DISSERTATION REPORT

AT

DR LAL PATHLABS, NATIONAL REFERENCE LABORATORY, DELHI

(07th MARCH TO 07th JUNE, 2022)

A REPORT ON

Effect of Pre-Analytical Errors on Quality of Lab Results

BY

Dr. Shuchi Soti

(PG/20/078)

POST-GRADUATE DIPLOMA IN HOSPITAL AND HEALTH MANAGMENT

2020-2022

Completion by organization

The certificate is awarded to

Name Dr. Shuchi Soti

in recognition of having successfully completed his/her Internship in department of

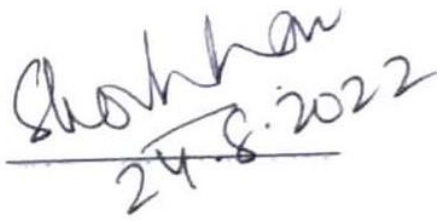
Title Technical- Quality associate

and has successfully completed his/her Project on Effects of Pre-analytical errors on quality of Lab results.

Organization: Dr Lal Path labs

She comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.

We wish her all the best for future endeavors.



Dr. Seema Kochhar

Principal Director-Quality management

Date: 24-08-2022

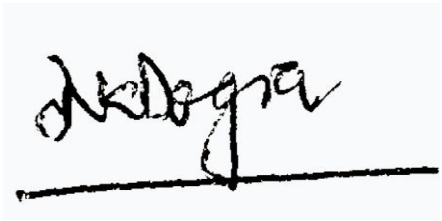
TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Dr. Shuchi Soti** student of PGDM (Hospital & Health Management) from International Institute of Health Management Research, New Delhi has undergone internship training at Effect of Pre-Analytical errors on the quality of Lab results from **07-3-22 to 07-05-22.**

The Candidate has successfully carried out the study designated to her during her internship training and her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all success in all her future endeavors.



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Certificate of Approval

The following dissertation titled **"Effect of Pre-Analytical errors on the quality of Lab results"** at **"Dr. LAL Path Labs"** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **PGDM (Hospital & Health Management)** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

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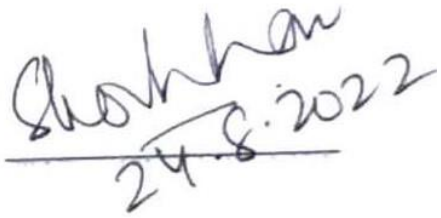
Certificate from Dissertation Advisory Committee

This is to certify that **Dr. Shuchi Soti,** a graduate student of the **PGDM (Hospital & Health Management)** has worked under our guidance and supervision. She is submitting this dissertation titled "Effect of Pre-Analytical errors on the quality of Lab results at "Dr. Lal Pathlabs" in partial fulfillment of the requirements for the award of the **PGDM (Hospital & Health Management).**

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.



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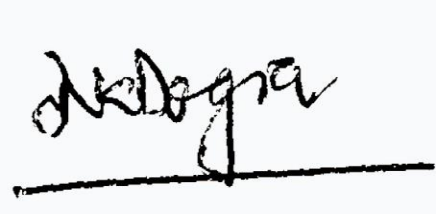
This is to certify that the dissertation titled **Effect of Pre-analytical Errors on quality of Lab results** and submitted by **Dr. Shuchi Soti**, Enrollment No- **PG/20/078** under the supervision of **Dr. Nitish Dogra** for award of PGDM (Hospital & Health Management) of the Institute carried out during the period from **07-03-2022 to 07-05-2022** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.



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Name of the Student: Shuchi Soti

Name of the organization in Which Dissertation Has Been Completed: Dr. Lal Path Labs, NRL, Rohini, Delhi

Area of Dissertation: Effect of Pre-analytical errors on quality of Lab results.

Attendance: 100%

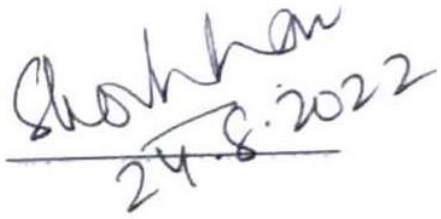
Objectives achieved: Yes

Deliverables: Yes

Strengths: Keen learner

Suggestions for Improvement: Presentation Skills

Suggestions for Institute (course curriculum, industry interaction, placement, alumni):



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Date: 24-08-2022

ACKNOWLEDGEMENT

Any attempt at any level cannot be satisfactorily completed without the support and guidance of learned people. I owe a great debt to all the professionals at Dr Lal PathLabs, for sharing generously their knowledge and time, which inspired me to do my best during my dissertation.

I express my gratitude and sincere thanks to Dr Seema Kochhar (Principal Director - Quality Management, Dr Lal Pathlabs, NRL, Rohini, Delhi) for her valuable guidance and co-operation in my endeavour. I am thankful to the management of Dr Lal Pathlabs, for giving me the opportunity to carry-out dissertation project in their esteemed organization.

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Title of the Dissertation/Summer Assignment	Effect of Pre-Analytical errors on quality of Lab results		
Plagiarism detects software used	"TURNITIN"		
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About Dr Lal PathLabs

- **History of the Organization:** Late Dr. Major S.K. Lal, commenced the business of providing pathology services and maintaining a blood bank in the year 1949. The business of diagnostic and related healthcare tests and services now continues to be provided by the Company.
- They focus on providing patients quality diagnostic healthcare services in India. Through their network, they offer patients convenient locations for their **diagnostic laboratory services** and efficient service. With over 5000+ diagnostic tests & related healthcare tests and services offered, they believe they are capable of performing substantially all of the diagnostic healthcare tests and services currently prescribed by physicians in India. By delivering **most accurate** reports over the years, Dr. Lal PathLabs has earned the reputation of being amongst the most **trustworthy and reliable pathology labs in India**.
- Their network has coverage across India, including metropolitan areas such as New Delhi, Mumbai, Bengaluru, Chennai, Hyderabad and Kolkata. They offer access to one of the **best diagnostic pathology services in India** through their nationwide network of clinical/medical laboratories (including National Reference Laboratory), lab patient service centers and pickup points.

LABORATORY ACCREDITATIONS

Dr. Lal PathLabs, Rohini is NABL **certified pathology lab in India**. It is also among the few Indian laboratories which accredited by CAP (College of American Pathologists) and Certified by ISO 9001 (International Organization of Standardization)

VISION:

Be the most trusted healthcare partner, enabling healthier lives.

MISSION:

To be the undisputed market leader by providing accessible, affordable, timely and quality healthcare diagnostics, applying insights and cutting edge technology to create value for all stakeholders.

VALUES:

- Technology & innovation
- Quality & Excellence
- Highest ethical standards

INTRODUCTION

Laboratory results play a vital part in clinical choices and treatment of a patient in today's health care. Lab test findings are thought to account for about two- thirds of critical healthcare decisions such as admits, discharges, and treatment. As a result, lab testing is a common cause of healthcare mistakes that might jeopardize safety of patients.

For all labs, quality is paramount, and this necessitates total quality control throughout the lab procedure, including the pre- analytic, analytic & post- analytic phases. Total quality management refers to all stages included in specimen preparation, right from the test order to analysis of results by the physician with the goal of reducing or eradicating any potential errors that might occur along the way. The adoption of optimal phlebotomy & sample transport guidelines is crucial for optimal lab operation.

Because reliable lab findings are required for diagnosis, labs must assure responsibility & integrity of results in order to avoid inaccurate diagnosis owing to a poor report. Regular monitoring of mistakes at all levels of assessment and developing remedial techniques to prevent them in the future may help a lab eventually become error-free.

Lab testing is a complicated procedure split into 3 different phases: pre- analytical, analytical, and post- analytical. Pre- analytical phase takes place beyond the lab control, & includes choosing relevant tests based on the medical issue, as well as scheduling, collection, packing, transporting, and processing of specimens for evaluation. The patient is generally at the beginning and completion of the procedure.

Pre- analytical errors arise from the moment clinician orders a lab test until the specimen is available for examination. In regards to analytical phase in lab testing, developments in

equipment tech and automation have reduced workload and enhanced the quality of test results. The similar cannot be said for the pre- analytical phase, which continues to be the most predisposed to errors, with 46% to 68% of errors occurring across the entire testing procedure. As a result, the pre- analytical phase is an important part of lab diagnostics that requires additional care.

Historically, the analytical phase has been used to examine the validity of lab findings. The pre-analytical phase has received little scrutiny, and its possible effect has been overlooked. The majority of errors, though, happen even before samples enter the lab, that is during the pre-analytical stage. Throughout this phase, many errors are attributed to manual interventions. The phase in the diagnostic procedure when the errors happen, and who is accountable for them, is inconsequential to the patient. Patients are entitled to obtain accurate results. Tests relying on false facts should be redone, causing the healthcare industry to incur increased expenses. It might result in treatment lags for the patients & might influence therapeutic decisions.

Pre- analytical phase of the total testing procedure has a significant impact on the accuracy of lab test results, as well as the quality and safety of patient care. As a result, lab staff and phlebotomists face a struggle in recognizing these characteristics, which have a negative impact on lab output. Phlebotomists and lab staff play a critical part in collecting and processing samples, as well as in delivering correct information to patients prior to tests. They must be well informed about the consequences of distinct pre- analytical variables and their permutations on test outcomes.

Aim: To outline different types of Pre-Analytical errors & determine their impact on quality of Lab results.

Objectives:

1. To explore and define various types of pre-analytical errors within the laboratory total testing process, starting from test request to processing of the blood sample.
2. To understand the causes and effects of pre-analytical errors on quality of lab results, overall lab performance and patient health.
3. To identify the possible corrective and preventive measures to be taken to minimize pre-analytical errors.

Research Methodology:

- **Research Design-** Exploratory Study
- **Type of Data-** Secondary Data
- **Methods of Data Collection-** Literature Review and Reviews of Case Studies.
- **Data Sources-** Published articles, News articles & Sites
- **Key words-** Preanalytical, error, lab and results
- **Tools-** Tables, Diagrams and Figures

PHASES OF TOTAL TESTING PROCESS (TTP)

Lab testing is a very complicated procedure that begins with the scheduling of a test and ends with the analysis of a test report, which is referred to as the Total Testing Process (TTP). In a nutshell, it's a multi- step procedure which starts and finishes with concerns of the patient. TTP is described by Lundberg as a 9 phase 'brain-to-brain' loop that begins with the doctor's brain and continues through the test prescription, sample collection, sample and patient recognition, transportation, processing, assessment, and return to the clinician [1].

Later, a post- post analytical phase was added, which comprised explanations from the lab and the associated clinician, as well as explaining the results in presence of the patient. Lundberg also has suggested that the method be extended in order to reach a value of diagnostic efficacy in relation to public health.

Lab processes are divided into 3 phases by the International Organization for Standardization (ISO). The following are the 3 major phases:

• The **Pre- analytical phase** is described as the phase that initiates with the physician's test recommendation, followed by examination request, patient preparation, sample identification, collection, handling, transportation of sample, and concludes with the beginning of the analytical assessment process.

• The **Analytical Phase** starts when the sample is prepped for testing in the lab, proceeds with sample processing, and concludes with the test result being analyzed and validated by the lab technician.

• The **Post- analytical phase** focuses on assessing the findings of lab tests for clinicians to confirm the diagnostic and treatment method.

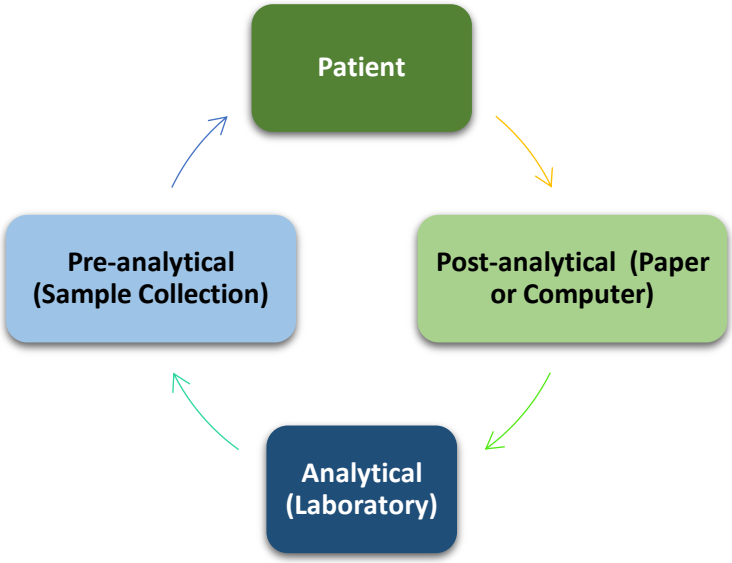


Figure 1: Phases of the Total Testing Process (TTP)

An additional idea of the pre- pre-analytical phase has also been added, albeit the distinction between this and pre- analytical phase is uncertain. The pre- pre-analytical phase is defined as the step wherein the concerned clinician develops the suitable request for the test and then chooses the tests to be performed. While on the other side, Plebani defines the pre- pre-analytical phase as all of the steps that take place just before the lab receives the sample i.e. test request, patient identification, sample collection & transport [2]. The pre-analytical phase is described as the procedures such as labeling, confirmation, centrifugation, and isolation which happen as a portion of the sample's preparation for evaluation inside the lab.

ERRORS IN TOTAL TESTING PROCESS

A lab error can be described as any fault which happens through the whole total testing process, right from requesting tests to publishing results & has an impact on the quality of lab activities in some or the other way. Lab errors may occur in any part of the total testing procedure, or in all three phases.

The lack of consistency in the terminology used in TTP might cause challenges in collecting information and error detection owing to the similarities in the description of TTP phases and key performance indicators. Some other important analytical errors in lab are caused by a lack of economic and personnel resources, a lack of consistency, and a bad operation structure.

The proportion of errors in each phase of the TTP, is shown in Table 1.

TTP Phase	Examples of Errors	Estimated proportion of errors
Pre-analytical	Incorrect test ordering, Wrong patient identification, patient preparation & condition, sample collection, sample quality, transportation, storage, sample sorting, centrifugation, labelling, separation.	46-68%
Analytical	Equipment malfunction, Calibration drift, Non conformity with QC, Reagent contamination, Systemic Error; probe or lamp, blocked tubing, Random Error	7-13%
Post-analytical	Failure or delay in reporting, Improper data entry	19-47%

Pre- and post- analytical phases account for about more than 95% of total testing errors.

When lab errors happen or are recognized, they lead to specimen rejection, repeated collection & delays in delivering results, putting a financial strain on the lab and requiring more employee time. Patient safety is clearly impacted by errors which actively influence the diagnostic

results, therapy, or recommendations provided to the patient, like an inaccurate ABO blood group, inaccurate genetic evaluation, wrongly diagnosed infectious pathogen.

Every phase of the lab testing procedure must be defined in order to identify & avoid errors in the lab. The use of a quality management framework and ISO regulations could greatly minimize errors & assist staff in understanding the phase wherein the error happened. To assure and avoid recurrence of errors throughout lab testing process, preventative and corrective measures should be implemented. The lab has a number of set standards which must be followed to assure the quality & validity of the specimens, as well as to confirm & assess the accuracy of the findings obtained.

PRE- ANALYTICAL PHASE & ERROS

The pre- analytical phase is defined by the ISO 15189:2008 standard for laboratory accreditation as steps beginning in chronological order, from the physician's recommendation and including the examination requisition, patient preparation, specimen collection & transportation to the lab,

and concluding when the analytical assessment starts.

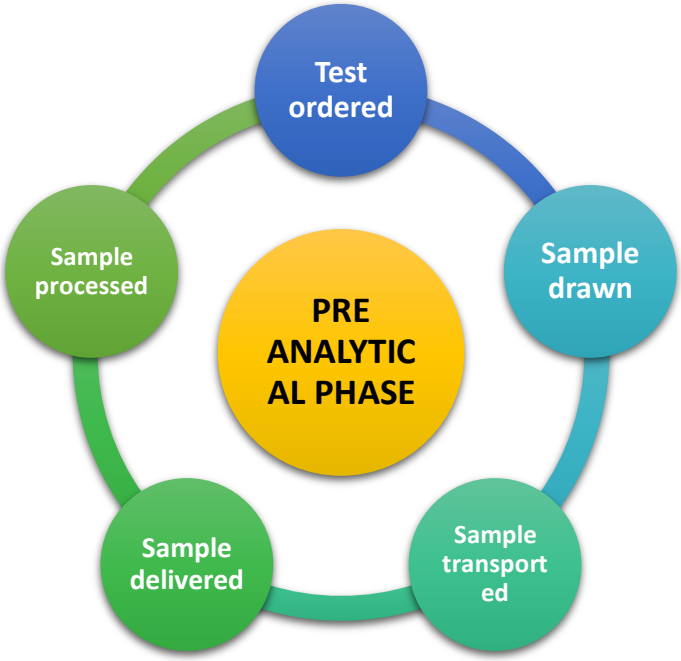
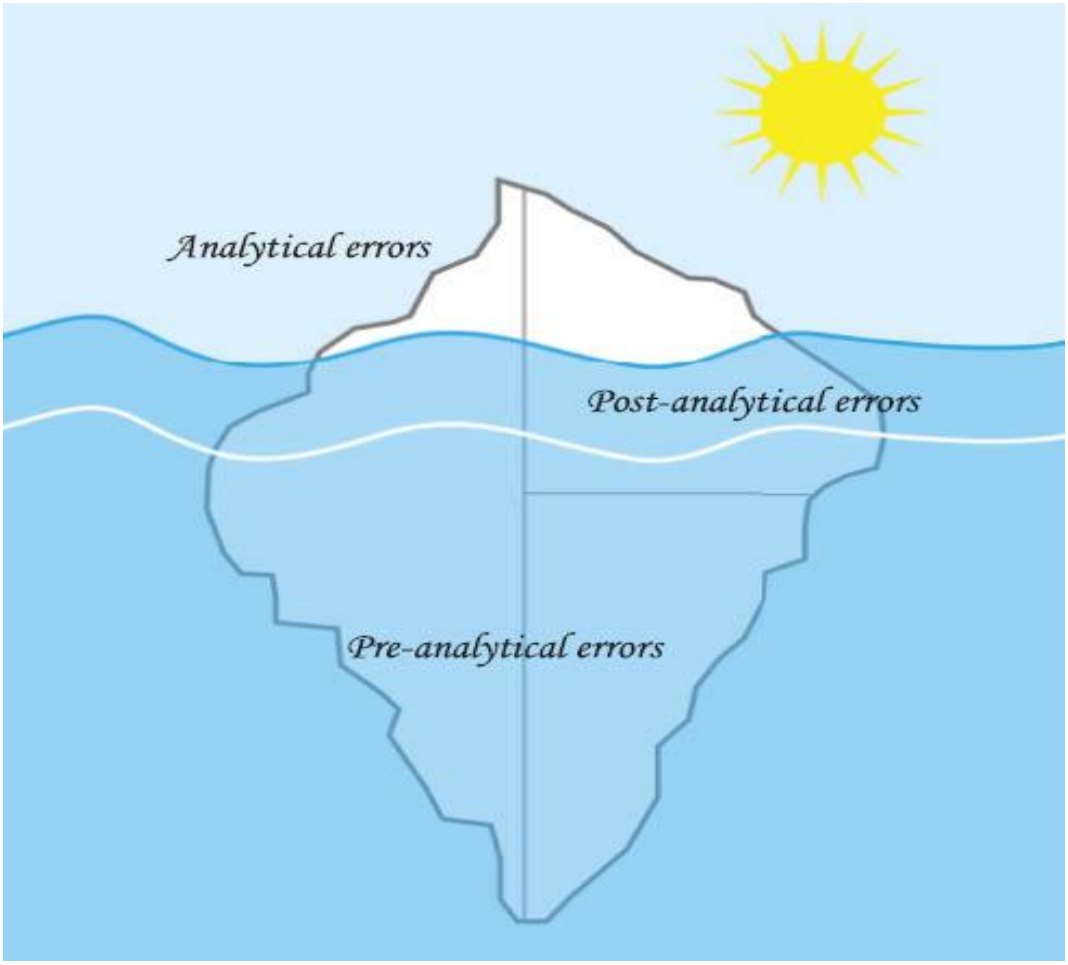


Figure 2: Cycle of Events in Pre-Analytical Phase

NEED FOR PRE-ANALYTICAL ERROR MANAGEMENT

The primary attention of lab professionals has been on analytical phase errors and diagnostic faults. But, because of the large incidence of errors, lab specialists have now gradually shifted attention on the pre- and post- analytic phases. Such errors have a significant impact on the client's protection and wellbeing. Approximately, 70% of clinical lab errors are due to pre-analytical errors. Pre- analytical errors can occur during a variety of processes, like logging in, pipetting, centrifugation, and classifying specimens into groups for automated sample analyzers. According to several reports, the majority of laboratory errors happen prior to and post the analytical phase, with just some errors arising during the analytical phase.

In regards to analytical phase in lab testing, developments in equipment tech and automation have reduced workload and enhanced the quality of test results. The similar cannot be said for the pre- analytical phase, which continues to be the most predisposed to errors, with 46% to 68% of errors occurring across the entire testing procedure [3]. As a result, the pre- analytical phase is an important part of lab diagnostics that requires additional care [4].



Manual errors account for the majority of pre- analytical errors, which are avoidable since they entail more people interaction than the analytic and post- analytic phases. There are 2 sorts of parameters in pre- analytical errors. Age, gender, postural influences, activity, stress & menstruation are all factors that affect the patient test results. Hemolysis of sample, sample

collecting procedure, transport & preservation are all sample- related parameters. Thus it is consequently critical for lab staff members to recognize potential sources of inaccuracy, especially when dealing with urine and blood samples.

Wrong or Incomplete Test Orders

Owing to the effect on overall expenses as well as the underlying danger of clinical errors & harm, misuse of lab services by ordering improper lab tests is being scrutinized around the world. Inadequate or insufficient data on the test order or labels, that has been observed in more than two- thirds of all discarded specimens at the lab, is a major cause of pre- analytical error [5]. Many more papers have found that diagnostic orders could be a significant cause of medical errors [6]. Inadequate lab request forms are seldom refused at the point of services and the lab receptionist personnel might not always understand the relevance of the insufficient information in several cases. The doctor's name, client misidentification, and ordered testing were among the details that were lacking [7].

Patient preparation

Many patient characteristics should always be considered prior to collecting samples. To minimize incorrect findings, overnight fasting of at least 12 hours is recommended for analytes like glucose and lipids. Analyte such as cortisol has recognized diurnal fluctuations. In these kind of instances, an aggregate of specimens taken at two distinct periods of the day could be taken into account.

Patient identification

It's critical to correctly recognize patients in order to obtain the required specimens from relevant patients. It is essential to mention the patient's full name, residence, identity numbers, or date of birth while recognizing them. Because accurate patient recognition is the most crucial responsibility in all clinical processes, attempts to guarantee adherence to standardized recognition processes ought to be priority. Up to 25 percent of total of all pre-analytical errors are caused by errors in patient recognition prior to sample retrieval [8]. Patient recognition errors are common during human operations that can be prevented with the use of digital solutions such as barcodes, radio frequency recognition, and wristband [9].

Owing to the lag in the delivery of proper reports, collecting samples from the incorrect individual or tagging the specimen incorrectly will lead to inaccurate findings, which may influence the treatment plan. It also might necessitate repeated testing, increasing treatment costs significantly.

Sample Identification

Labeling sample containers must be completed prior to specimen collection, as labelling containers just after the event elevates the chance of collecting specimens from the wrong individual. Mis-labeling is to be blamed for half of all recognition errors [10].

Sample Collection & Quality

The collection of high-quality samples is a crucial aspect of excellent lab practice. Erroneous specimen collection may result in postponed reports, additional re-evaluation, worse client experience, higher expenditures, poor treatment, medical damage & even death.

Inadequate specimen collection may result in delayed reports, unwanted re-tests, poor client experience, additional expenditures, wrong treatment, injuries, and even death. Prescription rehearses, researches have indicated that monitoring the sample quality is an important determinant in the reliability & validity of test results [11].

A high number of pre- analytical errors are caused by specimens which are lost, coagulated, hemolysed, inadequate, or incorrect as a result of improper sample collection & processing.

i. **Inadequate Volume:** A primary issue contributing to specimen rejection is lack of quantity. The major cause of this discrepancy is the phlebotomist's lack of knowledge, as well as challenging sampling in paediatric patients, handicapped patients, those on chemo-therapy & those with difficult-to-locate veins [12].

ii. **Incorrect Phlebotomy Practices:** Pre- analytical errors are caused by a dearth of expertise or a tremendous burden, and faulty phlebotomy methods are one of the leading causes [13].

iii. **Lipemic Samples:** Lipemic specimens are frequently collected after large meal or as a result of a pre- existing metabolism condition. A handful of such errors could be prevented by taking blood samples post over-night fasting or stating the metabolism disease on the request sheet. Fat may influence electrolytic readings by interfering with device's optic readout. Most of the lipemic specimens are frequently the result of doctors' failure to disseminate data about patient readiness & patient misinterpretation [14]. Physicians and laboratory staff are responsible for ensuring that correct patient prep is implemented prior to specimen retrieval.

iv. **Hemolysis:** Hemolysis occurs whenever blood is pushed past a small needle, the tubes are violently shaken & the samples are centrifuged prior to clots. Hemolysis is

responsible for most of sample denials in the lab. Shortage of phlebotomy training is a roadblock to blood collection & transportation. Once the specimen has been obtained, red top containers with really no anti-coagulant ought not be shook & containers for plasma must be lightly flipped just a couple of times so that the anti-coagulant blends with the sample. According to one research, almost 95% of the hemolysed specimens were attributable to improper sample collection or transporting [15].

Sample Transport

Owing to lags in transport to the lab, major medical mistakes may arise if transport arrangements aren't really improved. All specimens must be tested after 6 hrs of collecting, if possible. Long-term specimen storage is a valuable advantage, however, it may result in pathological alterations. Extreme warmth or cooling of the specimen may potentially render it unfit for examination.

Storage of Samples

When the test is going to be postponed, the samples are to be kept at 2-8 °C. In case, centrifugation is required for the whole blood sample, it must be done within 2 hrs of the blood collection. The specimen would be viable for 8 hrs at normal temperature & up to 48 hrs at 2-4 degrees Celsius once the serum has been extracted. Covering the tubes in aluminium sheet may assure durability for light sensitive analytes that are to be sheltered from daylight (Bilirubin).

Table 2: Common Pre-analytical errors & their consequences

Phase	Error	Consequences
Patient identification	Incorrect or inadequate information	Mis-diagnosis or delayed diagnosis because of repeated sampling
Patient preparation	Collection post meal for tests requiring fasting samples	False high values for parameters which increase after a meal eg. glucose, resulting from collection after a heavy meal can interfere with optical measurements and electrolyte analysis.
Sample identification	Inadequate labelling	Misdiagnosis or delayed diagnosis due to repeat sampling
Sample Collection & Quality	• Inadequate Volume • Incorrect Phlebotomy Practices • Lipemic • Hemolysis • Clotting	Faulty values leading to misdiagnosis, inappropriate treatment, additional pain & discomfort due to multiple pricks, delayed diagnosis due to repeat sampling, delayed reporting of time-critical results.
Sample Transport	Prolonged time in transit, Extremes of temperature in transit	Delayed reporting of time-critical results, sample deterioration
Sample preparation	Inadequate or excessive mixing prior to analysis, delayed processing and centrifugation conditions	Spurious cell counts, faulty values leading to misdiagnosis or delayed diagnosis due to repeat sampling
Sample Storage	Improper storage, length of time, temperature, freezing and thawing	Sample deterioration, delayed diagnosis due to repeat sampling

MATERIALS AND METHODS

The **Pubmed** database was used to conduct a literature search. The papers were written in **English** and published between **2000 and 2022**, and they looked at the impact of pre-analytical mistakes on lab results. Key search keywords included '**preanalytical**,' '**error**,' '**lab**,' and '**result.**' There were 201 studies found in the first search (Figure 3). Additional 11 relevant

researches were discovered by looking at the citations mentioned in the chosen papers. As a result, the search method returned a total of 212 citations.

An original study or review was taken into consideration, as were papers investigating pre-analytical errors in medical testing laboratories.

After removing the 5 duplicates, 207 papers were extracted. Their abstracts were examined and 124 papers relating to sample material other than blood were excluded. The selected papers were screened and 63 irrelevant studies were excluded. In total, **20** studies were identified and examined (Table 3).

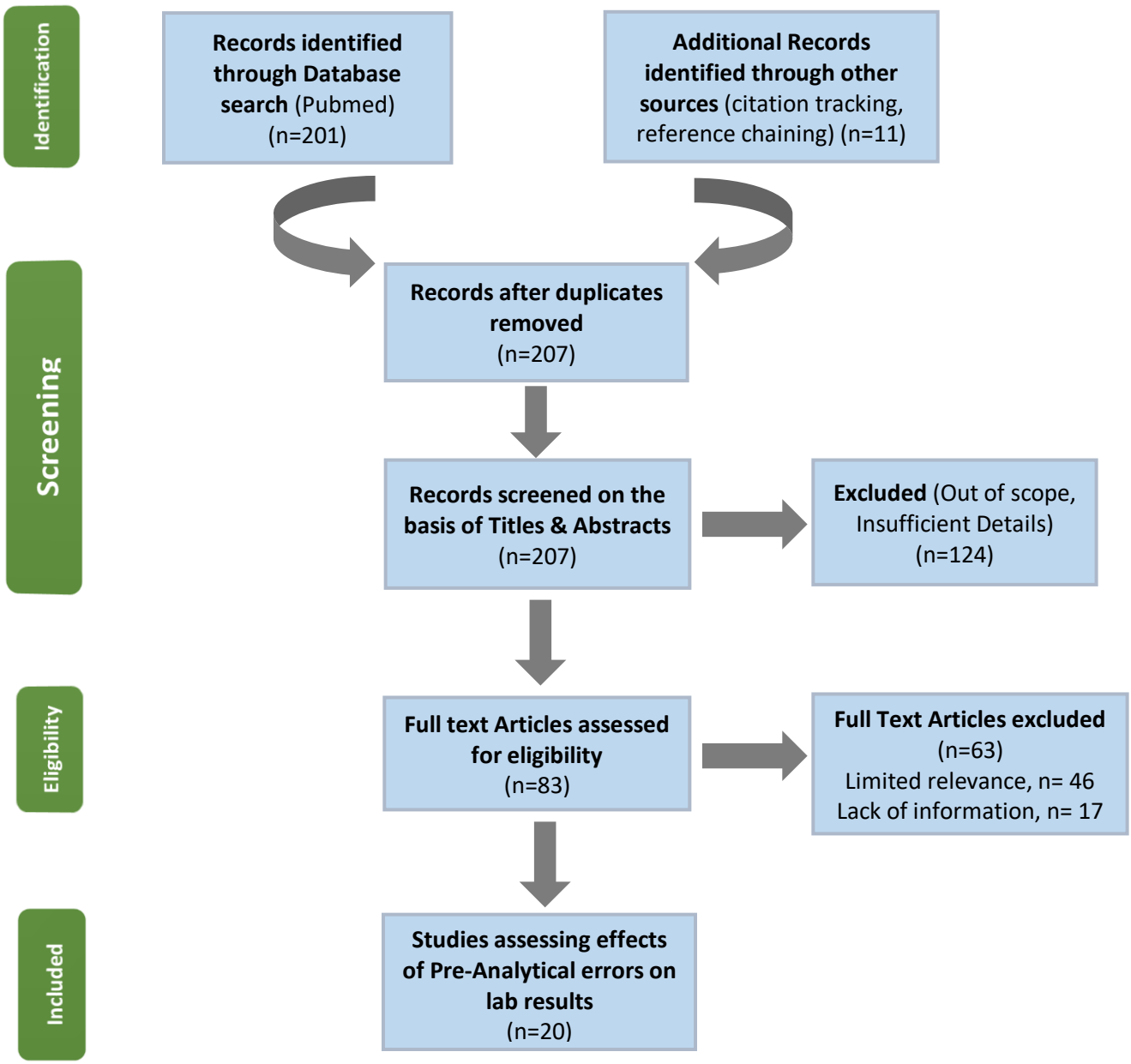


Figure 3: Modified Diagram, Flowchart of the study selection for the review

Table 3: The studies included in the review (n=20)

S.No.	Reference and Titles	Type of Study	Pre-analytical Quality Errors
1.	Gräsbeck R [16] The evolution of the reference value concept	Review	Prolonged tourniquet use
2.	Gama R, Teale J, Marks V [17] Clinical and laboratory investigation of adult spontaneous hypoglycaemia	Theoretical	Wrong Specimen Type
3.	Chaigneau C, Cabioch T, Beaumont K, Betsou F [18] Serum biobank certification and the establishment of quality controls for biological fluids: examples of serum biomarker stability after temperature variation	Experimental	Site of collection Rate of collection Prolonged tourniquet use Type of collection Tube additive Transport Hemolysis Blood cells
4.	Wagar EA, Tamashiro L, Yasin B, Hilborne L, Bruckner DA [19] Patient Safety in the Clinical Laboratory: A Longitudinal Analysis of Specimen Identification Errors	Experimental	Mis-labelled specimens Un-labelled specimens Clotted samples Container leaking Contaminated samples Hemolysis Improper collection Improper handling Specimen not suitable for test Quantity not sufficient Tube over-filled Tube under-filled
5.	Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V et al. [20] Causes, consequences, detection, and prevention of identification errors in laboratory diagnostics	Review	Misidentification in laboratory diagnostics: • Physician ordering laboratory tests on the wrong patient • Incorrect or incomplete entry of patient's data in the information system • Collection of specimens from the wrong patient • Inappropriate labelling of the specimens

6.	Lippi G, Montagnama M, Giovanni D [21] National survey on the pre-analytical variability in a representative cohort of Italian laboratories	Survey	Specimen not suitable for tests Lack of reference guidelines Conditions for specimen storage Sample transportation
7.	Lippi G [22]) Governance of pre-analytical variability: Travelling the right path to the bright side of the moon	Review	Inaccurate procedures Collection of specimens from wrong patient. Inappropriate labelling of the specimens Variation in tube filling
8.	Rattan A, Lippi G [23] Frequency and type of preanalytical error in a laboratory medicine department in India	Review	Incorrect specimen received Hemolysed samples Specimens not received Inappropriate storage conditions Discrepancy between test code and test request Clinical history not received Identification errors Insufficient sample Test prescription not received Specimen lipemic Whole blood specimen clotted
9.	Stroobants A, Goldschmidt H, Plebani M [24] Error budget calculations in laboratory medicine: linking the concepts of biological variation and allowable medical errors	Theoretical	Error frequencies specified in pre-pre-analytical and pre-analytical phase were 12.0% and 5.0% in the laboratory process
10.	Bowen R, Hortin G, Csako G, Otanez O, Remaley O [25] Impact of blood collection devices on clinical chemistry assays	Review	Discuss how blood collection devices such as needle, syringes, and catheters, collection tube components can alter laboratory results
11.	Da Rin G [26] Pre-analytical workstations: A tool for reducing laboratory errors	Review	Inappropriate test request Misidentification of patient Inappropriate container Mis-labelled specimens Specimen not suitable for test Variation in tube filling Improper storage period and conditions
12.	Wiwanitkit V, Lekngarm P [27] Requisition Errors for Blood Glucose Tests: A Hospital-Based Study	Review	Overlapping Tests
13.	Plebani M [28] Exploring the iceberg of errors in laboratory medicine	Review	Describes testing process errors in primary care and in an emergency department
14.	Piva E, Plebani M [29] Interpretative reports and critical values	Review	Describes how to prevent interpretation errors and improve patient safety

15.	O' Kane M [30] The reporting, classification and grading of quality failures in the medical laboratory	Theoretical	Reports, classifies and grade quality failures in laboratory policies and procedures
16.	Nauck M, Nauck M, Koetting J [31] A Recapping System for Automatic, Semiautomatic, and Manual Use	Review	Samples are covered insufficiently when storing
17.	Steindel S, Jones B [32] Routine Outpatient Laboratory Test Turnaround Times and Practice Patterns	Review	Delays in collection and transport stages
18.	Favaloro E, Soltani S, McDonald J, Grezchnik E, Easton L [33] Laboratory Identification of Familial Thrombophilia: Do the Pitfalls Exceed the Benefits? A Reassessment of ABO-Blood Group, Gender, Age, and other Laboratory Parameters on the Potential Influence on a Diagnosis of Protein C, Protein S, and Antithrombin Deficiency and the Potential High Risk of a False Positive Diagnosisn	Review	Describes some pre-analytical variables effect on thrombofilian testing. Request wrong time Wrong person
19.	Tripodi A, Breukink-Engbers W, Besselaar A and M [34] Oral Anticoagulant Monitoring by Laboratory or Near-Patient Testing: What a Clinician Should Be Aware Of	Review	Describes pre-analytical conditions and analytical variability in relation to INR Blood collection tubes Temperature and storage time
20.	Roshan T, Rosline H, Rapiaah M, Zaidah A, KhattakM [35] Hematological reference values of healthy Malaysian population	Theoretical	Patient preparation Blood sampling and processing

Studies were categorized into 3 broad groups according to content in order to synthesize the findings. Based on the procedures in the pre- analytical phase, the material of the chosen papers was divided into 3 groups (Table 4).

• Articles in **Group 1: before collection** deal with prepping patients for blood testing and the importance of lab findings for clients.

• Articles in **Group 2: during collection** deal with the collection & monitoring of blood specimens, as well as the impact on the reliability of customers' lab findings.

• Articles in **Group 3: after collection** deal with the preservation & transport of blood specimens, as well as their impact on the reliability of lab findings for customers.

Table 4: Pre-Analytical errors in blood sampling

1. Before Collection	**Reference**
Incorrect test request	Winwanitkit V, Lekngarm P. (1), Da Rin G. (2)
Improper time of collection	Tripodi A, Breukink-Engbers WG, van den Besselaar AM (3), Lippi G, Montagnana M, Giavarina D. (4)
Order entry errors	Da Rin G. (2), Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Plebani M. (5) , Plebani M. (6)
Misidentification of patient	Da Rin G. (2), Plebani M. (6), Lippi G, Montagnana M, Giavarina D. (4), Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Plebani M. (5), Rattan A, Lippi G. (7), Stroobants A, Goldschmidt H, Plebani M. (8), Favaloro E, Soltani S, McDonald J, Grezchnik E, Easton L. (9)
Patient preparation	Stroobants A, Goldschmidt H, Plebani M. (8), Tripodi A, Breukink-Engbers WG, van den Besselaar AM (3), Lippi G, Montagnana M, Giavarina D. (4), Roshan T, Rosline H, Rapiaah M, Zaidah A, Khattak MN. (10), Piva E, Plebani M. (11), Lippi G. (12)
2. During Collection	
Duration of Tourniquet use	Gräsbeck R. (13), Chaigneau C, Cabioch T, Beaumont K, Betsou F. (14)
Inappropriate container	Stroobants A, Goldschmidt H, Plebani M. (8) Da Rin G. (2), Chaigneau C, Cabioch T, Beaumont K, Betsou F. (14), Plebani M. (6), Lippi G. (12), Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Plebani M. (5)
Mis-labelled specimens	Wagar EA, Tamashiro L, Yasin B, Hilborne L, Bruckner DA. (15), Da Rin G. (2), Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Plebani M. (5), O'Kane M.(16)
Specimen not suitable for test	Gama R, Teale J, Marks V. (17), Stroobands A, Goldschmidt H, Plebani M. (8), Lippi G, Montagnana M, Giavarina D. (4), Wagar EA, Tamashiro L, Yasin B, Hilborne L, Bruckner DA. (15), Da Rin G. (2), Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Plebani M. (5), Bowen R, Hortin G, Csako G, Otanez O, Remaley O. (18)
Variation in tube filling	Stroobands A, Goldschmidt H, Plebani M. (8), Wagar EA, Tamashiro L, Yasin B, Hilborne L, Bruckner DA. (15), Rattan A, Lippi G. (7), Da Rin G. (2), Plebani M. (6), Lippi G. (12), Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Plebani M. (5), Bowen R, Hortin G, Csako G, Otanez O, Remaley O. (18)
Clotted Sample	Wagar EA, Tamashiro L, Yasin B, Hilborne L, Bruckner DA. (15), Rattan A, Lippi G. (7), Lippi G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Plebani M. (5)
Hemolysis	Wagar G, Blanckaert N, Bonini P, Green S, Kitchen S, Palicka V, Vassault AJ, Plebani M. (15), Chaigneau C, Cabioch T, Beaumont K, Betsou F. (14), Rattan A, Lippi G. (7)
3. After Collection	
Improper storage conditions	LippiG, Montagnana M, Giavarina D. (4), Rattan A, Lippi G. (7), Da Rin G. (2), Bowen R, Hortin G, Csako G, Otanez O, Remaley O. (18)
Delays in processing samples	Steindel S, Jones B. (19), Stroobands A, Goldschmidt H, Plebani M. (8), Lippi G, Montagnana M, Giavarina D. (4), Nauck M, Nauck M, Koetting J. (20), Da Rin G. (2)

RESULTS

Before Collection:

Test orders and patient recognition are the emphasis of this group. Client mis-identification in the pre- analytical phase is a major error which could be linked with such a substantial danger to the actual patient, according to numerous studies [3,20,22,24,26,33]. The main critical objective in enhancing patient health is reliability in client recognition [3,29]. Da Rin used both patient care recommendations & identification wrist bands to solve patient mistaken identity [26].

Patients misrecognition & incorrect guidance to customers were found to be the main critical errors prior to blood specimen collection. It's critical to guarantee that blood specimens are taken from the relevant individuals. Blood tests must not be collected prior the patient's identity has been verified. Throughout all instances, it is essential to adhere to approved specimen collecting protocols. The uniformity of drawing blood is ensured by adopting these criteria.

During Collection:

The emphasis in this group is on taking blood from the patients, which is a common cause of errors. Using a tourniquet renders it easier to detect vessels, however it affects lab findings if used for an extended period of time. Specimens were taken in improper vessels in certain trials, risking injury to clients due to the requirement for re- testing [3,18,20,22,24,26]. Loading tubes had issues as well, both with over-filling & under-filling, resulting in inconsistent lab findings [19,20,22,24,25-26,28]. Whenever blood collection is not done correctly, hemolysis is common. Hemolysis was a prevalent complaint, that prevented several lab tests [18-19,31]. Furthermore, in the pre-analytical phase, mis-labeled and unlabeled specimens were frequent mistakes [3,18-19,29].

The most common mistakes made while collection were, such as long time application of a tourniquet. It is critical that lab personnel learn how to utilize various tools and supplies, as well as why consistent management is necessary to maintain the reliability of the blood specimen.

After Collection:

This group is concerned with specimen processing in order to make a specimen ready for evaluation. The investigations revealed that both the management and preservation of blood specimens outside the lab have an influence on their viability [21,24-25]. Clotted specimens is a real issue in practice [19-20]. Clot formation may occur if blood specimens are not adequately blended post collecting. Clotted specimens aren't good for testing. If the specimens are treated aggressively following collection, hemolysis may ensue. The specimens must be transferred to lab as soon as feasible post collection. Evaporative cooling can dramatically modify analyte levels, according to Nauck et al. [31]. Lab data could be tainted by improper preservation settings [29]. Process lags could potentially have an impact on lab findings & as a consequence, patient treatment [19,21,24,28,31]. In pre- analytical phase, specimen transport & preservation are crucial.

In order to avoid the risk of hemolysis, specimens must be kept at optimal temperature & managed carefully.

DISCUSSION

The top prevalent pre-analytical errors were detected in this review, and they were linked to blood collection far outside the labs. The errors happened in 3 steps: before, during & after the sample collection. Patient mistaken identity & incorrect guidance to patients were found to be the top significant errors prior to blood sampling. It really is critical to verify that specimens

are taken from the appropriate people. Samples must not be collected until the person's identity has been verified. The uniformity of sample collection is ensured by adopting these criteria.

The most common mistakes made throughout collection were technical in kind, such as applying a tourniquet for prolonged time. Lab staff and Phlebotomists must know & comprehend how to utilize various tools & substances, as well as why standardized handling is necessary to maintain the reliability of the specimen. Lastly, in pre-analytic phase, transit & preservation of specimens are crucial post specimen collection. So, as to prevent hemolysis, specimens must be kept at the proper temperature & handled cautiously.

Earlier researches have shown that patient associated variables like position, rigorous activity, strain, mental stress, starvation & sample scheduling could affect the results of later lab tests [18,36-37]. The discourse on sample collection errors must take place in the setting of multi professional & interdisciplinary exercise. Health personnel are critical in the retrieval of specimens and in counselling individuals about how to prep for them. The knowledge of quality errors in the sample procedure, as well as collaboration with employees outside lab, are critical aspects in increasing the performance of lab processes & delivering accurate findings, hence improving patient protection.

This paper includes data from medical investigations which could be applied at the very basic stage of practice. Pre- analytical variability in collection might be decreased & client care improved by using this information. When experts are counselling individuals on how to prep for lab testing or whenever they are collecting specimens directly, it is essential that they utilize up-to-date understanding about pre- analytical variables when obtaining specimens. To avoid mistakes, collection must be viewed as a skill that must be learned rather than a technological

technique. Customers are members of the community because the procedure starts & finishes with them. The patients are the ones who lose the utmost if the group falters.

SUGGESTIONS TO LAB IN ORDER TO MINIMIZE PRE-ANALYTICAL ERRORS

Labs should focus on the following in order to reduce the number of Pre-analytical errors:

Phlebotomy Education:

To remain updated with latest breakthroughs in pre- analytical error minimization, both phlebotomists & laboratory staff should really be compelled to attend continuous education programs. Staff skills must also be evaluated on a yearly basis. They also ought to be aware of the impact of pre- analytical errors on sample quality.

Using appropriate technology:

Bar-codes, radio-frequency recognition & wrist-bands are examples of innovations that could aid in client recognition. Automatic phlebotomy trays prepping, sample labelers and automated pre-analytical mechanical workspaces could all help to decrease the incidence of errors caused by human variables.

Developing clear written procedures:

Within the laboratory, distinct standards & operational procedures (SOPs) assist to eliminate procedural variability & streamlining laboratory workflow. Well documented protocols should be in place throughout all laboratories that describe procedures to recognize a patient, collect &

tag a sample, transfer it & process it for evaluation. Diagnostic laboratories must set & adhere to precise exclusion rules for samples. Every sample that is discarded must be noted in a record sheet with all pertinent information. Whenever a sample is discarded, relevant people must be notified as soon as possible so that remedial measures, like requesting a new sample, could be implemented.

Validating any new instrument or procedure:

Every items & techniques should be validated in the lab to confirm if they are suitable & satisfactory for testing. When moving to a fresh item or methodology, it is also the duty of the specific lab to evaluate the validity of examination findings. Confirmation is also required whenever changing from one collection tube to another.

Monitoring quality indicators in the lab:

Laboratories must maintain track of any pre- analytical errors that are discovered. Developing & implementing remedial procedures could help a laboratory become more error-free over time. Lab error information are also useful for monitoring the efficiency of the blood collection procedure & evaluating the effectiveness of the actions performed.

CONCLUSION

The emphasis in lab has typically been on the analytical phase, wherein lab reports are generated, less consideration has been given to pre- analytical phase & its value has been overlooked. The pre- analytical stage does have a significant impact on the validity of lab findings as well as the health of individuals, according to this review.

Pre- analytical errors are the leading source of sample invalidation in different lab departments. Lost samples, incorrect specimen recognition, specimen tampering, usage of unsuitable vessels, incorrect client recognition & inadequate sample transport conditions are among the most serious pre- analytical errors. Clot development, inadequate quantity & hemolysis are the most common reasons for specimens being discarded. Lab professionals must use an interconnected approach to lab assessment and collaborate closely with physicians in order to give efficient medical aid for optimal client care. According to emerging data, lab credibility can't be attained solely by promoting precision in the actual examination of the diagnostic procedure. The stages preceding the specimen arrives at the lab & post the specimen has been tested are both critical.

The pre-analytical procedure is loaded with faults, spanning from a careless approach toward filling request forms to a paucity of knowledge among the employees about proper phlebotomy methods. It is vital to implement quality control methods not just in analytical techniques, however also in the pre- analytical and post- analytical phases to maintain client interests as well as to deliver solutions in the foreseeable.

To eliminate failures in this stage, the health-care system should be extra attentive in implementing factual information. This really is critical in order to reduce the impact of individual mistakes on lab procedures.

This paper explains the pre- analytical errors which could exert a significant impact on the reliability of lab findings & as a consequence, patient security. Such variables must be made known to all Phlebotomists who obtain specimens so that they can prevent them. Merging of lab & health-care facilities is required to increase client protection.

The amount of inaccuracies in the pre- analytical stage may be reduced by multi- professional sample collection collaboration including lab employees & Phlebotomists. As a consequence of this study, specimen procedures ought to be able to be improved & evaluated. This paper offers a fresh perspective on the stages involved in sample collection, as well as the importance of involving patients & other experts throughout the procedure. Thus, it improves the awareness of the pre-analytical variables at play throughout sample collection procedure & the insights must be utilized by the Phlebotomists & Lab staff, to better sample collection process and lab performance.

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