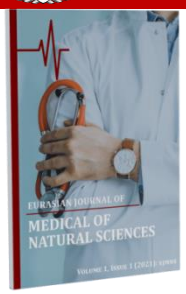
EURASIAN JOURNAL OF MEDICAL AND NATURAL SCIENCES
Innovative Academy Research Support Center
IF = 7.921 www.in-academy.uz




# CLINICAL DIAGNOSIS THE NEGATIVE CONSEQUENCES OF DIAGNOSTIC ERRORS IN LABORATORY PRACTICE AND THE RELEVANCE OF THEIR ELIMINATION

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https://doi.org/10.5281/zenodo.16416930

**ARTICLE INFO**

Received: 19th July 2025
Accepted: 24th July 2025
Online: 25th July 2025

**KEYWORDS**

*Laboratory medicine iatrogenic injury, incorrect diagnosis, potential diagnostic errors, diagnostic process, diagnostic testing phase.*

**ABSTRACT**

*One prominent form of medical error and avoidable iatrogenic injury is diagnostic error, which includes missed, delayed, or incorrect diagnosis. Diagnostic errors may result from mistakes made during the laboratory testing procedure. The purpose of this retrospective study of voluntary event reports was to look into the types, reasons, and clinical effects of errors—including diagnostic errors—that occur during clinical laboratory testing. A number of papers published in the past 20 years have brought laboratory professionals' attention to the pre- and post-analytical phases, which currently seem to be more susceptible to errors than the analytical phase. This is true even though the frequency of laboratory errors varies greatly, depending on the study design and steps of the entire testing process investigated. Specifically, the pre-pre- and post-analytical phases of the cycle, which are typically outside the laboratory's control, have been found to have a high incidence of errors and a risk of errors that could endanger patients. The International Organization for Standardization's 2008 publication of a Technical Specification was crucial in gathering data and shifting public perceptions about laboratory errors by highlighting the necessity of a patient-centered approach to testing errors. Laboratory testing process problems frequently result in potential diagnostic errors. Voluntary incident reports are a useful source for research on diagnostic error linked to clinical laboratory testing process errors, despite their tendency to provide insufficient information on causes and clinical consequences.*

**Introduction.** Diagnostic errors, which are defined as a diagnosis that was incorrect, missed, or communicated to the patient with a significant delay, are a frequent source of iatrogenic injury to patients. According to recent data from the Netherlands, diagnostic errors were responsible for 40% of serious incidents in hospitals reported to the Dutch Healthcare Inspectorate and 11% of adverse events that happened in patients who died in the hospital. Internationally, diagnostic errors are likewise seen as a serious patient safety issue. For instance, the National Academy of Medicine in the United States came to the conclusion that most people will encounter a diagnostic error at least once in their lives in their seminal

report on enhancing diagnosis in healthcare [1,2,3]. In a survey of physicians, Schiff et al. found that errors occurred most frequently (44%) in the diagnostic testing phase (failure to order, report, and follow-up laboratory results). Clinical laboratory testing is a major component of the diagnostic process; up to 80% of medical decisions are influenced by laboratory data. Diagnostic errors can result from errors in the laboratory testing process. For instance, Gandhi et al. found that incorrect interpretation of the laboratory test result caused 37% of diagnostic errors in the ambulatory setting that resulted in malpractice claims. There are no research that have examined diagnostic error as a result of a laboratory testing procedure error, despite the fact that the effects of errors on patients are widely recognized from these studies. The development of focused risk management techniques to successfully raise the safety of diagnostic testing may benefit from this information [4,5,6]. It's critical to look at potential solutions to help reduce the likelihood of diagnostic errors in order to protect patients from harm. Priority should be given to identifying the primary failure areas in the diagnostic process as well as in creating, putting into practice, and testing certain interventions, as recently indicated in their paper on the present status of research on diagnostic errors. Numerous data sources, including claims data, obduction data reports on significant incidents, and voluntary incident reports, can be used for this kind of research. Compared to other sources, these reports are intriguing because they offer a comprehensive perspective on the therapeutic process and a glimpse into the aspects of occurrences that healthcare professionals deem pertinent and that represent circumstances that could escalate into significant incidents [7,8,9]. Whether the incidences resulted in (possible) diagnostic mistakes was not particularly examined in those investigations. The results of the first study were validated by the third study conducted by the same group using data from the British Columbia Patient Safety and Learning System. We performed a retrospective analysis of voluntary incident reports in our hospital, a large academic teaching hospital with high diagnostic testing volume (e.g., approximately 500,000 orders for clinical chemistry testing annually), in order to better understand diagnostic errors related to errors in the clinical laboratory testing process. We examined the phases of the testing process, the types of errors, the causes, the clinical impact, including potential diagnostic errors, and the relationship between these [10,11,12]..

**The main purpose** of this review is to conduct a brief analysis of clinical and diagnostic laboratory practice for the negative consequences of diagnostic errors and the relevance of their elimination.

**The new finding that laboratory medicine errors** are a subset of a broader problem known as "diagnostic error" is another step in the direction of a better understanding of the problem. This finding establishes a clear connection between laboratory-associated errors and patient safety issues. The old paradigm, which only focused on errors found within laboratory walls, should change as a result of the current understanding of the nature of errors associated with laboratory testing, particularly the relationship between appropriate test ordering and result interpretation/utilization, and their potential to reduce diagnostic errors. A powerful technique for enhancing quality and lowering the possibility of errors in the entire testing process is evidence-based quality indicators [1,7,8,11].

**A synopsis of laboratory medicine mistakes throughout history.** Early research only examined the analytical phase and showed significant frequencies and seriousness of analytical errors, beginning with the groundbreaking 1947 publication by Belk and Sunderman and continuing through numerous works before the 1990s. Nevertheless, in spite of the restricted research design, they offered numerous chances to enhance analytical performance, such as the creation of external quality assurance programs (EQA) and enhanced internal quality control (IQC) regulations [1-4]. A substantial amount of evidence was gathered in the late 1990s that showed: a) a sharp decline in analytical error rates from 162,116 errors per million laboratory tests (parts per million, ppm) to 447 ppm; b) high rates of errors in the pre- and post-analytical steps; and c) the risk of adverse events and inappropriate care as a result of laboratory errors, particularly those in the pre-pre-analytical steps [7,8]. This kind of inaccuracy occurs occasionally and is most likely underreported. Although not strictly speaking a "analytical error," the inability of various methodologies and clinical laboratories to be interchanged can potentially confuse clinical reasoning and patient treatment. This, in turn, is the primary cause of the growing consciousness and worry about the necessity of laboratory medicine standardization and harmonization initiatives [2,3,6].

**Phases before and after analysis.** A series of papers published between 1989 and 2007 brought laboratory professionals' attention to the pre- and post-analytical phases, which currently seem to be more susceptible to errors than the analytical phase, even though the frequency of laboratory errors varies greatly depending on the study design and the specific steps of the total testing process (TTP) investigated. Specifically, two 1997 and 2007 articles employed a study design that enabled us to examine the majority of TTP stages in the same clinical setting (stat laboratory) [12,13,14]. The pre-analytic phase in both experiments had the highest error rate, with the most common issues stemming from incorrect tube filling, improper specimen containers, and improper requesting processes. Although the study design did not take into account the appropriateness of the test request, identification errors were also found. These findings were supported by additional research, and it is currently estimated that pre-analytical errors—or more precisely, pre-pre-analytical errors—account for as much as 70% of all errors in laboratory diagnostics. These errors are primarily caused by issues with patient preparation, sample collection, transportation, analysis preparation, and storage [7,11,12].

**Errors in laboratories and risk control.** The vast majority of laboratory errors offer significant learning opportunities but have minimal direct effects on patient care from the perspective of risk management. In actuality, any mistake, no matter how minor it may seem, could point to flaws in rules and processes that, while they might not result in negative outcomes in their specific setting, could endanger the patient in somewhat different situations. Our takeaway is that the system as a whole should be built to account for both the actual patient harm that was caused and the worst possible clinical consequence in the event that such a mistake were to occur again [14,15,16]. In order to take remedial and preventative steps before any adverse event or patient harm may occur, this prompted a patient-centered examination of laboratory testing errors as well as a greater concern to uncover procedures and systems' flaws and vulnerabilities. Recent evidence that laboratory medicine errors are a component of a broader problem known as "diagnostic error" is another step in the direction

of a better understanding of the problem. This conclusively connects laboratory-associated errors to patient safety issues [11,14].

**Moving toward a patient-centered strategy for errors related to laboratories.** The old paradigm, which only focused on errors found within the laboratory walls, should change as a result of the increased awareness of the current nature of errors associated with laboratory testing, particularly the relationship between appropriateness in test ordering and result interpretation/utilization, as well as their potential to address diagnostic errors. Investigating and improving not only the processes and procedures carried out directly under the clinical laboratory's control, but also the first and last steps of the testing cycle that are typically overseen by other healthcare professionals, is crucial to putting the idea of "patient-centered care" from theory to practice. Therefore, projects that seek to enhance both quality and patient safety must be founded on a comprehensive quality perspective, specifically the search for valuable quality indicators (Qls) for every stage of the testing process and the accreditation of clinical laboratory services in accordance with the International Standard. According to the International Standard, clinical laboratory accreditation specifically requires the discovery and application of important Qls. According to this paper, quality indicators "can measure how well an organization meets the needs and requirements of users and the quality of all operational processes" and "are a measure of the degree to which a set of inherent characteristics fulfill requirements." [1-9].

**Directions for the future.** Although the majority of errors still happen in the preanalytical stage, we discovered that their influence on the patient outcome was minimal when compared to earlier estimations. The most detrimental incidents happened during the analytical and postanalytical stages and were brought on by human factors. We believe that in order to improve patient safety, these areas of clinical laboratory diagnostics currently require the greatest focus. In addition to the new classification of laboratory testing process fault types introduced in this study, hospital volunteer incident report systems can incorporate classification for cause and clinical impact [13,17,21]. Widespread use would yield useful information to direct efforts to further improve care quality. In conclusion, this review demonstrates how AI may help pathologists with several facets of BC diagnosis and evaluation. Even though AI has shown increased precision, effectiveness, and uniformity in the field of breast cancer, issues with preanalytical factors, the need for manual annotation, and the inability to distinguish between certain types of breast lesions still exist. To overcome these obstacles and fully utilize AI's promise in BC pathology, more study and advancement are required [19,21,22].

**Discussion.** The nature, causes, and clinical implications of errors in clinical laboratory testing are all clarified by this study. To the best of our knowledge, this is the first study involving voluntary incident reports on laboratory testing errors that looked at the clinical ramifications of the error and how it related to the type of error. We discovered that whereas analytical and postanalytical errors are less common but cause more harm to patients, preanalytical errors, which are the most common, have comparatively minor effects on patients. This is hardly a surprising discovery. The test procedure is frequently stopped or delayed as a result of preanalytical mistakes. Analytical and postanalytical errors are more difficult to identify and can lead to incorrect diagnostic follow-up and therapy, which can

seriously injure the patient [4,5,6]. Our research's overarching goal is to reduce patient harm from diagnostic errors. The current study's findings can help us determine which steps in the diagnostic process we should concentrate on in order to have the biggest impact. The causes and effects of errors in laboratory testing are as varied as the errors themselves. One strategy for preventing these kinds of errors with a systemic approach is to concentrate on the errors that have the greatest therapeutic impact, namely analytical and postanalytical errors. We believe that while laboratory tests are highly developed, controlled, and automated, it is impossible to prevent analytical errors, which are primarily caused by technological faults. Analytical errors are mainly causes by technical errors. Compared to preanalytical and analytical errors, postanalytical errors have a greater impact despite having a relatively small quantity. Postanalytical procedures, particularly test result follow-up, heavily rely on human behavior at crucial stages [17,18,19]. The danger of failing to follow up on test results has been recognized as a significant patient safety concern in recent decades. A minimum requirement is a closed-loop system where test findings are sent to the ordering physician via the electronic health record. These technologies must, however, assist the doctor in a way that makes it unlikely that they will overlook a test result or neglect to follow up on it. According to recent research, patients' health is still seriously threatened by test result follow-up. One of the causes is the improper application of policies and solutions. This made it difficult to categorize some of the reports; for instance, most of the reports concentrated on the primary cause, making it impossible to examine several causes for a given incidence. Additionally, it's possible that not all laboratory incidents were recorded because incident reporting are optional. Nonetheless, there is little evidence to suggest that diagnostic errors are significantly underreported in comparison to other kinds of errors. However, we are unable to determine the frequency of laboratory errors based on our data [20,21,22].

**Conclusion.** Recent data from malpractice claims suggests that, among medical errors that occur in both inpatients and outpatients, diagnostic errors seem to be the most frequent, expensive, and harmful. Diagnostic errors and lingering issues with test performance are largely caused by improper ordering of laboratory tests and improper application of test data. Thus, based on the groundbreaking idea of the brain-to-brain loop, the primary takeaway is the necessity of enhancing the quality of laboratory services, preventing mistakes, and enhancing patient safety while using a global strategy across the TTP. An efficient method for raising patient safety, lowering mistake risk, and enhancing quality is the application of a consensus-defined set of evidence-based Qls in clinical laboratory accrediting procedures in accordance with the current International Standard.

The nature, consequences, and clinical significance of errors in laboratory testing were better understood thanks to this study. Errors in the analytical and postanalytical phases have a greater clinical impact, however the majority of errors happen in the preanalytical steps. Laboratory testing mistakes frequently result in possible diagnostic errors, namely a delay in the diagnosis procedure. Voluntary event reports must include more thorough and consistent information, particularly regarding the cause and clinical impact, in order to be an even more valuable source for investing in the safety of diagnostic tests.

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