# The Impact Of Laboratory Errors On Patient Care And Outcomes

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**Abstract**

Medical practice heavily relies on laboratory data, therefore making laboratory mistakes very influential on patient safety. Hence, it is essential to develop systems aimed at detecting and mitigating laboratory mistakes, while also implementing targeted tactics to decrease these errors and enhance patient safety. The objective of this study is to identify prevalent laboratory mistakes that are often encountered in laboratory work, assess their potential risks to patient healthcare, and provide techniques and suggestions to reduce or eliminate these types of mistakes. Errors have been categorized based on the different stages of laboratory processes and their impact on patient well-being. The results of this research were consistent with those reported from the USA and other nations. This demonstrates the universality of laboratory issues and the need for comprehensive standardization and benchmarking protocols. The first statistics provided from Arabic nations assessed laboratory mistakes and highlighted the urgent need for worldwide standards and benchmarking procedures to regulate laboratory operations.

**Keywords:** Laboratory errors, patients, medical practice, patient care.

## Introduction

The health care industry has seen several technological advancements that, while improving the quality of life, also provide an increased risk of occurrences resulting in avoidable injury to patients, known as adverse events (AEs) (Ruciman et

al., 2009). Healthcare operating systems lack error mitigation and AE prevention features, and their insufficient management has been extensively discussed in several publications (Okorodudu, 2009). Despite the significant number of individuals worldwide who experience serious harm, including disability and death, as a result of unsafe practices in healthcare, there is limited knowledge regarding the frequency, types of adverse events (AEs), and contributing factors in both hospital and non-hospital settings. The economic consequences of adverse events (AEs) are significant and shameful, leading to expenses related to prolonged hospitalization, AE treatment, consequent disability, and legal disputes (Weingart et al., 2001).

Laboratory medicine plays a significant role in health care systems. It is crucial for several decision-making activities performed by physicians, nurses, and other healthcare workers. It is closely linked to the prevention, diagnosis, treatment, and management of diseases, as well as patients' rehabilitation. Laboratory test findings provide valuable data for evidence-based medicine, since they are included into the algorithms of clinical recommendations. Laboratory medicine offers valuable insights for the treatment of chronic illnesses, enabling the monitoring of their daily condition, the need for medication dosage modification, and the assessment of improvement resulting from lifestyle changes. Each of these pieces of information constitutes essential elements of healthcare quality and safety (CDC, 2011).

Laboratory tests, like to other aspects of healthcare, occur in an intricate setting as a result of the use of information technology and the growing automation (Plebani, 2009). The intricate nature of this situation may provide challenges for clinical labs, clinicians, and patients (Wagar and Yuan, 2007). Although the occurrence of mistakes is rather modest when considering the high volume of laboratory tests conducted worldwide on a daily basis, there are significant consequences for patient safety. There is a significant amount of literature available on research about laboratory mistakes, but, only a few writers specifically address their effects. The quantification of adverse events (AEs) associated to laboratory mistakes is a complex and relatively unknown topic. This is mostly owing to the variety in research designs, under-reporting in incident notification systems (sometimes due to fear), and the challenge of linking diagnostic errors to AEs (Wang, 2004; Leape, 2008).

As per the specifications outlined in ISO standard 15189:2003 by the International Organization for Standardization (ISO) for medical laboratories, laboratories are required to implement investigation procedures to identify any deviations from their quality system's procedures or requirements. These procedures must be associated with corrective and preventative actions (ISO. 2003). ISO 22367:2008 defines risk management as a deliberate procedure that is integrated into both corrective and preventative measures, and is concerned with ensuring the stability and predictability of outcomes in medical labs. It is important to emphasize that both types of action need reports or notifications, which rely on the presence and execution of a culture focused on providing high-quality treatment and ensuring patient safety (ISO. 2008).

Medical mistakes in the USA are estimated to be the seventh most common cause of mortality. Approximately 7,000 people are projected to die solely as a result of drug mistakes. According to a study by the Institute of Medicine (IOM) in November 1999, the number of deaths resulting from medical mistakes exceeds those caused by motor vehicle accidents, work-related injuries, breast cancer, or AIDS (Kohn et al., 1999). As per the IOM study, the whole healthcare team has the collective duty of minimizing mistakes and resolving safety concerns. Therefore, the IOM established four projects with the aim of preventing mistakes and enhancing patient safety:

Develop a nationwide emphasis on leadership, research tools, and methods to improve the collective understanding of safety.
Recognize and acquire knowledge from medical mistakes via the use of both compulsory and voluntary reporting mechanisms;
Enhance safety by setting higher standards and expectations via regulatory bodies, collective buyers, and professional associations.
Enforce secure protocols at the delivery stage.

The IOM established the latest universally recognized definition of healthcare quality as the extent to which health services for people and groups enhance the probability of achieving positive health outcomes and align with current professional knowledge (Lohr et al., 1992). Laboratory services are essential in both individual and population-based

healthcare. According to Silverstein (2003), laboratory testing have a significant impact on around 70 percent of medical choices. Some clinical themes that depend on laboratory service quality include the diagnosis of acute myocardial infarction, infectious illnesses, endocrine disorders, diabetes mellitus, and cancer follow-up indicators. Improper laboratory services may have detrimental effects on a patient's health in several ways, such as misdiagnosis. If a dangerous illness like cancer is misdiagnosed at an early stage, the chances of recovery are significantly reduced, perhaps resulting in a sentinel event.

Inadequate care and lack of sufficient monitoring may result in the progression of diseases and the occurrence of harmful side effects due to the prescription of inappropriate drugs.
Disease prevention: In situations of highly infectious diseases, incorrect diagnosis contributes to the spread of infection among the surrounding population.

The pursuit of solutions to the challenges faced in the clinical laboratory sector is supported by the need to protect patient safety, making it an opportune endeavor. The objective of this study is to thoroughly examine the occurrence and description of adverse events caused by laboratory mistakes, as well as the methods used to evaluate them.

**Stages of laboratory protocols**

The laboratory services include the following specialized areas: clinical chemistry, hematology, microbiology, pathology, and transfusion medicine. The process of laboratory testing is began when a physician orders a specific test in order to arrive at a diagnosis. After the laboratory test is requested, the patient is identified and the sample is collected, delivered, and prepared for analysis. Following the analysis, the findings are analyzed and then published. Action is executed according to the interpretation of the test results. The laboratory cycle has three distinct phases: pre-analytic, analytic (which may be performed using either automated or manual procedures), and post-analytic. An investigation was carried out utilizing the MEDLINE database, spanning the last eight years, to ascertain the incidence and nature of analytical errors (Bonini et al., 2002).

There was a high level of agreement on the distribution of errors across the laboratory working process: the majority of errors occurred in the pre- or post-analytical stages, while a smaller percentage (13-32 percent according to the studies) happened in the analytical phase. The number of errors was correlated with the method of identification used, especially when a meticulous analytical procedure was conducted. A much higher number of mistakes were identified compared to studies that relied on complaints or near accident reports (Bonini et al., 2002).

Clinical laboratory personnel have traditionally focused their emphasis on quality control techniques and quality assessment programs pertaining to analytical issues. These endeavors substantially decreased mistakes resulting from analytical issues over a period of time. However, there is evidence, especially in the case of immunoassays, indicating that interference might have a considerable influence on patient outcomes (Plebani, 2007). Nevertheless, mounting data indicates that ensuring clinical laboratory quality cannot be achieved just by concentrating on purely analytical factors. Recent studies on laboratory mistakes have indicated that the majority of errors in laboratory testing occur during the pre-analytical phase, accounting for 46-68.2 percent of overall errors. Additionally, high-error rates ranging from 18.5-47 percent have been seen in the post-analytical phase (Plebani, 2007).

**Summary and suggestions**

Medical practitioners heavily rely on laboratory results in their work. According to Silverstein (2003), laboratories provide around 70-80 percent of the information in the healthcare system. Therefore, mistakes that occur in the laboratory have a direct influence on the safety of patients. Accurate data about medical mistakes and their influence on patient health or life are lacking in Arabic countries. The extent of medical mistakes is sometimes underestimated due to the lack of documentation (Khashaba Ola, 2007). The presence of medical record flaws hinders the acquisition of reliable measurement data. Moreover, there is a scarcity of research that have specifically examined the correlation between medical mistakes and adverse outcomes. The issues with error reporting arise due to the presence of diverse data, limited standards, and inadequate specifications about the acceptable maximum error rate and mistake categorization.

The ministry consultants conduct regular field visits to various labs to assess many aspects of the quality assurance program. These include reviewing the expiration dates of reagents, ensuring that quality control measures are in place, inspecting the equipment, verifying the accuracy of laboratory findings by examining samples, ensuring that laboratory professionals have the necessary licenses, and evaluating the safe disposal systems for waste. The dependability and improvement of the analytical cycle technique need collaboration between doctors and healthcare professionals responsible for sample collection, those doing the analysis, and those involved in preparing test results (Silverstein, 2003).

The occurrence of pre-analytical mistakes in laboratory testing is often due to unsuitable practices, whereas post-analytical errors mostly arise from incorrect interpretation and application of laboratory results (van Walraven and Naylor, 1998). Not every mistake leads to negative consequences. Several faults may not provide noticeable odd outcomes or prompt inquiries from the user. According to a research conducted by Goldschmidt and Lent (1995), it was predicted that as much as 75 percent of mistakes in laboratories may still provide findings that fall within the reference ranges. However, may laboratory errors be fatal? Estimating the coagulation profiles of patients who are taking anticoagulants and relying on blood transfusion test inaccuracies might potentially expose the patient to serious and critical consequences. Therefore, the below actions might be implemented to decrease laboratory mistakes and ensure patient safety:

Choosing laboratory staff that has suitable credentials, expertise, and experience.
Regular training programs and seminars are conducted to augment the knowledge and abilities of laboratory professionals.
Overseeing and promoting a safety culture, modifying behavior, and instilling standards among laboratory staff.
Consistently implementing quality control techniques across various laboratory operations to reduce analytical mistakes.
Clinical laboratory scientists should establish assessment procedures to document and treat medical mistakes, as well as propose strategies to mitigate their occurrence. Comprehensive

evaluation programs should include the whole of the testing process.

By using evidence-based information, one may establish standards for identifying mistakes in various laboratory techniques, allowing for the identification and learning from these errors.

Utilizing individual anecdotes and establishing a mechanism for receiving input. Distributing surveys on laboratory services to end customers in order to enhance the quality of the services provided.

Stringent protocols are necessary to inform doctors of key outcomes. Establishing effective communication and collaboration between laboratory experts and healthcare practitioners is crucial to prevent people from being exposed to sentinel events.

Regularly use performance assessment data to assess laboratory workers. It is advisable to take into account penalties or financial incentives.

The Ministry of Health is responsible for licensing laboratory personnel.

Ensuring the accreditation of labs via a comprehensive quality assurance procedure.

The scope of peer review should be expanded to include laboratory work. Data from reporting systems should be gathered, examined, and used to detect recurring errors and ensure enhancements in quality.

Creating settings that facilitate the production of reliable and exact laboratory findings by ensuring sufficient laboratory space, advanced apparatus, necessary supplies, and a competent support team to maintain the equipment.

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