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PREVALENCE, TYPES, AND CAUSES OF PRE-ANALYTICAL ERRORS IN CLINICAL LABORATORIES: A SYSTEMATIC REVIEW

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Abstract

Background: Pre-analytical errors are widely recognised as the most vulnerable step of the total testing process and can compromise patient safety through specimen rejection, delays and misleading results. This systematic review aimed to synthesise evidence on the prevalence, types and causes of pre-analytical errors in clinical laboratories. **Methods:** The review followed PRISMA 2020 guidelines. Electronic databases were searched for observational studies conducted in clinical laboratory settings that reported quantitative data on pre-analytical error rates, described specific error types and/or investigated contributing factors. Eligible full texts were screened against predefined criteria, and data were extracted on study characteristics, error definitions, overall error or rejection rates, distributions of error types and reported causes. Findings were summarised narratively because of heterogeneity in designs and outcome measures. **Results:** Seven cross-sectional or retrospective audits from hospital laboratories in different countries were included. Sample sizes ranged from 200 audited specimens to more than 300,000 samples and over 2 million tests. Across studies, pre-analytical errors represented the largest share of total laboratory errors or were the leading cause of sample rejection. Reported overall pre-analytical error or rejection rates varied from below 1% to more than 12%, while one quality-indicator audit found at least one pre-analytical defect in almost all samples. The most frequent error types were hemolysed and clotted samples, insufficient volume, use of inappropriate containers, delayed or non-received specimens, and incomplete or inaccurate request forms. Contributing factors included inadequate staff training, high workload, suboptimal phlebotomy practice, poor adherence to protocols and lack of harmonised quality indicators. **Conclusion:** Pre analytical errors remain highly prevalent across diverse clinical laboratory settings and are largely driven by preventable human and organisational factors. Targeted interventions combining continuous education, standardised procedures, robust informatics and routine monitoring of quality indicators are essential to reduce pre-analytical risk and strengthen patient safety.

Keywords: Pre-Analytical Errors, Laboratory Errors, Specimen Rejection, Clinical Laboratory, Quality Indicators, Phlebotomy, Sample Handling, Patient Safety.

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INTRODUCTION

Clinical laboratory medicine generates essential clinical information by analysing the concentration, composition and structure of analytes in biological fluids, and an estimated 70–80% of diagnostic and treatment decisions depend on laboratory test results (Asmelash et al. 2020; Sepúlveda Maturana et al. 2025). Despite major advances in automation, information systems and analytical technology, laboratory errors remain a persistent threat to diagnostic accuracy, patient safety and the efficient use of healthcare resources (Alghamdi et al. 2024; Dugad et al. 2022). The total testing process is conventionally divided into pre-analytical, analytical and post-analytical phases, from the initial test request and sample collection to result reporting and interpretation (Dugad et al. 2022; Asmelash et al. 2020). Multiple systematic reviews show that most laboratory errors occur outside the analytical phase: extra-analytical errors (pre- and post-analytical) account for about 93% of total errors, with approximately 70% attributed to the pre-analytical phase (Asmelash et al. 2020; Alghamdi et al. 2024). Reported estimates indicate that pre-analytical errors contribute 46–68% of all detected laboratory errors, making this the most vulnerable segment of the testing pathway (Dugad et al. 2022; Cui et al. 2025).

Pre-analytical errors include inappropriate test requests, incomplete or illegible laboratory request forms, failure to correctly identify patients, incorrect sampling time, problems in specimen collection, use of unsuitable containers, inadequate sample volume and errors in sample transportation or storage (Asmelash et al. 2020; Dugad et al. 2022). These defects may lead to specimen rejection, delayed turn-around times, repeat phlebotomy, unnecessary costs and even erroneous clinical decisions with direct harm to patients (Dugad et al. 2022; Sepúlveda Maturana et al. 2025). In African laboratories, a meta-analysis reported pooled prevalences of 17.5% for pre-analytical errors and 2.0% for specimen rejection, together with high rates of incomplete request forms, underscoring the magnitude of these problems in resource-limited settings (Asmelash et al. 2020). The stability of biochemical analytes is also strongly influenced by pre-analytical handling. A systematic review of 34 commonly measured analytes showed that factors such as tube type, delays between collection and centrifugation, storage time and temperature can produce clinically relevant changes, with some measurands remaining stable for hours while others require rapid processing (Hedayati et al. 2020). Consequently, inappropriate pre-analytical conditions can degrade sample quality even when the analytical phase is well controlled.

Recent work has emphasised that reducing pre-analytical errors depends on structured quality management and education. An integrative review highlighted that continuous training, protocol adherence and use of quality indicators are central to improving pre-analytical performance and patient safety (Sepúlveda Maturana et al. 2025). A before-and-after study applying the Donabedian structure–process–outcome model to pre-analytical quality management demonstrated significant reductions in non-compliant samples and improvements in nurses' knowledge, behaviours and clinician trust in results (Cui et al. 2025). Building on this body of evidence, the present systematic review focuses

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specifically on the prevalence, types and causes of pre-analytical errors in clinical laboratories. By synthesising data from observational studies of routine testing, it aims to characterise the burden and patterns of pre-analytical errors and to clarify the key contributing factors that can be targeted by quality-improvement strategies.

METHODS

This systematic review was designed and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines. The review question focused on the prevalence, types and causes of pre-analytical errors in clinical laboratories. A comprehensive search of major electronic databases was performed to identify relevant studies. The search combined terms related to “pre-analytical error”, “laboratory error”, “specimen rejection”, “sample quality” and “clinical laboratory”. No restriction was placed on country or patient population, but only articles published in English and reporting human data were considered. Additional records were identified by screening the reference lists of included articles and relevant reviews. All records retrieved from the databases were imported into a single file and duplicates were removed before screening. Eligibility criteria were prespecified. We included original quantitative studies conducted in clinical laboratory settings that reported data on the prevalence and/or frequency of pre-analytical errors, described specific types of pre-analytical defects (for example, hemolysis, clotted samples, insufficient volume, mislabeling or incomplete request forms), and/or analysed their underlying causes or contributing factors. Reviews, editorials, conference abstracts without full data, case reports, studies focusing exclusively on analytical or post-analytical errors, and non-laboratory settings were excluded.

Study selection proceeded in two stages. First, titles and abstracts were screened against the eligibility criteria. Potentially eligible articles were then assessed in full text to confirm inclusion. Screening and selection were performed independently by at least two reviewers, with disagreements resolved by discussion and, when necessary, consultation with a third reviewer. Reasons for exclusion at the full-text stage were recorded, and the study selection process is summarised in a PRISMA flow diagram. Data were extracted into a standardised form, including bibliographic details, country and setting, study design, sample size, type of laboratory, definition of pre-analytical error, overall error or rejection rates, distributions of error types, and described causes or risk factors. Because of variability in study designs and outcome definitions, findings were synthesised narratively, with results grouped by prevalence estimates, error types and reported causes.

RESULTS

Seven observational studies published between 2014 and 2025 were included, all cross-sectional audits of routine hospital laboratories (Abdollahi et al. 2014; Najat 2017; Kadić et al. 2019; Alcantara et al. 2022; Addisu et al. 2023; Tasneem et al. 2024; Gupta et al. 2025). Reported sample sizes ranged from 200 audited specimens in a tertiary Indian

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hospital to 303,866 samples and 2,430,928 tests in a large Iranian teaching hospital (Abdollahi et al. 2014; Gupta et al. 2025).

Across studies, pre-analytical errors formed the largest proportion of total laboratory errors. In Iran, 153,148 testing errors yielded an overall rate of 6.3%, with most errors occurring before analysis and fewer in the analytical and post-analytical phases (Abdollahi et al. 2014). In Bosnia, 602 of 35,343 blood samples were rejected because of pre-analytical problems, giving a rejection rate of 1.7% and a higher proportion of rejected inpatient than outpatient samples (Kadić et al. 2019). The Saudi clinical chemistry laboratory identified 6,705 pre-analytical errors among 55,345 requests (12.1%), with the highest rate in the emergency department (Alcantara et al. 2022). A Pakistani nephrology center reported 1,722 unsuitable samples among 254,816 specimens, corresponding to a rejection rate of 0.67% (Tasneem et al. 2024). In an Indian quality-indicator audit, 199 of 200 samples contained at least one pre-analytical problem, giving an overall error rate of 99.5% (Gupta et al. 2025).

The pattern of error types was consistent. Hemolyzed and clotted samples dominated rejected-specimen categories in Bosnia and Pakistan (Kadić et al. 2019; Tasneem et al. 2024). In Saudi Arabia, non-received samples and hemolysis were the leading problems, followed by insufficient volume and incorrect test requests (Alcantara et al. 2022). The Iraqi multicenter study quantified delay in sample transportation (39%), expired reagents (27%), hemolyzed samples (26%) and clotted samples (26%) as the most frequent pre-analytical events and identified hemolysis, misidentification and clotting as key causes of rejection (Najat 2017). The Ethiopian hematology study showed that every request form had at least one omission; clinical diagnosis, clinician name or signature, patient address and collection time were absent in 72–100% of forms, and more than half of phlebotomy procedures lacked proper patient identification or vein-site disinfection (Addisu et al. 2023). Gupta et al. (2025) also documented very high rates of incomplete physician and patient information, with additional integrity defects such as insufficient volume, hemolysis and clots. Overall, the evidence indicates that pre-analytical errors are common and multifactorial, mainly related to inadequate request-form completion, staff training and phlebotomy practice.

Table 1: Characteristics of the included original studies on pre-analytical errors

Study (year)	Country, setting	Design & period	Laboratory scope	Sample size (specimens, requests)
Abdollahi et al. 2014	Imam Teaching Hospital, Tehran, Iran	Descriptive cross-sectional study during 2012	Comprehensive hospital clinical laboratory (hematology, biochemistry, microbiology, hormonology, serology, coagulation, flow cytometry, etc.)	303,866 samples; 2,430,928 tests

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Najat 2017	Ten public clinical chemistry diagnostic labs, Sulaimani City, Iraqi Kurdistan	Prospective cross-sectional study over a 2-month period (Feb–Apr 2016)	Clinical chemistry labs (venous blood samples)	5,500 venous blood samples
Kadić et al. 2019	Department of Medical Biochemistry & Immunology, Cantonal Hospital Zenica, Bosnia & Herzegovina	Retrospective analysis over 3 months (Dec 2016–Mar 2017)	Central laboratory processing inpatient and outpatient blood samples	35,343 blood samples (25,545 inpatient; 9,798 outpatient)
Alcantara et al. 2022	Clinical chemistry laboratory, tertiary care hospital, Saudi Arabia	Retrospective 2-year study (2019–2020)	Clinical chemistry requests from emergency, inpatient, and outpatient departments	55,345 laboratory requests; 6,705 pre-analytical errors identified
Addisu et al. 2023	Hematology lab, Hawassa University Comprehensive Specialized Hospital, Hawassa, Ethiopia	Observational cross-sectional study (Apr–Jun 2019)	Hematology test request forms and corresponding phlebotomy practices	393 hematology requests, patients
Tasneem et al. 2024	ICON Learning Hospital & Multan Institute of Kidney Diseases, Multan, Pakistan	Descriptive cross-sectional study (Jan 2021–Dec 2022)	Specialized kidney center laboratory receiving routine specimens from multiple clinical areas	254,816 specimens over 2 years (120,189 in 2021; 134,627 in 2022)
Gupta et al. 2025	Central clinical laboratory, Dr. D.Y. Patil Medical College Hospital, Pune, India	Descriptive cross-sectional audit over 3 months	Central laboratory handling samples from multiple hospital departments; errors assessed via predefined pre-analytical quality indicators	200 randomly selected samples (EDTA, fluoride and plain vacutainers)

Table 2: Prevalence of pre-analytical errors in the included studies

Study	Numerator, denominator	Main measure of pre-analytical error	Additional notes
Abdollahi et al. 2014	153,148 testing errors, 2,430,928 tests	Overall testing error rate 6.3%; pre-analytical errors accounted for 65.09% of all detected errors	Analytical errors 15.3% and post-analytical 19.6%; pre-analytical phase clearly dominated total error burden.
Najat 2017	5,500 samples observed; 15 categories of pre-analytical error	High overall pre-analytical error burden; delay in sample transportation 39%, expired reagents 27%, hemolyzed samples 26%, clotted samples 26%	Major reasons for sample rejection: hemolyzed samples 9%, incorrect sample identification 8%, clotted samples 6%.

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Kadić et al. 2019	602 rejected samples, 35,343 received	Overall blood sample rejection rate 1.70% due to pre-analytical problems	Rejection higher in inpatients (2.26%) than outpatients (0.26%), indicating setting-related vulnerability.
Alcantara et al. 2022	6,705 pre-analytical errors, 55,345 requests	Overall pre-analytical error rate 12.1%	Department-specific error rates: ED 21%, inpatient 13.4%, outpatient 7%.
Addisu et al. 2023	393 hematology request forms	100% of request forms had at least one pre-analytical error in documentation	Omission rates: clinical diagnosis 76.08%, clinician name, signature 72.8%, patient address 100%, specimen collection time 100%.
Tasneem et al. 2024	1,722 unsuitable samples, 254,816 specimens	Sample rejection rate 0.67% across 2 years	Annual rejection: 0.60% (2021) and 0.73% (2022), indicating a slight increase over time.
Gupta et al. 2025	199 samples with ≥1 pre-analytical error, 200 samples	Overall pre-analytical error prevalence 99.5% based on quality indicators	Dominated by documentation deficiencies; sample integrity problems affected 14% of samples.

Table 3: Types and causes of pre-analytical errors in the included studies

Study	Most frequent pre-analytical error types	Other important errors	Reported underlying causes, contributing factors
Abdollahi et al. 2014	Pre-analytical phase accounted for 65.09% of all errors; frequent problems in test ordering and specimen collection (inappropriate test request, wrong container, improper volume, labeling errors).	Errors in sample transport, freezing, receipt, and distribution contributed to remaining pre-analytical defects.	Complexity of work in a large tertiary lab; human factors in order entry and phlebotomy; inadequate adherence to SOPs from ordering to specimen handling.
Najat 2017	Delay in sample transportation 39%, expired reagents 27%, hemolyzed samples 26%, clotted samples 26%.	Rejection most often due to hemolyzed samples 9%, incorrect sample identification 8%, clotted samples 6%.	Long transport distances, high ambient temperatures, transport by untrained staff and poor reagent stock management; phlebotomy and handling deficiencies.
Kadić et al. 2019	Among rejected samples, hemolysis 48.50% and clotted samples 39.87% were dominant causes.	Insufficient sample volume 7.81%, inappropriate container 2.16%, identification errors 1.66%.	Higher rejection among inpatients points to more complex phlebotomy and less controlled environment; issues with venipuncture, tube filling and tube selection.

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Alcantara et al. 2022	Non-received samples 30.7% and hemolysis 29.2% were leading pre-analytical errors; insufficient sample quantity 13.8% and incorrect test order 9.4%.	Transport specimen errors 3.7%, unauthorized orders 3.6%, duplicated requests 2.8%, inappropriate tube 1.5%, clotted specimens 0.7%, labeling errors 0.5%, incomplete request data 0.4%.	Errors linked to untrained ward staff transporting specimens, heavy workload, and poor orientation to test-request and barcode policies, especially in ED and OPD.
Addisu et al. 2023	On request forms: clinical diagnosis missing 76.08%; clinician name and signature missing 72.8%; patient address and specimen collection time absent in 100% of forms.	Omission of age 2.5%, sex 3.8%, hospital ID 6.4%; phlebotomy errors included failure to verify patient identity, inadequate vein-site cleaning, improper mixing of blood, labeling errors.	Poor awareness among clinicians of the importance of complete request information; weak culture of documentation; insufficient training in patient identification and phlebotomy.
Tasneem et al. 2024	Among rejected specimens, hemolyzed samples 41.6%, clotted samples 22.5%, and insufficient sample volume 12.6% were most frequent.	Remaining rejections due to labeling problems, leakage, use of wrong container and other collection, handling issues.	Human errors in phlebotomy and initial sample handling in a high-throughput nephrology center; increasing rejection rate suggests need for continuous staff training and monitoring.
Gupta et al. 2025	Documentation-related indicators showed highest error: incomplete physician information 94%, incomplete patient identification 74%.	Sample integrity problems (insufficient volume, hemolysis, clots, inadequate anticoagulant ratio) in 14% of samples; transport-related issues around 13.5%.	Deficient staff training (especially nurses and interns), lack of standardized pre-analytical quality indicators and poor oversight of request form completion.

DISCUSSION

Our review confirms that pre analytical errors represent the dominant source of laboratory failure and places the findings of individual observational studies within a broader evidence base. Extra-analytical error studies from Africa reported that pre-analytical defects account for about 70% of all laboratory errors and contribute to a pooled pre-analytical prevalence of 17.5%, with specimen rejection around 2% and incomplete request forms 7.55% (Asmelash et al. 2020). Similar proportions are described in global reviews, where pre-analytical errors are estimated to contribute 46 to 68% of total errors and to be the “most error-prone” part of the testing cycle (Dugad et al. 2022; Sepúlveda

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Maturana et al. 2025). Our pooled range of error rates and rejection frequencies therefore sits well within these previously reported intervals and reinforces that the pre-analytical phase remains the main target for improvement.

The pattern of error types in the included primary studies also mirrors what has been synthesised in systematic and narrative reviews. Asmelash et al. list inappropriate test ordering, incomplete or illegible request forms, failure to identify patients, wrong sampling time, hemolysis, lipemic samples and inappropriate transport or storage as the most frequent pre-analytical defects (Asmelash et al. 2020), which closely matches the combination of hemolysed and clotted samples, insufficient volume, mislabeling, and delayed or non-received specimens observed in our review. Nordin et al. describe poor blood sample quality as the “essence” of pre-analytical variability and estimate that hemolysis alone accounts for 40–70% of such errors, with additional contributions from wrong volume, incorrect containers and clots (Nordin et al. 2024). The dominance of hemolysis and clotted specimens in several of our included studies is therefore consistent with the broader literature.

Our findings on incomplete request forms and documentation failures are also in line with previous evidence. The African meta-analysis documented poor request-form completion and highlighted that many laboratories struggle with standardisation of extra-analytical quality indicators (Asmelash et al. 2020). West et al. reviewed methodologies for collecting pre-analytical quality-indicator data and showed wide variation in definitions and recording practices, arguing that harmonised indicators from the IFCC Working Group and routine capture in laboratory information systems are essential for benchmarking and continual improvement (West et al. 2016). The high rates of missing clinical information, clinician identifiers and collection times in our data support these calls for harmonised quality indicators and better informatics support.

Several of the background reviews emphasise that pre-analytical vulnerability is not only a matter of counting errors but also of understanding the impact of handling conditions on analyte stability. Hedayati et al. systematically demonstrated that for 34 commonly used biochemical analytes, acceptable stability ranges from as little as two hours up to one week, depending on tube type, storage temperature and delays before centrifugation (Hedayati et al. 2020). These findings underscore that some of the “non-received,” delayed or improperly stored samples in our review may have generated clinically misleading results even when not formally rejected.

The intervention focused papers provide a framework for interpreting the causes we identified and for designing responses. Sepúlveda Maturana et al. synthesised evidence that reducing pre-analytical errors depends on continuous training, protocol adherence and the explicit integration of education into quality programmes (Sepúlveda Maturana et al. 2025). In a similar vein, Dugad et al. and Nordin et al. highlight that training, standard operating procedures and harmonisation efforts are central to reducing both pre- and post-analytical errors (Dugad et al. 2022; Nordin et al. 2024). Alghamdi et al. report that staff training, automation and protocol standardisation were consistently effective prevention strategies in recent primary studies, particularly for errors due to incorrect

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sample collection and delays in transport (Alghamdi et al. 2024). Our finding that many errors originate from non-laboratory personnel, such as ward nurses and phlebotomists, directly supports the emphasis on multidisciplinary education.

The before-and-after study by Cui et al. demonstrates that structured quality-management pathways based on the Donabedian structure–process–outcome model can significantly reduce non-compliant samples and improve nurses' knowledge, behaviour, patient satisfaction and clinicians' trust in laboratory results (Cui et al. 2025). Taken together with the educational and methodological reviews, these data suggest that the high prevalence and multifactorial aetiology of pre-analytical errors documented in our systematic review should be addressed through comprehensive programmes that combine standardised quality indicators, robust informatics, continuous staff education and institution-wide quality-management frameworks.

CONCLUSION

This systematic review shows that pre-analytical errors remain the most frequent and preventable source of failure in clinical laboratories, with high rates of unsuitable specimens and widespread deficiencies in request forms and sample handling. Hemolysis, clotted samples, insufficient volume, non-received specimens and incomplete clinical information were the dominant problems across diverse settings. Most errors arose outside the core laboratory, reflecting gaps in phlebotomy practice, staff training and protocol adherence. Implementing harmonised quality indicators, strengthening education for all personnel involved in the pre-analytical phase and integrating these measures into laboratory quality-management systems are essential to improve patient safety.

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