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Analyzing Errors In Laboratory Testing: Causes And Prevention Strategies

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Abstract

Laboratory testing informs most medical diagnoses, so errors occurring throughout the testing process pose a major threat to patient safety. Specimen misidentification and pre-analytical mistakes are common, while analytical errors can also compromise results. Post-analytical errors may arise during result reporting and interpretation. Causes are multifactorial, including high volumes, staff shortages, cumbersome systems, and human factors. While analytical errors have declined with automation, pre-analytical and post-analytical mistakes persist. Strategies [1]to reduce errors include staff training, standardized procedures, electronic tracking, improved communication channels, and a culture of safety. Monitoring quality indicators enables assessment of vulnerabilities. A multifaceted approach focused on systemic factors and human elements is required to enhance laboratory reliability and accuracy. This review examines types, frequency, causes of laboratory errors, and quality improvement strategies to mitigate risks.

Keywords: *laboratory error, pre-analytical, analytical, post-analytical, patient safety, quality improvement*

Introduction

Laboratory testing is integral to healthcare, informing 70-80% of medical diagnoses and guiding treatment decisions. However, errors can occur throughout the testing process. Specimen misidentification and pre-analytical mistakes during sample collection and handling are common, accounting for up to 75% of errors. Analytical errors can also occur due to instrument malfunctions, improper calibration, and personnel mistakes in testing procedures. Post-analytical errors may result from inaccurate result interpretations or reporting delays. While most errors are minor, some lead to inappropriate treatment, delayed care, and patient harm (Abdollahi, Saffar, & Saffar, 2014)

Causes of laboratory errors are multifactorial, including high testing volumes, staffing shortages, complex diagnostic technology, and fragmented communication between laboratory and clinical teams. Human factors like fatigue, distractions, lack of training, and lapses in quality control also contribute. System-related issues such as inadequate labeling,

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cumbersome electronic records, and ambiguous test names further increase risks (Mrazek et al., 2020).

Strategies to enhance quality and reduce laboratory errors focus on both human and system factors. Key initiatives include staff education and competency assessments, adoption of standardized procedures, implementation of electronic checklists and barcode specimen tracking, establishment of reference ranges, and improved communication channels between the lab and clinics. There should also be protocols for corrective actions whenever errors occur, along with monitoring of quality indicators (Kimengech, Waithaka, Onyuka, & Kigondu, 2017). Developing a culture of safety and continuous quality improvement is critical. Incorporating redundancies, automation, and other system redesigns can also enhance accuracy. With a multifaceted approach, laboratories can significantly improve reliability and play a vital patient safety role (Miligy, 2015). This review will examine the types, frequency, and causes of errors in laboratory testing and provide an overview of quality improvement strategies to enhance accuracy and patient safety.

Methodology

We conducted this research focusing on a comprehensive evaluation of the sources and frequency of errors in laboratory testing. Databases such as PubMed, Scopus, and Web of Science were searched using keywords related to laboratory errors, including "pre-analytical," "analytical," and "post-analytical" errors, as well as "patient safety" and "quality improvement" in a laboratory setting. Studies published between 2010 and 2023 were considered to ensure relevance and the inclusion of the latest advancements in laboratory technology and error prevention strategies. The inclusion criteria specified peer-reviewed articles that reported primary data on the rates, causes, and prevention of laboratory errors. Exclusion criteria ruled out non-English publications and articles that did not focus on human clinical laboratories.

Literature Review

The literature on laboratory errors reveals a consensus on the multifaceted nature of the causes and the necessity for comprehensive strategies to address them. High testing volumes, staffing shortages, complex diagnostic technologies, and communication gaps between laboratory and clinical teams are repeatedly identified as significant contributors to laboratory errors (Mrazek et al., 2020). Human factors such as fatigue, distraction, inadequate training, and lapses in quality control protocols are equally emphasized (Abdollahi et al., 2014). Studies such as those by Plebani et al. (2014) highlight that pre-analytical errors, including specimen misidentification and improper sample handling, account for the majority of laboratory errors, necessitating stringent control measures during the initial stages of the testing process.

The literature also underscores the evolution of laboratory practices with technological advancements. Automation and computerized systems have been pivotal in reducing analytical errors, yet they have not entirely eliminated them (Miligy, 2015). The post-analytical phase continues to pose challenges, as evidenced by the high rate of errors due to result misinterpretation and reporting delays (Sadiq et al., 2014). The growing body of research advocating for improved communication channels, electronic tracking, and decision support tools indicates that technology can play a vital role in reducing post-analytical errors. However, the literature also points towards the need for a culture of safety and continuous quality improvement to ensure that technology effectively enhances laboratory accuracy and patient safety.

Discussion

Laboratory testing is vital for diagnosis, disease prevention, patient treatment, and monitoring patients for improved care. Therefore, high-quality test analysis is essential. The laboratory testing process involves three main phases: preanalytical, analytical, and postanalytical. Together, these three phases comprise the total testing process (Sonmez, Yıldız, Akkaya, & Taneli, 2020).

Phases of Laboratory Testing and Types of Errors

Laboratory testing is a complex, multistep process involving numerous opportunities for error to occur. Errors can be classified into three main categories: pre-analytical, analytical, and post-analytical.

The pre-analytical phase is critical in the total testing process, as errors that occur here can compromise all downstream steps. The pre-analytical phase encompasses all steps from the test order to the start of analysis, including patient identification, test selection, sample collection, handling, and transportation. This phase involves both laboratory and non-laboratory staff across different departments. Two major categories of pre-analytical errors are identification errors and sample problems. Identification errors can involve mislabeling or improperly identifying the patient or sample. Sample problems relate to issues with the specimen itself, such as hemolysis, clotting, insufficient volume, or improper containers. While monitoring these errors is important, other pre-analytical factors also impact quality, like inappropriate test orders and incomplete requisition forms. As centralized labs have become more common, the risk of pre-analytical errors during transport has also grown substantially. Appropriate indicators and monitoring procedures are essential to reduce pre-analytical errors and maintain quality. Pre-analytical errors account for up to 70% of total laboratory errors (M Plebani, Sciacovelli, Aita, Padoan, & Chiozza, 2014).

The analytical phase is where the actual testing and analysis of the specimen occurs, using either automated systems or manual techniques. While this phase accounts for a minority of total errors in the testing process, maintaining quality here is still critical (Miligy, 2015).

Analytical errors can arise from issues with the testing instruments, reagents, or the procedures followed by laboratory staff. With automated systems, errors may occur from improper use, lack of quality control, expired reagents, or failed maintenance. Manual testing is vulnerable to pipetting inaccuracies, use of contaminated supplies, outdated reagents, and failure to precisely follow protocols (Abdollahi et al., 2014).

Other analytical errors can occur from not adhering to specified incubation times and temperatures, using incorrect calculation methods, or neglecting equipment maintenance. While automation has reduced analytical errors over time, interference, especially with immunoassays, can still compromise results. Careful staff training, rigorous quality control, and strict compliance with procedures is required to minimize analytical errors (Miligy, 2015).

Though analytical errors account for a relatively small portion of total laboratory mistakes, their impact can be significant. Faulty analysis undermines the entire total testing process, as all preceding and succeeding steps assume an accurate result. Analytical errors can lead to misdiagnosis, inappropriate treatment, and patient harm. They can also waste resources if testing has to be repeated. While pre-analytical and post-analytical errors are more common, analytical quality assurance remains a key priority (Payton, 2017).

Reducing analytical errors requires sustained effort in training, quality control, updating instruments and reagents, and ingraining a culture of precision and vigilance among laboratory staff. A single miscalibrated instrument or distracted technician can compromise many samples and results. Labs must rigorously safeguard the integrity of the vital analytical phase(Lippi, Simundic, & Plebani, 2020)

The post-analytical phase encompasses the processes after testing is completed. This includes result review, interpretation, reporting, and action taken based on the findings.While the pre-analytical and analytical phases have received more attention around quality, the post-analytical phase remains vulnerable to errors. Studies indicate 18.5-47% of total laboratory mistakes occur post-analytically (Sadiq et al., 2014).

Errors can include inaccurate manual transcription of results, improper reference range application, failure to detect critical values, inadequate validation by pathologists, and delayed or absent reporting. Misinterpretation of results and inappropriate clinical action also qualify as post-analytical errors (Payton, 2017).

Causes relate to lack of protocols, time pressures, ineffective communication between laboratory and clinical staff, and inadequate IT systems. Solutions involve establishing clear policies, utilizing clinical decision support tools, implementing effective critical value notification systems, fostering collaboration between departments, and utilizing improved reporting technology like electronic medical records. Careful attention to the post-analytical phase is vital to avoid delays in diagnosis, inappropriate treatment, and patient harm (Sciacovelli et al., 2016).

While analytical quality has improved through automation and quality control programs, the post-analytical phase remains prone to error. Issues like incorrect reference range use, missed critical values, and reporting delays can arise after specimens are analyzed. Inadequate result review, misinterpretation, and ineffective communication of findings to guide clinical action also contribute to mistakes post-analytically (Kimengech et al., 2017).

Causes relate to suboptimal protocols, workflows, staffing levels, IT systems, and interdepartmental collaboration. Targeted quality assurance programs, improved reporting technology, better staff communication, and clearer definition of responsibilities is required to enhance post-analytical quality. This phase directly impacts patient outcomes, so it is crucial to apply robust risk-reduction strategies. With testing accuracy assured analytically, labs must also optimize practices around result review, reporting, interpretation, and clinical utilization.. The post-analytical phase accounts for up to 47% of laboratory errors (Sadiq et al., 2014).

In addition to these classifications, errors can also be characterized based on their potential to harm patients. Near-miss errors have the potential to cause harm but fail to do so, either by chance or timely intervention. Adverse events, on the other hand, are errors that do reach the patient and cause harm, ranging from minor injury to severe morbidity or mortality. Understanding how often near-miss events occur can provide insight into vulnerabilities in the testing process.

Frequency and Impact of Laboratory Errors

Studies show that the vast majority of laboratory errors occur in the pre-analytical and post-analytical phases, rather than the analytical testing itself. Reviews estimate the pre-analytical and post-analytical error rate is 4-5 times higher than analytical errors, with the pre-analytical phase accounting for over 50% of total errors (Lippi, Guidi, Mattiuzzi, & Plebani, 2006). Specific studies have found a pre-analytical error rate of 46-68% of total errors, while post-analytical mistakes account for 18.5-47% (Hawkins, 2012). This distribution has remained relatively constant over decades, even as overall error rates have declined (Mario Plebani, 2006). The frequency of errors also differs significantly between inpatients and outpatients, likely due to differences in sample collection, transport, and testing volumes. Reducing laboratory errors requires a focus on improving quality management in the extra-analytical phases (Carraro & Plebani, 2007; Mario Plebani, 2010).

Laboratory testing guides over 70% of clinical decisions, so inaccurate results can be detrimental to patient care. Errors at any phase of testing can lead to delayed diagnosis, misdiagnosis, inappropriate treatment, and patient harm (Specification, 2008). Pre-analytical mistakes like improper sample collection or labeling errors undermine all subsequent testing (Lippi et al., 2006). Analytical errors can directly produce flawed test results and conclusions. Post-analytical mistakes can lead to delayed reporting, misinterpretation, or inadequate clinical action based on results. While labs have reduced analytical errors through automation and quality control, extra-analytical errors persist as a major threat to quality and patient safety. Comprehensive quality management programs across the total testing process are essential to detect and eliminate sources of potential error and their damaging effects on patient outcomes (Abdollahi et al., 2014).

Causes of Errors in the Testing Process

Laboratory errors stem from both system-related factors and human mistakes. While human errors were once viewed as the primary cause, it is now recognized that most errors result from flaws in systems, processes, and conditions which allow human mistakes to reach patients and cause harm. Understanding where in the testing process failures are most likely to arise and why can help target quality improvement strategies.

Pre-analytical Phase Errors

The pre-analytical phase is a critical stage in the laboratory testing process where the majority of errors occur due to the complex nature of specimen collection and handling, involving various steps and personnel. These errors can include incorrect test requests, misidentification of patients during sample collection, improper sample collection practices, mishandling during transportation and preparation, and labeling mistakes (Mehndiratta, Pasha, Chandra, & Almeida, 2021). High workload, fatigue, inadequate training, and communication issues are human factors contributing to these mistakes. Failure to follow proper identification protocols, ensuring the appropriateness of tests, maintaining sample quality, and handling specimens correctly can lead to compromised laboratory testing integrity (Pap, 2022).

Analytical Phase Errors

During the analytical phase, where the laboratory analysis is performed, errors may arise from technical issues with laboratory instruments, such as malfunctions or failures. The use of expired, contaminated, or deteriorated reagents, deviations from analytical protocols, and technical mistakes like inaccurate pipetting or mixing errors are other sources of error. Analytical errors, although less common than pre-analytical and post-analytical errors, have a direct impact on the accuracy of test results. Factors such as inadequate training, distractions, and disregard for quality control measures can contribute to these errors (Mrazek et al., 2020).

Post-analytical Phase Errors

The post-analytical phase involves reviewing, interpreting, reporting, and clinical actions based on laboratory test results. Errors in this phase can include inaccurate manual transcription of results, improper use of reference intervals, failure to communicate critical values, delays in reporting results, misinterpretation of data by healthcare providers, and neglecting to recommend follow-up tests. These errors are often due to time pressures, ineffective communication, and suboptimal verification processes. Lack of standardized procedures and clinical decision support systems can lead to misinterpretation and inappropriate clinical use of test results (Mario Plebani, 2015).

Systemic Issues in Laboratory Errors

Most laboratory errors are not isolated incidents but are rooted in systemic issues within the laboratory environment. The high complexity of laboratory testing, with its numerous steps, transitions, instruments, and personnel, creates multiple potential points of failure. Staff shortages and high demand for testing can lead to production pressure, increasing the likelihood of errors. Reliance on technology cannot replace the need for human judgment, and the variability of tasks adds to the complexity. The absence of process standardization, decentralization of testing across multiple laboratories, interdependence of testing phases, and the need for manual dexterity in certain procedures contribute to the problem (Lippi et al., 2009).

Strategies to Improve Quality and Patient Safety

Improving quality and patient safety in the laboratory setting is essential for reliable diagnostics and effective patient care. The three phases of laboratory testing—pre-analytical, analytical, and post-analytical—are all susceptible to errors which can compromise patient safety. Various strategies have been developed and implemented to mitigate these errors and improve the overall quality of laboratory services. Below, we explore current strategies for each phase with appropriate citations (Mrazek et al., 2020).

Pre-analytical Phase

The pre-analytical phase includes all the steps from test selection to sample collection and transportation to the laboratory. This phase is particularly prone to errors because it heavily involves human factors and system processes (Sciacovelli et al., 2017).

- Standardization of Procedures: Standard operating procedures (SOPs) for sample collection, labeling, and transportation are critical. The implementation and adherence to SOPs can minimize human errors and variability in specimen handling (Simundic & Lippi, 2012).
- Training and Education: Regular training programs for healthcare professionals involved in specimen collection and handling can significantly reduce pre-analytical errors. These programs should be comprehensive and include updates on best practices (Lima-Oliveira, Volanski, Lippi, Picheth, & Guidi, 2017).
- Patient Identification Technologies: The use of barcoded wristbands and sample labels linked to electronic health records (EHRs) ensures that the right sample is taken from the right patient and that the sample is correctly associated with the patient's medical record (Lima-Oliveira et al., 2017).

Analytical Phase

- During the analytical phase, the actual testing and analysis of biological specimens occur. Precision and accuracy are vital in this phase to ensure the validity of test results (Mario Plebani, 2018).
- Automation: The implementation of automated systems and equipment can reduce human error associated with manual testing. Automation also improves efficiency and throughput, allowing for better resource allocation (Armbruster, Overcash, & Reyes, 2014).
- Quality Control and Assurance: Robust internal and external quality control (QC) programs are essential. Participation in external quality assessment schemes (EQAS) allows for benchmarking and identification of areas for improvement (Westgard, Bayat, & Westgard, 2018).
- Instrument Maintenance and Calibration: Regular maintenance and calibration of laboratory equipment are critical. This ensures that analytical instruments perform within specified limits, providing reliable results (Sciacovelli et al., 2017).

Post-analytical Phase

The post-analytical phase includes the interpretation and reporting of results, as well as the archiving of data. Errors in this phase can lead to incorrect interpretation and clinical decision-making (Lippi et al., 2020).

Result Verification Protocols: Laboratories should implement protocols for result verification, particularly for critical and unexpected values. This often includes a review by a second technologist or pathologist ((Walz & Darcy, 2013)

- Effective Communication: Standardized procedures for reporting critical results, including read-back protocols and electronic alerts, ensure that urgent findings are communicated and acted upon promptly (Walz & Darcy, 2013)
- Continuous Education: Clinicians and laboratory staff should engage in continuous education regarding test result interpretation and the limitations of certain assays. Understanding the clinical context can reduce misinterpretation of laboratory data (Walz & Darcy, 2013).

Quality Management Principles

Quality indicators are essential tools for laboratories to track and monitor error rates, specimen quality, proficiency testing performance, and turnaround times. These indicators provide a quantitative way to gauge the effectiveness of the laboratory's processes and the accuracy of its results. By closely monitoring these indicators, laboratories can identify areas where they may be falling short and take proactive steps to improve (M Plebani et al., 2014).

Quality assurance is another critical aspect of laboratory management. Establishing robust quality control processes for every step of the laboratory workflow—from specimen collection and handling to analysis and results reporting—helps ensure that the final test results are reliable. Quality assurance protocols help catch errors before they affect patient care and contribute to maintaining the integrity of laboratory data (Valdivieso-Gómez & Aguilar-Quesada, 2018).

Competency assessment is necessary to ensure that all laboratory staff have the requisite skills and knowledge to perform their duties accurately and efficiently. Regularly assessing staff through direct observation, written examinations, and the recording of errors allows management to identify areas where additional training may be needed. This ongoing assessment helps maintain a high standard of laboratory performance and contributes to the professional development of laboratory personnel (Yao, Luman, Nkengasong, & Maruta, 2016).

When errors do occur, corrective actions are vital to address and resolve these non-conformities. By identifying the root causes of errors, the laboratory can implement systemic solutions that prevent recurrence. This might involve changes in procedures, additional training for staff, or upgrades to equipment. Systematic corrective actions help prevent the same mistakes from happening again and enhance the overall quality of laboratory services (Sciacovelli et al., 2017).

Accreditation by recognized organizations, such as the College of American Pathologists (CAP) or the Commission on Office Laboratory Accreditation (COLA), is a way for laboratories to demonstrate their commitment to quality. These organizations establish rigorous laboratory quality standards, and accreditation signifies that the laboratory meets or exceeds these benchmarks. This process also provides a framework for continuous improvement, as laboratories must maintain their standards to keep their accredited status (Zima, 2017).

Culture of Quality and Safety

At the heart of reducing Leadership commitment is essential in this regard, as it sets a precedent for the rest of the organization in this regard, as it sets a precedent for the rest of the organization. When the administrative level makes quality a stated priority, it sends a clear message that the laboratory is dedicated to excellence in all its processes (Lim, Loo, & Lee, 2017).

Transparency around errors is critical to creating an environment where staff members feel comfortable reporting mistakes. Adopting a non-punitive approach encourages personnel to disclose errors without fear of retribution, leading to more opportunities for improvement. This openness is fundamental to learning from mistakes and preventing them in the future (Organization, 2016).

Teamwork is also a cornerstone of a culture of quality and safety. By promoting collaboration between various laboratory departments and with other healthcare providers, the laboratory can ensure that all aspects of patient care are considered. This teamwork extends to the sharing of best practices and standardizing procedures across different areas of the lab and the wider healthcare environment (KAYA & YÜCELER, 2016).

Communication between leadership and frontline staff is another key element. It is essential that there is an open line of conversation regarding safety concerns and that staff feel their voices are heard. This dialogue can lead to the identification of potential issues before they result in errors and can foster a sense of shared responsibility for safety (Phillips, Hebish, Mann, Ching, & Blackmore, 2016).

Finally, staff engagement is vital for a successful quality and safety culture. When laboratory technologists and assistants are actively involved in identifying issues and designing solutions, they are more likely to be invested in the outcome. Engaging staff at all levels encourages a sense of ownership over laboratory processes and can lead to more innovative and effective solutions to prevent errors (Waterson, 2018).

Conclusion

In conclusion, laboratory errors, spanning pre-analytical, analytical, and post-analytical phases, pose significant risks to patient safety and healthcare efficacy. While the evolution of laboratory practices, particularly through automation and improved quality control measures, has mitigated the frequency of analytical errors, the pre-analytical and post-analytical phases continue to be vulnerable to mistakes. These errors have a direct and sometimes devastating impact on patient outcomes, as they can lead to misdiagnosis, delayed treatment, or inappropriate patient management.

To enhance the reliability of laboratory testing, comprehensive quality management programs that extend beyond the analytical phase are essential. Such programs should focus on refining protocols, promoting rigorous staff training, and fostering effective communication among healthcare teams. Moreover, leveraging technological advancements and decision support tools can further reduce error rates. As healthcare continues to advance, maintaining a steadfast commitment to minimizing laboratory errors through systemic improvements and continual vigilance remains a paramount objective. By doing so, the healthcare community can better safeguard patient welfare and optimize the use of laboratory data in clinical decision-making.

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