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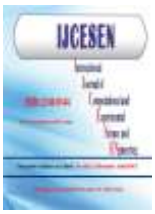

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Research Article

Sample Misidentification Errors in Clinical Laboratories and Prevention Strategies

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Abstract:

Sample misidentification errors are significant concerns in clinical laboratories, as they can lead to incorrect diagnoses, inappropriate treatments, and adverse patient outcomes. These errors often stem from improper labeling, sample handling, or miscommunication among healthcare staff. For instance, mislabeling specimens can occur during collection, processing, or transportation, resulting in samples being mixed up or attributed to the wrong patient. Such incidents not only compromise the integrity of the laboratory results but also erode patient trust in healthcare systems. The repercussions can be severe, ranging from unnecessary medical interventions to delayed diagnosis and treatment, ultimately affecting patient safety and health outcomes. To mitigate sample misidentification errors, clinical laboratories must implement robust prevention strategies. One effective approach is adopting the use of barcoding systems, which facilitate accurate sample tracking from collection to analysis. Automation and electronic health records can further enhance accuracy by providing real-time access to patient information and sample status, reducing the likelihood of human error. Additionally, staff training and education are critical components of prevention, as they ensure that all personnel are aware of protocols and best practices related to specimen handling and identification. Regular audits and quality control measures can also identify potential weaknesses in the laboratory process, allowing for continuous improvement and enhanced patient safety.

1. Introduction

The clinical laboratory occupies a central, indispensable role in the modern healthcare paradigm. It is the silent engine of diagnosis, the arbiter of therapeutic efficacy, and the sentinel for disease surveillance. An estimated 60-70% of all critical medical decisions, encompassing diagnosis, treatment, management, and hospital admission or discharge, are predicated on the results generated within these facilities [1]. The output of the clinical laboratory is, therefore, not merely data but a fundamental translation of human biology into actionable clinical intelligence. The integrity of this translation process is paramount, as errors introduced at any stage can propagate through the clinical decision-making chain, leading to profound and sometimes irreversible consequences for patient safety, quality of care, and healthcare economics. Within the vast and complex landscape of laboratory errors, pre-analytical variables have been consistently identified as the most prolific source of inaccuracy, accounting for an estimated 46% to 68% of all mistakes documented in laboratory medicine [2, 3]. Among these pre-analytical pitfalls, specimen misidentification stands out not only for its frequency but for its catastrophic potential to cause direct patient harm.

Sample misidentification can be broadly defined as any failure that results in a discrepancy between the patient's identity and the identity attributed to their specimen or the test results derived from that specimen. This error creates a chasm between the biological truth of the patient and the information presented to the clinician, rendering even the most precise analytical technology dangerously misleading. The consequences are not theoretical; documented cases abound where misidentification led to patients receiving blood transfusions of an incompatible type, undergoing unnecessary surgical procedures based on another patient's malignant pathology report, or being administered incorrect and potentially toxic doses of medication due to erroneous therapeutic drug monitoring results [4]. Such events shatter the covenant of trust between patient and provider and represent a fundamental failure of the healthcare system's duty to "first, do no harm."

The historical context of specimen identification is one of evolving complexity. In earlier, simpler healthcare environments, with lower test volumes and more direct caregiver involvement, identification relied heavily on hand-written labels and visual recognition. However, the dramatic expansion of laboratory testing, driven by technological advances and evidence-based medicine, has exponentially increased the number of specimens processed daily. Concurrently, the healthcare workflow has become increasingly fragmented, with patient care involving multiple handoffs between departments and professionals. This high-throughput, multi-operator environment has amplified the opportunities for identification errors at every touchpoint: during collection, labeling, transportation, receipt, and processing within the laboratory itself [5]. The problem is further compounded by systemic pressures common in healthcare settings, including staff shortages, high workload, fatigue, frequent interruptions, and the persistent use of error-prone manual procedures. Quantifying the exact prevalence of specimen misidentification is challenging due to significant under-reporting and variations in detection methods. However, studies utilizing direct

observation, prospective audits, and sophisticated tracking systems have provided alarming insights. Rates of mislabeled specimens—where the label information is incorrect or incomplete—have been reported to range from 0.1% to as high as 1.2% of all specimens received in clinical laboratories [6]. While these percentages may seem small, when projected against the billions of laboratory tests performed annually worldwide, they translate into millions of opportunities for patient misidentification every year. Furthermore, the error rate for patient misidentification—where the wrong test result is filed in a patient's record—though less frequently measured, is considered a severe downstream event often stemming from initial labeling mistakes. The cost of these errors is multifaceted, encompassing direct financial burdens from repeat testing, legal liabilities, and extended hospital stays, as well as the incalculable human cost of patient morbidity and mortality [7].

In response to this persistent threat, the field of laboratory medicine, in conjunction with disciplines like human factors engineering and healthcare informatics, has engaged in a concerted effort to understand, mitigate, and ultimately prevent specimen identification errors. This has led to a paradigm shift from a culture of blame, focused on individual practitioner fallibility, to a systems-based approach that recognizes errors as the predictable outcomes of flawed processes. This approach seeks to redesign systems to make errors difficult to commit and easy to detect. The strategies emerging from this philosophy are diverse, spanning technological innovation, such as barcoding and radiofrequency identification (RFID); rigorous procedural standardization; and a renewed focus on creating a culture of safety that empowers every member of the healthcare team to act as a vigilant checkpoint [8].

2. Taxonomy and Types of Sample Misidentification Errors

Understanding the precise nature of specimen misidentification errors requires a detailed taxonomy. These errors are not monolithic; they occur at different stages of the pre-analytical pathway and manifest in distinct forms, each with its own set of causes and potential remedies. Broadly, they can be categorized into labeling errors and identification errors occurring during specimen collection or handling.

2.1 Mislabeling Errors at the Point of Collection.

This category represents the most common point of origin for identification failures and occurs when the physical label affixed to the specimen container is incorrect or inadequate. **Wrong Blood in Tube (WBIT)** is a particularly egregious and high-risk subtype. It describes the scenario where a specimen is collected from one patient but labeled with another patient's identifying information. This creates a complete and undetectable (without specific intervention) disassociation between the specimen and its true source. WBIT errors are a leading cause of major transfusion incidents and can lead to catastrophic diagnostic errors. **Incomplete Labeling** is another frequent occurrence, where the label lacks one or more critical data elements mandated by laboratory policy and accreditation standards, such as the patient's full name, a unique identifier (e.g., medical record number), date and time of collection, and collector's identity. An unlabeled or incompletely labeled specimen is inherently unsafe, as its provenance cannot be reliably verified. **Labeling with Incorrect Information** involves attaching a label with deliberate but wrong data, such as misspelling the patient's name, transposing digits in the identifier, or recording an erroneous collection time. **Mislocation of the Label**, where a correct label is placed on the wrong tube (e.g., on the cap instead of the side, obscuring the view of the specimen, or on another patient's tube in a batch), also falls under this category [9, 10].

2.2 Identification Errors During Specimen Handling and Processing.

Errors can propagate or originate within the laboratory itself, even from a correctly labeled specimen. **Transcription Errors** were historically rampant when laboratory staff manually entered patient data from requisition forms into laboratory information systems (LIS). Manual typing is prone to keystroke mistakes, leading to misidentified records in the digital domain. While automation has reduced this risk, it persists in interfaces without adequate electronic connectivity. **Specimen Mix-up or Aliquotting Errors** occur when technologists, during manual processing steps such as pouring off serum, preparing aliquots for different testing departments, or loading samples onto analyzers, inadvertently swap the physical positions of two or more specimens. This can result in Patient A's specimen being analyzed and reported as Patient B's, even if both original primary tubes were correctly labeled [11]. **Order Entry Errors** in the electronic health record (EHR) or LIS represent a digital form of misidentification.

If a clinician or nurse accidentally selects the wrong patient from a list when placing test orders, the electronic order will be linked to an incorrect patient identifier. Unless a robust specimen-label verification protocol catches the mismatch at the phlebotomy stage, the subsequently collected specimen will be processed against the wrong order, guaranteeing a misidentification event [12].

3. Root Cause Analysis: Systemic and Human Factors

A systems-based approach to error prevention necessitates moving beyond superficial blame to uncover the underlying, often latent, conditions that enable errors to occur. Root cause analyses of specimen misidentification consistently reveal a confluence of active failures (unsafe acts by individuals) and latent conditions (hidden flaws in the system).

Workload, Fatigue, and Interruptions. The high-pressure environment of both clinical wards and laboratories is a significant contributor. Phlebotomists facing long draw lists, frequent urgent ("stat") requests, and concurrent demands are more likely to skip verification steps or hurry through labeling. Laboratory technologists handling hundreds of tubes per shift are susceptible to lapses in attention during repetitive tasks like aliquoting. Interruptions during the critical identification and labeling process—such as phone calls, questions from colleagues, or urgent clinical needs—are a well-documented precursor to error, as they disrupt working memory and procedural flow [13, 14]. Fatigue, whether from long shifts, night work, or cumulative sleep deprivation, impairs cognitive function, vigilance, and fine motor skills, increasing error rates across all procedural tasks.

Inadequate Training and Procedural Non-Compliance. Inconsistent or insufficient training on proper patient identification and specimen labeling protocols is a fundamental latent condition. New staff, temporary agency personnel, or trainees may not be fully aware of the gravity of the protocols or the specific steps required. Even among experienced staff, procedural drift—the gradual deviation from established protocols—can occur, especially if the rationale for certain steps is not reinforced. A culture that implicitly tolerates "shortcuts," such as pre-labeling tubes before patient contact or labeling specimens away from the bedside, creates an environment ripe for WBIT errors [15].

System Design and Ergonomics. Poorly designed systems almost invite error. This includes reliance on manual, paper-based processes for ordering and requisition, which require multiple error-prone transcription steps. Lack of integrated technology at the point of care is a major hurdle. If the phlebotomist must carry a paper list, handwritten labels, and manually match them, the cognitive load is high. Poor ergonomics also play a role: labels that are difficult to write on or adhere poorly to tubes, poorly lit drawing stations, cluttered workbenches in the lab, and non-intuitive software interfaces in the LIS all contribute to use errors [16].

Patient Factors and Environmental Challenges. In certain clinical situations, standard identification protocols are challenged. Patients who are unconscious, confused, non-responsive, or speaking a different language cannot actively participate in the identification process. In busy emergency departments or during rapid response situations, the urgency of care can lead to perceived justification for bypassing identification steps. Neonatal and pediatric settings present unique difficulties with identical twins or babies who lack distinctive identifiers before naming [17].

4. Detection Methods for Misidentification Errors

Before errors can be prevented, they must be detected. A robust laboratory quality system employs multiple, overlapping methods to identify misidentification events, understanding that no single method is foolproof.

Traditional and Procedural Checks. The visual verification of specimen labels against requisition forms or patient wristbands by laboratory accessioning staff is a fundamental first-line defense, though it is subjective and can fail due to inattention or confirmation bias. Delta checks are a powerful analytical tool within the LIS. They compare a patient's current test result with previous results from the same patient, flagging physiologically implausible changes that may indicate a specimen mix-up (e.g., a hemoglobin concentration dropping from 14 g/dL to 5 g/dL in 24 hours without clinical explanation). Blood Group Verification in transfusion medicine is a critical specific check. A new sample's ABO/Rh type is always compared against any historical record for that patient; a discrepancy is a red flag for possible misidentification and triggers a mandatory investigation before any blood is issued [18, 19].

Advanced Technological Detection. Technology offers more objective and automated detection capabilities. Automated Specimen Processing Systems equipped with high-resolution cameras and barcode readers can reject specimens with missing, unreadable, or non-matching labels at the point of

laboratory entry, providing a hard stop for many labeling errors. Data Analytics and Middleware can aggregate data from multiple sources (orders, collections, results) to identify patterns suggestive of systemic identification problems, such as a particular nursing unit having a high rate of mislabeled specimens or a specific phlebotomist being associated with frequent order-specimen mismatches [20].

The Gold Standard: Specimen Provenance Testing. For absolute confirmation of specimen identity, particularly in high-stakes situations like pre-transfusion testing or forensic toxicology, DNA profiling can be employed to match the specimen's DNA to a reference sample from the presumed patient. While too costly and slow for routine use, it serves as the definitive arbiter. Biometric verification, though still emerging, uses unique physiological characteristics (e.g., fingerprints linked to a sample at collection) to confirm identity at a later stage [21].

5. Prevention Strategies: A Multi-Layered Defense System

The most effective approach to specimen misidentification is the implementation of a multi-layered, or "Swiss cheese," model of defense. This model acknowledges that each preventive measure (a slice of cheese) has holes (weaknesses). By layering multiple strategies, the goal is to align the slices so that a hole in one layer is covered by an intact section of another, preventing an error from penetrating the entire system and reaching the patient.

Technological Solutions and Automation. Technology is the most powerful tool for creating "forcing functions" that make errors difficult or impossible to commit. Barcode-Based Patient Identification Systems represent the cornerstone of modern prevention. The process involves: 1) Generating barcoded labels at the patient's bedside only after positive patient identification (using a barcoded wristband scanned by the phlebotomist's mobile device). 2) Printing the label on-demand. 3) Scanning both the patient's wristband and the specimen label after collection to electronically verify a match before the specimen leaves the bedside. This closed-loop system electronically links the patient, the order, and the specimen, virtually eliminating WBIT and mislabeling errors when used correctly [22, 23]. Radiofrequency Identification (RFID) technology offers a potential advancement over barcodes. RFID tags embedded in wristbands and tube labels can be read without direct line-of-sight and can store more information, enabling real-time tracking of specimens throughout their journey from patient to analyzer [24]. Positive Patient Identification (PPID) at Analyzers involves configuring automated laboratory instruments to scan the barcode on each specimen tube and compare it to the test order in the LIS before aspirating sample. This final check prevents an incorrectly placed or mis-aliquoted tube from being analyzed, catching errors that originated earlier in the chain [25].

Process Standardization and Best Practices. Technology must be underpinned by ironclad processes. Standardized Patient Identification Protocol mandates the use of at least two unique patient identifiers (e.g., full name and date of birth or medical record number) before any procedure, including phlebotomy. This verification must be performed actively *with* the patient (or a designated surrogate) whenever possible. The "Label at the Bedside" mandate is a non-negotiable rule: the specimen must be labeled in the presence of the patient immediately after collection. Tubes must never be pre-labeled or removed from the patient's room unlabeled [26]. Standardized Specimen Acceptance/Rejection Policy empowers laboratory staff to reject any specimen that does not meet strict labeling and identification criteria. This policy must be supported by hospital administration to avoid pressure to "make an exception" for clinically urgent cases. Clear rejection pathways with rapid recollection options are essential [27].

Human Factors and Cultural Interventions. The most sophisticated technology will fail if the human element is neglected. Comprehensive and Ongoing Staff Education is critical. Training must move beyond simple procedure to include the "why," using real case studies of patient harm to drive home the consequences. Simulation training for high-risk scenarios (e.g., drawing from an unidentified patient in the ER) can build competence. Cultivating a Culture of Safety and Just Accountability is paramount. This involves moving from a punitive "name, blame, and shame" approach to a just culture that encourages error reporting without fear of retribution for honest mistakes, while maintaining accountability for reckless behavior. Safety culture surveys and leadership walkrounds can assess and improve this climate [28, 29]. Error Reporting and Root Cause Analysis Systems like incident reporting software are vital for capturing near-misses and actual errors. Each event should trigger a structured RCA to identify systemic fixes, not individual scapegoats. Sharing the lessons learned from these analyses across the organization is a powerful tool for collective learning [30].

Regulatory and Accreditation Drivers. External requirements provide a powerful impetus for change. Standards from The Joint Commission (TJC), particularly the National Patient Safety Goal (NPSG) 01.01.01 on improving patient identification, mandate specific protocols that directly target specimen misidentification [31]. College of American Pathologists (CAP) accreditation checklists include rigorous requirements for specimen identification, labeling, and specimen integrity throughout the testing process, with non-compliance resulting in deficiencies [32]. International Organization for Standardization (ISO) 15189 standards for medical laboratories emphasize process management, risk assessment, and continuous improvement in all pre-analytical procedures, providing a comprehensive quality management framework [33].

Special Considerations and High-Risk Scenarios

Certain clinical areas require intensified focus due to their inherent vulnerability.

Transfusion Medicine and Blood Banking. This is a zero-tolerance domain. Prevention relies on an uncompromising multi-step process: a single dedicated sample for grouping and crossmatching, strict wristband identity confirmation at sample collection, automated barcode-based bedside verification systems, and a final "group check" where the blood unit's compatibility is verified by two qualified staff at the patient's bedside just before transfusion [34, 35].

Anatomical Pathology and Surgical Specimens. Misidentification here can lead to wrong-site surgery or incorrect cancer diagnosis. Strategies include direct visual verification by the surgeon of the label on the container in the operating room before the specimen is passed off, use of dedicated specimen labeling stations in OR, and macroscopic and microscopic correlation by the pathologist as a final diagnostic check [36].

Point-of-Care Testing (POCT). Testing performed outside the central lab (e.g., glucose meters, blood gas analyzers) is highly susceptible to identification errors as it often bypasses laboratory controls. Prevention requires integrating POCT devices with the hospital's patient identification system (e.g., barcode scanners on glucose meters), rigorous operator training, and applying the same strict patient identification protocols used for venous draws to fingerstick capillary collections [37].

6. Future Directions and Emerging Technologies

The fight against misidentification continues to evolve with new technological frontiers. **Blockchain Technology** is being explored for its potential to create an immutable, decentralized ledger for specimen provenance. Each step—order, collection, transport, analysis—could be recorded as a "block," creating a transparent and tamper-proof chain of custody from patient to result [38]. **Artificial Intelligence (AI) and Machine Learning** offer powerful predictive capabilities. AI algorithms could analyze workflow patterns, staff schedules, and historical error data to predict high-risk periods or situations for misidentification, allowing for proactive interventions. Image recognition AI could also be used to verify label completeness and accuracy more reliably than human visual checks [39]. **Biometric Integration** at the point of care, such as using a patient's fingerprint or palm vein pattern to instantly pull up their electronic record and generate a specimen label, could further streamline and secure the identification process, though it raises significant privacy and logistical considerations. Finally, the pursuit of the **"Zero Error" Laboratory**remains an aspirational but driving goal. This philosophy, underpinned by Lean and Six Sigma methodologies, involves continuous process mapping, waste elimination, and empowering every staff member to identify and solve problems in real-time, creating a self-correcting system focused on perfection [39].

7. Conclusion

Sample misidentification in clinical laboratories is a persistent, multifaceted, and high-consequence challenge that strikes at the very heart of patient safety and diagnostic integrity. It is a systemic problem born from the interaction of human cognitive limitations, flawed processes, and environmental pressures within complex healthcare systems. As this analysis has detailed, the error manifests in various forms—from Wrong Blood in Tube incidents to digital order entry mistakes—each with the potential to derail a patient's care trajectory. Combating this threat requires a rejection of simplistic blame in favor of a sophisticated, layered defense strategy. This strategy synergistically combines fail-safe technological solutions like barcode-based closed-loop systems, unwavering adherence to standardized best practices such as bedside labeling, and the cultivation of a robust safety culture that prioritizes learning and transparency over punishment. The integration of advanced detection tools like delta checks and the exploration of future innovations like blockchain and AI further strengthen this defensive lattice. Ultimately, achieving a reliable specimen identification system is not a destination but a continuous journey of quality improvement. It demands unwavering

commitment from healthcare leadership, active engagement from every staff member who touches the specimen pathway, and a patient-centered ethos that treats every tube not as a mere container of fluid, but as an inseparable extension of the person from whom it came. Only through such a comprehensive and sustained effort can clinical laboratories fulfill their fundamental promise: to deliver accurate, trustworthy information that forms the bedrock of safe and effective medical care.

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