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Original Research Article

ASSESSMENT OF ALL TYPES OF LABORATORY ERRORS IN THE TERTIARY CARE CARDIAC FACILITY LABORATORY

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Abstract: *A prospective examination of laboratory errors was performed during three months from July to September 2019 at the Rawalpindi Institute of Cardiology (RIC), a 272-bed tertiary care hospital serving the Punjab region and parts of Azad Jammu and Kashmir (AJK) and Khyber Pakhtunkhwa (KPK). The study aimed to thoroughly evaluate error incidence rates across the complete testing cycle, considering the pre-analytical, analytical, and post-analytical phases. During this time, nurses, physicians, and medical assistants from various hospital wards submitted samples and request forms to the clinical pathology laboratory at RIC. For a total of 17,917 patients, 73,540 tests were carried out. The overall observed laboratory error rate for the entire testing procedure (TTP) was 1.43%. Notably, pre-analytical mistakes made up the most significant percentage (0.82%), followed by post-analytical errors (0.51%) and analytical errors (0.10%). The data were carefully examined, and the results were presented using figures, charts, and tables to show the prevalence and magnitude of various mistake types. According to the distribution pattern, overall error rates had significantly decreased over the previous ten years. Despite this development, the largest error prevalence was still seen in the pre- and post-analytical processes. Interestingly, errors were frequently found during the pre- and post-analytical procedures outside the lab. To reduce the likelihood of mistakes, RIC undertook several initiatives, and the study highlighted these efforts, highlighting the significance of the laboratory testing procedure for mistake prevention throughout all testing phases.In addition to offering insightful information about the frequency of errors at RIC, this three-month descriptive analysis highlighted ongoing efforts to improve patient safety and lower laboratory errors. The observed gains over the past ten years are evidence of the success of adopted tactics. The results show how important it is to maintain constant watchfulness and employ methodical procedures to guarantee the accuracy and dependability of laboratory testing procedures, improving patient care and safety.*

Keywords: Patient Safety, Laboratory Errors, Total Testing Process (TTP), Pre-analytical Phase, Post-analytical Phase, Error Prevention, Tertiary Care Cardiac Facility

Introduction

The laboratory requires the total process of testing that consists of pre-analytical, analytical, and post-analytical phases of measurements. Comprehensive Quality Management must be implemented to minimize, or better still, completely eradicate, process flaws. It is true that any defect found during the testing procedure, from arranging the test to reporting the findings, qualifies as an "error." We will monitor OPD and patients in various wards of Rawalpindi Institute of Cardiology for three months to assess the frequency and types of errors identified in the Department of Pathology (Ross and Boone, 1989). The quality process is essential for healthcare executives to enhance patient outcomes, adjust to changing circumstances, and provide high-quality, reasonably priced care. Payers, patients, and regulators still want performance-based data proving adherence to benchmarks and quality standards (Sharaki et al., 2014). The previous few decades have seen the computerization of laboratories, the replacement and modernization of outdated equipment, the optimization of transportation networks, and the automation of specimen processing. Due to these modifications, laboratories can continue providing services despite an ever-growing amount of tests from all parts of the healthcare system. Additionally, over the years, testing locations have expanded due to the availability of point-of-care testing devices, which enable high-quality laboratory work to be completed at several care locations.

There has been much focus on the issue of medical blunders lately, which will likely continue (Alaagib et al., 2023). Clinical laboratories should gather data on the rates of errors that occur across the whole testing cycle, including the pre-, intra, and post-analytical phases, given the growing emphasis on patient safety and the necessity to lower laboratory errors (Goswami et al., 2010). Many parts of the healthcare system still do not provide high-quality patient outcomes. Labs appear to be at the forefront of guaranteeing the calibre of their analytical measurement (Howanitz and Medicine, 2005). Every day, the laboratory diagnostics quality assurance procedure is conducted. The pathology

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service's competence is responsible for 70% of illness diagnosis and treatment, making it a vital component of contemporary healthcare (Lippi et al., 2009). Although laboratory automation development has made a substantial contribution in that regard, mistakes can still happen (Hawkins, 2012). Three categories of errors are frequently seen in laboratories: pre-, analytical, and post-analytical errors. Clinical laboratories have long employed quality control materials and evaluation programs to address these mistakes. The significance of these mistakes and their effect on patient outcomes are felt intensely these days (Alaagib et al., 2023). More efforts are being made to raise awareness and implement various tactics to decrease these laboratory errors.

Some of these include internal quality control methods, external quality evaluation programs run by professional groups, and lab accreditation and certification. Despite this, current research indicates that pre-analytical errors account for most laboratory errors. A literature review also reveals that pre-analytical phase errors account for 46–68% of all errors during the testing procedure, analytical phase errors account for 7–13%, and post-analytical errors account for 19–47%. (Howanitz and Medicine, 2005). Any flaw, from test ordering to reporting and result interpretation, is a laboratory error. The rate of errors in clinical laboratories has significantly decreased over the past few decades across all phases.

Instead of relying just on the assumed clinical presentation to confirm a diagnosis, doctors are now required under evidence-based medicine (EBM) to perform laboratory tests. Due to variations in the methods used for data gathering, there are significant disparities between the current literature reviews. Furthermore, shifts in workload in various healthcare settings may potentially account for variations in data. We will prospectively collect data over three months to monitor the pre-, analytical, and post-analytical phases of mistakes in our lab and try to identify techniques to minimize these errors in our setting appropriately. Activities related to patient safety and quality improvement have drawn more attention from various healthcare facilities in recent years. It is now requested that the laboratories broaden their scope to include operations not directly under their control.

Accreditation agencies increasingly require laboratories to go beyond analytical quality and take responsibility for the pre and post-analytical phases where most errors arise. These new challenges are a change from the traditional laboratory-based activities with which many laboratory staff are comfortable, and this new role can cause some unease and discomfort. This research outlines the different phases of the total testing process, discusses laboratory accreditation requirements for the pre and post-analytical degree, and describes some of the resources available for the laboratories in managing this unfamiliar area.

Methodology

The study was conducted over three months, from July to September 2019. It was carried out at Rawalpindi Institute of Cardiology (RIC), a tertiary care facility with 272 beds. The institute's well-equipped Pathology Department was used for biochemical analysis. The clinical pathology laboratory at RIC comprehensively documented errors using 24 standardized operating procedures and automated analyzers. The mistakes in request forms from both In-Patient and Out-Patient Divisions were recorded and analyzed using Microsoft Excel, Microsoft Word, and SPSS. The laboratory sought accreditation from CAP, CPA, ISO 15189, EQAS, RIQAS, and URS to ensure reliable patient testing and adherence to quality standards.

Results

This descriptive study was conducted for three months (July-September 2019). During the period, a total of 73,540 tests were done under investigation by 17,917 patients. The overall laboratory error observed in all three phases of the total testing process (TTP) was 1.43 %, with pre-analytical errors contributing the highest at 0.82%, followed by post-analytical error with 0.51% and analytical being 0.10% (Figure 1).

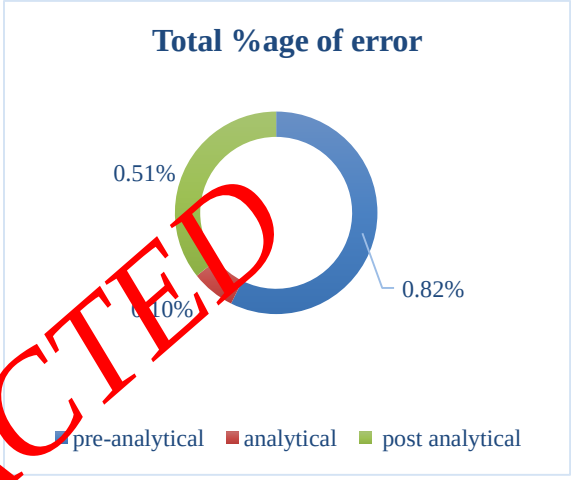

Figure 1 Percentage Error in different stages

The leading causes for pre-analytical errors are hemolyzed and insufficient samples, incorrect sample tubes, the wrong type of collection tubes being used, empty tubes, and delay in sample transportation from the ward to the laboratory were identified as peculiar to samples from the various wards. Samples with duplicate pathological numbers were all from the out-patient's sources. Table 1 provides a detailed breakdown of laboratory errors categorized into pre-analytical, analytical, and post-analytical errors for July, August, and September. In the pre-analytical phase, haemolysis is a notable concern, with occurrences decreasing from 85 (0.3%) in July to 60 (0.08%) in September. Insufficient samples, incorrect identification, and unlabelled samples also exhibit a declining trend. Analytical errors involving equipment malfunction and failure in quality control (QC) demonstrate relatively low occurrences, with equipment malfunctions showing a consistent pattern. Post-analytical errors, such as failure in reporting and improper data entry, exhibit variability, while uncollected results decrease from 97 (0.37%) in July to 91 (0.12%) in September. These trends highlight the need for targeted improvement efforts, particularly in addressing haemolysis and ensuring proper sample collection, with an

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ongoing focus on maintaining equipment integrity and enhancing reporting accuracy. Regular monitoring of these error types is crucial for quality management in the laboratory, ensuring reliable and accurate test results

Table 2 provides a comprehensive overview of the percentage distribution of total laboratory errors across three consecutive months (July, August, and September). The errors are categorized into three main types: pre-analytical, analytical, and post-analytical. The data is presented as percentages calculated based on the total number of monthly tests.

In July, the percentage of pre-analytical errors was 0.91% (236 errors out of 25,779 tests), which slightly decreased to 0.81% (189 errors out of 23,209 tests) in August and further decreased to 0.74% (184 errors out of 24,552 tests) in September. Pre-analytical errors encompass issues that occur before the actual analysis of a sample takes place, such as sample collection and handling. The decreasing trend in pre-analytical errors suggests improving these aspects over the three months, reflecting a positive impact on the overall laboratory testing process.

Analytical errors, representing issues occurring during the actual analysis of samples, showed a relatively stable pattern across the three months. In July, the percentage of analytical errors was 0.10% (28 errors out of 25,779 tests), which remained consistent at 0.09% (23 errors out of 23,209 tests) in August and slightly increased to 0.11% (28 errors out of 24,552 tests) in September. While the variations are minimal, monitoring analytical errors is crucial for maintaining the accuracy of laboratory results.

Post-analytical errors associated with result reporting and interpretation demonstrated a fluctuating trend. In July, the percentage of post-analytical errors was 0.51% (134 errors out of 25,779 tests), increased to 0.55% (128 errors out of 23,209 tests) in August, and then decreased to 0.46% (115 errors out of 24,552 tests) in September. This indicates some variability in the reporting phase, and further investigation may be needed to identify contributing factors.

Figure 2 presents a comprehensive overview of laboratory errors categorized by type and patient status, distinguishing between in-patients and out-patients. Hemolysis is the most prevalent error, occurring in 130 instances among in-patients and 83 cases among out-patients, totaling 213 occurrences. Insufficient sample and incorrect tube usage are more frequent among in-patients, with 98 and 32 occurrences, respectively, compared to 35 and 7 occurrences among out-patients. False labeling and unlabelled samples are more prevalent in in-patient settings. Notably, equipment malfunction is observed in 45 cases among in-patients and 19 patients among out-patients. Failure in reporting is more common among out-patients, with 52 instances compared to 10 cases among in-patients. Uncollected results are notably higher among out-patients, accounting for 263 cases compared to 20 points in in-patients. This analysis underscores the importance of tailoring quality improvement strategies to address specific error types based on patient settings, focusing on minimizing haemolysis, improving sample collection practices, and enhancing reporting accuracy, particularly for out-patients where uncollected results are more prevalent.

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(0.06)	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)

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

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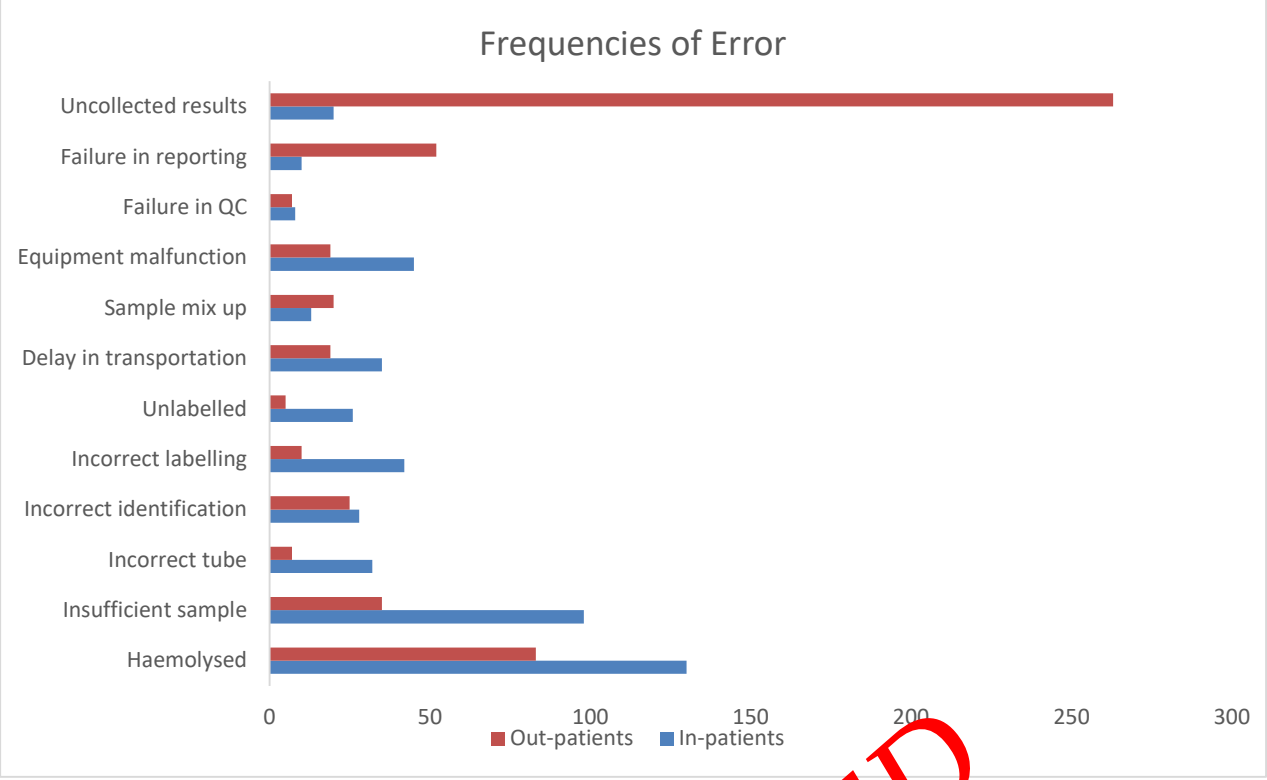

Figure 2: Distribution of error frequencies from July to September between in-patients and out-patients

Discussion

Reliable clinical laboratory services are becoming increasingly important to the healthcare system, but they are also prone to errors because they are a component of the more extensive healthcare system. While a great deal of research has been done to improve the quality of analytical laboratories, there is a dearth of information and several constraints around errors in laboratory medicine (Alsagib et al., 2023). Despite notable advancements that have made laboratory diagnoses less labor-intensive, manual, and more automated, there are still several pre-analytical errors in clinical laboratories. These errors can result in incorrect patient diagnosis and treatment (Alsagib et al., 2023). Mistakes continue to be expected in the lab environment. Throughout the testing cycle, conscious efforts must be made to attain 100% precision and accuracy. Adopted and implemented are strategies to minimize all types of laboratory errors, including licensing of laboratory professionals, accreditation of clinical laboratories, and certification of educational programs, external quality assessment programs, internal quality control procedures, and regulation of laboratory services.

Furthermore, total quality management must be reviewed regularly to minimize or completely eradicate errors that might occur at any stage of the sample processing process—from ordering tests to the physicians' ultimate interpretation of the results. We must embrace the procedure of documenting faults at every level of analysis and formulating remedial plans to avoid them. This can progressively rid a lab of these mistakes. In light of this, we would want to emphasize that, to treat patients effectively, laboratory scientists must embrace a holistic approach to laboratory diagnosis and collaborate with clinicians (Plebani and Carraro, 1997). Nonetheless, several noteworthy successes have been made. Error rates have dramatically decreased over the past forty years, especially for analytical errors, and analytical performance variability is now often less than one-twentieth of what it was forty years ago. Furthermore, data from current research indicates that a significant portion of laboratory errors happen during the pre-and post-analytical phases.

Laboratory diagnostics used to be a labor-intensive operation, but it is now virtually entirely automated thanks to modern developments, necessitating a corresponding workforce decrease. The results of this study unmistakably demonstrated that, despite all the automation, mistakes are still made in the laboratory, which can lead to poor patient care decisions. Much research has been done to improve analytical quality, but errors in the laboratory testing procedure are still common (Astion et al., 2003; Plebani and Medicine, 2006). In this study, we assessed the overall mistake rate during a three-month period that we observed in our laboratory and talked about relevant ways to reduce its recurrence. Pre--, analytical, and post-analytical contributions contributed 0.82 percent, 0.10 percent, and 0.51 percent, respectively, to the overall error rate of 1.43 percent during the three months, as we found. Once more, during the July–September period, there was a substantial ($P = 0.01$) decrease in the number of tests, but this did not translate into a similar reduction in the overall error rate ($P = 0.90$) among the months (Goswami et al., 2010). In our

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investigation, hemolysis was the primary cause of rejections.

Blood collection has become more accessible and efficient with the advent of vacuum tubes and the closed system. However, phlebotomy staff members' lack of training is a barrier to accelerating sample collection and transportation. When blood is pushed through a thin needle, the tubes are violently shaken, and the sample specimens are centrifuged before the clotting process is finished; hemolysis of the samples occurs (Carraro et al., 2000). After the sample is obtained, red top vacutainers without any 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. Blood samples that are frozen and then thawed may result in severe hemolysis. Inadequate blood volume was another reason why blood samples for our investigation were rejected. Each analytical procedure must analyze Serum or plasma in a defined volume. The primary causes of this anomaly include phlebotomists' ignorance and challenging sampling situations, such as pediatric patients, patients with chronic, incapacitating illnesses, and chemotherapy patients with tiny veins that are challenging to locate. The most common reason for test rejection in the sample was insufficient sample volume. The transport of pieces to the lab is still not adequately monitored. A specimen tracking system is currently being developed to ensure that every specimen is indeed received. The management of the laboratory should put in place a sufficient procedure to address issues found in the transportation of specimens and enhance the performance of clients who routinely submit specimens incorrectly (Holman et al., 2002). Because automation has been widely used and appropriate guidelines for establishing acceptable errors in internal quality control procedures have been adopted, the analytical error rate has decreased dramatically over time (Jenny and Jackson-Tarentino, 2000).

A related study found pre-analytical mistakes in 2.07% of all samples collected in the biochemistry lab at Hera's General Hospital between January and December of 2004. However, over a year, Chawla and associates recorded a smaller rate (1.52 percent) of rejections from the clinical chemistry laboratory due to mistakes made in the pre-analytical phase (Glavinović, 1986). The study's findings indicated that visible hemolysis was the most common pre-analytical mistake after sample centrifugation. Research has also observed hemolysis of samples, which happens when blood is driven through a small needle (McNulty et al., 2008; Plebani and Medicine, 2006), and these findings are consistent with our study. A 2010 study highlighted that the hemolysis of the sample caused most rejections at clinical biochemistry laboratories.

Furthermore, this finding is consistent with the 3-5% pre-analytical mistakes that Hawkins noted in his assessment (Sharaki et al., 2014). Additionally, an overall specimen rejection rate of 23.72 percent from the emergency department (ED) was found in this study. This finding may be connected to the ED's high workload and stressful atmosphere. However, the OPD claimed to have the lowest rate of rejected samples—1.8 percent. Today's medical laboratories have many tools and procedures to evaluate, measure, monitor, detect, correct, and improve quality. Based on their experience, however, it is more crucial to concentrate on pre- and post-analytical errors than on analytical errors. However, all potential sources of mistakes are significant, and today's medical laboratories struggle with analytical quality (Carraro and Plebani, 2007; Khoury et al., 1996).

Conclusion

Over the last decade, laboratory error rates have been significantly reduced. While the distribution pattern reveals that the pre-analytical and post-analytical processes continue to have the highest mistake prevalence, there have been notable variations in the types and frequency of errors within these phases. It is critical to improve diagnostic service quality, particularly regarding patient misidentification and result communication. These issues are being addressed at the national level through programs. Grading errors based on their significance and frequency assists in prioritizing quality improvement initiatives and focusing on corrective activities. Lessons learned highlight the significant benefit of using the laboratory testing procedure to prevent errors throughout all testing phases.

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned.

Consent for publication

Approved

Funding

Not applicable

Conflict of interest

The authors declared absence of conflict of interest.

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