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A Study on the Frequency and Types of Laboratory Errors in a Tertiary Care Cardiology Laboratory

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ABSTRACT

Background: Particularly in critical care settings like cardiology, where precise and prompt results are crucial, laboratory errors can have a substantial impact on patient diagnosis, treatment choices, and general safety. The objective of the study was to thoroughly analyse error occurrence rates throughout the entire process of testing, with regard to the pre-analytical, analytical, and post-analytical stages.

Method: Over the course of three months, from July to September 2019, a prospective analysis of laboratory errors was conducted at the Rawalpindi Institute of Cardiology (RIC), a 272-bed tertiary care facility serving the Punjab province and parts of Azad Jammu and Kashmir (AJK) and Khyber Pakhtunkhwa (KPK). During this time, the clinical pathology laboratory at the RIC received samples and request forms from nurses, physicians, and medical assistants from various hospital wards. A total of 17,917 patients underwent 73,540 tests. **Results:** The laboratories' total test procedure (TTP) had an overall error rate of 1.43%. It's interesting to note that pre-analytical errors made up the largest percentage (0.82%), followed by post-analytical (0.51%) and analytical (0.10%) errors. To determine the prevalence and scope of various errors, the data was carefully examined, and the findings were presented using figures and tables. The distribution pattern indicates that general mistake rates have significantly decreased during the last ten years. Even with this advancement, the pre- and post-analytical processes still had the highest rate of mistake. **Conclusion:** The findings show that in order to improve patient safety and quality, it is necessary to create systematic protocols and keep ongoing vigilance to guarantee the correctness and dependability of the test processes performed in the laboratories.

Keywords: Patient care, Clinical Laboratory Errors, Total Testing Process (TTP), Laboratory Errors, Error Prevention, Cardiac Facility.

INTRODUCTION

The pre-analytical, analytical, and post-analytical phases of measurement are all included in the laboratory testing procedure. Strict quality control is necessary to minimize, if not completely eliminate, process flaws. Unquestionably, errors happened during the test process; any mistake, from ordering the test to reporting and interpreting the results, is a laboratory error [1]. Over the past few decades, the rate of errors in clinical laboratories has significantly decreased for all phases. Evidence-based medicine (EBM) now requires doctors to order a laboratory test rather than relying just on the anticipated clinical presentation to make a diagnosis [2]. Nowadays, accrediting organizations demand that labs go beyond analytical quality and take accountability for the pre- and post-analytical phases, which are where the majority of errors happen. Since the new duty is a

departure from the conventional laboratory-based activities that many laboratory staff members are accustomed to, it may cause anxiety and discomfort [3]. This research defines the many steps of the whole testing process, covers the pre- and post-analytical stages of the laboratory from the angle of requirements for laboratory certification, and explains various sources accessible to the laboratories towards maintaining this new area [4].

For healthcare administrators to maximize patient outcomes, adjust to shifting conditions, and provide high-quality, reasonably priced treatment, the quality process is essential. Patients, payers, and regulators still want performance-based data that shows adherence to quality standards and benchmarks [5]. Over the past few decades, transportation networks have been optimized, outdated equipment has been replaced and upgraded, laboratories have been computerized, and specimen processing has been automated [6]. These modifications enable laboratories to continue providing services despite an ever-increasing volume of tests from every part of the healthcare system. Additionally, the availability of instruments for point-of-care testing has led to an expansion in testing locations throughout time, allowing for the execution of high-quality laboratory operations at different sites of care [7].

Much focus is placed on the topic of medical mistakes nowadays, and there will be a lot more. There is a call for clinical laboratories to gather statistics for error rates for the entire test process, from the pre-, intra-, and post-analytical phases, with the growing emphasis put on patient safety and the necessity for minimizing error within the laboratory testing [8]. There are still a lot of elements of the healthcare process that are not delivering quality patient results. Laboratories appear to be ahead of the game in attaining the quality of their analytical measurement. The quality assurance process for the laboratory diagnostics occurs every day [9]. The pathology department is an essential component of modern healthcare and is in charge of diagnosing and treating 70% of illnesses. Even while laboratory automation advancements made a significant contribution to this goal, mistakes can still occur. Clinical laboratories have used material quality controls and analytical algorithms using quality control material to solve such problems for decades [10,11]. The effect of these laboratory errors and their consequence for the patient results are realized with tremendous enthusiasm today. These days, more efforts are being made to raise awareness and put different tactics into practice to reduce these kinds of lab errors. These include certification and laboratory accreditation, external quality evaluation programs run by professional associations, and internal quality control procedures. Despite this, recent research indicates that pre-analytical errors account for the majority of laboratory errors [11]. This study observed the OPD (Outpatient Department) and patients in various wards of the RIC to identify the types and occurrence of errors in the Department of Pathology. According to a survey of the literature, pre-analytical phase errors account for 46–68% of all testing errors, analytical phase errors for 7–13%, and post-analytical phase errors for 19–47% [8,12]. There are significant variations in the reviews of the existing literature due to variations in the methods used for data collecting. Furthermore, variations in the variable data may also result from variations in the volume of workloads at various healthcare facilities. In an effort to determine the best ways to lower errors in the RIC pathology laboratory, this study prospectively collects data over a three-month period to track the pre-, analytical, and post-analytical phases of the errors. In recent years, various healthcare facilities have become increasingly interested in the activities pertaining to patient safety and quality improvement. The laboratories are now called upon to expand their scope to embrace activities not under their direct control [4,13].

METHDOLOGY

The research was performed from July to September 2019 for three months. The research was performed at Rawalpindi Institute of Cardiology (RIC), a 272-bed tertiary care hospital. The Pathology Department of the institute, which is well equipped for biochemical analysis, was used for the purpose. The clinical pathology laboratory at the RIC meticulously recorded errors with the help of 24/7 standard operating procedures and automated analysers. The errors in the request forms of both Out-Patient and In-Patient Divisions were noted and evaluated with the aid of Microsoft Excel, Microsoft Word, and SPSS. For the purpose of accurately evaluating patients and upholding quality standards, the laboratory also applied for CAP, CPA, ISO 15189, EQAS, RIQAS, and URS.

RESULTS

The duration of this descriptive study was three months, from July to September of 2019. A total of 17,917 patients had 73,540 tests conducted throughout this time under investigation. As shown in Figure 1, the pre-analytical error accounted for the highest, at 56.70 percent (0.82% of the total error), followed by the post-analytical error at 35.30 percent (0.51% of the total error) and the analytical error at 8.8 percent (0.10% of the total error). The total laboratory error recorded in the entire process of the total testing process (TTP) in all three stages was 1.43%.

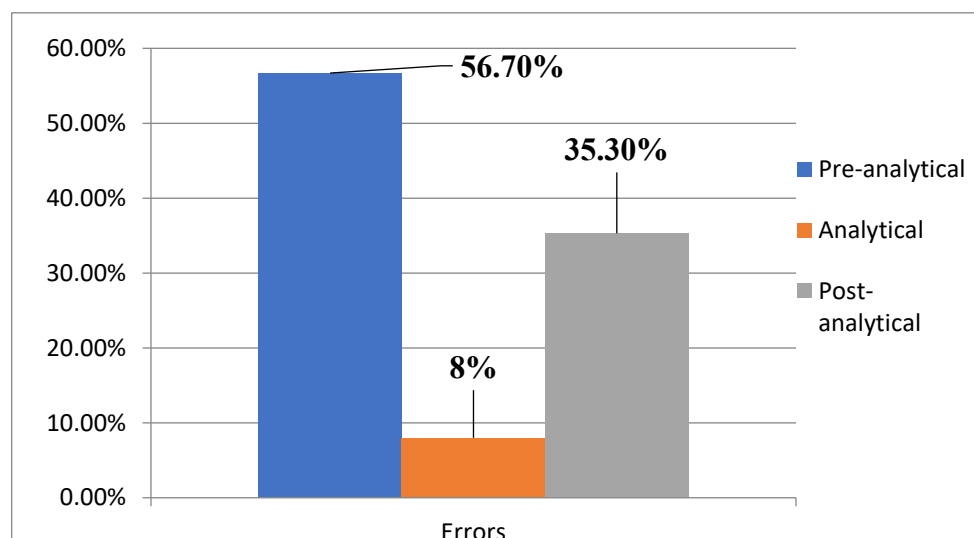


Figure 01: Distribution of errors frequency from July to September

The most common pre-analytical errors are haemolysed and under-filled samples, the incorrect tube types, the wrong type of collection tubes used, empty samples, and delay in transporting the samples from the ward to the labs as the anomalies for the samples of the different wards. Duplicate pathology numbers in the samples all from the out-patients. A detailed list of pre-, analytical, and post-analytical laboratory errors for the months of July, August, and September may be found in Table 1. In the pre-analytical stage, haemolysis is a reason for concern, since the number of occurrences dropped from 85 (0.3%) in July to 60 (0.08%) in September.

Table 1: Frequency of Laboratory errors

Parameters	July	August	September
Pre-analytical errors			
Haemolysed	85(0.3)	68(0.29)	60(0.08)
Insufficient sample	54(0.2)	39(0.16)	40(0.06)
Incorrect tube	15(0.05)	14(0.06)	10(0.04)
Incorrect identification	18(0.06)	17(0.07)	18(0.02)
Incorrect labelling	17(0.06)	16(0.07)	19(0.02)
Unlabelled	11(0.04)	08(0.03)	12(0.05)
Delay in transportation	21(0.07)	16(0.07)	17(0.02)
Sample mix up	14(0.04)	11(0.04)	08(0.03)
Analytical errors			
Equipment malfunction	23(0.08)	19(0.08)	22(0.02)
Failure in QC	5(0.01)	04(0.01)	06(0.08)
Post-analytical errors			

Failure in reporting	25(0.08)	22(0.09)	15(0.02)
Improper data entry	12(0.04)	11(0.040)	09(0.08)
Uncollected results	97(0.37)	95(0.40)	91(0.12)

Misidentification, unlabelled samples, and insufficient samples also show a downward trend. The frequency of analytical mistakes resulting from equipment malfunction and quality control (QC) errors is generally low, whereas the trend for equipment malfunction is consistent. Variable post-analytical errors include incorrect results input and failure to report; in July, there were 97 (0.37%) uncollected results; in September, there were 91 (0.12%). With a continued emphasis on equipment integrity and accuracy in report entries, the tendency for decline indicates a shift toward specific therapies, such as overcoming haemolysis and properly collecting samples. For the laboratory's quality management to provide accurate and dependable test results, such error kinds must be continuously monitored. The percentage distribution of the total laboratory error during the course of three consecutive months (July, August, and September) is fully displayed in Table 2. Three broad categories—pre-analytical, analytical, and post-analytical—are used to group the errors. Percentages of the total monthly tests are used to represent the errors. Pre-analytical mistakes accounted for 0.91% (236 errors out of 25,779 tests) in July, 0.81% (189 errors out of 23,209 tests) in August, and 0.74% (184 errors out of 24,552 tests) in September and August, respectively. Pre-analytical errors are those that occur before a sample is actually analysed, such as during sample handling or drawing. The decrease in pre-analytical errors suggests that these points will be improved over the course of three months, which will have a favourable impact on the laboratory testing procedure as a whole.

Table 2: Percentage distribution of total laboratory errors

Parameters	July	August	September
Pre-analytical errors	0.91(236/25,779)	0.81(189/23,209)	0.74(184/24,552)
Analytical errors	0.10(28/25,779)	0.09(23/23,209)	0.11(28/24,552)
Post-analytical errors	0.51(134/25,779)	0.55(128/23,209)	0.46(115/24,552)
Number of tests	25,779	23,209	24,552
Number of patients	6,109	5,882	5,926

This implies a degree of heterogeneity in the reporting phase, and additional research would be required to identify the contributing aspects. A general distribution of error types by type, patient type, and out-patient versus in-patient status is shown in Figure 2. The most frequent error is haemolysis, which accounts for 130 in-patient and 83 out-patient cases, for a total of 213. With 98 and 32 cases, respectively, for in-patients and 35 and 7 cases, respectively, for out-patients, the most frequent are sample misuse and lack of a suitable sample. Unlabelled samples as well as false labelling are also common in the in-patients. Unexpectedly, 45 in-patients and 19 out-patients are attributable to broken equipment. Based on decreasing haemolysis, the quality of the sample procedures, and the accuracy of the results, analysis indicates the need for a process approach to quality with error types by type of patient setting. Reports, particularly those for outpatients with a high number of uncollected information.

DISCUSSION

Although trustworthy clinical laboratory services are growing more and more important to the healthcare system, they are prone to mistakes because they are a component of the broader healthcare system. Even though a lot of work has been done to improve the caliber of analytical labs, there are still many obstacles and a dearth of knowledge regarding mistakes in the laboratory portion of medicine [14]. There are numerous pre-analytical errors in clinical laboratories, despite significant advancements that have reduced labour-intensive, labour-based, and automated laboratory diagnostics processes. These mistakes may result in the patient receiving the wrong diagnosis and treatment. In the laboratory, mistakes are still expected [7]. A deliberate effort was made to attain 100% accuracy and precision during the test cycle. Implementing and embracing automation is one way to reduce laboratory errors in all their forms. Other strategies include regulating laboratory services, certifying educational programs, certifying laboratory professionals, accrediting clinical laboratories, and implementing internal and external quality control procedures [15]. To further reduce or even eliminate errors that can occur at any stage of the process of handling a sample, from ordering the test to the physicians' final interpretation of the results, total quality management must

be subject to periodic reviews. The process of documenting errors at all levels of analysis and creating remediation plans to prevent them is necessary in order to gradually rid a lab of such errors, Jensen et al., emphasize that laboratory scientists must take a comprehensive approach to laboratory diagnostics and work in tandem with physicians in order to effectively treat patients [16].

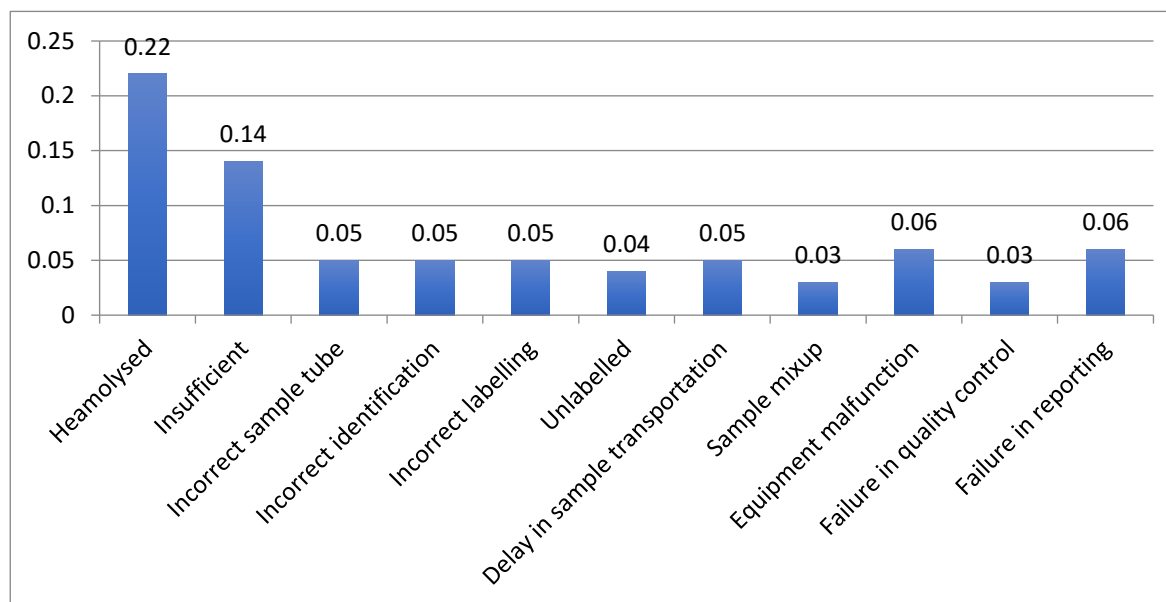


Figure: 02 shows the frequency distribution of errors in all three phases

However, several noteworthy accomplishments have been made. Over the past forty years, mistake frequencies have significantly decreased, especially for analytical errors, and the variability in analytical performance is now often less than one twentieth of what it was forty years ago [17]. Furthermore, there is evidence from previous research that a large number of laboratory errors take place before and after analysis. Previously a labor-intensive procedure, laboratory diagnosis is now nearly fully automated thanks to recent developments, necessitating a corresponding reduction in the workforce [2]. Unquestionably, the results of the aforementioned study showed that mistakes do happen in the laboratory even with all the automation, which might lead to less than ideal patient care. Although there is a lot of research focused on improving analytical quality, mistakes in laboratory test procedures remain common.

Over the course of this inquiry, we tracked the overall mistake rate in our laboratory over a three-month period and talked about relevant steps to reduce its occurrence. We found that the overall error rate for the three months was 1.43 percent, with pre-analytical, analytical, and post-analytical sources contributing 0.82 percent, 0.10 percent, and 0.51 percent, respectively. Once more, there was a significant ($P = 0.01$) decrease in the number of tests from July to September; however, this did not result in a comparable decrease in the general error rate ($P = 0.90$) by the months. The main reason for rejections during our investigation was haemolysis.

The development of vacuum tubes and the closed system made blood collection easier and more effective. One obstacle to expediting the sample collection and transportation process is the phlebotomy staff's lack of training. Hemolysis occurs when blood is pushed through a tiny needle, the tubes are shaken a lot, and the sample specimens are centrifuged while the clotting process is still in progress. After the sample is taken, red top vacutainers without anticoagulant should not be shaken, and vacutainers for plasma should be gently inverted a few times to allow the anticoagulant to mingle with the blood. Significant hemolysis can result by freezing and then thawing blood samples. The second reason the blood samples for our inquiry were rejected was that there was not enough blood. Every analytical procedure needs to process a specific volume of serum or plasma [18].

Phlebotomists' lack of knowledge and difficult sample circumstances—such as youngsters, patients with long-term incapacitating illnesses, and chemotherapy patients with tiny, difficult-to-find veins—are the primary causes of this abnormality. Insufficient sample volume was the most common reason for test rejection in the sample. There is still inadequate oversight of the

fragments' journey to the lab. To ensure that every specimen is received, a method for tracking specimens is being developed. The management of the laboratory should put in place a suitable process for dealing with issues that arise during specimen transportation and enhance the performance of clients who routinely submit specimens in an incorrect manner. Due to widespread automation and the implementation of established standards for acceptable error levels in internal quality control processes, the analysis error rate has significantly dropped over time [19].

Lay, Pinar, & Akbiyik observed a greater number of clinical biochemistry laboratory rejections due to pre-analytical mistakes [20]. The study's findings showed that the most common pre-analytical mistake after the sample's centrifugation phase was apparent haemolyses. Researchers also saw haemolyses of the samples, which happens when blood is pushed through a tiny needle. The results are consistent with the current study. According to the study, the majority of sample rejections in clinical biochemistry labs were caused by haemolyses [21].

CONCLUSION

Over the last decade, there has been a significant decline in the mistake rate. The types and quantity of errors in both stages have fluctuated significantly, despite the fact that the pre-analytical and post-analytical stages continue to lead in the occurrence of errors. Improving the diagnostic service's quality is crucial, particularly when it comes to patient misidentification and result communication. For the aforementioned issues, systematic action is made at the national level. It is helpful to group the faults according to their frequency and relevance in order to pinpoint quality enhancements and concentrate on corrective measures. The great benefit of using the laboratory test technique to prevent errors in all testing phases is validated by the lessons learnt.

STATEMENT OF DECLARATIONS

DATA AVAILABILITY STATEMENT

The article contains all of the data created or analysed throughout the investigation.

CONFLICT OF INTEREST

The authors said that they had no conflict of interest.

FUNDING SOURCE

Not Applicable

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