



## Missed and misdiagnosis in diagnostic hematology: Causes, consequences and strategies for improvement

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### Abstract

*This review examines the causes, consequences, and improvement strategies for missed and misdiagnosis in diagnostic hematology. Diagnostic errors—including misdiagnosis (incorrect diagnosis) and missed diagnosis (failure to identify a condition)—occur frequently in hematology laboratories and can have severe consequences for patients. The majority of errors (60-70%) occur during the pre-analytical phase (sample collection, handling, and transportation), with additional errors happening during the analytical phase (testing) and post-analytical phase (reporting and interpretation). Common causes include clotted or hemolyzed samples, patient identification errors, insufficient sample volume, communication breakdowns, lack of training, high workload, and inadequate quality control. Consequences range from disease progression and unnecessary treatments to emotional distress, financial burden, and even death. The document proposes strategies for improvement, including implementing quality management systems, staff education, automation, robust quality control protocols, effective communication channels, and fostering a culture of safety. Case studies illustrate real-world examples such as pseudo thrombocytopenia due to EDTA-dependent clumping and falsely diagnosed anemia from diluted samples. The conclusion emphasizes that while automation has reduced analytical errors, pre-analytical and post-analytical phases remain vulnerable, requiring continuous quality improvement efforts, staff training, and systematic error tracking to enhance patient safety.*

**Keywords:** Hematology, Diagnostic error, Misdiagnosis, Missed diagnosis, Pre-analytical error, Analytical error, Post-analytical error, Laboratory safety, Patient safety, Quality control, Sample hemolysis, Thrombocytopenia, Pseudo thrombocytopenia, Bone marrow, Complete blood count (CBC), Medical Laboratory Scientist, Diagnostic process.

## Introduction

Hematology (spelled haematology in British English) is the branch of medicine concerned with the study of the cause, prognosis, treatment, and prevention of diseases related to blood. It involves treating diseases that affect the production of blood and its components, such as blood cells, hemoglobin, blood proteins, bone marrow, platelets, blood vessels, spleen, and the mechanism of coagulation. Such diseases might include hemophilia, sickle cell anemia, blood clots (thrombus), other bleeding disorders, and blood cancers such as leukemia, multiple myeloma, and lymphoma. The laboratory analysis of blood is frequently performed by a medical technologist or medical laboratory scientist (Shirlyn & McKenzie, 2010).

## Diagnosis

Diagnosis is the cornerstone of medical practice, serving as the essential process by which healthcare professionals identify a patient's disease or condition. A correct diagnosis directs

treatment, management plans, and interventions, ensuring the best possible outcome for patients. The diagnostic process involves evaluating symptoms, conducting medical tests, and considering the patient's medical history to arrive at a conclusion. However, despite advances in medical technology and diagnostic techniques, diagnosis remains one of the most complex and sometimes error-prone aspects of healthcare (Tanaka & Nagata, 2018).

## Diagnostic Haematology

Diagnostic haematology is the specialized medical field focused on analyzing blood, bone marrow, and related tissues to detect, diagnose, and monitor blood disorders and diseases. Using laboratory tests such as full blood counts (CBC), blood films, and coagulation studies specialists identify conditions like anemia, infections, clotting disorders, and cancers like leukemia or lymphoma. Modern day diagnostics heavily depends on accurate laboratory test results, and hence it is necessary to ensure the reliability and accuracy of lab results. A medical lab plays a crucial role in providing timely and accurate results of laboratory investigations essential for patient management. One of the busiest areas of the clinical laboratory is the hematology laboratory. Hematology tests are frequently available even in tiny, limited-service laboratories (Shirlyn & McKenzie, 2010).

## Importance of accurate diagnosis

1. **Tailored Clinical Decision Making:** When a diagnosis is accurate and made in a timely manner, it provides the best opportunity for a positive health outcome. This is because clinical decision making can be tailored to a correct understanding of the patient's health problem.
2. **Reducing Diagnostic Uncertainty:** As the diagnostic process unfolds, the gathering of data either favours or argues against competing hypotheses, which helps reduce the level of diagnostic uncertainty. The goal is not to attain certainty, but rather to reduce uncertainty enough to make informed decisions.
3. **Enhanced Prognosis and Treatment Selection:** Patient prognosis and treatment selection are influenced by more than just disease diagnosis. Factors such as treatment responsiveness, toxicity, survival, physical well-being, and social factors all play a role in informing the likelihood of an individual's future outcome. This challenges the idea that prognosis and treatment selection are exclusively determined by diagnosis.
4. **Positive Health Outcomes:** Accurate diagnosis before treatment is vital for the best chance of a positive health outcome. Diagnostic errors can have serious consequences, affecting millions of individuals annually. Prompt and accurate diagnosis is essential to avoid such errors and ensure the best possible health outcomes.
5. **Empowerment and Self-Determination:** The recovery model of mental health emphasizes the importance of self-determination, responsibility, hope, and dignity. It suggests that people can recover from mental illness and that the goal of therapy is to help individuals achieve their fullest potential. Prompt and accurate diagnosis, along with appropriate treatment, supports this empowerment and recovery process.
6. **Informed Treatment Planning:** Diagnostic testing is a fundamental component of modern medicine and a critical part of the diagnostic process. It enables physicians to make better-informed decisions, identify the underlying cause of a patient's symptoms, develop a working diagnosis, and make expert treatment plan recommendations. This greatly improves the chances of a positive health outcome.

## Diagnostic Error

A diagnostic error in Hematology occurs when a blood-related condition is missed, incorrectly identified, or diagnosed after an inappropriate delay. In hematological practice, diagnoses may be completely missed, such as failing to detect leukemia despite abnormal blood counts or clinical symptoms. Errors may also involve wrong diagnoses, for example when a patient is treated for iron deficiency anemia when the underlying condition is actually aplastic anemia (Graber *et al.*, 2005).

In addition, diagnoses may be delayed, such as when abnormal laboratory findings like atypical cells seen on a peripheral blood film are not promptly communicated or acted upon, leading to late identification of conditions like lymphoma. These categories of diagnostic errors often overlap in hematology due to the complexity and similarity of clinical and laboratory findings.

Schiff and colleagues (2009, p. 1882) defined diagnostic error as "any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis, or a delayed diagnosis." Schiff and colleagues (2005) divide the diagnostic process into seven stages:

- (1) Access and Presentation,
- (2) History Taking/Collection,
- (3) The Physical Exam,
- (4) Testing,
- (5) Assessment,
- (6) Referral and
- (7) Follow-Up.

A diagnostic error can occur at any stage in the diagnostic process, and there is a spectrum of patient consequences related to these errors ranging from no harm to severe harm. Schiff and colleagues noted that not all diagnostic process errors will lead to a missed, delayed, or wrong diagnosis, and not all errors (either in the diagnostic process or related to misdiagnosis) will result in patient harm.

### Definition of Misdiagnosis

Misdiagnosis is a significant problem in diagnostic Haematology, which can negatively impact patients' lives, lead to unnecessary treatments, and increase healthcare costs. It occurs when a health professional makes an incorrect diagnosis, leading to inaccurate or delayed treatment. Misdiagnosis is not uncommon, and it can happen to anyone, including experienced and well-trained Medical Laboratory Scientist.

Misdiagnosis is a silent crisis in healthcare that affects millions of patients worldwide. It occurs when a health condition is incorrectly identified, leading to a wrong, missed, or delayed diagnosis. In simple terms, a misdiagnosis means the clinician got it wrong either naming the wrong illness, overlooking the illness entirely, or discovering it much later than ideal (Plebani & Carraro, 2000).

Misdiagnosis underlie a significant proportion of adverse events in Medical practice. In the early Harvard study, the incidence of diagnostic error (14% of total errors) exceeded that of medication error (9%) and carried a significantly worse prognosis, yet published studies of medication error far exceed those of diagnostic error. In the USA, misdiagnosis (26%) now rivals laboratory accidents (25%) as the leading cause of medicolegal claims, (Leape *et al*, 2015). Regrettably, such data are not readily available elsewhere. With misdiagnosis, often days pass between the first opportunity to make the correct diagnosis and the realisation that an error has occurred, and usually there is no opportunity to discuss the issues with the scientist involved. In the USA, there has been one large study of misdiagnosis based on aggregates of confidential reports made by Medical Scientist (Schiff *et al*, 2009).

In a comprehensive review of previous studies of misdiagnosis, diagnostic errors were assigned to one of three categories: no fault, system-based and human-cognitive. 'No fault' included unusual or silent presentation of disease and cases in which patients provided confusing descriptions of symptoms; 'system errors' included technical and organisational malfunctioning; and human-cognitive failures included the faulty gathering of data, inadequate reasoning and faulty verification. Allocation of errors to such broad categories varies because systems are rarely clearly defined and clinical considerations are difficult to assess. The authors of a comprehensive Dutch study concluded that, for diagnostic adverse events, human cognitive factors played a significant part in 96% and system failures in only 25%. In contrast, an American study found cognitive errors important in 74% and systems-based failures in 65% (Graber *et al*, 2005).

### Definition of Missed Diagnosis

Missed diagnosis is a major concern in healthcare systems worldwide. It occurs when a medical condition is not identified at the time it should have been detected, despite the presence of signs, symptoms, or available diagnostic information. This failure can lead to delayed treatment, worsening of the disease, and in severe cases, death.

Accurate diagnosis is essential for effective treatment and patient safety. However, due to human error, system limitations, and the complex nature of diseases, missed diagnoses still occur in clinical practice.

A missed diagnosis refers to the complete failure to recognize a patient's illness during medical evaluation when it could reasonably have been identified. Unlike delayed or incorrect diagnosis, the condition remains entirely undetected at the critical time. (Singh *et al*, 2014).

A missed diagnosis happens when a Medical Laboratory Scientist completely fails to identify a medical condition. Instead of giving the wrong diagnosis, they don't give any diagnosis. This means patients may not get any treatment at all, and their condition is allowed to progress unchecked.

A missed diagnosis is similar to a misdiagnosis; however, a missed diagnosis happens when a patient's condition is not diagnosed at all. This can happen for a number of reasons, many of which are similar to a misdiagnosis, including incompetence and negligence. In some cases, doctors may not diagnose a patient because they suspect the patient is faking an illness and seeking drugs (Singh H. 2014).

A missed diagnosis can also have severe consequences for patients. If a condition is not diagnosed, it can go untreated and progress to a more severe stage. This can lead to further medical complications and even death. A missed diagnosis can also cause emotional distress and financial hardship.

When healthcare professionals miss making a diagnosis, patients may never receive the treatment they need. In some cases, this can lead to serious illness or death. Patients, or the families of those who die when missed diagnosis occurs due to negligence, may consider pursuing compensation for their associated losses with the help of Chicago medical malpractice lawyers.

## Causes of missed & misdiagnosis

Laboratory errors are mistakes made during the entire testing process. Such errors might be due to miscommunication between laboratory personnel as well as actions performed by others in the process or might be due to a poorly designed process (Parco *et al.*, 2014). The laboratory errors have a significant impact and may cause a delay in diagnosis or treatment if they are detected before the issue of results, and therefore lead to patient inconvenience or anxiety, and in some cases the opportunity can be missed for diagnosis or screening if the specimen cannot be retaken. Furthermore, the errors which go undetected before the release of results will present unwanted errors and may result in the wrong diagnosis or missed diagnosis, unwanted retesting or treatment, and might put the safety of patient at risk (De la Salle, 2019).

Laboratory sample processing errors can be divided into three categories: preanalytical, analytical, and postanalytical errors (Shukla *et al.*, 2017). Automation has significantly reduced the errors occurring in the analytical and postanalytical phases, whereas the preanalytical stage still has a long way to go as it is mostly dependent on manual labor (Mehndiratta *et al.*, 2021). Although there is plenty of automation in the laboratory processes, there are numerous variables that can affect laboratory results, which are mainly due to human intervention and hence are preventable.

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

### Pre-analytical Causes (Highest Incidence)

Pre-analytical errors are the leading cause of misdiagnosis, often due to manual handling, poor technique, or lack of training which constitute about 60%–70% of all errors in laboratory results, emerge as the most crucial phase. During the testing process, laboratory errors may arise, often stemming from poorly planned procedures, insufficient communication among laboratory staff, and actions related to other processes. The hematology laboratory stands out as one of the most bustling sections of the clinical laboratory (Iqbal *et al.*, 2023). The preanalytical phase encompasses all the actions preceding the sample processing by the autoanalyzer.

Examples of errors that arise in the pre-analytical phase include errors in test ordering, patient identification, patient preparation, collection of samples, quality of collected sample (diluted, clotted, and hemolyzed sample), inappropriate containers and anticoagulants, and sample transportation and storage. Sorting of sample, its centrifugation, labeling, and separation (Upreti *et al.*, 2013).

- **Miscommunication:** Miscommunication, whether between Medical Laboratory Scientist and patients or other healthcare professionals, is a common factor in missed diagnosis cases.
- **Sample Insufficiency (Underfilling/Overfilling):** Incorrect blood-to-anticoagulant ratio, especially in citrate tubes for coagulation, leads to invalid results.
- **Clotted Samples:** Poorly mixed blood or delays in transferring blood from syringe to vial, especially common in high-workload, inpatient, or emergency settings.
- **Hemolysis:** Caused by difficult venipuncture, using small-gauge needles, or drawing from intravenous (IV) catheters, which causes false-positive potassium and lactate dehydrogenase (LDH) levels.
- **Patient Identification Errors:** Wrong blood in tube (WBIT) due to failure to use two unique identifiers, leading to incorrect lab values being assigned to the wrong patient. Identification errors can involve mislabeling or improperly identifying the patient or sample.
- **Improper Tube Selection/Additives:** Using the wrong anticoagulant (e.g., EDTA in a coagulation tube).
- **Sample Contamination:** Collecting blood from an IV line, causing dilution or contamination with infusion fluids.
- **Delay in Transportation/Storage:** Prolonged time before analysis, leading to cell deterioration, increased Mean Corpuscular Volume (MCV), or sample degradation (e.g., cold agglutinins).
- **Premature Completion:** Stopping the diagnostic process before the final diagnosis is confirmed.
- **Lack of Knowledge/Experience:** Inadequate training in recognizing rare hematological malignancies or interpreting complex hemograms.
- **Incomplete History/Physical Exam:** Failure to notice key signs like splenomegaly or detailed symptoms.
- **Misinterpreting "Normal" Symptoms:** Fatigue, fever, or pain mistaken for stress or infection rather than a blood cancer.

## Analytical Causes

Analytical errors are rarer due to automation but still occur, particularly in complex testing.

- **Analytical Interference:** Substances like high white blood cell (WBC) counts, giant platelets, microspherocytes, or cryoglobulins can cause falsely elevated platelet or WBC counts.
- **Instrument Failure:** Technical failure of hematology analyzers, often due to poor maintenance or electrical issues.
- **Reagent Issues:** Using expired or improperly stored reagents.
- **Misinterpretation of Morphological Studies:** Relying solely on Romanowsky-stained blood pictures without advanced techniques like flow cytometry or molecular testing, particularly for leukemia/lymphoma.
- **High Workload/Fatigue:** Leads to increased errors by phlebotomists and clinicians.
- **Lack of Equipment:** Inability to access advanced diagnostic tools like immunophenotyping, cytogenetics, or PCR in resource-limited settings.
- **Inadequate Training:** Lack of continuous education for paramedical staff on proper blood collection techniques.

## Post-analytical Causes

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).

- **Communication Breakdown:** Delays in reporting critical results (e.g., life-threateningly low neutrophil counts) or communicating to the wrong provider.
- **Failure of Follow-up:** The laboratory report is produced, but the clinician fails to read or act on it.
- **Data Entry/Transcription Errors:** Manually entering results into the system, leading to incorrect data.

## Consequences of misdiagnosis and missed diagnosis

Misdiagnosis puts patients at risk of not receiving the medical treatments that they need or receiving unnecessary treatments for a condition that the patient does not have. This can lead to poor health outcomes, including serious injury, permanent disability, increased mortality and morbidity rates, and wrongful death.

### 1. Physical Health Consequences

The physical health consequences of diagnostic errors can be severe and far-reaching. When a diagnosis is missed or delayed, patients may not receive the timely treatment they need, allowing their condition to progress unchecked. For example, a delayed cancer diagnosis can result in the disease advancing to a more aggressive stage, reducing the likelihood of successful treatment and increasing the risk of mortality. Similarly, a missed diagnosis of a cardiovascular condition can lead to catastrophic events such as heart attacks or strokes, which could have been prevented with early intervention (Plebani, 2015).

In addition to the progression of the underlying condition, diagnostic errors can lead to unnecessary treatments and procedures. A false positive diagnosis may result in patients undergoing invasive tests, surgeries, or treatments that carry their own risks and side effects. These unnecessary interventions can cause significant physical harm, including complications from surgery, adverse reactions to medications, and long-term health issues stemming from inappropriate treatments. The physical toll of diagnostic errors underscores the critical need for accuracy and diligence in the diagnostic process to ensure patients receive the appropriate care for their conditions.

### 2. Mental and Emotional Health Effects

The mental and emotional health effects of diagnostic errors are often profound and can have lasting impacts on patients' well-being. The uncertainty and fear associated with a missed or delayed diagnosis can lead to significant anxiety and stress. Patients may experience a sense of helplessness and frustration as they struggle to understand their symptoms and seek answers. This prolonged period of uncertainty can take a considerable emotional toll, affecting patients' overall quality of life and mental health.

Moreover, diagnostic errors can erode patients' trust in the healthcare system. When a diagnosis is incorrect or delayed, patients may lose confidence in their healthcare providers and the medical system as a whole. This loss of trust can lead to reluctance in seeking medical care in the future, potentially exacerbating health issues and delaying necessary treatments. The psychological impact of diagnostic errors highlights the importance of effective communication, empathy, and support from healthcare providers to help patients navigate these challenging experiences and maintain their mental and emotional well-being. (Hunter, *et al.*, 2015).

Misdiagnosis can result in physical and emotional suffering for patients. A wrong diagnosis can cause patients to undergo painful or invasive treatments that could have been avoided if the correct diagnosis had been made. It can also lead to psychological distress, such as anxiety and depression.

### 3. Long-term Health Implications

The long-term health implications of diagnostic errors can be significant, often resulting in chronic conditions that could have been managed or cured if diagnosed correctly and timely. For instance, a delayed diagnosis of diabetes can lead to complications such as neuropathy, retinopathy, and cardiovascular disease, which might have been prevented with early intervention and proper management. Similarly, a missed diagnosis of an autoimmune disorder can result in irreversible damage to organs and tissues, leading to long-term disability and reduced quality of life.

In addition to the direct health consequences, diagnostic errors can have broader implications for patients' overall health and well-being. Chronic conditions resulting from diagnostic errors often require ongoing medical care, frequent hospital visits, and long-term medication, placing a significant burden on patients and their families. The financial costs associated with managing these conditions can also be substantial, leading to economic strain and reduced access to necessary healthcare services. Addressing diagnostic errors is crucial not only for preventing immediate harm but also for mitigating the long-term health and economic impacts on patients and their families. (Juarez *et al.*, 2006).

### 4. Significant financial burden

Misdiagnosis leads to a significant financial burden by causing unnecessary spending, repeated medical costs, loss of income, and increased expenses due to worsened health conditions. What could have been managed at a lower cost becomes expensive and difficult, placing serious economic pressure on patients and their families (McIntyre, *et al.*, 2022).

## Strategies for Improvement

Improving quality and patient safety in the laboratory setting is essential for reliable diagnostics and effective patient care. The three phases of laboratory testing preanalytical, 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 (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 *et al.*, 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).

Therefore, improving hematology labs guarantees accurate and dependable test results for users, providing safe healthcare requires high-quality medical diagnostics. A laboratory's total testing procedure (TTP) includes all steps from requisitioning tests to obtaining the results. Accurate and reliable laboratory test results are essential for clinical decision-making, as they influence approximately 70 percent of cases (Parco *et al.*, 2014).

Reducing Diagnostic 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, 2020).

## Strategies to prevent preanalytical errors

### 1. Quality management systems

To minimize preanalytical errors in sample handling and processing, it is crucial to implement quality management systems. The key components of these systems include the utilization of SOPs, timely employee education programs, and routine audits. The adoption of SOP guarantees uniformity in sample collection, handling, and processing across all personnel and departments. This not only upholds elevated standards in sample management quality but also diminishes the potential for errors stemming from variations in approaches (Akyar, 2012).

The SOP plays a crucial role in identifying the error sources during the preanalytical phase through the root cause analysis. Once these errors are pinpointed, corrective and preventive actions can be implemented to prevent the recurrence of the same errors in future. Regular and well-timed employee education programs ensure that the staff has the essential information, knowledge, and skills to proficiently handle samples (Rajalakshmi *et al.*, 2017).

Regular internal or external audits of laboratories evaluate the successful implementation of quality management systems, pinpoint various preanalytical errors, and assess the measures taken by laboratories to mitigate them. As a result, adherence to a well-implemented quality management system establishes consistency and standardization in

all laboratory procedures, ultimately lowering preanalytical errors. This, in turn, contributes to enhanced patient safety by reducing the risks of misdiagnosis and improper treatment (Agmarketing, 2020).

## 2. Staff education and training

Continuous education on preanalytical techniques is essential for laboratory personnel to guarantee the proper handling and processing of samples up to the highest standards. Training should highlight the correct procedures for sample collection, transportation, and preparation. To execute these tasks reliably and accurately, laboratory personnel must stay current with the latest standards and best practices (De Plato *et al.*, 2019). Regular training programs enhance the comprehension of the preanalytical process among laboratory personnel, resulting in more precise test findings. Regular training empowers laboratory employees to proficiently identify the root cause of the errors and effectively address the underlying issues. They become skilled at managing challenges related to sample quality and identifying potential sources of issues. Training programs provide an excellent environment to foster teamwork and effective communication among laboratory staff.

Human error is one of the biggest factors that affects accuracy and precision in a laboratory. The better training and support that teams receive, the more equipped they will be to correctly follow formalised procedures and best practices.

## 3. Technology and automation

Within laboratory environments, technology and automation are pivotal in reducing human error and improving the accuracy of preanalytical procedures. An essential application is automated specimen labeling systems, replacing manual labeling by technicians. These systems efficiently connect patient and sample information through barcode or radiofrequency identification technology, minimizing the likelihood of incorrect labeling or data input errors. The automation of the labeling process significantly diminishes the risk of sample mismatches and inaccurate patient identification, thereby maintaining the precision of the entire testing workflow (Yeo *et al.*, 2018).

Furthermore, the adoption of electronic data capture technologies has transformed the preanalytical phase of data management by facilitating the real-time collection of information on patients, tests, and sample details.

Moreover, there has been the introduction of automated specimen processing devices designed to streamline the preparation and handling of samples. These devices can accurately transport, centrifuge, and aliquot samples, thereby reducing the risk of contamination or hemolysis. The automation of these labor-intensive tasks significantly diminishes the likelihood of human error, ensuring the consistency and reliability of the test results. The overall efficiency of preanalytical operations is heightened, and human error rates are reduced through automation and technological integration. Automated systems can handle a larger number of samples in a shorter timeframe, enabling laboratories to provide results to patients and health-care professionals more expeditiously (ASCP) JR MBA, 2023).

## 4. Collaboration and communication

Facilitating accurate and prompt patient treatment hinges on the efficient collaboration and communication among health-care professionals engaged in the preanalytical phase. This collaboration involves clinicians, phlebotomists, and laboratory staff. Effective communication among these professionals is crucial for generating high-quality health-care outcomes, as the preanalytical phase lays the groundwork for diagnostic decisions. (Zajac *et al.*, 2021). Clinicians, being at the forefront of patient care, rely on precise laboratory test results to formulate well-informed diagnoses and treatment decisions. Sustaining open communication with the laboratory team enables clinical staff to ensure the proper tests are requested and that the laboratory is informed of any specific concerns or considerations.

Phlebotomists, who are responsible for collecting blood and other specimens, must complete the preanalytical stage. They must appropriately identify patients, collect samples, and record information to prevent the errors from the beginning. Because phlebotomists and physicians effectively coordinate, the right tests are gathered, and any special requirements or time-sensitive tests are given priority (Da Rin G, 2009).

Laboratory staff, comprising technologists and technicians, are responsible for processing and analyzing specimens. The accuracy and reliability of the test results hinge on their expertise. Collaborative discussions among laboratory personnel, clinicians, and phlebotomists allow them to delve into clinical situations, medical histories, and specific testing requirements for patients. This collaborative effort enables laboratory staff to interpret the outcomes within the appropriate clinical context and identify the potential issues or anomalies (Gebreyes *et al.*, 2020).

Efficient teamwork and communication facilitate the exchange of information among health-care providers. Timely communication allows for clarification, retesting if necessary, and informed patient care decisions in case of discrepancies or issues arising during the preanalytical process or the interpretation of test results. Furthermore, it fosters a collaborative and respectful workplace environment, both of which are the vital elements in creating a health-care setting.

## Strategies to prevent Analytical errors

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 (Plebani, 2006).

1. **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). The right automated lab equipment will not only carry out tasks, but will help to identify errors if they arise. We are currently working on further developing our Myra liquid handler, so not only will it automate calibration through its integrated camera, but very soon it will also be able to actively monitor for user errors in deck layout, such as missing tubes.
2. **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).
3. **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)

## 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. 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. 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 & Yücel, 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.

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).

## Case Study of Misdiagnosis in hematology laboratory

### Practical examples of misdiagnosis in the Diagnostic haematology

#### 1. Pre-analytical Error: Falsely Diagnosed Severe Anemia

- **Scenario:** A 33-year-old female patient presented to the Emergency Department (ED) with mild shortness of breath. The complete blood count (CBC) showed a hemoglobin level of 5 g/dL (reference range: 12-16 g/dL).
- **Misdiagnosis:** The Medical Laboratory Scientist suspected life-threatening internal bleeding, leading to two blood transfusions and an urgent endoscopy.
- **Root Cause:** The blood sample was collected from a peripheral intravenous (IV) line. The IV fluid infusion caused severe dilution of the blood sample, leading to a falsely low hemoglobin reading.

- **Result:** Unnecessary and invasive diagnostic workup and treatment.

## 2. Pre-analytical Error: "Milk Box" Misdiagnosis of von Willebrand Disease (VWD)

- **Scenario:** Patients are tested for bleeding disorders, and a laboratory reports a diagnosis of Type 1 or Type 2 VWD.
- **Misdiagnosis:** Patients are treated for a bleeding disorder they do not have.
- **Root Cause:** The blood samples were collected and placed in a refrigerator (cold storage) prior to centrifugation. This "cold activation" causes in vitro degradation of von Willebrand Factor (VWF) and Factor VIII, leading to low VWF levels that do not reflect the patient's actual status.

## 3. Analytical Error: Misclassification of Lymphoma Subtypes

- **Scenario:** A pathological sample is sent to a laboratory for diagnosis of a lymphoid neoplasm.
- **Misdiagnosis:** High-grade B-cell lymphoma (HGBL) is misdiagnosed as Burkitt lymphoma (BL) or Diffuse Large B-cell Lymphoma (DLBCL).
- **Root Cause:** The laboratory failed to perform necessary fluorescence in situ hybridization (FISH) tests to identify MYC, BCL2, and BCL6 rearrangements, or misinterpreted strong positive BCL2 staining, leading to incorrect subtyping.

## 4. Analytical/Pre-analytical Error: Pseudo thrombocytopenia

- **Scenario:** A patient's CBC shows a critically low platelet count (thrombocytopenia), suggesting a risk of severe bleeding.
- **Misdiagnosis:** The patient is suspected of having immune thrombocytopenic purpura (ITP) or other platelet-destructive disorders, leading to unnecessary platelet transfusions or therapies.
- **Root Cause:** EDTA-dependent platelet agglutination. Platelets clump together in the presence of EDTA anticoagulant (the standard tube used for CBCs) and the analyzer counts the clumps as red blood cells, not platelets.

## 5. Pre-analytical Error: Sickle Cell Trait Misdiagnosis

- **Scenario:** A couple undergoes premarital hemoglobin genotype testing to prevent having children with Sickle Cell Disease.
- **Misdiagnosis:** An individual with Sickle Cell Trait (AS) is told they have normal hemoglobin (AA), leading to a high-risk marriage.
- **Root Cause:** Privately owned laboratories often use less specific screening methods (e.g., sickle solubility tests) instead of high-performance liquid chromatography (HPLC) or hemoglobin electrophoresis, coupled with poor lab regulation and under-qualified staff.

## Case Study of Missed Diagnosis in haematological laboratory

Practical example of missed diagnoses in a hematological laboratory project, categorized by error type:

### 1. Preanalytical Errors (Sample Quality & Handling)

- **Clotted Samples (Pseudo-thrombocytopenia):** Clotted EDTA tubes are a major cause of sample rejection (over 20% of rejected samples in some studies). If a clotted sample is processed, the analyzer may produce a false "critical" low platelet count (thrombocytopenia) or a low WBC count. This can lead to a missed diagnosis of a true hematological disorder because the clinician assumes the low count is due to a technical error.
- **Inappropriate Sample Volume (Diluted/Under-filled Tube):** Insufficient sample volume is the most common preanalytical error (up to 54% of errors). An improper blood-to-anticoagulant ratio can falsely alter red cell indices, resulting in a misdiagnosis of anemias (e.g., falsely low hematocrit) or inaccurate INR/clotting times.
- **Hemolyzed Samples:** Hemolysis (destruction of RBCs) can interfere with lab instruments, potentially masking true biochemical parameters or indicating an artificial increase in certain analytes, leading to misinterpretation of acute hemolytic events.
- **Sample Transportation Delay:** A delay in transporting samples to the lab can lead to spurious white blood cell (WBC) differential results or platelet clumping, which might be mistaken for a disease state, resulting in a missed diagnosis of leukemia or sepsis.

### 2. Analytical Errors (Instrument/Testing)

- **Analytical Interference:** A very high lipid content (lipemic sample) can interfere with hemoglobin measurements, producing a false reading.
- **Misclassification of Lymphoma Subtypes:** Misdiagnosis between lymphoma subtypes is common, with studies showing that, out of all laboratory errors, 60.8% of these cases involved misclassification.
- **Instrument Calibration Failure:** Inadequate calibration or failure of quality control (QC) procedures to detect problems can lead to inaccurate reporting of WBC differentials, potentially missing leukemia or severe anemia.

### 3. Postanalytical Errors (Reporting and Interpretation)

- **Result Misinterpretation/Failure to Communicate Criticals:** A failure to immediately report a critical, life-threatening result (e.g., extremely low neutrophil count) to a clinician can lead to a fatal delay in treating sepsis, even if the analyzer correctly identified it.
- **Data Entry Errors:** A transcription mistake when entering results from a manual report into the Laboratory Information System (LIS) can lead to a totally incorrect diagnosis being treated.

### Conclusion

This study concluded that clinical hematology laboratory errors occurred at a high frequency, with the majority detected during the pre-analytical phase, followed by the post-analytical phase. Analytical errors were the least frequent. Among pre-analytical errors, incomplete request forms and unsuitable samples were the most common. Lack of adherence to SOPs and patient addresses from IPD and unknown wards were significantly associated with poor sample quality. Similarly, the first work shift, IPD, and unknown addresses were significantly associated with prolonged turnaround time (TAT). Overall, the Hematology Laboratory demonstrated poor sigma metric values ( $<3$  sigma), indicating that the quality of services provided was not assured. In conclusion, this study finding indicted high magnitude of errors in the extra analytical phase laboratory. The information mostly absent in laboratory request forms assessed were physician phone number followed by clinical data of patients and excessive TAT. Regarding to factors that associated with extra analytical error of laboratory services, our finding revealed that high workload, lack of knowledge, lack of training, lack of communication between lab personnel and physician, have not written procedure for laboratory activities and lack of continues education program were the major factors that affecting Extra analytical error of laboratory. These indicate essential to address shortcomings related to extra analytical phase of laboratory. Extra analytical error of laboratory can lead to misdiagnosis and mishandling of patients.

Thanks to recent technical progress, modern analyzers are capable of fully-automated digital assessment of blood cell counts and blood smear staining. However, despite this high degree of automation in medical laboratories, the results of laboratory tests can be influenced by a number of factors which may be sources of error. A thorough knowledge of pre-analytical phase variables and their impact on the results of hematological tests and/or analytical phase pitfalls is necessary to obtain accurate results which reflect the patient's true condition and to minimize the need to repeat analyses of potentially pathological samples to avoid unnecessary treatment and ensure proper medical care.

Pre-analytical errors are lower than analytical and post-analytical errors due to using barcode and laboratory information systems (LIS). Recent discoveries in science and technology have changed laboratory diagnostics from laborious, time-consuming manual testing procedures to fully automated laboratories, but lab performance must be objectively defined. A laboratory error refers to a flaw in the entire process that has reduced the calibre of the laboratory service. However, it needs intervention to control and improve because a timely response to critical values is essential for patient diagnosis, treatment, and safety.

### Recommendations

Based on the study result, the following recommendations were made; Continuous practice of measuring errors and provide capacity building, educated or inform the haematologist to fill properly all necessary patient information on laboratory request forms, keep well documented standard operation procedures (SOP) at working area and apply rejection practice in incomplete LRFs and specimen were required to help in reducing extra analytical error of laboratory. Basic components of laboratory processing with an emphasis on the extra analytical phase of laboratory work movement/flow should be noticeable in the orientation training of all new staff, continues education program of lab personnel and other users of laboratory services (physicians, scientist, nurse and Health officer). Improve and tolerate common physician-laboratory communication, periodical meetings to share knowledge and strengthen communication. Periodic complete laboratory audits on extra analytical error could be beneficial to reduce the extra analytical error in the laboratory. Lab manager control all lab staff to record all extra analytical errors and their root causes as and when they happen. An analysis of documented lab errors and taking corrective actions to avoid such errors in future would go a long way to reduce extra analytical errors and thereby deliver reliable test results within the shortest possible Turnaround time (TAT).

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