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Investigation of pre-analytical errors during covid-19 pandemic phase in a tertiary care hospital -a retrospective study

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ABSTRACT

Aims and objectives: - To investigate the sample rejection rate of pre analytical errors in a clinical laboratory tertiary care centre. To identify the types, frequency of pre analytical error and to detect the percentage of pre analytical errors.

Materials and methods: - This was the retrospective analytical study by collecting the data over the period from November 2020 to February 2022 at clinical biochemistry laboratory at Mahatma Gandhi Medical College and Research Institute. Data analysis was done on samples were received and tested which includes sample like blood, urine and other fluids. Types of errors were as follows: - inappropriate labelled samples, improper collection tubes, clotted sample, hemolysis, insufficient volumes, lipemic samples.

Results: - Out of 2,39,327 total samples received from both OPD and IPD, 891 samples were found to be unsuitable for further processing. The majority of the sample rejected due to hemolysis (43%), the second most frequent pre analytical error encountered in insufficient volume (21%), clotted sample (16.2%), mislabelling of samples by the laboratory personnel was seen as caused of rejection is 9.9%, lipemic samples were also rejected is 5.3%, inappropriate container accounted for faulty results in 3.3% of samples.

Conclusion: - The concept of TQM encompasses all the steps involved in sample processing, beginning from test ordering to the final interpretation of results by clinicians to reduce or eliminate the errors that may rise during various steps. The dependence on accurate lab results for diagnosis makes it mandatory for labs to ensure accountability and accuracy of results for diagnosis as a consequence of faulty reporting.

Key words: Preanalytical errors, Covid-19, Total Quality Management, Total testing Process, Turnaround Time.

INTRODUCTION: -

Clinical laboratory testing plays a vital role in the diagnosis, prevention of disease treatment and monitoring patients.(Bonini et al., 2002) (1) . laboratory services have a great influence on clinical decision making;60%-70%n of the most important decisions on admissions, discharge and medication based on laboratory test results. The total testing process (TTP) starts and ends with the patients and subdivided into three typical phases – (i) pre analytical phase, (ii) analytical phases, (iii) post analytical phases.

SARS-COV-2 is disease which has propound several challenges to clinical laboratories across the world. World health organisations (WHO) declared pandemic on March 11, 2020 it has prompted a startling global emergency and had huge influence on health care professionals, health structure and clinical laboratory (Mukhopadhyay et al., 2021) (2). Laboratories plays a crucial part during an infectious outspread from the time of diagnosis till surveillance.

The pre analytical phase comprises all of the processes occurring before the sample is processed in analyser. In 1977, Statland and Winkel devised the term pre analytical phase. (Plebani, 2006) (3). Clinical laboratories standard institute (CLSI) and world health organisation (WHO) published quality assurance guidelines for the pre analytical phases. These includes examination requisition, patient preparation, sample collection, transportation and ending when analytical examinations begin (4,5). The important clinician decisions on patient treatment and management are based on laboratory test results. Quality, accuracy, short turnaround time (TAT) are very important in effective laboratory services. Total quality management (TQM) is a management philosophy and approach that focuses on processes and the improvement as the means to satisfy the customers. (Kaushik and Green, 2014)(6). The preanalytical errors primes to sample rejection which definitely affects the eminence of patient care, delay in diagnosis and treatment, postpone of scheduled operating procedure, increase the patients staying in hospital and reduces the customer satisfaction.

Laboratory driven improvements can help improve health care management more broadly. The International Organizations for Standardization (ISO) 15189:2012 standard for laboratory accreditation defines the pre analytical phase as “the processes that start, in chronological order, from the clinician request and include the examination request, preparation and identification of the patient, collection of the primary samples and transportation to and within the laboratory and end when the analytical examination begins.(Schneider et al., 2017) (7).

Since the preanalytical phase step is mainly performed by the staff working outside the laboratory, it is difficult to manage and evaluate quality in this phase (1,5). If the occurrence of the error is manmade then it can always be identified and reduced. However, the human factor in the specimen collection and transport procedure are the root cause of these preanalytical phase errors. During ongoing pandemic, the healthcare professionals are required to wear the personal protective equipment (PPE) while taking care of the patients, Furthermore, the sample collection and transportation logistics are also different from pre pandemic times.(Loh et al., 2020) (8).

Thus, the aim of my study is to determine the nature and frequency of the occurrence of preanalytical errors. The error during Covid 19 pandemic phase found was rectified and corrective measures has been suggested.

MATERIALS AND METHODS: -

This retrospective analytical study, was performed in clinical biochemistry laboratory, at Mahatma Gandhi Medical College and Research Institute with the capacity of 1200 beds comprising of various super specialty department. The present study was conducted by collecting data of 14 months – November 2020 to February 2022, a total of 2,89,327 samples were received in clinical laboratory.

The biochemistry department is equipped with auto analysers such as SYSMEX-BX-3010 for routine clinical chemistry, HITACHI-Cobas e411 for thyroid function tests, Vitamins & Fertility profiles, BIORAD D10 and ARKRAY-ALAMS TMA1C lite for glycated haemoglobin analysis, KC1 DELTA TCOAG for coagulative studies, EASYLYTE for electrolyte analysis (Na/K/Cl), BIOMERIUAX Mini Vidas for immunochemistry, ABL 500 & GEM PREMIER 3500 for arterial blood gas analysis and other ancillaries for sample processing. Blood samples collected in vacutainers during this period were included in the study. All the methods used here in were approved by the International Federation of clinical chemistry & laboratory medicine (IFCC).

2 ml and 5 ml syringe in the red capped tube (clot activator) for routine biochemical tests, blue tube for coagulative studies (sodium citrate), violet tube for HBA1C (EDTA-Ethylenediamine tetracetic acid), grey tube for blood sugar estimation (sodium fluoride+ potassium oxalate) whereas the urine and other body fluids were collected in sterilized containers. The ABG samples were collected in heparinized syringes.

Internal quality control was facilitated using Bio-Rad (USA) samples. External quality assessment (EQAS) was facilitated with the help of clinical biochemistry laboratory, CMC hospital, Vellore, under the aegis if ACB I. The clinical Biochemistry laboratory at CMC Hospital is NABL certified under ISO/IEC 15189.

In the study, we observed the types and frequency of pre analytical error by screening all samples from OPD & IPD. The OPD sample were collected by on duty laboratory personnel for different section of central lab which cater the samples to various sections such as haematology, biochemistry and microbiology and IPD sample were collected by ward nurses sent to the laboratory attenders to the central lab. The samples were segregated at the IP collection and each lab attendant of biochemistry, microbiology and pathology will carry the samples to respective laboratory. These samples are analysed for following preanalytical variables.

- Inappropriate labelled samples
- Improper blood collection tubes (screened by cap of the container)
- Clotted sample (observed on naked eye & by inverting the tubes).
- Hemolysis (confirmed after centrifugation).
- Insufficient volume (types of tests requested)
- Lipemic samples (milky white, turbid serum).

The samples with any of the above-mentioned errors are rejected after informing to the ward (or) to the health care workers at the site and it is recorded systematically. Lab personnel were asked to register rejections and causes for rejection in specimen rejection register when error occurs. The data collection procedure involved review of blood samples received from the IPD as well as OPD.

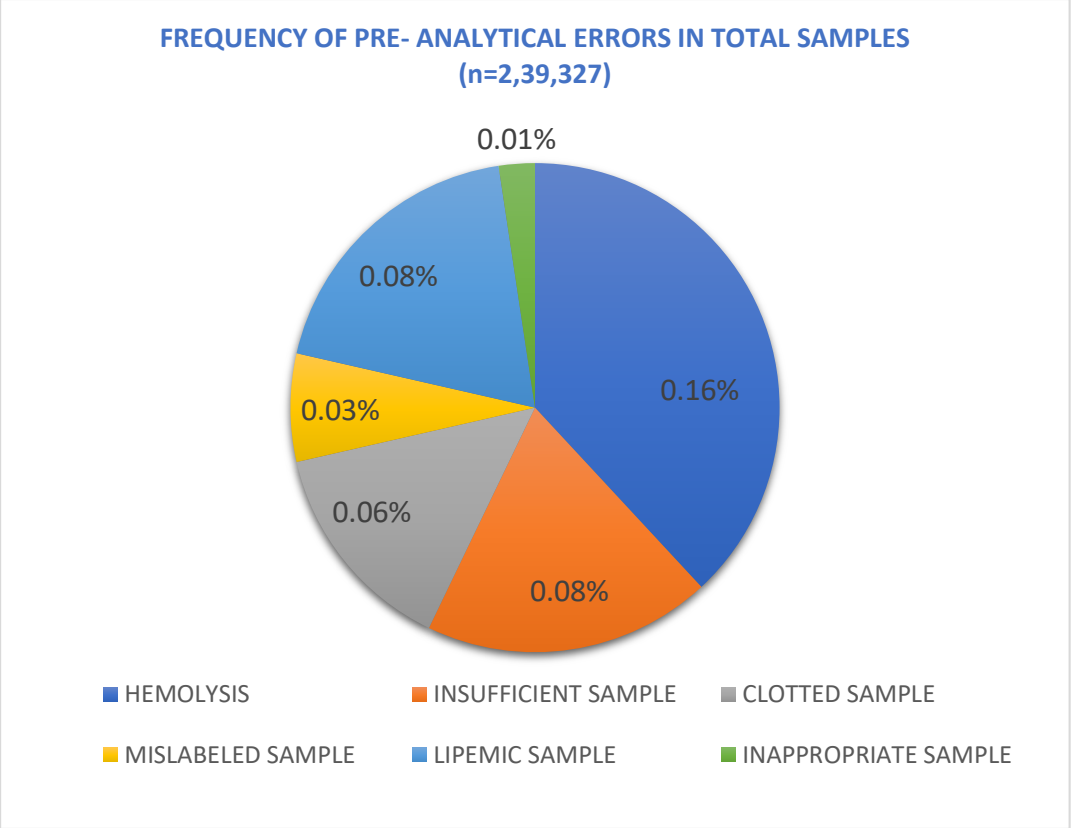
RESULTS: -

Out of 2,39,327 total samples received from both OPD & IPD, pre analytical errors of 891 samples were observed in our central clinical laboratory which has been represented in (Table: -1)

TABLE 1 - FREQUENCY OF PRE-ANALYTICAL ERRORS

PRE-ANALYTICAL VARIABLES	NO OF REJECTED SAMPLES	FREQUENCY OF PREANALYTICAL ERROR IN REJECTED SAMPLES
Haemolyzed sample	384	43%
Insufficient sample	195	21%
Clotted sample	145	16.2%
mislabelled sample	89	9.9%
Lipemic sample	48	5.3%
Inappropriate sample	30	3.3%

The majority of the samples rejected due to hemolysis (43%), the second most frequent pre analytical error encountered in insufficient volume (21%), clotted sample resulted in 16.2%, mislabelling of samples by the laboratory personnel was seen as a cause of rejection is 9.9%, lipemic (milky) samples were also rejected is 5.3%, inappropriate container accounted for faulty results in 3.3% of samples.



Discussion: -

Lab plays a foremost role in patient care. Advances in science and technology directed to many path breaking innovations that have renovated lab diagnosis from manual, cumbersome testing methods to fully automated science, ensuring accuracy and speed. Although quality controls are accessible for monitoring analytical errors still there is a need to progress pre analytical process which subsidizes 60% of total lab errors.

The pre analytical phase occurs outside the lab, consisting of selection of estimated tests on the basis of the clinical questions ordering, collection and handling, transportation and preparation samples to make them for suitable for analysis.

In our study, Hemolysis accounted for the majority of the rejections (43%). These findings were similar to that of the study done by Priyanka prasad et al, 2019. Instances such as forcing blood through a fine needle, vigorous shaking of BCT, forceful transfer of blood samples from syringe to containers and centrifugation of samples before clotting (red tubes), plasma vacutainers should be gently inverted for few times so the anticoagulant mixes with the blood.(Prasad et al., 2019) (9). It can be prevented by using suitable vacutainers, proper mixing of samples by inversion and proper centrifugation technique. However, at present, extra measures and safety protocols were implemented while handling blood specimens of COVID-19 patients. The haemolyzed samples should be rejected as serum enzyme levels gets elevated alanine transaminase (ALT), amino transferase (AST), lactate dehydrogenase (LDH) and also potassium levels. The concerned departments and wards were informed about the haemolyzed samples and asked for repeat sample. It may affect Turn Around Time (TAT) and delay in reporting.

Another factor leading to rejection of blood samples in our study was insufficient blood volume. Every analytical process requires a fixed volume of plasma /serum for analysis. The main reasons behind this anomaly are ignorance of the phlebotomists, difficult sampling in neonates or

too many investigations ordered for one sample. Lippi et al (2014) reported insufficient quantity and quantity accounting for over 60% of pre analytical errors. The lab professionals, nursing staff should be aware each analytical process needs a specific quantity of sample for processing. (Lippi et al., 2013) (10).

Clotting of blood in blood collection vacutainer with anticoagulants generally occurs either Clotted sample reported to be the commonest cause of pre analytical error in the clinical chemistry (16.2%). due to improper mixing after blood collection or due to improper blood-to- anticoagulant ratio. The error rate of mislabelled samples is 9.9%, the errors due to mislabelling of tubes affect patient identification, and may lead to patient identity mix up and also cause serious potential harm to patients. The error rate for lipemic sample was 5.3%. Lipemic samples arise due to collection after heavy meals or the presence of some metabolic disorder (hyperlipoproteinemia's). This can be avoided by sample collection, preferably an overnight fast. Lipemia interferes in optical reading by the instrument and can affect interpretation of electrolyte values (Nikolac, 2014) (11). Hence, many patients give samples in non-fasting states leading to erroneous reporting. It is the responsibility of the clinicians and the phlebotomists to ensure that proper patient preparation is instituted before sample collection.

Till date, there is large epidemiological data available, but still is need of rectification for pre analytical errors that happens frequently in small scale labs as well as multi-specialty hospital laboratories. Hence, we took up this study during covid pandemic period in order to see the consequences occurring in our tertiary care hospital and we have given suggestions for rectification in future.

TABLE_: - CORRECTIVE ASSURES FOR REDUCING PREANALYTICAL ERRORS

VARIABLES	CORRECTIVE MEASURES
Insufficient volume	• Request for repeat sample. • Sample rejection maintenance register. • Use of microtubes and microcontainers for sample collection for neonates. • Training programme should be conducted.
Haemolyzed samples	• Request for repeat sample. • Proper storage and transportation by cryo carry boxes. • Not to collect sample from IV cannula or central line.
Clotted sample	• Request for repeat sample. • Education and training of healthcare staff responsible for sample collection. • Assessment of the frequency of system errors caused by clot.
Mislabelled sample	• request for the correct sample. • Review or double check of labelling process. • Education and training of healthcare staff responsible for sample collection.
Lipemic sample	• Request for repeat sample. • Providing proper instructions to the patients before collection of samples. • Patients with metabolic disorders should be mentioned in the form
Inappropriate sample	• Request for request sample. • Use if colour coded sample vacutainers. • Copy of guidelines for order of draw has to be stick on walls right above the sample collection tray in wards.

Conclusion: -

The concept of total quality management encompasses all the steps involved in sample processing, beginning from test ordering to the final interpretation of results by the clinicians to reduce or eliminate the errors that may rise during the various steps. Identification of lab errors, rectification and vigilance serve as pillars of total quality management. The dependence on accurate lab results for diagnosis makes it mandatory for labs to ensure accountability and accuracy of results to negate incorrect diagnosis as a consequence of faulty reporting.

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