that most laboratory errors occur in this phase , mainly due to the lack of standardized protocols . The main reason for the high error rate in this important step of the testing process .

- Patient identification : Proper identification of the patient is a step to ensure that first data from the laboratory . Many factors can contribute to misidentification , such as issues related to the workload of sampling, materials used in the identification process , or the approach of staff confirm the patient's identity.
- Phlebotomy Procedure:
- 1. **Preparation of tubes**: CLSI recently advised the specific order for collection of tubes and recommend following order:
- (i) Blood Culture bottles
- (ii) Red Top ( Non Additive.)
- (iii) Light Top ( Citrate tubes)
- (iv) Green Top ( Heparin tubes )
- (v) Lavender Top ( EDTA tubes )

**2.Use of PPEs** : All Phlebotomists must wear fresh gloves for collecting the sample. Unfortunately it is observed that many phlebotomist do not wear gloves, have tend to use same gloves for several patients that is the one main reason is likely to contaminate the sample collected.

**3.Site selection**: Place and the opening of a suitable venous access is an important prerequisite for ensuring successful attempts sampling. Two factors are influenced on rate of success of venous blood drawing. (i) the availability of appropriate and easy venous access, which is mainly dependent on the anatomical characteristics of the patient, (II), skills and training of a phlebotomist.

**4.Site preparation**: Before blood collection, the site should be cleaned with alcohol. Cleaning starts in the center of the vein, and further continue outward in cocentric circles. Sufficient time to dry in the alcohol, so the sample has not contaminated with the alcohol which may cause haemolysis. Allowing the alcohol to dry completely would also cause less pain and burning to the patient. [4] Solomon, DH. (1998)

**5. Apply tourniquet** : A tourniquet may be defined as a constriction device temporarily sealing compression of the blood at the end of a given period. If tourniquet 3-4 inches above the ground to be the proving of veni puncture and release it when shoulder stand his blood starts flowing in the collector , the duration of venous occlusion can ( > 1 min ) affect the sample composition . Tourniquet -time of more than a minute is therefore associated with a significant increase magnification of the risk of hemolysis

**6.** Use of vacationer: Instead of syringes some laboratories use vacutainer for blood collection but still other laboratories use syringes . In the use of syringes , there is always the risk of hemolysis. Blood pressure is applied too much to move the blood from the syringe into the container.

Vacutainer consists of a needle, a plastic holder or adapter and a series of tubes with stoppers. The chances of blood loss inadequate or more are less blood in Vacutainer as with a syringe.

# 7. Blood Drawing:

Not enough blood is the second leading cause of rejection. All blood collection tubes must be filled to the correct volume .Each method of analysis requires a fixed volume of serum / plasma for analysis. Inadequate amounts can either collected or excess amount of blood, because of the small volume of blood.

## 8. Proper tube mixing:

After collection, the collection tubes are inverted several times to maintain (6-8 times) effective mixing of blood and anticoagulant, but without causing hemolysis or coagulation (if available allow additive added to the blood collection tubes must be filled to the correct level.

## 9. Sample identification (Patient name, case no. or lab code)

After mixing, the correct labeling of the tubes needs to be done to ensure the unique identity of the sample. The phlebotomist must label the tube immediately after blood collection .

## **10. Dispose off supplies**

It is essential that the phlebotomist disposes of all the used materials . Used materials should never be re used.

## **11. Dispatch the sample to the concerned lab.:**

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

## **Outcome Variables : Indicators**

- 1. Hemolysed sample : for both serum and plasma samples ,any degree of hemolysis is considered as Hemolysed sample .
- 2. Clotted sample
- 3. Inadequate sample
- 4. Incorrect identification
- 5. Empty tube
- 6. Lipemic sample Request missed
- 7. Broken and leaking

# **Evaluation Of Lab Errors: Analytical Phase**

## Analytical Process:

Advancement in technology, computerization, certification, accreditation have significantly impact on reliability and quality of lab testing results but not completely eradicate the chances of errors at this stage. Comparatively analytical phase has less error than pre analytical phase but to keep the errors controllable it is necessary to understand types of error occur at this phase.

## 1. Systemic Error:

- Probe
- Lamp
- Blocked tubing
- 2. Random Error
- Inappropriate justors
- Improper used of micropipettes
- Too early or delayed reading measures
- Improper temperature functioning

## 3. Calibration out.

- 4. Non conformity with QC
- 5. Reagent Contamination

#### Evaluation Of Lab Errors: Post Analytical Phase Post analytical Process

In this step , the most common mistakes , accounting of total laboratory errors are: wrong validation , results that are delayed , not reported or reported to the wrong providers , and incorrect results reported because of post – analytical data entry errors and transcription errors[5]

- 1. Report Validation
- 2. Communicating report to the physicians .
- 3. Interpretation of test result by clinicians

# II. Review Of Literature

In view of the increasing attention to patient safety and the need to focus on reducing laboratory error, it is important that clinical laboratories are working on error occurrence rate over the total test procedures, including pre analytical, analytical and post- analytical phases. Many laboratory managers believe that the lab errors is rare in the laboratory and therefore no need for a continuous monitoring and recording errors. The case has serious draw backs as wrong lab reports could have adverse effects on the patient's health Laboratory errors in every phase of the Total Testing Process. Errors in Phlebotomy represent the majority of errors in the pre analytical phase, the lack of quality assurance could lead to wrong test results to the analytical phase, while misidentification errors are common in post analytical phase. Laboratory Errors also occur at various stages; before collecting the sample during sample collection, sample transport to the laboratory, centrifuged, and after the test results obtained. Lab errors, detected at any stage call for sample rejection. This leads to delayed reports and additional costs for the laboratory and also effecting quality of service and customer

satisfaction. It is also possible that some laboratory errors could even go un detected and thus could adversely affect the health of patient due to improper treatment protocols. Laboratory errors and its consequences have implications on quality of service, additional workups on training of staff as well as extra financial burden that effect on profitability .For laboratory managers / management decreasing lab errors is a key task of their jobs.

In this mini review, we tried to review various research literature to understand where laboratory testing error occur, evaluate the impact of laboratory testing error on patient care, describe common study findings and lab initiatives that improve patient care.

Pre - analytical steps, the main source of errors in laboratory diagnostics, which will occur during the preparation of the patient, sampling, sample transport, sample preparation, and storage of the sample. However, while it is reported that pre- analytical phase is prone to error, so it is need of the hour to ensure that the best evidence for testing shall be provided by using the laboratory to the physician or clinicians.

This had the effect of making the best decision based on the results of tests that could lead to an increased likelihood of better health outcomes, so it is necessary for the laboratory to maintain the stringent quality. Here we look at the steps of pre- analytical phase and the various points where errors can occur and how to reduce them. Pre- analytical phase is most important in the process of trial and associated with certain variables that are not under the control of the laboratory.

Pre analytical phase comprises on two steps that consist of two major activities:

## 1. Investigation ordered by clinicians ( orally / hand written) .

Oral and hand written orders both can cause errors at the time of request generation if not properly heard by the lab staff, or doctors prescription are not legible and therefore wrong test requisition generated by lab staff that leads to the wrong test done.

## 2. Sample Collection:

It was observed that most laboratory errors occur at time of sampling. The main reason for the high incidence of errors in this critical stage of testing is that it is currently difficult to control all pre- analytical variables such as phlebotomy , which are not under the direct control of laboratory .

## i Received test requisition.

It is the responsibility of Phlebotomist after receiving test requisition sort out normal and urgent test requisition . Any delay of phlebotomists in urgent requests leads to delayed collection of specimens , and hence delayed test reports .

## ii Identification of patient.

Accurate patient identification is one of the first step in ensuring correct results of laboratory tests. There are many factors that can contribute to misidentification, such as work load, negligence, not follow SOPs to identify the patient. Another reason for error in this stage of the barriers to communication,

## iii Blood drawing procedure .

In appropriate drawing blood procedure also lead to errors :

**Gloves:** do not wear gloves, or wearing same gloves for multiple patients might cause contamination in sample . Selection of vein: is another important step in blood drawing and its success depends upon two variables i.e, expertise of phlebotomist & availability of vein.

**Decontamination of skin:** To avoid contamination in collected sample it is necessary to decontaminate the site with pyodine as sometime use of alcohol may cause hemolysis in sample if skin dry not properly.

**Applying tourniquet :** Application and time of tourniquet both are equally important in blood drawing, select appropriate position and time of tourniquet decreased the risk of hemolysis and vice versa

**Order of Blood drawing :** For collection of multiple test in single prick phlebotomist has to followed the recommended order .Disordered blood sample collection can constitute a major source of error, as it is a great chance of needle contaminate with additive of previous tubes , especially for chemistry test .

**Use of Vacutainers :** The chances of drawing insufficient blood or more blood are less in vacutainers as compared to syringes. Vacutainers are three to four times more expensive than syringes, but they are safe.

**Size of Needle:** Use of needle with appropriate gauge size is very important .Higher gauge cause less pain, but thin needles will take more time and can cause one of the reason of blood sample clotting.

**iv Blood Collection:** Inadequate amount of sample is another reason of sample rejection. As every analytical process needs a fixed volume of sample for analysis, . So it is important that all collection tubes must be filled to the mark mention on tubes .It is also observed that under fill samples for hematology tests gives doubtful results

**v Proper Mixing:** To avoid clotting , just after blood collection tubes are gently inverted several times that allow to mix samples with additives very well,

**vi Identification of sample :** After proper mixing , before moving to next sample the previous sample immediately label for the identification of sample. Any delay in labeling may lead to errors like mislabeling, non labeled .

vi Discarding of use materials : Before call to next patient it is necessary to dispose off all used material according to waste policy, all discarded material should never be reused.

**vii Dispatch sample for analysis.** Time is very important in sample dispatching ,any delay can render a sample invalid for analysis.

Analytical process is less prone to errors than pre analytical and post analytical process.

To minimize and control the errors at analytical phase it is necessary to understand all analytical steps. In analytical phase, analytical reliability is utmost important to generate the reliable test results, Reliability of test results is dependent upon two determinants of quality, accuracy and precision. Analytical process focuses on ensuring test worthy results. Errors at analytical phase can be classified into following categories such as Systematic Errors, Systemic Errors, Random Errors and other errors.

**Systematic Errors**: Those errors occur due to any detect or problem in instrument or analytical method. Sources of systematic errors include interferences, lot to lot variation ,matrix effect and carry over .

**Systemic Errors:** Those error due to some inherent technical problem or tear or wear of the equipment. It includes malfunctioning of probes, aging of lamp and blocked or kinked tube can affect the delivery of proper amount of sample or reagents.

**Random Errors:** It can be caused due to timing, temperature or pipetting variations. They occur randomly during the measurement process .

**Other Errors:** factors outside of analytic variability can have a profound impact on a laboratory's ability to produce result.

To minimize the errors at analytical phase it is necessary to understand all the activities occur at this phase. Following are the steps that occur in analytic phase.

- Processing of sample prior to analysis includes labeling , centrifugation and aliquoting.
- To ensure the instrument working condition is proper, the instrument is switched on and full system check is carried out before going to start any analysis. This will prevent improper shutdown of system, calibration errors and wear and tear problems of instrument.
- To ensure the reliability of sample results, run quality controls. It is good practice to run quality controls before loading the test on instrument, it gives reassurance and confidence to technologist in the test result.
- Another reason of error that calibration not done or reagent lot differences that ultimately gives doubtful results.
- To avoid any error, ensure that sample that is taken for analysis fulfill all the criteria of sample integrity.
- In analytic phase, addition of reagent is very critical steps. Reagent expiry, lot number, number of test these all must be updated otherwise it will lead mistakes during analysis.
- Improper mixing ,incubation and detection of sample and reagent can lead to random analytical error.
- Readout result for reporting by data processing that includes data acquisition, calculations, monitoring and displaying data.
- It is the responsibility of technologist properly transcribed the result from the instrument ,and ensure that there are no mathematical errors, use of correct formula to interpret ate the result.

In the post- analytical phase of the testing process, the results are released to the doctor and clinician interprets and makes diagnostic and therapeutic decisions accordingly. Things such as inappropriate use of laboratory results, critical reporting results, and transmission of correct results are areas of potential error in the post- analytical phase of the overall process laboratory.

Using the results of laboratory tests for clinical diagnosis in decision-making is an integral part of clinical medicine .More than 60-70 % of the most important decision of acceptance, responsibility and drugs on the basis of the results of laboratory tests. This high degree much influence on the reliability of laboratory tests and report is essential. Although automation advances have been greatly improved, and the recommendation of the laboratory testing is the analysis of technical standardization, yet errors occur in the pre-analytical and post- analytical mode of the overall test system. It is the responsibility of the head minimizing errors at each stage of the testing process.

Laboratory errors led to the rejection of the sample , which in turn calls for the collection and analysis of repeat sample , and thus lead to a delay in the reporting of test results. Any delay in test results may adversely affect the health of patients .

Therefore , monitoring and control of laboratory errors is a major challenge in controlling clinical laboratory , manufacturing reliable test results as soon as possible either , and better laboratory performance. Laboratory medicine plays a vital role in modern diagnosis and treatment. So it is appropriate that the laboratory results generated are accurate as the patient's health depends on it. The process of clinical laboratory testing consists of three phases. Pre - analytical, analytical and Post- analytical . Pre- analytical phase includes a set of processes that take place from the time the lab request is made by a physician until the sample is ready for testing. It consists of a process of ordering of the test by the physician to request forms filled sample collected , a sample was transported to the laboratory , and finally the prepared test sample. Analytical phase consists of analysis of samples and generation of reports , and in the post – analytical phase laboratory reports shall be communicated to doctors for proper management of the patient

Errors in any of the phases can have a significant impact on the proper diagnosis and overall health of the patient. By automating the laboratory for analysis of laboratory errors significantly reduced, especially those that occur during the analytical phase.70% of the total errors throughout the diagnostic process happens in pre analytical phase.

Various researchers have reported it as 77.1%, 81% and 31.6-75%. Errors may occur in each of these steps in the Pre – analytical phase and should be evaluated during this phase. However, occasionally found in the analytical and post analytical phases, as seen in the case of samples of infusion route glycolysed samples.

Although analytical errors are reduced, but a large percentage of pre- analytical errors strongly affect the overall error and therefore the accuracy of the test results . This study was conducted to enumerate the various errors that take place in the pre- analytical phase and frequency, so that they can be taken to remove them and to ensure the accuracy of laboratory results.Pre- analysis phase of the overall process, laboratory test where the majority of the laboratory errors occur . analytical errors in the evaluation of receiving test order request completion , or patient identification ,collection, sample transport or received in the laboratory - In a report of Bonini and colleagues that pre- analytical errors in the laboratory occur in the range of 31.6 % to 75 %. In 2008 to 2009 , Chawla and

colleagues conducted a study in 1 year-old clinical chemistry laboratory of the frequency of preanalytical errors observed in hospitalized patients and outpatients . For hospitalized , reported pre- analytical error rate of 1.9 %. The variable receiving the most common rating models hemolysis in 1.10% . For ambulatory use, the error rate was 1.2 % and that of the variable with the highest frequency rating is insufficient volume for testing. Some of the other common sources of pre- analytical error are: ordering tests on another patient , ordering the wrong test , misidentifying patients choosing container for collecting inappropriate or improper labeling of containers.

There are five interrelated steps that can prevent pre analytical errors.

- 1. Establish clear written procedures.
- 2. Improving the health professional training.
- 3. Automating functions, operations support and enforcement operations .
- 4. The qualitative indicators for monitoring.
- 5. Improving communication between health care professionals and the promotion of cooperation between departments

Written procedures should clearly explain how to identify patients, collection and sample label and subsequently transported model and prepare it for analysis. Those individuals who perform preliminary analytical procedures need to understand not only what the procedures are, why they are important to follow. They need to know not only what if do not comply with the right steps, but what may be some mistakes and what effect it may have on the sample and ultimately the patient. There should be ongoing training for these employees and competence should be assessed annually.

Modern robotic technology and information systems can help to reduce pre- analytical errors. Computer order entry simplifies test and removal of the second person of the recording contracts. Automated

training phlebotomy tray provides a complete set of labeled blood tubes and labels for labeling or manual tray for each patient.

Pre - analytical robotic work station automate some of the steps and reducing the number of manual steps , the more people. Barcodes are therefore to simplify sample routing and tracking. Recent advances in laboratory technology have led to new and reliable means for automatic detection of serum parameters , including the index of hemolysis. Visual evidence of hemolysis should be abandoned : because of the low sensitivity and poor reproducibility .

Laboratory staff should ask for new samples, in case of hemolysis, if can not get a new sample, it is the responsibility of laboratory personnel to report the problem to the doctor. Data from the serum indices can be used to monitor the quality of the recovery process. The success of efforts to reduce mistakes, be followed to the effectiveness of the measures taken. Quality indicators should be used for the assessment. In the test process areas involving non-laboratory personnel , interdepartmental communication and cooperation are crucial to avoid errors . So the whole health care system should be involved in the improvement of the overall testing process. An adequate and effective training of personnel must be in the whole institution empowered to be on following processes and procedures.

The use of indicators in the pre analytical phase as a laboratory management tool. Errors in pre analytical phase usually occur from high levels of staff turnover, negligence, lack of understanding of good laboratory practices and ineffective training. These include inappropriate test request, inadequate samples, delays in transport or improper storage, illegible orders, improper venipuncture, insufficient indication of the patient, improper identification of samples, insufficient sample volume. Such errors usually result in sample rejection, and therefore, they produce uncertainty, frustration, inconvenience and anxiety in physicians and patients; excessive costs; prolonged execution time; rework; loss of trust and laboratory loss of confidence in the laboratory. Difficult to control pre- analytical variables and make process improvements are possible reasons for the prevalence of errors in this phase.

In healthcare, quality philosophy does not differ from that applied to industries. Adequacy of the product or service to meet customer needs is a key element of quality fully applicable to several health services. Providing quality services implies two main components of quality : operational, corresponding to the process; and perception, and how customers perceive the service. These components can be measured by quality indicators (QIS), and recognition is obtained through the process of certification and accreditation. QIs is an opportunity for internal and external comparisons with other services that share the same characteristics. They are called , in quality management , control devices. The application of the quality or laboratory tests requires total quality management during laboratory process, includes pre and post- analytical phases. ISO 9002: 1994 is a model for quality assurance in production, installation and maintenance, -which includes a number of provisions that provide guidance for use in clinical laboratories. Regardless which step is involved and whether the error can be occur due to laboratory specialist ( calibration and testing error) or from non laboratory personnel ( in appropriate test request, error in patient identification or blood collection ) must be considered as its direct or indirect negative effects associated with laboratory testing . Patients with misidentification problem and problems in communicating results affect the provision of all diagnostic services are widely recognized as a major destination for quality improvement. Therefore develop, implement, an evidence -based quality indicators for the monitoring of certain shortcomings inherent errors in laboratory medicine, should lead to preventive and corrective measures .

Quality in Laboratory Medicine should be defined as a warranty that every step throughout the testing process (TTP) has been carried out correctly, creating a valuable medical decision-making and effective patient care. As noted by Lundberg few years ago, the concept of " chain of brains " to introduce to describe the TTP, the production of any laboratory test result has nine steps : acquisition, collection, identification, transportation, separation or preparation, analysis, reporting and action. It is interesting that the term " brain to brain " as long as 40 years, It is quiet -considered a working paradigm in the provision of quality and safety for the request of physicians and patients . In fact, subsequent offer will be changes in the medical landscape made clear by the quality and delivery of laboratory services affected. In recent decades, a ten- fold reduction of the analytical error rate achieved thanks to improvements in security and standardization of analytical techniques , reagents and equipment and advances in information technology , quality control and quality assurance methods. However, while the current QIS in laboratory medicine are usually on the operational focus and efficiency of the analysis process , recent data have most of the errors in the loop, fall outside the analytical phase , and before and after the analysis steps they have found that the more risk of interference . this lack of attention outside the Laboratory factors thus in sharp contrast with the evidence for the many mistakes still in the pre- analysis phase occurs.

Therefore consent of the Technical Committee of the International Organization for Standardization (ISO / TC 212) on a comprehensive definition of errors in laboratory tests was a milestone in that it encourages the approach to patients and emphasizes the need to evaluate all steps whether or not under the direct control of

the laboratory staff. Therefore, initiatives to improve quality must take into account both the " classical " preanalytical steps and the initial procedures listed in the so-called "pre- pre- analytical phase", which is normally perform any clinical laboratory at least partly, under the control laboratory staff. This is important, since it seems that the automation of repetitive, error - prone and bio - dangerous pre analytical processes performed within the laboratory walls, effectively reduces errors during sample preparation, centrifugation, preparing fraction, pipetting and sorting. In addition, the ISO 15189: standard for accreditation of laboratories 2007 provides pre analytical phase as " steps that begin in chronological order on the request of the physician, including application testing, preparation of the patient, the primary collection and transportation of samples in the laboratory and ends when starting the projection process. "This clearly recognizes the need for evaluation, monitoring and improvement of all procedures and processes in the initial phase of the circle of the brain to the brain. Following the approach of the Institute of Medicine (IOM) of the quality of health care, identifying reliable indicators of quality (QIS) is an important step to allow users to determine, the quality of a selected aspect of care and comparison with a certain criterion. Therefore, when assessing the quality of laboratory services with OI, it is important systematic and consistent collection and analysis of data, using a variety of indicators, and covered all phases of TTP and focus on areas with important implications for patient care health outcomes.

The need to harmonize underlining the Proposed QIS . However, as Indicated by Shahangian and Snyder , there is a " major challenge in identifying , defining, and ultimately performance indicators for the various phases of the TTP this address IOM domains , different environments for testing, as well as many relevant stakeholders.

Development of QI is the Accreditation of Laboratory Medicine is an important step in providing robust evidence of quality in all procedures and processes of the TTP. QI therefore plays a key role in ensuring we have targeted measures for continuous improvement in reducing the risk of error in clinical practice .However, especially in the pre- analysis phase , data collection and monitoring of the QIS ( investigation processes are normally performed by healthcare outside the laboratory walls ), not necessarily lead to an improved quality. Can only be achieved if efforts made to reach a consensus on the further elaboratory tests efficiency gains in the first (and last ) steps of the TTP. A pre analytical phase a continuous improvement area Human role in the collection of samples makes complete elimination of errors associated with laboratory tests unrealistic. This is an area of continuous improvement. Some of the silent processes can lead to a significant reduction in pre- analytical errors. These include best practices and compliance with new strategies to prevent errors , and the use of quality products for sampling, handling, processing , transport and storage.

# Good Practice is not limited to :

- Lab design process in order to identify and detect errors, generating reports, and tracking
- process and risk analysis
- Process redesign
- Enhanced health training
- Improved communication between health professionals

Pre - analytical errors are a major source of problems in the entire testing process (TTP); They had been located -considered as one of the main indicators of quality. Pre – analytical phase are generally held outside the clinical laboratory; it is not under the control of laboratory management, the active monitoring and control of all possible defects that are characterized by non-laboratory personnel are essential to allow the inclusion of actions outside the laboratory and within the laboratory quality assurance plan. To prevent and manage pre analyticals error should clearly confirm concept when dealing with medical errors, laboratory errors and pre analytical error that there is not a magic wand to solve all problems. In fact it can be assumed that drastic solution, remove all synthesis process is prone to error and uncertainty. The most reliable strategy for reducing uncenternity and contextual errors in this inevitable step in the overall process of testing is to establish a multilateral strategy leads to prevention of emergency events through a comprehensive process analysis, reevaluation and re- adapt the requirements for quality, distribution operational guide line and on the recommendation of practice, reducing error prone activities, introduction of system for bug tracking and continuous monitoring of performance ,increasing and diversification of the defense mechanism and barriers through the implementation of multiple and heterogeneous system to identify discrepancies and reduce vulnerability over the entire system through the introduction of reliable and objective system to detect and occasional links to charts, education and training.

The second step is the continuous training of medical personnel, in particular outside the laboratory .Considering that most pre- analytical steps are carried out before arriving to the specimen in the laboratory environment, dissemination of best practices for the collection and processing of samples.

The information that is available to all operators involved in the processing of samples include a clear concept of pre- analytical variables such as time of sampling , biological variability , posture , tourniquet application , collection tools in order of equality, a procedure for the handling, transportation , storage of samples showing the effect of the least common influence and interference factors. The third step is the termination or reduction of these (human ) pre- analytical activities that are vulnerable to error and uncertainty. Automation has the potential to streamline workflow , reduce stress , reduces the burden of manual errors. Computer physicians order entry , automated drafting tool for collecting a sample of pre- labeling of the primary tubes.

The fourth crucial step is the implementation of a comprehensive strategy for risk management focuses on the why, when, where could be a problem and what can be done to avoid, tolerate or reduce their negative out comes.

Strategies for risk management and patient safety are designed to prevent, detect and mitigate adverse events through analysis of errors. In all clinical laboratory errors must be measured and controlled by the most obvious to those who do not come from the laboratory, using indicators that provide an objective assessment of the problem and, where appropriate, by performing comparisons between different laboratories and from different time periods.

In accordance with Section 4.12.4 of ISO 15189, "Medical laboratories - Particular requirements for quality and competence", laboratory managers should implement indicators for systematic monitoring and evaluation of the contribution of the laboratory

to patient care quality. The European Committee of Experts on the management of safety and quality in health indicators proposed should be useful to identify critical steps in each process reflects their potential and make it possible to continuously assess the safety of medical procedures in order to accredit sustainable improvement and to determine when gaps occur .Since 1960, with the introduction of analytical quality control approach adopted for quality assurance has developed, focusing in turn on concepts such as quality assurance , quality management, use of quality objectives, the specification of operational processes and resources needed to achieve the objectives of the system and total quality management to a more recent focus on clinical safety and risk management .

From this perspective, the Technical Specification ISO / TS 22367, "Medical Laboratories .Reduce errors through risk management and continual improvement" is designed to show how risk management should be applied in structure, organization, operation and management the quality of clinical laboratory system, with special emphasis on pre- and post - analytical phases .Of the three main processes in a clinical laboratory, the analytical phase is the most highly standardized, with well-defined indicators and internationally accepted specifications for a number of biological parameters. All studies agree that it is in the extra- analytical processes that occur at a large number of errors, particularly in the pre- analytical step. These processes, moreover, are the most critical and the most difficult to manage because of the decentralization of extractions associated with the participation of different specialists (doctors, specialists in laboratory medicine, nurses, laboratory technologists and technicians, phlebotomists etc.), organizations and health centers.

Effective integration between automation and information management is the key to providing more sophisticated control laboratory process. Automation is responsible for assessing the samples early in the process, optimized routing and scheduling, accurate and reliable measurements and reduce errors due to the human factor, for example, repetitive and manual operations

For example, the risk of errors in the pre-analytical process outside the laboratory is reduced by the introduction of distribution of the driving management system for attaching the unique identification label to produce additional labels deliver and collect sample tubes in the "kit of appropriate patients."

Similarly, the introduction of pre-analytical workstations significantly reduce the number of errors in pre-analytical procedures performed in the laboratory. Processes include managing access to tracking information of data recording and reporting model, documentation, quality control and validation of the results of laboratory tests.

In particular, an increasing interest has been shown that the development and validation of selfassessment system. The term "self- validation " is used to define the "intelligent system after -Analytical computer designed to simplify the interpretation of the test."

These systems enable laboratory technicians to conduct the assessment and analytical data communication in the normal range and quick and fast assessment of unusual data to generate diagnostic guidelines and to identify trends the data could become abnormal and disclosure of "hidden "disease, based on the automatic interpretation of complex data. This, in turn, transformed into a more accurate and reliable laboratory information. So expect an effective process control and automation through the management information between integration to significantly improve safety throughout the testing process.

The entry of computer control allows doctors ( or --other authorized officials ) to enter lab orders directly into the computer. These systems may include mechanisms to support the decision, such as orders of

certain requirements to support the selection and proper use screening and treatment; parameter settings controls that contracts are within the test frequency or dose deadlines; and complex rule based on the signals that rapid clinicians with information on the results of previous tests, patient characteristics and the test selection available

Concentrating on the stage of laboratory analytical testing, analysis phase begins when the patient sample is prepared in the laboratory for testing, and it ends when the test result is interpreted and verified by the laboratory technologist . Not just treatment of samples prior to analysis or interfere with the assay performance test substances may affect the results of the analytical phase . Establish and verify the test performance test method specifications as to the accuracy , precision , sensitivity, specificity and linearity errors are other areas which may occur in the testing phase analysis laboratory. The laboratory has spent decades Improved quality of analysis by establishing internal quality control (IQC) and external quality assessment (EQA). The role of EQA and proficiency testing (PT) is to provide reliable evaluation and allow laboratories to monitor the status of the quality of internal processes and procedures, the adequacy of diagnostic systems the responsibility and competence of staff, and the definition of the measurement uncertainty in the laboratory results.

The responsibility of laboratory professionals is to analyze samples appropriately EQA / PT and reports, identify trends or bias cannot be apparent in the single results, study the root causes produce unacceptable performance, implement and monitor appropriate measures to remove the cause (s) of the underlying instrument to verify the effectiveness and, above all, to determine whether the problem affects clinical decision making.

**Post-** analytical laboratory processes -considered less error-prone than analytical processes through the widespread adoption of laboratory automation and related laboratory reporting. Quality Monitoring and control body - modified analysis process to focus on critical notification by the implementation of the objectives , the execution time and review the reports. The rapid increase in the adoption of electronic health records has created a new role for laboratory staff in the management of test results for patients. Laboratory professionals must be linked with the clinical side of the health care team in establishing quality control post - analytical processes , especially in high risk transitions of care .In the post Analytical test process , the results send the doctor and he / she performs diagnostic and therapeutic solutions. Things such as the misuse of the results of laboratory tests, the critical results reporting and results are transmitted correctly zones of potential errors in the post analytical process of comprehensive laboratory testing.

Post analytical activities review and evaluate effectiveness of the corrective actions, procedures and policies to prevent re occurrence, accuracy and completeness of result and report, disposition of un acceptable samples, turn around time, referral specimen and their reports, corrected reports, procedures for notification of test results with statistic, assurance of confidentiality of patient information.

Laboratory tests are used to diagnose diseases, monitor progress and response to treatment. So the purpose of laboratory medicine and report accurately on the results of the test. To evaluate the rate and causes of post- analytical errors focused on a) delay in reporting of test results and 2) the uncertainty of the test results. Together with the continuing education program and improving the automation, it seems necessary to add a periodic evaluation and testing error of the benchmark programs, in particular in the process of test results to ensure error-free service and their doctor patients.

Collaboration with clinicians and other personnel outside the laboratory is also important to reduce errors .In today health care system the spread of medical errors , seems high , as shown in the report by the Institute of Medicine (IOM). An error rate of about 10% in clinical medical laboratories is still in the literature. Most of these errors occur in the pre analytical phase. Since analysis only a small number of errors will be seen in the analysis phase , it is very likely that they can be often overlooked. This review will focus on the quality that is not only based on the measurement of the quality control sample.

Knowledge of analytical interferences and critical quality sample will provide valuable solutions to improve the overall quality of the total testing process such as calibration , quality control, the reference interval , drug response , the statistical analysis, and work volume effect. Focus on the analytical stage of laboratory tests, the analysis phase begins when the patient sample was prepared in the laboratory for testing, and ends when the test results are interpreted and verified by the laboratory technologist . Not working properly sample just before analysis, or interfere with the test substances that can affect the test results in the test phase. Identification and verification of the performance test method for checking the accuracy, precision, sensitivity , specificity and linearity other areas are likely to be few errors in the analysis phase of laboratory tests. The analytical laboratory has spent decades improving quality through the establishment of the internal quality control ( IQC ) and external quality assessment (EQA ) . The role of EQA and proficiency testing (PT) is to provide reliable information to laboratories to monitor the status and evaluation of the quality of internal processes and procedures , the adequacy of diagnostic systems , responsibility and competence of staff , as well as the definition of the measurement uncertainty in the laboratory results. The success of any attempt to reduce errors should be monitored to evaluate the effectiveness of the measures taken. Quality indicators should be

used for evaluation. In the areas of the test procedure, including non laboratory staff, communication and interagency cooperation are essential to avoid mistakes.

Therefore, the health of the overall system must be included in improving the overall testing process. There must be adequate and effective training of staff in the institution to be competent in the following processes and procedures. Now there is need for better definition of laboratory errors and their causes . In fact, we can all agree that mistakes can be defined as a defect of ordering the test for reporting results and corresponding interoperating and answer them, but our goal is to identify the most important steps in the overall process of testing and create a plan of correction strategies differ errors only in the laboratory and laboratory errors caused by organizational problems outside the laboratory .

Error within the lab, evidence shows that the analytical error rate has improved significantly over time, it is affected by the training and qualification of test personal, and the correct rules on determination of the uncertainties in the internal quality control practices. Moreover the effectiveness of the external circuits to evaluate the quality and programs for skills is widely demonstrated not only in the determination of the analytical errors, but also in the detection of their possible sources, thereby allowing laboratories to prevent a further errors. Laboratory errors caused by organizational problems outside the laboratory, these reasons are associated with other common errors in health and need similar corrective actions.

The role of clinical audit in detecting this type of error and improve clinical presentation is increasingly recognized ; Laboratories should monitor adverse events to learn how to minimize the risk by teaching and establish procedure to prevent.

It is important to classify the laboratory errors of them relating to the actual or potential impact on their results to the patients, which allows the determination of the relevance of the error itself. abnormal hemolysis, which interfere with the analysis of samples may lead to the request of the fresh sample extended TAT and could potentially be very harmful for patients in critical condition. Standard for detecting and reporting laboratory error needs to be determined, and accurate analysis of the risk of error in the clinical laboratory must be met. It is important to identify ways t reduce laboratory errors. It is impossible in medicine, as in any other human activity completely eliminates the error,

but they may be reduced. Appropriate program for debugging and adequate measures to reduce the error that quantify the impact of these measures and assess whether the reduction can be considered satisfactory , are crucial . Reducing the number of errors is valid and sensitive indicator of the effectiveness of corrective actions. Another major step towards creating a culture in which there is a risk is to recognize and patient safety is recognized as each responsibility.

Transforming insight for laboratory management that errors due to personal errors and otherwise have not worked in tackling and reducing errors. To change the approach and focus on how people, individually and groups of the organization make safety that need training, education and culture.

# III. Research Methodology

## 3.1 Rationale

The total testing process is a source of clinically significant errors as well as several aspects of the errors are far larger number than what is customary in industry standards. Furthermore, reports and error rates that reflect only the errors detected probably represent only the tip of the iceberg. This raises the question of how the total testing process can be improved and where there is the greatest potential for improvement.

Most of the errors in the overall testing process originating from the pre- analytical phase This phase comprises a few error prone manual tasks or easily avoided with technological solutions. Analytical phase contributes very little error in the near future to be fully automated in the future .Thus , the total testing process will be even more dependent on the quality of pre- analytical phase .Due to the importance of pre- analytical phase research has mainly focused on assessing the frequency of different types of error in pre- analytical phase and high light managerial challenges to control laboratory errors to improve laboratory performance.

# 3.2 Research Objective:

To achieve the objectives of the research, our tasks include:

- detailed understanding of laboratory activities in total testing process.
- focus on possible lab errors and their frequency .
- Define the role of laboratory management control laboratory errors to improve laboratory performance .

## The Setting:

Laboratory services department provides diagnostic services in the areas of clinical chemistry, Microbiology, Histopathology & Cytology, Molecular Pathology as well as Haematology & Blood Bank Transfusion service.

With qualified & highly trained faculty and over 150 skilled & professional laboratory staff, lab services is ISO 9001:2008 certified and equipped with latest and state of the art instruments. Approximately 600 routine and special diagnostic tests are offered ,24 hours a day including inpatient ward, emergency department, integrated home care for the elderly or those who experiencing degenerative disease. To meet international standards lab services ensure quality measures of accuracy and Precision for its analytical testing services . It takes part in both internal and external

Quality assurance program include EQAs by CAP (College Of American Pathologists),

EQAS (External Quality Assurance survey), National Reference Lab Australia, & NEQAPP (National External Quality Control Program Pakistan)

## **3.3 Population & Sampling:**

This research study conducted in lab services department of tertiary care hospital . the research based on observations by using three month data of lab services that helped us to observe the lab process in details and working practices followed by the health workers (includes clinicians , physicians , lab technicians ) .As previously described the Lab services department is ISO 9001:2008 certified, laboratory quality team identified different quality parameters for lab services . These parameters are customer satisfaction , responsiveness , service quality, behavior of staff, turn around time, pre analytical errors .Among all these parameters 'pre analytical errors are considered the most critical quality indicator for lab service as it directly relates with customer satisfaction. We define pre analytical errors are those that include all steps before complete distribution of test samples to their respective departments., that influenced of further lab process.

**Sampling**: The data obtained to evaluate pre analytical errors by means of analysis of sample rejections and requests of new sample collection test .

The three month data (April – June 2014 were collected for pre analytical errors.

Pre analytical errors can not be considered inevitable that they can easily be avoided with proper training and the use of proper quality control procedures in all aspects of the collection and testing process All the Opd samples were screened for the following pre analytical errors.

## 3.4 Parameters On Lab Requisition

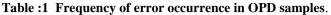
Criteria for Patient information

- Name
- Age
- Gender
- Case Number
- Nature of specimen
- Date of Collection
- Criteria for Pre analytical Error
- Insufficient Sample Volume
- Incorrect Identification of patient
- Lost / Missing sample
- Sample collected in inappropriate tube
- Clotted sample in EDTA
- Wrong sample
- Hemolysed sample
- Lipemic sample
- Sample not an ice
- Incomplete Laboratory requisition
- Delayed transport of specimen
- Errors in sample preparation

# IV. Data Analysis And Result

All Opd samples were generated by computerized requisition slip which carried patient information and test details . All samples were examined OPD based on predetermined criteria parameter must indicate on the application forms and laboratory criteria for pre analytical errors.

Data Collection Period	APR	MAY	JUN	TOTAL
Number of test	166314	176912	171601	514827
Number of samples	41601	40816	35637	118054
Number of Pre analytical mistakes	813	927	647	2387
Frequency in %	1.95%	2.27%	1.81%	2.02%



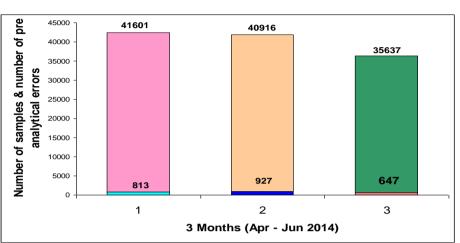


Fig 2 Number of pre analytical errors

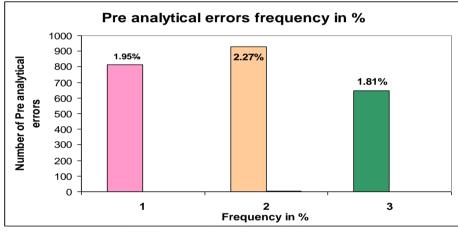


Fig 3 frequency in % of preanalytical error

The number of tests sent for analysis were greater than number of patients because more than one test are requested to performed on a single sample

Table.? Frequency	of Pre analytical mistakes in Laboratory testing 3 Months -238'	7
Table: 2 Frequency	of Fre analytical mistakes in Laboratory testing 5 Months -256	/

Errors in Pre analytical steps	Number	Frequency in %
Patient information		
Name	0	0
Age	149	6.24%
Gender	118	4.94%
Case Number	34	1.42%
Nature of specimen	63	2.63%
Time of Collection	147	6.15%
Insufficient sample volume	129	5.40%
Sample not received	439	18.39%
Wrong sample	263	11.01%
Clotted sample in EDTA	138	5.78%
Sample collected in inappropriate tube/container	32	1.34%
Sample not an ice	25	1.04%
In correct identification of sample	17	0.71%
Hemolysed sample	807	33.80%
Lipemic samples	26	1.08%

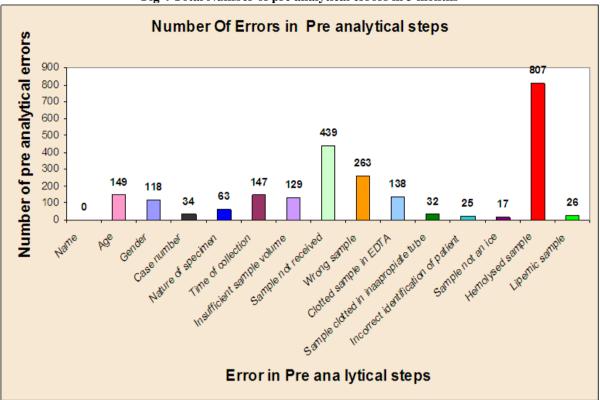
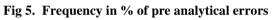
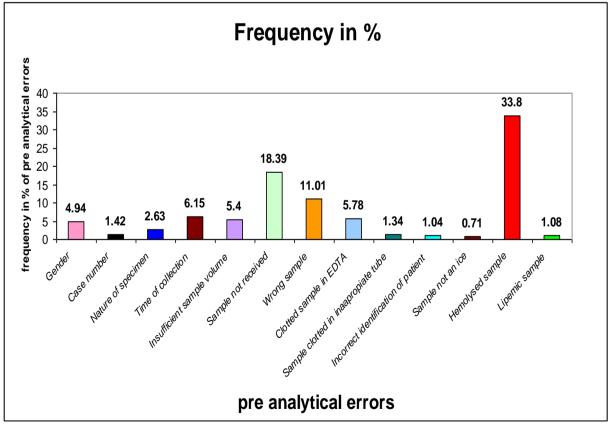


Fig 4 Total Number of pre analytical errors in 3 months





# **Defination of Specimen:**

- **Hemolysed Sample:** Visible hemolysis following configuration is defined as the presence of free hemoglobin in serum or plasma.. Hemolysis of sample occur when blood is forced through a fine needle, shaking the tube vigorously and centrifuging the specimen before clotting [6].
- Lipemic Sample : Lipemic samples are often seen following collection after heavy meals or due to pre existing metabolic disorder
- **Clotted Sample** : Those specimen that present with visible clots either as a red cell clot in whole blood or a fibrin clot in plasma .

## V. Findings, Conclusion & Recommendations

**Findings:** During three month period, 118054 specimen were conducted, of which 2387 presented some type of pre analytical error 2.02 %. The three main observed causes of pre analytical errors were hemolysis 33.80 %. Sample not received or missed 18.39 %. And third one is insufficient sample volume 5.40 %.

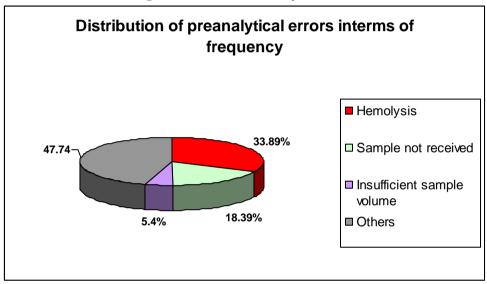


Fig 6 Distribution of Pre analytical errors

# VI. Discussion

The health system is increasingly dependent on reliable clinical laboratory services that are part of the overall health system prone to error .. laboratory error has been significantly reduced , with the advancement of technology, automation. The size of the effect of the synthesis error on patient care is not negligible because the information relates to clinical laboratories up to 60-70 % of clinical decision-making .. So it is the duty of lab personal to ensure that report generation is prompt and precise In this study , when we examined the laboratory requisition form was noted that requisition forms do not carry all the information regarding the patient's sample. Only 1% forms out all necessary information. This may be due to excessive load of the patient, negligence or lack of awareness of laboratory staff on the importance of required information in an appropriate sample processing and sending reports.

The name of patient was recorded in all the forms whereas their age was not mentioned in 6.24%, gender 4.94% and case number 1.42%. The use of age and sex of the patient's laboratory requests forms is important for correct interpretation of the results as normal tests are different for different age groups and gender. As to the sample details the nature of the sample is not mentioned in the 2.63% sample .time of collection in 6.15%. Failure mention the nature of the sample , has led to difficulties in the analysis of the sample as a body fluid . One of the most important detail required in the analysis of the sample is the time when it collects information such as age, gender, nature of sample interpret ate the result and minimize erroneous determination of the disease.

During the study, it was observed the most occurring pre analytical error was hemolysed samples. hemolysis accounts for the majority of failures in the sample received at the laboratory. The introduction of vacuum tubes with a closed system for the collection of blood made blood collection effectively and easily. But the lack of training of personnel involved in the bloodletting prevent the acceleration of sample collection and transport. Red Top Vacutainer without anticoagulant should not be shaken after the sample was collected, and Vacutainer plasma should be gently inverted several times so that the anticoagulant thoroughly mixed with blood. Freezing and thawing of the blood sample also leads to massive hemolysis. A study reported that over 95% of the hemolysed sample were due to in correct sample procedure or transportation [7]. Hemolysis leads to extra vacation of intra cellular contents into the plasma leading to falls high values of potassium, sugar, LDH, etc The next most common pre- analytical error was found is a sample not received i.e 18.39 %. It was found that during the analysis of the root cause improper tube or container, the wrong sample incomplete patient identification, sample condition were the cause of the sample is not received. further awareness and low automation pre- analytical phase in our routine can be other possible causes.

Insufficient sample volume is the third cause of error, responsible for 5.40% error. This may be attributed to the fact that it is difficult to collect blood samples of children especially newborns, patient with chronic degenerative diseases with difficult venous access and elderly patients. Lippi and his fellow members reported insufficient specimen quality and quantity accounting for over 60% of pre analytical error.[7]

# VII. Recommendations

Systematic control of the overall process of continuous analytical monitoring and management of non - conformities is obligation of all medical laboratories . Although preanalytical quality standards are well established in international and national level ,mostly errors occurs in laboratory in preanalytical phase .Inappropriate samples due to misidentification , quantity ( insufficient volumes to perform analysis , insufficient blood / anticoagulant ratio ) or quality issues ( hemolitic , cloted , contaminated samples , samples collected in containers or wrong )represent the leading preanalytical problems .

In this study analyzed pre- analytical errors in details for clinical laboratory system. To improve the efficiency of the laboratory is recommended for the management of the laboratory analyzes pre- analytical, analytical and post analytical phase of the total testing process, highlight possible errors at every step in laboratory operations and stressed the need to monitor laboratory errors to be reduced to a minimum of rejection of the sample and thus to improve the laboratory results.

Recommendations include staff education and responsibility, implementation of objective and standardized criteria and procedures for the detection of inadequate samples and samples of inappropriate management. Training of health workers involved in the process of collecting, handling, preparation and shipment of samples is critical to understanding the effects of preanalytical factors on the quality of the sample. Since standardized preanalytical procedures can reduce the impact of short -term methodological and biological factors, guidelines for the collection, handling and transport of samples must be clear, comprehensible and easily accessible to all healthcare entities involved in preanalytical processes, both inside and outside the laboratory.

For effective implementation, it is essential to ensure constant communication and cooperation between all members of the health care team . Hemolysis , lipemia , and jaundice are factors that affect the quality of the sample. The intensity of the interference depends on the manner and the analyte. The use of technology can automatically check if it is necessary to detect and repair a wide range of analytical interference , including hemolysis , lipemia , jaundice , as well as insufficient or thick samples is recommended because it would help to overcome the subjectivity of visual inspections , increased sensitivity in the detection of inappropriately samples and harmonize deals with the behavior of the medical staff .

The laboratory should be under its clearly specify the type of operating procedures inappropriately samples and procedures adopted for their identification , the type of analyzes that may be affected by the presence of interfering substances and apply solution for managing non - discrepancies identified. Procedures for handling hemolysed and instructions for rejecting samples. By the standards of good laboratory practice , each laboratory should develop its own strategy for the identification , detection and monitoring inappropriately samples. Implementation of international recommendations with continuous monitoring , sampling and analysis of factors associated with rejection ,appropriate` corrective measures can reduce errors and promote continually improving the quality of the entire analytical process

To prevent laboratory error management should regularly review the number of samples rejected and the reasons for rejection by conducting audits and training, phlebotomy education, continuing education, technology and management review of a sample, as and when necessary..

It is the responsibility of the laboratory manager to instruct staff to record all errors and their causes . Promptly inform the authorized person that is inappropriate for testing and need a fresh sample .

In conclusion, we as laboratory workers should adopt a holistic approach to laboratory diagnosis and function in close coordination with clinicians so as to provide effective services for the diagnosis of patients. Adoption of quality control, not only in analytical processes and regular assessments and audits, but in all phases of the diagnostic process is necessary to safe guard the interests of patients and deliver quality services.

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#### References

- [1]. Angeles, G. (2014) Pre –analytical Errors Management in the Clinical laboratory : a five year study .Biochemia medica ;24(2):248-57 [2]
- [2]. A Review of Medical Errors in Laboratory Diagnostic and where we are today.Lab .Med 2012, 43 (2) 41-44
- [3]. Alsin ,MJ et all (2008) Pre analytical Quality Control Program an over view of result 46(6),849-854 Clin Chem Lab Med
- [4]. Ashavaid TF, et al (2008) Influence of blood specimen collection method on various pre analytical sample quality indicators , 23(2):144-149 Indian Journal of Clinical Biochemistry.
- [5]. Bhat V,et al (2012) Analysis of laboratory sample rejections in the pre-analytical stage at an oncology center. Clinica Chimica Acta
  [6]. Bonini , (2002) Clinical Chemistry 48:5, 691 698, 2002
- [7]. Bras, J (2014) The use of indicators in the Pre analytical Phase as a Laboratory Management Tool. Vol 50 no.2
- [8]. Carraro P,et al (2012) Exploring the Initial steps of the Testing process: Frequency and nature of preanalytical errors. 58(3): 638-642. Clinical Chemistry. Clinical consequences of specimen rejection. (2011) CAP, Q-Probes
- [9]. Chawla R,et al (2010) Identification of the types of preanalytical errors in the clinical chemistry laboratory. 41(2): 89-92. Laboratory Medicine
- [10]. Dale JC, et al(2002) Outpatient Phlebotomy success and reasons for specimen rejection.126:416-419. Arch pathol lab Med.
- [11]. Howanitz ,(1983) Clin.Lab .Med ,3:541-551, [3]
- [12]. Hawkins R.(2012) Managing the pre- and post-analytical phases of the total testing process. 5-16. Annals of Laboratory Medicine
- [13]. Kittanakom S, Kavsak PA.(2014.) Metrics for identifying errors related to pre analytical sample handling. Clinical Biochemistry,
- [14]. Lippi G, Bassi A, BroccoG.:(2006) Pre analytical error tracking in a laboratory medicine Department : results of 1 year experience, Clin Chem ;52:1442-4 [7]
- [15]. Lippi G et al.(2013) Preanalytical Quality Improvement: in Quality we trust. 51(1): 229-241. Clin Chem Lab Med
- [16]. Mario, P Medical Errors. Pre analytical issue in Patient Safety. Vol29, issue 4 Pg310-314 Journal of Medical Biochemistry
- [17]. Mario, P (2007) Laboratory Errors : How to improve pre and post analytical phases 17(1) 5-9 Biochemia Medica
- [18]. Neelam ,C. (2011) Effect of Pre Analytical Errors on Quality of Laboratory Medicine at a Neuropsycharity Institute in North India.. 26(1): 46-49 DOI 10.1007/s12291-010-0082-2. [1]
- [19]. Naz S, et al (2012) Preanalytical errors and their impact on tests in clinical laboratory practice ; 51(1).Patiskan Journal of Medical Research 2012; 51(1).
- [20]. Narayanan S, (2000) The Pre analytical Phase- an important component of laboratory medicine. Vol.113 pp429-52 American Journal Of Clinical Pathology.
- [21]. Oswald S, (2010. Quality in the analytical phase. Vo20. No.2pp147-53 Biochemia Media.
- [22]. Ottomano C, (2010) Errors in medicine and errors in laboratory medicine what is the differenceVol8.pp79-81 Blood Transfusion
- [23]. Plebani M, (2006) Errors in clinical laboratories or errors in laboratory medicine Clinical Chemistry Laboratory Medicine , Vol.44,No.6 pp 750-759 [5]
- [24]. Plebani M, et al. (2013) Frequency of Errors in Quality indicators to detect Preanalytical errors in laboratory testing. Clinica Chimica Acta.
- [25]. Plebani, M. (2009) Exploring the Ice berg of Errors in Laboratory medicine 404(1):16-23 Clinical Chem Acta.
- [26]. Pelbani M. (1997) Mistakes in a STAT laboratory :types and frequency. Vol 43.pp1348-51. Clinical Chemistry.
- [27]. Rieppi C.(2009) Pre-Analytical variables and laboratory total error. . Laboratory Management Magazine
- [28]. Revere A.(2007) National Patient safety Goals for 2007. Vol 7 No.1Topics in Patient safety.
- [29]. Solomon, DH. (1998) Techniques to Improve Physician's use of Diagnostic tests, a new conceptual frame work. Vol.280 No.23, pp 2020-7The Journal of American Medical Association. [4]
- [30]. Salvagno G, et al.(2013) Is a Specific Order of Tube Draw Required during blood collection by Veni puncture? Clinical Chemistry and Laboratory Medicine,
- [31]. Sadiq F, et al.(2013) Frequency of Errors in Clinical laboratory practice Iranian Journal of Pathology.
- [32]. Serdar MA et al (2008) Tourniquet application Time during Phlebotomy and the influence on the clinical chemistry testing ; Is it negligible.Vol.33.No.3pp85-88 Turkish journal of Biochemistry.
- [33]. Silverstein MD, (2003) An Approach to medical errors and and patient safety in laboratory services . A white paper. The quality institute Meeting Atlanta.
- [34]. Stantkovic AK< (2004) The laboratory is a key partener in assuring patient safety, Vol.24 No.4pp1023-35Clinical Laboratory Medicine.
- [35]. Soderberg J, etal (2009) Pre analyticals errors in primary health care: a questionnaire study of information search procedures, test request management and test tube labeling .47(2):195-201 Clin Chem Lab Med.
- [36]. The Importance of Quality in the Preanalytical Phase'. Presentation given at the WorldLab congress in September 2008.
- [37]. Wagar EA et al.(2006) Patient safety in clinical laboratory : A longitudinal analysis of specimen identification errors. 130:1662-1668 Arch Pathol Lab Med.
- [38]. Wiwanikit V, (2001) Types and frequency of preanalytical mistakes in first thai ISO9002:1994 certified clinical laboratory, a 6 month monitoring, Vol.1No.5. BMC Clinical Pathology.
- [39]. Zaninotto M,et al (2012) Effects of Sample Transportation on commonly requested Laboratory testing tests .50(10): 1755-1760 Clin Chem Lab Med