Evaluation of preanalytical errors in the central clinical laboratory of a tertiary care hospital in Pune, India.

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KEYWORDS

ABSTRACT

Introduction
Preanalytical errors, account for 46%–68% of laboratory errors. These errors impact diagnostic accuracy, patient safety, and healthcare costs. This study investigates preanalytical errors in the central clinical laboratory of Dr. D.Y. Patil Medical College, Hospital, and Research Centre, Pune, identifying key issues and proposing corrective measures.

Methods
A descriptive study was conducted over three months on 200 randomly selected samples. Errors were evaluated using predefined quality indicators (QIs). Root cause analysis identified contributing factors, and corrective measures were implemented, including staff training and continuous quality monitoring.

Results
The study identified an overall preanalytical error rate, with the most common issues being incomplete physician information (94%), incomplete patient identification (74%), and sample integrity problems (14%). Root cause analysis highlighted deficiencies in staff training, particularly among nurses and interns handling inpatient samples.

Conclusion
Preanalytical errors remain a significant challenge in laboratory medicine. Addressing these issues requires stringent quality control measures, comprehensive staff training programs, and continuous assessment of preanalytical processes. Implementing corrective actions can enhance diagnostic accuracy, improve patient safety, and reduce hospital costs.

IMPACT STATEMENT

The study identifies significant preanalytical errors in a clinical laboratory setting. The most prevalent issues include incomplete physician information (94%) and patient identification (74%), causing potential delays in treatment. Challenges in sample quality, such as insufficient volume and hemolysis, further highlight the need for stringent oversight. These findings underscore the importance of targeted training for healthcare staff, regular quality assessments, and proactive error mitigation strategies. Addressing these issues can enhance diagnostic accuracy, reduce turnaround time, and improve patient care outcomes, emphasizing the critical role of the preanalytical phase in laboratory operations.

INTRODUCTION

In a central laboratory setting, errors that occur during any stage of the testing process are commonly referred to as "laboratory errors" or "clinical laboratory errors." These errors can encompass a wide range of mistakes or oversights that can impact the accuracy and reliability of test results.[1] Patient safety and the accuracy of medical diagnoses heavily rely on laboratory findings. Studies show that around 60% to 70% of medical diagnoses depend on the accuracy and reliability of laboratory test results. Identifying and addressing system errors and their

underlying causes is a proactive approach to enhancing patient safety. Clinical laboratories, despite advanced automation, frequently experience significant error rates. It's essential to comprehend and be vigilant about the origins of errors to rectify unexpected laboratory findings that do not align with clinical data. (2)

Errors can be classified in three phases-Preanalytical, Analytical and Post analytical. The preanalytical phase of laboratory testing plays a critical role in ensuring the accuracy and reliability of diagnostic results. The preanalytical phase encompasses all processes from the moment a patient sample is collected to the point it is ready for analysis in the central laboratory. During this phase, various factors can contribute to errors that may impact patient care and treatment decisions. Understanding and assessing errors during the preanalytical phase is essential for optimizing the quality of healthcare services provided by the central laboratory. By identifying common sources of errors, implementing quality assurance measures and promoting best practices, healthcare facilities can enhance the efficiency and effectiveness of laboratory testing processes.(3)

The primary cause of errors in laboratories is found during the preanalytical phase, accounting for approximately 46% to 68% of all errors. The involvement of multiple professionals including nurses, doctors, pathologists, technicians and phlebotomists underscores the critical importance and complexity of managing and overseeing the preanalytical phase. Therefore, this study sought to assess errors occurring during the preanalytical phase of testing in a central clinical laboratory in Dr. D.Y. Patil Medical College, Hospital and Research Center, Pimpri, Pune. The findings emphasize the importance of implementing quality controls and assurance measures during the preanalytical phase to detect and mitigate errors, thereby enhancing both patient safety and the accuracy of laboratory diagnoses.(2)

Material and methods:-

This is a descriptive study focusing on preanalytical errors occurring in the central clinical laboratory in our institution. We employed simple random sampling to select a total of 200 samples. Each sample was chosen and evaluated randomly and completely by chance, ensuring that each had an equal likelihood of being selected at any point in the sampling process. The study observed samples collected in ethylenediaminetetraacetic acid (EDTA) vacutainer, sodium fluoride vacutainer and plain vacutainers with clot activator.

Sampling was conducted over three months, with ethical approval obtained from our college's Institutional Ethics Committee. Throughout the study, each sample was evaluated according to predefined quality indicators (QIs). Both the test requisition forms and the individual vials were meticulously examined. Samples were inspected, centrifuged and sent for analysis. No patient interactions occurred at any stage of the study and all records were kept completely confidential. To assess preanalytical errors we prepared a questionnaire as quality indicators as described in Table 1.

Table1: Questionnaire for the preanalytical error -

Q1 Whether a test request is appropriate for clinical diagnosis?
Q2 Whether the test request form has complete patient identification?
Q3 Whether the test request form has correct/complete physician information?
Q4 Whether the test request form has any errors concerning tests?
Q5 Whether samples are transported correctly?
Q6 Was any sample container lost/damaged during transportation?
Q7 Was there any error in sample labelling?
Q8 Was there any delay in transportation? (Beyond 30 minutes)
Q9 Was there any problem with sample integrity/quality?
Q10 Whether urgent samples were labelled with green tags and sent to the concerned department for processing on priority?
Q11 Number of samples collected in inappropriate containers.
Q12 Number of samples hemolyzed.
Q13 Number of samples clotted.
Q14 Number of samples with insufficient volumes.
Q15 Number of samples with inadequate sample-anticoagulant ratio.

RESULT:-

During the three-month prospective study, data was gathered from 200 randomly selected samples in Dr. D.Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune to investigate preanalytical errors. Out of 200 samples, 128 samples were from IPD, 64 samples were from OPD and 8 samples were not labelled. Of the 200 samples, all but one had preanalytical errors. The most repeated error was not filling the form with the physician's contact information and the isolated error was in labelling the sample. Overall error in 200 samples was 99.5%.

Table 2:- All errors of quality indicator.

Quality Indicator (QI)	**Error present**	**Total no. of samples entered**	**Error in Percentage**
Q1 Whether a test request is appropriate for clinical diagnosis?	0	198	0
Q2 Whether the test request form has complete patient identification?	148	200	74
Q3 Whether the test request form has correct/complete physician information?	188	200	94
Q4 Whether the test request form has any errors concerning tests?	5 illegible 1 incorrect	6	83.3 16.7
Q5 Whether samples are transported correctly?	27	200	13.5

Q6 Was any sample container lost/damaged during transportation?	2	200	1
Q7 Was there any error in sample labelling?	1	200	0.5
Q8 Was there any delay in transportation? (Beyond 30 minutes)	6 delay 128 could not be evaluated	64	9.4
Q9 Was there any problem with sample integrity/quality?	28	200	14
Q10 Whether urgent samples were labelled with green tags and sent to the concerned department for processing on priority?	1	24	4.2
Q11 Number of samples collected in inappropriate containers.	1	28	3.6
Q12 Number of samples hemolyzed.	6	28	21.4
Q13 Number of samples clotted	4	28	14.3
Q14 Number of samples with insufficient volumes.	13	28	46.4
Q15 Number of samples with inadequate sample-anticoagulant ratio.	3	28	10.7

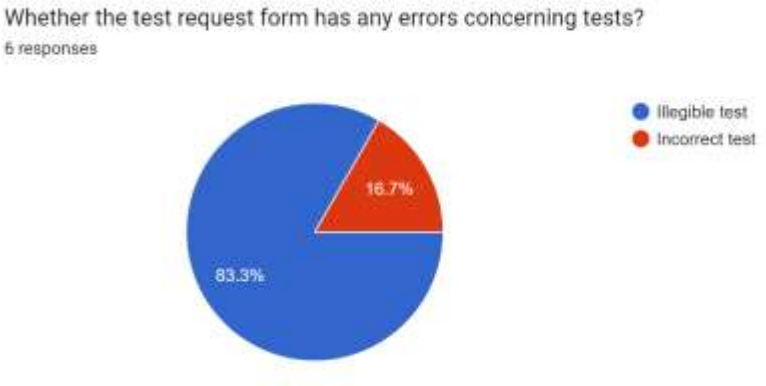

Figure 1 - Pie chart of QI4

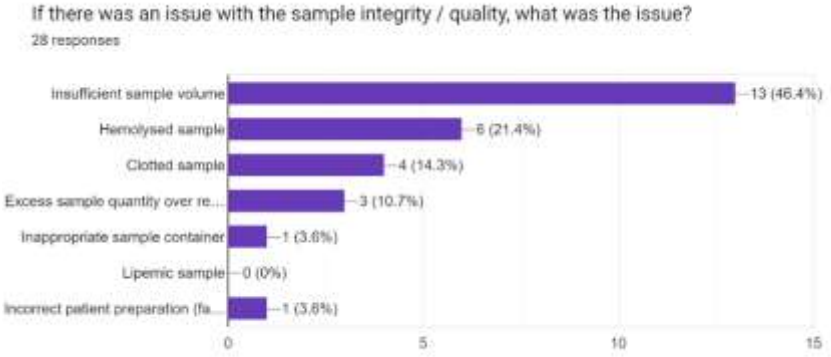

Figure 2 - Bar chart of QI11,QI12,QI13,QI14,QI15

DISCUSSION:-

The implementation of automation within the laboratory has led to a notable decrease in error rates. However, comparable advancements have not been achieved in the

preanalytical phase.[3] Recent advancements in science and technology have revolutionized laboratory diagnostics, replacing manual and cumbersome testing methods with fully automated systems that ensure both accuracy and efficiency. However, the laboratory operates in conjunction with other departments, particularly relying on the clinical division for correctly filled requisition slips and properly handled samples for analysis.

There is increasing evidence that achieving reliability in a clinical laboratory goes beyond promoting accuracy during the analytical phase of testing. The phases preceding (preanalytical) and following (post-analytical) sample analysis are equally critical. The preanalytical phase, in particular, is marked by numerous deficiencies, including laxity in requisition slip completion and insufficient staff education on optimal phlebotomy procedures. It is essential for the healthcare system to apply scientific knowledge more rigorously to mitigate errors in this phase. Doing so is crucial to minimizing disruptions in laboratory services caused by human errors.[4]

During this study, 15 QIs were assessed, of which the maximum error identified was in QI 3 (whether the test request form has complete physician information ?) accounting for 94% error. Of this 94%, majority of the missing information was incomplete / absent physician contact information. In our laboratory setting, critical results are notified to the healthcare providers through the intercom. However in case the physician is not available in the ward or the intercom communication system is down, a scenario may occur where the critical results may not reach them promptly resulting in delayed treatment of concerned patient. Impact of this error was mitigated by collecting contact details of all physicians working in the hospital. In another study by Mehndiratta, Mohit et al., the similar QI was of lesser magnitude (20.8%).[3]

The second most common error in our study was QI 2 (whether the test request form has complete patient identification?). The error percent was found to be 74%. Similar to QI 3, significance of this error results in delay to treatment of patients. This is specially applicable for OPD patients. We reduced the impact of this error by collecting the contact details in a separate register prior to collection of patient sample so the patient contact details can be easily retrieved. In another study by Wiwanitkit, V. et al., the similar QI was of smaller magnitude (26.8%) (6)

The next significant error was QI 9 (Was there any problem in sample integrity/ quality?) which was found to be 14%. Common causes found in this QI was insufficient sample volume (QI 14, 46.4%), hemolysed sample (QI 12, 21.4%), clotted sample (QI 13, 14.3%) and inadeqaute sample:anti-coagulant ratio (QI 15, 10.7%). A root cause analysis was done and maximum errors were originating in IPD patient samples. Further analysis revealed that IPD patient sample collection were primarily done by nurses and interns followed by resident doctors. As corrective action, training of the above healthcare providers was done on phlebotomy, sample collection and good laboratory practices in pre-analytical phase by authorised trained personnel. Effectiveness of training was done in the form of post-training evaluation and monitoring of sample rejection log on a monthly basis. If there is an increasing trend in sample rejections from a particular ward, another training will be conducted for those healthcare providers. In another study by Iqbal MS, Tabassum A, Arbaeen AF, Qasem AH, Elshemi AG, Almasmoum H. et al., the similar QI 14 has 54.18 % error, QI 12 has 4.63% , QI 13 has 20.9% error and QI 15 has 1.13% [7]

Finally QI 4 (Whether the test request form has any errors concerning tests?) was another error identified with magnitude of 3%. Of this 3%, the majority was due to illegible tests. The error was mitigated by personally calling the concerned physician and confirming the tests but these type of errors cause further delay in TAT (TurnAround Time) of tests. In another study by Duraiswami, Ramanan; Gaiki, Varun Vijay1et al., the similar QI was of (0 %) [8]

Pre-analytical errors result in longer wait times for laboratory test results, inconvenience for patients needing to provide additional blood samples and increased indirect expenses for hospitals. Therefore, ensuring thorough quality checks at every stage before analysis, coupled with comprehensive staff training, would undoubtedly decrease errors. This approach not only improves the accuracy of test results but also reduces the time required to make clinical decisions and decrease hospital costs.[5]

Conclusion:-

This study affirms that there is a significant incidence of errors during the preanalytical phase, which tends to be overlooked. These errors might go unnoticed due to the high volume of samples processed in the clinical laboratory of a tertiary care hospital. To mitigate these errors, it is crucial for the laboratory to train all personnel involved in the preanalytical phase. Regular assessment of quality improvement scores on a monthly basis should be implemented to identify and address shortcomings, thereby enhancing the quality of patient care.[3]

CONFLICT OF INTEREST – Nill.

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