

SOURCES AND MANAGEMENT OF PREANALYTICAL ERRORS IN CLINICAL LABORATORIES

BASEM SALEH MUSSALLI¹, BASSAM FARHAN AWAD AL-RUWAILI², HESHAM SALEH BAJAHZAR³, RAED ABDULLAH AL NOWAIS⁴, AYEDH HADI AYEDH ALQAHTANI⁵, MAZEN SAEED ALZAHRANI⁶, ABDULRHMAN AREF ALSALEH⁷, SARAH SAAED ALBISHI⁸, ABDULELAH MAMDOUH AL-HARBI⁹, ADEL ALI ALHARBI¹⁰, WALEED MANSOUR SAEED ALQAHTANI¹¹, MOHAMMED MORAYA ALQAHTANI¹²

¹ SECURITY FORCES HOSPITAL, PHLEBOTOMIST, LAB TECHNICIN
² SECURITY FORCES HOSPITAL, RIYADH, MEDICAL LABORATORY SPECIALIST, BLOOD BANK
³ SECURITY FORCES HOSPITAL, LABORATORY SPECIALIST
⁴SECURITY FORCES HOSPITAL PROGRAM, MEDICAL LABORATORY SCIENTIST, LABORATORY TECHNOLOGIST

⁵ RADIOLOGY TECHNOLOGIST, EMAIL: alqahtaniai@mngha.med.sa
 ⁶ NATIONAL GUARD HOSPITAL, LABORATORY TECHNICAIN MICROBIOLOGY
 ⁷ NATIONAL GUARD HOSPITAL, LABORATORY TECHNICAIN LL, MICROBIOLOGY
 ⁸ LAB TECHNICIAN, NGHA, RECEIVING LAB

 $^9\,\rm HEALTH$ INFORMATION TECHNICIAN, KING ABDULAZIZ MEDICAL CITY RIYADH $^{10}\,\rm VASCULAR$ AND INTERVENTIONAL RADIOLOGY TECHNOLOGIST, NATIONAL GUARD HEALTH AFFAIRS

¹¹ TECHNICIAN-EMERGENCY MEDICAL SERVICES, KING KHALID MILITARY COLLEGE CENTER ¹² ANESTHESIA SPECIALIST, KING FAHAD MEDICAL CITY

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Abstract

Preanalytical errors account for 60-70% of all laboratory testing errors, significantly impacting result reliability, patient outcomes, and healthcare resource utilization. This study reviews the major sources of preanalytical errors, their impacts on laboratory testing, and evidence-based strategies for their prevention and management. Common sources include patient preparation issues, sample collection problems, transportation challenges, and processing errors. These errors can compromise analytical accuracy through interference mechanisms like hemolysis, lipemia, and icterus. Management strategies encompass standardized procedures, staff education, technological solutions, quality indicators, and structured improvement methodologies. A comprehensive quality management framework that integrates risk assessment, performance monitoring, clear staff responsibilities, and continuous improvement processes is essential for reducing preanalytical errors. Emerging trends, including artificial intelligence applications, patient-centered approaches, and systems thinking, offer promising opportunities for further reducing these errors. By implementing structured approaches to preanalytical error management, laboratories can enhance result reliability, improve patient safety, and optimize healthcare resource utilization.

Keywords: Preanalytical errors, laboratory testing, quality management, sample collection, hemolysis, patient safety

INTRODUCTION

Laboratory testing plays a crucial role in healthcare delivery, with test results influencing approximately 70% of medical decisions (Mrazek et al., 2020). The laboratory testing process comprises three phases: preanalytical, analytical, and postanalytical. Despite technological advancements that have substantially reduced analytical errors, the preanalytical phase—encompassing processes from test ordering to sample analysis—remains particularly vulnerable to errors (Cornes, 2020).

Studies consistently demonstrate that preanalytical errors account for 60-70% of all laboratory errors (Simundic & Lippi, 2012). This high prevalence stems from numerous variables in the preanalytical phase, many occurring outside direct laboratory control and involving multiple healthcare professionals



(Cadamuro & Simundic, 2023). The consequences of these errors range from minor inconveniences like repeated blood draws to severe outcomes including misdiagnosis and inappropriate treatment.

The financial impact of preanalytical errors is substantial, contributing significantly to the estimated \$20 billion spent annually on laboratory error-related costs in the United States (Neogi et al., 2016). Beyond financial consequences, these errors cause psychological distress to patients through unnecessary procedures, delayed diagnoses, and diminished confidence in healthcare services.

This study examines the sources and impacts of preanalytical errors in clinical laboratories and presents evidence-based strategies for their management, serving as a practical resource for laboratory professionals seeking to enhance testing quality and reliability.

Common Sources of Preanalytical Errors

Test Selection and Ordering Errors

The laboratory testing process begins with test selection and ordering, which can generate several types of errors:

Inappropriate test selection occurs when tests not clinically indicated are ordered, leading to unnecessary testing, increased costs, and potentially misleading results. This may stem from insufficient knowledge about test utilization, defensive medicine practices, or failure to review existing results (Mrazek et al., 2020).

Duplicate test orders waste resources and subject patients to unnecessary blood draws, often resulting from poor communication between healthcare providers or inadequate review of existing results (Naz et al., 2012).

Incomplete test requisitions with missing or incorrect patient information, unclear test requests, or absence of relevant clinical information can lead to improper test selection, incorrect reference range application, or result misinterpretation (Pradhan et al., 2022).

Failure to provide critical information, such as medication use or fasting status, may affect test interpretation and lead to misdiagnosis or inappropriate clinical decisions (Katanić et al., 2023).

Patient Preparation Errors

Proper patient preparation is crucial for many laboratory tests, as physiological variables can significantly influence results:

Fasting violations can significantly alter results for glucose, triglycerides, and other analytes. Many biochemical tests require patients to fast for 8-12 hours before sample collection (Simundic et al., 2014). Timing errors occur when samples are collected at inappropriate times relative to medication administration, diurnal variations, or menstrual cycles, producing misleading results (Neogi et al., 2016). Physical activity before testing affects various parameters, including cardiac markers, hormone levels, and enzyme activities. Failure to ensure appropriate rest before sample collection may lead to erroneous results (Naz et al., 2012).

Patient posture during blood collection affects plasma volume and the concentration of various analytes. Changing from a supine to standing position can increase protein concentration and cellular elements due to fluid shifts (Cornes et al., 2019).

Dietary effects can interfere with specific tests. Even seemingly minor actions like chewing gum can stimulate salivary and pancreatic secretions, potentially affecting test results (Stonys et al., 2020).

Medication interference occurs when various medications interfere with laboratory tests through pharmacological effects, analytical interference, or biological effects. A notable example is biotin, which can significantly interfere with many immunoassays (Ostrowska et al., 2019).

Patient and Sample Identification Errors

Accurate patient and sample identification is fundamental to laboratory testing integrity:

Patient misidentification occurs when samples are collected from the wrong patient or labeled with incorrect patient information, leading to serious diagnostic errors and inappropriate treatment decisions (Cornes et al., 2019).

Sample mislabeling represents a significant risk, particularly in busy clinical settings or when multiple patients are being phlebotomized simultaneously (Lippi et al., 2019).

Barcoding errors with barcode generation, printing, or scanning can lead to sample misidentification or tracking problems throughout the laboratory process (Simundic et al., 2019).

Missing or illegible labels prevent proper sample identification and typically result in sample rejection and recollection (Naz et al., 2012).

Sample Collection Errors

The physical process of sample collection presents numerous opportunities for preanalytical errors:

Hemolysis, the rupture of red blood cells causing the release of intracellular components into the plasma, is the most common preanalytical error. It typically occurs due to traumatic blood collection, use of inappropriate needle sizes, excessive syringe pressure, or vigorous sample mixing (Lippi et al., 2019; Simundic et al., 2020).

Improper venipuncture technique, including difficulties in venous access, prolonged tourniquet application, excessive probing, or inappropriate needle insertion angle, can lead to hemolysis, sample contamination, or insufficient sample volume (Cai et al., 2018).



Contamination from intravenous lines occurs when blood is drawn from sites near or above intravenous lines, resulting in sample dilution or contamination with infusion fluids and leading to falsely decreased or increased analyte values (Simundic et al., 2019).

Incorrect order of draw can lead to additive carryover between tubes, particularly affecting coagulation tests and electrolyte measurements (Jacobsen et al., 2018; Bazzano et al., 2021).

Improper tube filling—under-filling or over-filling collection tubes—can alter the blood-to-additive ratio, affecting test results, particularly for coagulation studies where the correct blood-to-anticoagulant ratio is critical (Lima-Oliveira et al., 2013).

Inadequate mixing of blood with additives in collection tubes can lead to improper anticoagulation, clot formation, or hemolysis (Ercan et al., 2021).

Use of inappropriate collection tubes with incorrect additives or preservatives for specific tests can render samples unsuitable for analysis or produce erroneous results (Simundic et al., 2015).

Sample Transportation and Storage Errors

After collection, samples must be appropriately transported and stored to preserve their integrity:

Delayed transportation leading to excessive time between collection and analysis can cause sample deterioration, affecting various analytes differently. For example, glucose levels in whole blood decrease over time due to cellular metabolism, while potassium levels may increase due to leakage from cells (Gomez-Rioja et al., 2023).

Exposure to extreme temperatures during transportation can affect sample stability. Some analytes are particularly sensitive to temperature variations, such as certain enzymes, hormones, and coagulation factors (Lippi et al., 2019).

Improper transportation conditions, including rough handling during transportation, can cause hemolysis, while inadequate packaging may lead to sample leakage or contamination (Lippi et al., 2018).

Light exposure can degrade photosensitive analytes such as bilirubin, vitamin A, vitamin B12, and certain drugs during transportation or storage (Cano-Corres et al., 2023).

Failure to maintain vertical tube position, particularly for gel separator tubes, can compromise the integrity of the gel barrier, leading to contamination of serum or plasma with cellular elements (Gomez-Rioja et al., 2023).

Sample Processing Errors

Before analysis, samples undergo various processing steps, each susceptible to errors:

Delayed centrifugation can affect the stability of various analytes through ongoing cellular metabolism, protein degradation, or analyte diffusion between plasma and cells (Naz et al., 2012).

Improper centrifugation at incorrect speed, duration, or temperature can lead to incomplete separation of cellular elements, affecting result accuracy (Lippi et al., 2019).

Inadequate clotting time before centrifugation can result in fibrin formation in serum samples, interfering with analysis and potentially causing instrument blockages (Neogi et al., 2016).

Improper aliquoting of samples for different tests can lead to sample mix-ups, contamination, or insufficient volume for testing (Naz et al., 2012).

Sample contamination during processing through introduction of contaminants can alter results or cause analytical interference (Lippi et al., 2019).

Interfering Substances and Sample Quality Issues

Various substances and sample quality problems can interfere with laboratory measurements:

Hemolysis represents a major quality issue that can interfere with numerous chemical, immunological, and coagulation assays through spectral interference, release of intracellular components, or direct chemical interference with assay reactions (Simundic et al., 2020).

Lipemia (elevated lipids in samples) can interfere with many laboratory tests through light scattering, volume displacement, or interference with assay reactions. This can occur due to non-fasting status, certain medications, or underlying conditions (ArulVijayaVani et al., 2023).

Icterus (elevated bilirubin) can cause spectral interference in various chemistry assays, particularly those using photometric detection methods (Cano-Corres et al., 2023).

Pseudohyperkalemia can occur with conditions like thrombocytosis, leukocytosis, or hemolysis, causing falsely elevated potassium values due to release of intracellular potassium during clotting or sample processing (Saleh-Anaraki et al., 2022).

Carryover contamination from inadequate separation between samples or incomplete cleaning of specimen processing equipment can lead to carryover of analytes between samples, potentially causing significant errors in low-concentration analyte measurements (Lippi et al., 2019).

Microclot formation due to incomplete mixing with anticoagulants or delayed processing can interfere with automated analyzers and cause erroneous results (Naz et al., 2012).

Impact of Preanalytical Errors

Preanalytical errors influence laboratory test results in ways that affect patient care, healthcare resource utilization, and overall healthcare quality.

Analytical Impact

Falsely abnormal results frequently arise from preanalytical errors when the patient's true physiological status is within normal limits. For instance, hemolysis can cause falsely elevated potassium, lactate

dehydrogenase, and aspartate aminotransferase levels due to the release of these components from ruptured red blood cells (Simundic et al., 2020).

Falsely normal results may occur when preanalytical errors produce apparently normal results despite actual abnormalities. For example, lipemia can cause falsely decreased sodium levels through volume displacement effects, potentially masking hyponatremia (Koch et al., 2021).

Analytical interference from sample quality issues like hemolysis, lipemia, and icterus can directly interfere with analytical methodologies through spectral interference, chemical reactions, or physical properties, affecting result accuracy (Lippi et al., 2019).

Increased analytical variability introduced by preanalytical errors makes it difficult to distinguish true physiological changes from artifactual variations, particularly when monitoring patients over time (Mrazek et al., 2020).

Sample rejection occurs when severe preanalytical issues lead to sample rejection by laboratory analyzers or staff, resulting in the absence of test results for clinical decision-making (Cadamuro et al., 2019).

Clinical Impact

Diagnostic errors can result from inaccurate laboratory results due to preanalytical errors, leading to misdiagnosis, missed diagnoses, or delayed diagnoses. For instance, falsely elevated cardiac markers resulting from hemolysis might lead to an incorrect diagnosis of myocardial infarction (van Moll et al., 2023).

Inappropriate clinical decisions may be prompted by erroneous results, leading to unnecessary treatments, additional testing, or inappropriate medication adjustments. For example, falsely elevated potassium levels might lead to unnecessary interventions for pseudohyperkalemia (Saleh-Anaraki et al., 2022).

Delayed treatment occurs when sample rejection necessitates recollection, delaying the availability of results and potentially postponing critical treatment decisions (Chavan et al., 2019).

Extended hospital stays may result from diagnostic uncertainties or delays due to preanalytical errors, prolonging hospitalization as clinicians await accurate test results, increasing healthcare costs and exposure to hospital-acquired conditions (Naz et al., 2012).

Patient discomfort and dissatisfaction increase with repeated blood draws necessitated by preanalytical errors, causing additional physical discomfort and potentially reducing satisfaction with healthcare services (Cadamuro & Simundic, 2023).

Decreased trust in laboratory services may develop when inconsistent or questionable laboratory results erode clinicians' trust, potentially leading to over-ordering of tests or seeking alternative diagnostic approaches (Simundic & Lippi, 2012).

Operational and Economic Impact

Preanalytical errors generate significant operational and financial consequences:

Increased workload results from addressing preanalytical errors, including sample recollection, repeat testing, result verification, and communication with clinical teams (Sciacovelli et al., 2019).

Workflow disruptions occur when managing rejected samples and repeating tests, potentially affecting the timely processing of other samples (Bellini et al., 2020).

Additional resource utilization for supplies, reagents, and analyzer time is required to repeat tests affected by preanalytical errors, potentially straining laboratory resources (Mehndiratta et al., 2021).

Staff time diversion from routine activities is necessary to investigate and resolve preanalytical issues, communicate with clinical units, and document error occurrences (Delianu et al., 2021).

Direct laboratory costs increase with repeat testing due to preanalytical errors, raising consumption of reagents, supplies, and laboratory staff time (Naz et al., 2012).

Healthcare system costs rise when delayed or incorrect diagnoses extend hospital stays, generate unnecessary treatments, or prompt additional testing to clarify the clinical picture (van Moll et al., 2023).

Strategies for Managing Preanalytical Errors

Effective management of preanalytical errors requires a multifaceted approach addressing the entire testing process from test ordering to sample analysis.

Standardization of Procedures

Standardizing preanalytical procedures reduces variability and associated errors:

Venous blood collection protocols based on international guidelines, such as those developed by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), help ensure consistent sample quality (Simundic et al., 2019). These protocols should detail appropriate patient identification, equipment selection, venipuncture technique, order of draw, tube filling, and sample mixing procedures. Patient preparation guidelines with clear, standardized instructions for fasting requirements, medication timing, physical activity limitations, and positioning during collection minimize variability in test results (Simundic et al., 2014).

Sample transportation standards establish specifications for transport conditions, including temperature ranges, maximum allowable time, positioning requirements, and protection from light or physical stress, helping preserve sample integrity (Lippi et al., 2019).

Sample processing procedures standardize centrifugation parameters, clotting times, aliquoting methods, and storage conditions to ensure consistent sample preparation for analysis (Gomez-Rioja et al., 2023).



Color-coded collection systems with internationally harmonized color-coding for collection tube closures help prevent tube selection errors and facilitate correct order of draw (Simundic et al., 2015).

Standardized laboratory request forms capture all essential information, including relevant clinical details, medications, and specific collection requirements, supporting appropriate test selection and interpretation (Pradhan et al., 2022).

Staff Education and Training

Comprehensive education and training programs are essential for all personnel involved in the preanalytical phase:

Phlebotomy training provides structured instruction for phlebotomists and other healthcare professionals who collect blood samples, with emphasis on proper technique, common errors, and their consequences (Delianu et al., 2021).

Competency assessment implemented regularly for staff involved in preanalytical processes, with remedial training when deficiencies are identified, ensures ongoing skill maintenance (Chavan et al., 2019).

Interdisciplinary education educates clinicians, nurses, and other healthcare professionals about proper test ordering, patient preparation, and sample collection to extend quality practices beyond laboratory staff (Cadamuro et al., 2022).

Continuing education offers ongoing programs addressing new guidelines, emerging issues, and quality improvement initiatives related to preanalytical processes (Delianu et al., 2021).

Error awareness campaigns raise awareness about common preanalytical errors, their impacts on patient care, and strategies for prevention (Cadamuro & Simundic, 2023).

Feedback mechanisms provide regular information to staff about error rates, quality indicators, and improvement opportunities to reinforce learning and motivate quality-focused behavior (Chavan et al., 2019).

Technological Solutions

Various technological approaches can help prevent and detect preanalytical errors:

Patient identification systems with electronic verification, barcode wristbands, or biometric verification reduce misidentification errors (Cornes et al., 2019).

Computerized physician order entry (CPOE) systems with decision support features guide appropriate test selection, flag duplicate orders, and verify patient preparation requirements (Mrazek et al., 2020).

Barcode labeling systems for specimens link directly to patient identification and test orders, reducing labeling errors and facilitating tracking (Lippi et al., 2019).

Automated specimen processing systems standardize sample processing steps, including centrifugation, aliquoting, and sorting (Bellini et al., 2020).

Transportation monitoring devices track temperature and time during sample transportation to ensure maintenance of appropriate conditions (Gomez-Rioja et al., 2023).

Interference detection systems automatically detect and quantify hemolysis, lipemia, and icterus through spectrophotometric scanning of samples before analysis (Cadamuro et al., 2019).

Laboratory information systems (LIS) can be configured to flag potential preanalytical issues based on delta checks, interference indices, or other quality indicators (West et al., 2017).

Mobile applications and digital tools provide real-time guidance on collection procedures, patient preparation, and troubleshooting common issues (Lippi et al., 2020).

Quality Indicators and Monitoring

Systematic monitoring of preanalytical processes using quality indicators enables identification of problem areas and evaluation of improvement initiatives:

Preanalytical quality indicators measure various aspects of preanalytical performance, such as sample rejection rates, hemolysis rates, identification errors, and collection volumes (Sciacovelli et al., 2019).

Benchmarking compares quality indicator results with established benchmarks or peer institutions to identify areas requiring improvement (Mehndiratta et al., 2021).

Regular audits systematically assess compliance with established procedures and identify improvement opportunities (Vermeersch et al., 2021).

Statistical process control techniques monitor trends in preanalytical quality indicators, enabling early detection of systematic issues (Alshaghdali et al., 2022).

Error reporting systems encourage staff to report preanalytical issues, near-misses, and adverse events in a non-punitive environment (van Moll et al., 2023).

Root cause analysis for significant or recurrent preanalytical errors identifies underlying systemic issues rather than focusing solely on individual mistakes (Bellini et al., 2020).

Process Improvement Methodologies

Applying structured improvement methodologies helps systematically address preanalytical issues: Failure Mode and Effects Analysis (FMEA) proactively identifies potential failure points in preanalytical

processes, assesses their risks, and implements preventive measures (Bellini et al., 2020).

Plan-Do-Study-Act (PDSA) cycles provide an iterative approach to test and refine interventions for reducing preanalytical errors (Cadamuro et al., 2022).

Lean and Six Sigma methodologies eliminate waste and inefficiencies in preanalytical workflows and reduce variability and defects (West et al., 2017).

Process mapping creates detailed visualizations of preanalytical processes to identify bottlenecks and target improvement efforts (Cadamuro et al., 2022).

Checklist implementation for critical preanalytical steps ensures consistent adherence to standardized procedures (Lippi et al., 2020; Cornes et al., 2020).

Implementation in Laboratory Quality Systems

Effective management of preanalytical errors requires integration into the laboratory's overall quality management system.

Regulatory and Accreditation Framework

Understanding and meeting regulatory and accreditation requirements provides a foundation for preanalytical quality management:

ISO 15189 standard for medical laboratories includes specific requirements for preanalytical processes, documentation, and quality indicators. Laboratories should ensure their preanalytical error management aligns with these requirements (Vermeersch et al., 2021).

Accreditation program standards from organizations like the College of American Pathologists and the Joint Commission include standards addressing preanalytical quality. Laboratories should map their error management strategies to these standards to ensure compliance (Sciacovelli et al., 2019).

Documentation requirements establish comprehensive records of preanalytical procedures, quality control activities, and error management approaches to meet regulatory and accreditation requirements for transparency and traceability (Cornes et al., 2020).

Risk-Based Approach

A risk-based approach helps prioritize preanalytical error management efforts:

Risk assessment tools like Failure Mode and Effects Analysis (FMEA) identify high-risk areas in preanalytical processes (Bellini et al., 2020).

Risk prioritization focuses improvement efforts on preanalytical processes with the greatest potential impact on patient safety, result reliability, and operational efficiency (Mrazek et al., 2020).

Risk mitigation strategies address identified risks through preventive measures, detection methods, and contingency plans for when errors occur (Lippi et al., 2020).

Continuous risk monitoring through quality indicators, incident reports, and periodic reassessment identifies emerging issues (Sciacovelli et al., 2019).

Quality Management Structure

A comprehensive quality management structure supports effective preanalytical error reduction:

Quality team structure with representatives from relevant areas (e.g., phlebotomy, specimen processing, laboratory management) oversees error management initiatives (Cadamuro et al., 2022).

Role definitions clearly establish responsibilities for preanalytical quality at all levels, from frontline staff to laboratory management, ensuring accountability for quality practices (Delianu et al., 2021).

Quality champions promote preanalytical quality improvement and serve as resources for their colleagues (Chavan et al., 2019).

Performance evaluation integration incorporates adherence to preanalytical quality practices into staff evaluations to reinforce the importance of quality (Cadamuro & Simundic, 2023).

Continuous improvement cycles systematically address preanalytical issues, evaluate interventions, and refine approaches based on results (West et al., 2017).

Knowledge management systems capture and share lessons learned from preanalytical errors and improvement initiatives throughout the organization (Lippi et al., 2019).

Future Directions

As laboratory medicine evolves, new approaches and technologies offer promising opportunities for further reducing preanalytical errors.

Technological Advancements

Evolving technologies create new possibilities for preventing and detecting preanalytical errors:

Artificial intelligence and machine learning algorithms can analyze patterns in laboratory data to identify potential preanalytical issues, predict error risk, and recommend preventive actions. These technologies may enable more sophisticated detection of subtle preanalytical influences that are currently difficult to identify (Mrazek et al., 2020).

Internet of Things (IoT) applications enable real-time monitoring of critical parameters throughout the preanalytical phase, including transportation conditions, processing times, and storage environments. Connected devices can automatically alert staff to conditions that may compromise sample quality (Lippi et al., 2019).

Advanced sample identification technologies such as RFID, microchips, or blockchain-based tracking systems may provide more secure and comprehensive sample identification and tracking throughout the testing process (Cornes et al., 2019).

Digital visualization tools like those offered by BioRender can help create clear, standardized visual guides for preanalytical procedures, enhancing staff training and adherence to proper techniques (Nordin et al., 2024).

Patient-Centered Approaches

A growing emphasis on patient engagement in healthcare is influencing approaches to preanalytical quality:

Patient education initiatives using multimedia formats, mobile applications, or personalized instructions based on individual test requirements can improve preparation compliance (Cadamuro & Simundic, 2023).

Patient-reported outcomes incorporate patient perspectives and experiences into preanalytical quality assessment through systematic collection of feedback about phlebotomy experiences, preparation instructions, and communication quality (Naz et al., 2012).

Shared decision-making more actively involves patients in laboratory testing decisions, including discussions about proper preparation and potential consequences of preanalytical errors (Cadamuro & Simundic, 2023).

Home-based sample collection with appropriate quality controls can reduce some preanalytical variables associated with clinical settings while introducing new considerations for sample stability during transportation (Lippi et al., 2019).

Systems Thinking and Standardization

Broader systems perspectives are informing more comprehensive approaches to preanalytical quality: Total quality management moves beyond isolated quality control activities toward comprehensive quality management systems addressing the entire testing process, with particular attention to interfaces between different phases and departments (Cadamuro et al., 2022). factors engineering applies principles to preanalytical process design, focusing on creating systems that accommodate human limitations rather than expecting perfect human performance (Bellini et al., 2020).

International standardization initiatives expand efforts to standardize preanalytical procedures, quality indicators, and terminology across different healthcare systems and regions (Vermeersch et al., 2021). Evidence-based guidelines develop more robust direction for preanalytical processes through systematic research on factors affecting sample quality and test results (Cornes et al., 2020).

CONCLUSION

Preanalytical errors represent the most vulnerable aspect of the laboratory testing process, with significant implications for patient care, healthcare resources, and quality performance. Common sources include issues in test selection, patient preparation, sample identification, collection, transportation, and processing. These errors can manifest as sample quality problems such as hemolysis, lipemia, and icterus, which interfere with accurate analysis and result interpretation.

The consequences of preanalytical errors extend beyond the laboratory, affecting clinical decision-making, patient outcomes, operational efficiency, and healthcare costs. Effective management requires a multifaceted approach combining standardization of procedures, comprehensive staff education, technological solutions, systematic quality monitoring, and continuous improvement methodologies.

Implementing these strategies within a structured quality management framework ensures alignment with regulatory requirements while supporting sustainable quality improvement. Emerging technologies such as artificial intelligence, IoT applications, and advanced identification systems offer promising opportunities for further reducing preanalytical errors.

The journey toward minimizing preanalytical errors requires ongoing commitment from laboratory professionals, healthcare providers, administrators, and patients. By understanding the sources and impacts of these errors and implementing evidence-based management strategies, laboratories can significantly enhance the reliability of their results, ultimately contributing to improved patient care and healthcare efficiency.

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