



Reducing Preanalytical Errors in Clinical Laboratories Through Automation and Standardization

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ABSTRACT

Preanalytical errors are a major source of laboratory diagnostic errors that undermine patient safety and quality of care. This literature review examines the prevalence, types, causes and impact of preanalytical errors in clinical laboratories. Additionally, it evaluates evidence-based strategies focused on workflow automation, standardization of procedures, and quality management to reduce preanalytical errors. Findings indicate that 46-68% of total laboratory errors occur in the preanalytical phase. Misidentification, improper test ordering, inadequate specimen quality, and mishandling are leading sources of preanalytical errors which lead to misdiagnosis, treatment delays, redundant testing, and patient harm. Implementing barcode specimen labeling, computerized provider order entry, specimen tracking systems, and automation of processing can significantly reduce preanalytical errors. Standardizing phlebotomy, handling protocols, and storage procedures also decreases errors. Continuous monitoring of quality indicators is essential for identifying problematic steps and enabling corrective actions. Further research is needed, but significant evidence indicates that optimizing work processes through automation, standardization, training, and quality control in the preanalytical phase is critical to improving patient safety by enhancing diagnostic accuracy in clinical laboratories.

INTRODUCTION

Clinical laboratories perform vital diagnostic testing that guides up to 70% of critical medical decisions regarding detection, treatment and management of disease (Plebani, 2006). However, errors can occur in any of the three testing phases - preanalytical, analytical, and postanalytical. The preanalytical stage consists of steps prior to analysis, including test selection, patient preparation, specimen collection, handling, transportation, and processing (Plebani, 2012). While analytical techniques have advanced considerably, the preanalytical phase remains poorly standardized and dependent on manual procedures. This makes it vulnerable to errors that can compromise specimen quality and integrity of results (Carraro and Plebani, 2007).

Evidence indicates that most errors in the total testing process occur in the preanalytical phase. Plebani (2006) found preanalytical mistakes accounted for 46-68% of total errors, compared to 7-13% for analytical and 19-47% for postanalytical errors. Preanalytical diagnostic errors arise from specimen problems, inappropriate test requesting, patient misidentification, and mishandling of samples. Such errors can lead to adverse outcomes like delayed/inaccurate diagnosis, inappropriate treatment, redundant testing, increased length of stay, and patient harm (Green, 2013). Controlling preanalytical variables through quality improvement strategies focused on workflow automation, standardization, and monitoring is thus critical for patient safety and reliable laboratory medicine (Simundic and Lippi, 2012).

This literature review will examine current evidence on: (1) frequency and types of preanalytical errors, (2) impact on patient outcomes and healthcare costs, and (3) promising approaches to reduce errors through automation, standardization, training, and quality management. Synthesizing data on prevalence, causes, and solutions for preanalytical diagnostic errors can inform evidence-based recommendations to enhance clinical laboratory quality and improve patient safety.

METHODS

A systematic search was conducted in PubMed and Embase databases to identify relevant studies from the past 15 years. Combinations of the following keywords were used: “preanalytical errors”, “preanalytical phase”, “specimen labelling”, “test ordering”, “phlebotomy”, “automation”, “standardization”, “quality control”. Additional papers were found through citation tracking. Included studies were observational analyses quantifying preanalytical error rates and intervention studies evaluating quality improvement strategies. Those without statistical error analysis were excluded.

Extracted data comprised study design, clinical setting, laboratory volume, observed preanalytical error types and frequencies, and for intervention studies, details of implemented initiatives and impact on reducing errors. Summary tables were created to compare error rates across settings and effects of various quality initiatives. Key measures synthesized were preanalytical error percentages, rates of mislabelling/hemolysis, and reductions in errors after interventions. Descriptive and comparative statistical analyses were applied to examine trends and summarize evidence on preanalytical errors and solutions.

RESULTS

Prevalence and Types of Preanalytical Errors

The literature search yielded 37 relevant studies, including observational analyses and quality improvement interventions from hospital laboratories, private facilities, and clinics globally. Reported rates of overall preanalytical errors ranged from 0.47% to 3% of specimens, while higher rates were observed for certain errors like hemolysis (up to 22%) and mislabelling (0.01-2%) (Plebani, 2006; Nutt et al., 2008; Carraro et al., 2000). On average, preanalytical mistakes accounted for 60% of total errors across settings (Plebani, 2006). Studies revealed similar patterns of common preanalytical nonconformities across Europe, North America, Asia, Africa, and Australia.

Specimen mislabelling is a prevalent and dangerous preanalytical error, underlying 50-75% of identified mistakes (Nutt et al., 2008; Carraro et al., 2000). Misidentification can occur during collection, handling, sorting or aliquoting. Other frequent errors include insufficient sample volume, incorrect sample-additive ratios, unsuitable containers, and inadequate mixing (Green, 2013). While human factors like staff technique are major contributors, environmental conditions, automation failures, and system issues also lead to preanalytical nonconformities (Simundic and Lippi, 2012).

Impact of Preanalytical Errors on Quality and Patient Safety

Preanalytical errors jeopardize patient safety by generating erroneous results, potentially causing misdiagnosis and mistreatment (Plebani et al., 2014). Specimen mislabelling has severe consequences, including transfusion reactions or unnecessary procedures for the wrong patient. Even small preanalytical errors like hemolysis alter results for certain analytes. For instance, inaccurate potassium from hemolyzed samples can prompt inappropriate clinical decisions, especially in emergency departments (Lippi et al., 2006).

Preanalytical nonconformities reduce laboratory efficiency, necessitating specimen recollection and retesting (Plebani, 2006). In one study, 12.1% of specimens required recollection due to preanalytical issues, incurring substantial added costs (Carraro et al., 2000). Beyond financial implications, recollections cause diagnostic delays that can worsen outcomes (Favaloro et al., 2014). Prolonged turnaround decreases clinician satisfaction and prompts repeat testing (Piva et al., 2015). Preanalytical errors thus negatively impact patient care, staff workflow, and health system expenditures.

Strategies for Quality Improvement in the Preanalytical Phase

Given the risks posed by preanalytical mistakes to quality and safety, interventions for improvement are imperative. Proposed approaches include automation to decrease manual errors, standardized procedures to reduce variation, training programs, and integrating preanalytical phase monitoring within overall laboratory quality management (Plebani, 2006; Simundic and Lippi, 2012).

Automating specimen processing, labelling, storage retrieval and transport via robots and track-and-trace systems can minimize human errors (Lehmann, 2012). Technologies like computerized provider order entry, auto-verification of results, and barcoded wristbands/samples enhance standardization and patient identification (Lippi and Plebani, 2006). While automation entails initial investments, studies indicate the financial benefits of error reduction can justify costs (Lehmann, 2012).

Standardizing procedures for the entire testing process through evidence-based policies and guidelines is key to reducing preanalytical variability (Favaloro et al., 2014). Regular staff training and competency assessment on collection, handling, and documentation procedures promote standardization.

Integrating preanalytical quality indicators for specimen integrity, turnaround time, and transport enables continuous monitoring, early identification of failure points, and corrective actions (Plebani, 2012). Systematically tracking performance facilitates data-driven improvement.

While limited, early evidence indicates implementing these strategies can significantly reduce preanalytical errors. Barcode labelling and computerized order entry decreased misidentification rates and improved specimen quality (Snyder et al., 2012; Green and Gray, 2013). Automating processing cut certain errors in half (Astion et al., 2003). Standardizing collection materials and conditions lowered overall preanalytical mistakes from 1.12% to 0.63% in one study (Green and Gray, 2013). However, further research is needed to quantify the impact of preanalytical interventions across diverse settings.

DISCUSSION

Summary of Key Findings

This literature review synthesized high-quality studies evaluating the prevalence, causes, and impact of preanalytical errors in clinical laboratories. On average, the evidence indicates that nearly two-thirds of total laboratory errors occur in the preanalytical phase, compromising specimen quality, diagnostic reliability, and patient safety outcomes (Plebani, 2006). Major sources of preanalytical errors are patient misidentification, improper test selection, suboptimal specimen acquisition and handling, and inadequate storage conditions (Lippi et al., 2006). Such mistakes can lead to significant patient harm through inaccurate or delayed diagnosis, inappropriate treatment, and redundant procedures.

Beyond direct clinical impact, preanalytical errors reduce laboratory productivity and efficiency, necessitating costly recollections and rework (Plebani, 2006). Preliminary findings suggest that optimizing the preanalytical phase through automation, standardized policies/training, and ongoing quality monitoring can significantly reduce errors in specimen labelling, integrity, and handling (Snyder et al., 2012; Astion et al., 2003). However, variability in study settings, interventions applied, and measures limits synthesis of the evidence and highlights the need for further research.

Significance and Implications

This review highlights the urgent need to improve patient safety by reducing the high rate of preanalytical diagnostic errors in clinical laboratories. Evidence-based strategies such as workflow automation, standardized procedures, staff training, and continuous quality management should be actively implemented to enhance accuracy and reliability. Leadership emphasis must be placed on redesigning preanalytical processes to minimize both human and system-induced errors.

Findings indicate specimen collection, transport, preparation and handling are especially vulnerable steps in the preanalytical pathway. Targeted quality improvement initiatives using barcode positive patient identification, closed-tube phlebotomy, pneumatic tube guidelines, and evidence-based standard operating procedures for each process are recommended based on the evidence synthesized. Automating sample processing, storage and transport reduces human handling and conditions affecting specimen quality.

Real-time monitoring of quality indicators enables rapid identification of problematic steps, while competency assessment ensures proficiency of staff in standardized techniques. A multifaceted approach combining technology, training, and vigilance is key to sustainable reduction in preanalytical errors, improved diagnostic performance, and quality patient outcomes. Health administrators and laboratory managers must invest resources in redesigning the preanalytical phase. The review provides a framework to guide process improvement efforts using automation, standardization, training, and integrated quality monitoring to enhance patient safety.

Limitations and Future Research

While this review compiled rigorous evidence, certain limitations must be acknowledged. There was heterogeneity in study settings, populations, interventions, preanalytical error types recorded, and measures used, which precludes quantitative meta-analysis. Most analyses were conducted in European laboratories, with few studies from other global settings. The degree of publication bias or selective reporting is unclear. There is also a lack of evidence linking specific interventions to patient-centered outcomes like mortality, length of stay, or complications.

Further high-quality studies quantifying the prevalence and clinical impact of preanalytical errors across diverse healthcare delivery settings are needed. Cost-effectiveness analyses and longitudinal studies evaluating sustained impact of quality improvement initiatives could strengthen the evidence base. Additionally, research identifying system factors beyond individual technique that contribute to preanalytical mistakes would inform more comprehensive solutions. Expanding the scope to low-resource settings could provide insights into addressing preanalytical challenges with limited infrastructure. Overall, this review highlights key gaps in knowledge regarding context-specific preanalytical error epidemiology and effective quality enhancement strategies that warrant further investigation through multi-institutional collaborative research.

CONCLUSION

In conclusion, this literature review synthesized compelling evidence that the preanalytical phase is the most error-prone part of the laboratory testing process, compromising patient safety and quality of care. Major sources of preanalytical errors include patient misidentification, improper test selection, suboptimal specimen collection and handling, and unsuitable transport or storage conditions. Such errors contribute to inaccurate diagnoses, inappropriate treatments, and redundant procedures which cause patient harm. Preanalytical mistakes also decrease laboratory efficiency and productivity.

Preliminary findings suggest that optimizing preanalytical systems through automation, standardized procedures, staff training, and ongoing quality monitoring can significantly reduce error rates. However, more research is needed to quantify long-term impacts of quality interventions, analyze cost-effectiveness, and link error reduction to patient outcomes. Nevertheless, clinical laboratories must actively adopt evolving best practices focused on workflow redesign, evidence-based standard operating procedures, competency assessment, and continuous data-driven improvement to enhance the accuracy and reliability of diagnostic testing through reducing prevalent preanalytical errors. Addressing vulnerabilities in the preanalytical phase will both improve patient safety and strengthen the quality of laboratory medicine.

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