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Investigating the Impact of Pre-Analytical Variables on Laboratory Diagnostic Accuracy and Patient Clinical Outcomes

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ABSTRACT:

Background: Laboratory test results inform a large proportion of clinical decisions, including diagnosis, treatment selection, monitoring, and discharge. The accuracy of these results depends not only on analytical performance within the laboratory but on every step of the total testing process. The pre-analytical phase — from test selection and patient preparation through specimen collection, labelling, transport, and processing — is the most error-prone part of this process and lies largely outside the direct control of the laboratory.

Objective: This paper investigates the impact of pre-analytical variables on laboratory diagnostic accuracy and patient clinical outcomes, classifies the major sources of pre-analytical error, examines their clinical and economic consequences, and proposes an integrative framework for pre-analytical quality management in Saudi healthcare institutions.

Methods: A narrative review was conducted of observational studies, quality improvement reports, systematic reviews, international standards, and professional guidelines. Findings were interpreted using the total testing process ("brain-to-brain loop") model, Donabedian's structure–process–outcome model, and Reason's model of error causation.

Results: Studies consistently attribute the majority of laboratory errors — commonly reported at between about 60% and 70% — to the pre-analytical phase. Leading problems include haemolysed specimens, insufficient or clotted samples, incorrect containers, patient misidentification and labelling errors, inappropriate patient preparation, prolonged tourniquet application, delays and temperature deviations during transport, interference from drugs and supplements, and contamination of blood cultures. These errors can produce spurious results, delayed or missed diagnoses, inappropriate treatment,

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transfusion incidents, unnecessary repeat testing, prolonged hospital stay, and increased costs.

Conclusion: Pre-analytical variables are a major, modifiable determinant of laboratory diagnostic accuracy and patient safety. Because most pre-analytical steps are performed outside the laboratory by nurses, phlebotomists, physicians, and porters, improvement requires interprofessional ownership. The proposed PRECISE framework (Patient preparation and test appropriateness, Reliable identification and labelling, Evidence-based collection technique, Controlled transport and storage, Interference and integrity screening, Standardisation and training, and Evaluation through quality indicators) offers a structured approach for reducing pre-analytical error.

1. INTRODUCTION

Clinical laboratories are among the most heavily used diagnostic services in modern health care. Blood, urine, tissue, and other specimens are analysed millions of times each day to support the diagnosis of disease, the selection and monitoring of therapy, screening, prognosis, and decisions about admission and discharge. It is frequently stated that laboratory results influence around 70% of medical decisions, a figure traced to commentary in the 1990s (Forsman, 1996). Although the precise evidence base for this figure has been questioned (Hallworth, 2011), there is broad agreement that laboratory medicine plays a central and pervasive role in clinical decision-making.

Advances in automation, analytical technology, and internal and external quality control have substantially reduced analytical error within laboratories over recent decades. As analytical performance has improved, attention has shifted to the phases of testing that occur before and after analysis. Lundberg (1981) described the testing process as a "brain-to-brain loop" that begins with the clinician's decision to order a test and ends with the clinician's interpretation and action upon the result. Errors can occur at any point in this loop, and many of the most important occur outside the walls of the laboratory.

The pre-analytical phase encompasses all steps from test request to the point at which the specimen is ready for analysis: test selection and ordering, patient identification and preparation, specimen collection, labelling, handling, transport, reception, centrifugation, and storage. Research over several decades has consistently found that this phase accounts for the majority of laboratory errors (Plebani & Carraro, 1997; Carraro & Plebani, 2007; Lippi et al., 2011a). Because most pre-analytical steps are performed by healthcare workers outside the laboratory — nurses, phlebotomists, physicians, and transport staff — pre-analytical quality is an interprofessional and organisational challenge rather than a purely laboratory concern.

A laboratory result can be no more accurate than the specimen from which it was produced — and the fate of that specimen is often decided long before it reaches the analyser.

Pre-analytical errors matter because they can produce results that are wrong but appear plausible. A falsely elevated potassium from a haemolysed sample may trigger unnecessary treatment; a blood sample drawn from the wrong patient may lead to an incompatible transfusion; a contaminated blood culture may lead to unnecessary antibiotics and prolonged hospitalisation. These consequences link specimen quality directly to diagnostic accuracy, patient safety, and resource use.

In the Kingdom of Saudi Arabia, the Health Sector Transformation Program under Vision 2030 places strong emphasis on quality, patient safety, and efficiency (Health Sector Transformation Program, 2021). Laboratory services are being consolidated and modernised within health clusters, digital systems are expanding, and accreditation requirements — including national standards from the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) and international standards such as ISO 15189 — increasingly emphasise the entire testing process. Understanding and controlling pre-analytical variables is therefore central to achieving national quality goals.

1.1 Aim and Objectives

The aim of this paper is to investigate the impact of pre-analytical variables on laboratory diagnostic accuracy and patient clinical outcomes. Specifically, it seeks to:

- Describe the total testing process and situate the pre-analytical phase within it;
- Review evidence on the frequency and distribution of laboratory errors across testing phases;
- Identify and classify the major pre-analytical variables and their mechanisms of effect;
- Examine the consequences of pre-analytical errors for diagnostic accuracy, clinical outcomes, and costs;
- Review strategies and quality indicators for pre-analytical improvement;
- Consider implications for Saudi laboratories; and
- Propose the PRECISE framework to guide practice and management.

2. METHODOLOGY

This paper adopts a narrative review design, appropriate for synthesising heterogeneous evidence from error-frequency studies, experimental studies of specific variables, quality improvement reports, systematic reviews, and international standards and guidelines. Literature was identified through PubMed/MEDLINE, Scopus, and Google Scholar using combinations of *pre-analytical*, *preanalytical error*, *laboratory error*, *total testing process*, *specimen quality*, *haemolysis*, *patient identification*, *wrong blood in tube*, *specimen labelling*, *blood culture contamination*, *venous stasis*, *biotin interference*, *quality indicators*, and *ISO 15189*. Professional guidance from bodies including the Clinical and Laboratory Standards Institute (CLSI), the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), and the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) was also reviewed.

Three theoretical lenses guided the synthesis. The total testing process or brain-to-brain loop (Lundberg, 1981; Plebani, 2010) structures the analysis by phase. Donabedian's (1988) structure–process–outcome model links pre-analytical resources and processes to clinical outcomes. Reason's (2000) model of active failures and latent conditions explains how individual errors at the bedside arise from system weaknesses. As a narrative review, the paper provides a critical synthesis rather than pooled estimates.

3. THE TOTAL TESTING PROCESS

3.1 The Brain-to-Brain Loop

The total testing process is commonly divided into five phases: the *pre-pre-analytical* phase (test selection, ordering, and patient preparation), the *pre-analytical* phase (collection, labelling, transport, and processing), the *analytical* phase (measurement), the *post-analytical* phase (verification, reporting, and transmission), and the *post-post-analytical* phase (interpretation and clinical action) (Plebani, 2010). In this paper, the term pre-analytical is used broadly to include both pre-pre-analytical and pre-analytical steps, as is common in the literature.

Table 1. Phases of the total testing process and examples of errors

Phase	Steps	Examples of errors	Usual responsibility
Pre-pre-analytical	Test selection, ordering, patient preparation	Inappropriate test, wrong test ordered, non-fasting patient, incorrect timing of drug level	Physicians, nurses, patients
Pre-analytical	Identification, collection, labelling, transport, reception, processing	Misidentification, haemolysis, wrong tube, insufficient volume, delay, temperature deviation	Nurses, phlebotomists, porters, laboratory reception
Analytical	Measurement and quality control	Calibration error, instrument malfunction, interference undetected	Laboratory scientists
Post-analytical	Validation, reporting, transmission	Transcription error, delayed critical result notification	Laboratory, information systems

Phase	Steps	Examples of errors	Usual responsibility
Post-post-analytical	Interpretation and action	Misinterpretation, failure to act on result	Clinicians

Source: Adapted from Lundberg (1981) and Plebani (2010).

3.2 Distribution of Errors Across Phases

Studies of laboratory errors have consistently found that the pre-analytical phase accounts for the largest proportion. In a landmark study of errors in a stat laboratory, Plebani and Carraro (1997) found that 68.2% of errors occurred in the pre-analytical phase, 13.3% in the analytical phase, and 18.5% in the post-analytical phase. A follow-up study ten years later in the same setting found a reduced overall error rate, but the pre-analytical phase still accounted for 61.9% of errors, compared with 15% analytical and 23.1% post-analytical (Carraro & Plebani, 2007). Reviews of the literature have similarly concluded that pre-analytical errors represent the majority of laboratory errors across settings (Bonini et al., 2002; Plebani, 2006; Lippi et al., 2011a).

It is important to note that reported error rates vary widely depending on definitions, detection methods, and settings. Many pre-analytical errors are detected and corrected before results are released — for example, haemolysed samples are rejected — so their impact is often expressed as delay and repeat collection rather than as erroneous results. Others, such as misidentification, may be undetectable within the laboratory and therefore particularly dangerous.

4. CLASSIFICATION OF PRE-ANALYTICAL VARIABLES

Pre-analytical variables can be grouped into those related to the patient, those related to test requesting and identification, those related to specimen collection, those related to handling and transport, and those related to processing and storage. Some variables are *controllable*, in that they can be standardised (such as tourniquet time or tube order), whereas others are *uncontrollable* biological factors (such as age, sex, or pregnancy) that must be considered in interpretation.

4.1 Patient-Related Variables

Patient-related variables include fasting status, recent food intake, exercise, posture, circadian variation, stress, smoking, alcohol, medications, and dietary supplements. Postprandial sampling affects glucose, triglycerides, and several other analytes; posture changes from supine to upright shift fluid between compartments and alter concentrations of proteins and protein-bound substances; vigorous exercise can raise creatine kinase and other muscle-derived analytes; and many analytes, such as cortisol, show marked diurnal variation. Inappropriate timing of therapeutic drug monitoring samples relative to dosing is a frequent pre-pre-analytical error leading to misinterpretation of drug levels.

Interference from medications and supplements is an increasingly recognised problem. High-dose biotin, widely available in supplements, can interfere with immunoassays that use streptavidin–biotin binding. In a study of healthy adults taking biotin, Li et al. (2017) found clinically significant interference in a substantial proportion of hormone and non-hormone immunoassays, capable of producing falsely high or falsely low results, including for thyroid function tests and troponin. Such interference may not be detectable by the laboratory unless supplement use is reported.

4.2 Test Requesting and Patient Identification

Errors in requesting include ordering inappropriate or duplicate tests, incomplete clinical information, and illegible or ambiguous requests. Patient identification and specimen labelling errors are among the most serious pre-analytical problems because they can result in a patient receiving another patient's result. In a Q-Probes study of 147 laboratories, Wagar et al. (2008) documented specimen labelling errors across participating institutions and identified factors associated with lower error rates, including bedside labelling and the use of electronic identification.

The most serious form of misidentification is “wrong blood in tube” (WBIT), in which a sample labelled with one patient's details contains another patient's blood. In transfusion medicine, WBIT can lead to ABO-incompatible transfusion, a potentially fatal event. An international study of sample collection performance found WBIT rates of approximately one in 2,000 samples, with substantial variation between hospitals (Dzik et al., 2003). Because a mislabelled sample is often analytically perfect, WBIT is usually undetectable unless historical results are compared or a second sample is required.

4.3 Specimen Collection Variables

Collection technique strongly influences specimen quality. Key variables include site selection, prolonged tourniquet application (venous stasis), fist clenching, needle gauge, collection through intravenous lines, incorrect order of draw, incorrect tube type, under- or over-filling of tubes, inadequate mixing, and difficult or traumatic venepuncture. Prolonged venous stasis leads to haemoconcentration and can alter concentrations of proteins, cells, and protein-bound analytes (Lippi et al., 2005). Collection from an arm with an infusion running can dilute or contaminate the sample. Incorrect order of draw can result in carry-over of additives, such as potassium EDTA contamination causing spurious hyperkalaemia and hypocalcaemia.

Evidence-based recommendations for venous blood sampling have been published by professional bodies, including the CLSI GP41 standard (Clinical and Laboratory Standards Institute, 2017) and the joint EFLM–COLABIOCLI recommendation, which provides a detailed, step-by-step procedure intended to harmonise phlebotomy practice (Simundic et al., 2018).

4.4 Haemolysis

Haemolysis — the release of intracellular contents from red blood cells into serum or plasma — is the leading cause of unsuitable specimens in clinical laboratories (Lippi et al., 2008). In vitro haemolysis results mainly from collection and handling factors: small-gauge needles, difficult draws, collection through intravenous catheters, vigorous mixing, excessive suction, pneumatic tube transport, and delayed processing. Haemolysis falsely increases potassium, lactate dehydrogenase, aspartate aminotransferase, and other intracellular analytes, and may interfere with spectrophotometric assays and some cardiac troponin methods.

Haemolysis is particularly common in emergency departments, where samples are frequently drawn through intravenous cannulas during insertion. Lippi et al. (2011b) described haemolysed specimens as a major challenge for emergency departments and laboratories, contributing to delays, repeat sampling, and the risk of misleading results such as pseudohyperkalaemia, which can prompt inappropriate treatment or mask true abnormalities.

4.5 Transport, Processing, and Storage Variables

After collection, specimens may be affected by delays, temperature deviations, agitation, exposure to light, and evaporation. Delayed separation of serum or plasma allows continued cellular metabolism, leading to falsely low glucose and altered potassium and phosphate concentrations. Some analytes, such as ammonia, lactate, and blood gases, require rapid analysis or transport on ice. Light-sensitive analytes such as bilirubin must be protected. Inappropriate centrifugation, repeated freeze–thaw cycles, and prolonged storage before analysis can further compromise results. Microbiological specimens require prompt processing to prevent overgrowth of contaminants or loss of fastidious organisms.

4.6 Blood Culture Contamination

Blood cultures are a special case in which pre-analytical technique directly determines diagnostic accuracy for life-threatening infection. Contamination occurs when skin flora or environmental organisms are introduced during collection, producing false-positive results. Weinstein (2003) described blood culture contamination as a persisting problem with substantial clinical consequences. A classic study by Bates et al. (1991) found that contaminant blood cultures were associated with increased laboratory charges, more intravenous antibiotic use, and longer hospital stays. Practical guidance from clinical microbiology experts emphasises skin antisepsis, dedicated phlebotomy teams, avoidance of drawing from existing lines, adequate blood volume, and monitoring of contamination rates, with many institutions targeting rates below 3% and best-practice programmes achieving considerably lower rates (Doern et al., 2019). A systematic review and meta-analysis found that interventions such as dedicated phlebotomy teams, education, and the use of sterile collection kits reduced contamination (Hughes et al., 2018).

Table 2. Major pre-analytical variables, mechanisms, and analytes affected

Variable	Mechanism	Examples of affected tests	Potential clinical consequence
Non-fasting / timing	Postprandial changes; diurnal variation; dosing interval	Glucose, triglycerides, cortisol, drug levels	Misdiagnosis; incorrect dose adjustment

Variable	Mechanism	Examples of affected tests	Potential clinical consequence
Prolonged tourniquet	Haemoconcentration from venous stasis	Proteins, calcium, cholesterol, cell counts	Spurious abnormalities
Haemolysis	Release of intracellular contents; optical interference	Potassium, LDH, AST, some troponin assays	Pseudohyperkalaemia; repeat sampling; delay
Wrong order of draw / EDTA carry-over	Additive contamination	Potassium, calcium	Spurious hyperkalaemia and hypocalcaemia
Drip-arm collection	Dilution or contamination with infusate	Glucose, electrolytes	Grossly erroneous results
Misidentification / WBIT	Sample from wrong patient	Any test; blood grouping	Wrong diagnosis; incompatible transfusion
Delayed processing	Ongoing cellular metabolism	Glucose, potassium, phosphate, ammonia, lactate	Falsely low glucose; misleading values
Biotin and drug interference	Assay interference	Thyroid hormones, troponin, other immunoassays	False diagnosis (e.g., spurious hyperthyroidism)
Blood culture contamination	Introduction of skin flora	Blood cultures	Unnecessary antibiotics; longer stay

Source: Author synthesis based on Lippi et al. (2005, 2008, 2011b), Li et al. (2017), Dzik et al. (2003), and Bates et al. (1991).

5. IMPACT ON DIAGNOSTIC ACCURACY AND PATIENT OUTCOMES

5.1 Effects on Diagnostic Accuracy

Pre-analytical errors affect diagnostic accuracy in two main ways. First, they can produce *spurious results* that do not reflect the patient's true physiological state — such as falsely elevated potassium from haemolysis or EDTA contamination, falsely low glucose from delayed processing, or misleading hormone levels from biotin interference. Second, they can produce *misattributed results*, in which a correct result is assigned to the wrong patient. Both types of error may lead to false-positive or false-negative clinical conclusions. Because many such results fall within plausible ranges, clinicians may have no reason to suspect them.

5.2 Clinical Consequences

The clinical impact of pre-analytical errors ranges from minor inconvenience to serious harm. Pseudohyperkalaemia can prompt unnecessary treatment with insulin, glucose, or potassium binders, or conversely, a true hyperkalaemia may be dismissed as artefactual. Misidentification can lead to inappropriate treatment, missed diagnosis in the true patient, or fatal transfusion reactions. Contaminated blood cultures can lead to unnecessary antibiotic courses, contributing to adverse drug effects, *Clostridioides difficile* infection, and antimicrobial resistance, as well as prolonged hospital stays (Bates et al., 1991). Spurious thyroid function results caused by biotin interference have been reported to result in incorrect diagnoses of thyroid disease (Li et al., 2017).

Even when errors are detected and samples rejected, patients experience consequences: repeat venepuncture, discomfort, delays in diagnosis and treatment, and, in emergency settings, delayed disposition decisions. For critically ill patients, delays in key results such as potassium, troponin, or lactate may affect time-critical management.

5.3 Economic and Operational Consequences

Pre-analytical errors consume substantial resources through repeat collection, repeat testing, staff time, additional consumables, delayed decisions, and extended length of stay. Green (2013) reviewed the costs of poor blood specimen quality and pre-analytical errors and concluded that these costs, though difficult to quantify precisely, are significant for hospitals, including direct costs of recollection and indirect costs of delayed care and adverse events. Blood culture contamination alone generates considerable excess costs through unnecessary antibiotic therapy and additional hospital days (Bates et al., 1991; Doern et al., 2019).

Table 3. Consequences of pre-analytical errors across levels

Level	Consequences
Patient	Spurious or misattributed results, misdiagnosis, inappropriate treatment, transfusion reactions, repeat venepuncture, delayed care, adverse drug effects
Clinician	Misleading information for decision-making, loss of confidence in laboratory results, time spent on clarification and repeat requests
Laboratory	Specimen rejection, rework, delayed turnaround times, increased workload
Organisation	Longer length of stay, higher costs, adverse event investigations, accreditation risks, medico-legal exposure
Health system	Inefficient resource use, contribution to antimicrobial resistance, reduced public trust

Source: Author synthesis.

The most dangerous pre-analytical error is not the sample that is rejected, but the one that looks perfect and belongs to someone else.

6. STRATEGIES FOR PRE-ANALYTICAL QUALITY IMPROVEMENT

6.1 Standardisation of Procedures

Standardised, evidence-based procedures for patient preparation, identification, venous blood sampling, order of draw, tube filling, mixing, labelling, and transport are the foundation of pre-analytical quality. International guidance such as CLSI GP41 and the EFLM–COLABIOCLI venous blood sampling recommendation provides a basis for local standard operating procedures (Clinical and Laboratory Standards Institute, 2017; Simundic et al., 2018). Lippi et al. (2011a) argued that pre-analytical quality improvement requires harmonisation of practices, education, and continuous monitoring.

6.2 Positive Patient Identification and Technology

Positive patient identification using at least two identifiers, labelling at the bedside in the presence of the patient, and electronic systems such as barcode wristbands and point-of-collection label printing reduce labelling and identification errors (Wagar et al., 2008). For transfusion, many systems require a second, independently collected sample before issuing non-emergency group-specific blood, to detect WBIT. Delta checks — comparison of current results with a patient's previous results — can help identify misidentified samples.

6.3 Education, Training, and Competency Assessment

Because pre-analytical steps are performed by many professional groups, education and competency assessment must extend beyond the laboratory to nurses, physicians, phlebotomists, and transport staff. Regular training, competency validation, and feedback on individual and unit-level error rates have been associated with improvements. Dedicated phlebotomy teams have been shown to reduce blood culture contamination and may improve overall specimen quality (Hughes et al., 2018; Doern et al., 2019).

6.4 Collection Practices to Reduce Haemolysis

Measures to reduce haemolysis include avoiding collection through intravenous cannulas where possible, using appropriate needle sizes, limiting tourniquet time, avoiding vigorous mixing, ensuring correct tube filling, and validating pneumatic tube systems. Automated measurement of the haemolysis index on chemistry analysers allows objective, consistent detection and reporting of haemolysis (Lippi et al., 2008).

6.5 Transport and Sample Logistics

Defined transport times and conditions, temperature monitoring, appropriate packaging, and tracking systems ensure that specimens arrive in suitable condition. In health systems where laboratories are being centralised, transport logistics become increasingly important, as longer distances and multiple hand-offs create additional opportunities for delay and deterioration.

6.6 Quality Indicators and Monitoring

Systematic measurement is essential for improvement. The IFCC Working Group on Laboratory Errors and Patient Safety developed a model of quality indicators covering the total testing process, with a strong emphasis on pre-analytical indicators (Sciacovelli & Plebani, 2009). Harmonised pre-analytical indicators include rates of misidentification, inappropriate requests, haemolysed samples, clotted samples, insufficient volume, incorrect containers, improper transport, and blood culture contamination (Plebani et al., 2014). ISO 15189, the international standard for medical laboratory quality and competence, requires laboratories to manage pre-examination processes and to monitor quality indicators (International Organization for Standardization, 2022).

Table 4. Selected pre-analytical quality indicators

Indicator	Definition (example)	Purpose
Misidentification / labelling errors	Mislabelled or unlabelled samples per total samples	Patient safety; detect identification failures
Haemolysed samples	Samples with haemolysis index above threshold per total chemistry samples	Collection and handling quality
Clotted samples	Clotted samples per total anticoagulated samples	Collection and mixing technique
Insufficient volume	Samples with insufficient volume per total samples	Collection technique and tube selection
Incorrect container	Samples in wrong tube type per total samples	Knowledge of requirements
Transport deviations	Samples received outside time or temperature limits	Logistics quality
Blood culture contamination	Contaminated cultures per total blood culture sets	Collection technique; antimicrobial stewardship
Inappropriate requests	Duplicate or non-indicated tests per total requests	Test utilisation; cost control

Source: Adapted from Sciacovelli and Plebani (2009) and Plebani et al. (2014).

7. THE SAUDI ARABIAN CONTEXT

Saudi Arabia's laboratory services are undergoing significant modernisation as part of the Health Sector Transformation Program. Several features of the national context are relevant to pre-analytical quality.

Laboratory consolidation within health clusters. The reorganisation of services into health clusters creates opportunities for centralised, highly automated laboratories serving multiple facilities. Centralisation can improve analytical quality and efficiency but increases the importance of standardised collection practices across sites and robust transport logistics, particularly given long distances and high ambient temperatures in many regions.

Workforce diversity. Specimen collection in Saudi hospitals is performed by nurses, phlebotomists, and other staff trained in many different countries and educational systems. Variation in training background makes harmonised procedures, competency validation, and continuing education especially important. Professional development requirements administered by the Saudi Commission for Health Specialties (SCFHS) provide a mechanism for embedding pre-analytical competencies.

Accreditation and standards. CBAHI laboratory standards and the growing number of Saudi laboratories pursuing ISO 15189 and other international accreditations encourage systematic attention to pre-examination processes, including patient identification, specimen acceptance criteria, and quality indicators. Embedding harmonised pre-analytical indicators in national benchmarking could support comparison and improvement across institutions.

Digital transformation. Expansion of electronic health records, laboratory information systems, and electronic ordering supports positive patient identification, barcode labelling, specimen tracking, and decision support to reduce inappropriate requests. Integration of medication and supplement information with laboratory systems could help flag potential interferences such as biotin.

Climate and environmental conditions. High temperatures during much of the year make temperature-controlled transport especially important for temperature-sensitive analytes, particularly for samples collected in primary care centres and transported to central laboratories.

8. THE PRECISE FRAMEWORK FOR PRE-ANALYTICAL QUALITY MANAGEMENT

Drawing on the evidence reviewed, this paper proposes the **PRECISE framework**, an integrative model for reducing pre-analytical errors and their impact on diagnostic accuracy and patient outcomes. The framework follows the sequence of the pre-analytical pathway while recognising that improvement depends on shared ownership between laboratory and clinical teams. Mapping onto Donabedian's model, standardisation, training, and infrastructure represent structure; collection, identification, transport, and screening represent process; and evaluation through quality indicators links outcomes back to structure and process.

Table 5. The PRECISE framework: components, actions, and indicators

Component	Description	Key actions	Example indicators
P — Patient preparation and test appropriateness	Right test, right patient preparation, right timing	Order sets and decision support, fasting and timing instructions, drug-level timing protocols, supplement history	Inappropriate request rate; non-fasting samples
R — Reliable identification and labelling	Every sample belongs to the right patient	Two-identifier policy, bedside labelling, barcode wristbands, second sample for transfusion, delta checks	Misidentification rate; WBIT events
E — Evidence-based collection technique	Collection according to standards	CLSI/EFLM-based procedures, tourniquet time limits, order of draw, avoiding drip arms and cannula draws	Haemolysis, clotting, and insufficient volume rates

Component	Description	Key actions	Example indicators
C — Controlled transport and storage	Specimens arrive in suitable condition	Defined transport times and temperatures, tracking, validated pneumatic systems, timely processing	Transport deviations; turnaround time
I — Interference and integrity screening	Detecting compromised specimens before release	Automated serum indices, specimen acceptance criteria, interference flags, delta checks	Detected haemolysis and lipaemia; rejected samples
S — Standardisation and training	Shared competence across professions	Interprofessional education, competency validation, dedicated phlebotomy teams, CPD	Training coverage; competency pass rates
E — Evaluation through quality indicators	Measurement, feedback, and improvement	Harmonised indicators, unit-level feedback, benchmarking, root cause analysis	Trends in indicators; improvement actions completed

Note: PRECISE is a conceptual framework proposed in this paper and requires empirical validation.

8.1 Applying the Framework

Implementation should begin with the establishment of a pre-analytical quality committee that includes laboratory professionals, nursing leaders, physicians, phlebotomy staff, information technology specialists, and quality managers. A baseline assessment using harmonised quality indicators should identify priority problems — for example, high haemolysis rates in the emergency department or high blood culture contamination in particular units. Targeted interventions should then be introduced, such as dedicated phlebotomy teams, bedside barcode labelling, or revised cannula sampling practices, with regular feedback of unit-level data to frontline staff. Over time, indicators should be benchmarked across facilities within each health cluster, and successful practices spread system-wide.

9. DISCUSSION

The evidence reviewed in this paper supports four main conclusions. First, the pre-analytical phase is consistently the largest source of laboratory errors, accounting for roughly two-thirds of errors in many studies. Second, pre-analytical errors directly compromise diagnostic accuracy by producing spurious or misattributed results, some of which are undetectable within the laboratory. Third, these errors have meaningful consequences for patients, including misdiagnosis, inappropriate treatment, transfusion reactions, unnecessary antibiotic use, and delays in care, as well as substantial operational and economic costs. Fourth, many pre-analytical errors are preventable through standardisation, technology, training, and monitoring.

A central implication is that pre-analytical quality cannot be achieved by laboratories alone. The majority of pre-analytical steps are performed by clinical staff in wards, emergency departments, and outpatient clinics. Effective improvement therefore requires interprofessional collaboration, shared accountability, and integration of laboratory quality into broader patient safety programmes. In Reason's (2000) terms, individual collection errors are active failures, but their frequency is determined by latent conditions such as training gaps, workload, equipment, and procedures.

For Saudi Arabia, the modernisation and consolidation of laboratory services, expansion of digital systems, and emphasis on accreditation create a favourable environment for systematic pre-analytical improvement. At the same time, centralisation, workforce diversity, and climate conditions introduce specific risks that require deliberate management.

9.1 Implications for Practice and Policy

- Adopt harmonised, evidence-based procedures for venous blood sampling based on CLSI and EFLM guidance.
- Implement positive patient identification with barcode technology and bedside labelling across all collection sites.

- Establish interprofessional pre-analytical quality committees and include pre-analytical indicators in patient safety reporting.
- Deploy dedicated phlebotomy teams in high-risk areas such as emergency departments and for blood culture collection.
- Monitor and feed back unit-level rates of haemolysis, misidentification, and blood culture contamination.
- Integrate pre-analytical competencies into SCFHS continuing professional development and orientation for new staff.
- Strengthen temperature-controlled transport and tracking as laboratory services are centralised within health clusters.

9.2 Implications for Research

Research priorities include multi-centre studies measuring the frequency and types of pre-analytical errors in Saudi hospitals using harmonised indicators; studies linking pre-analytical errors to patient outcomes such as length of stay, antibiotic use, and adverse events; evaluation of interventions such as dedicated phlebotomy teams and electronic identification systems; and studies of transport conditions and specimen stability in centralised laboratory networks.

9.3 Limitations

As a narrative review, this paper did not follow a systematic search protocol or formal quality appraisal. Reported error frequencies vary widely across studies due to differences in definitions and detection methods. Much of the evidence originates from European and North American laboratories, and published Saudi data on pre-analytical errors remain limited. Direct evidence linking pre-analytical errors to patient outcomes is less abundant than evidence on error frequency. The PRECISE framework is conceptual and requires empirical evaluation.

10. Conclusion

Laboratory results are only as reliable as the specimens on which they are based. The pre-analytical phase — encompassing test requesting, patient preparation, identification, collection, labelling, transport, and processing — is the most error-prone stage of the total testing process and a major, modifiable determinant of diagnostic accuracy and patient safety. Pre-analytical errors can generate spurious or misattributed results, lead to misdiagnosis and inappropriate treatment, delay care, and impose significant costs on health systems.

The PRECISE framework — Patient preparation and test appropriateness, Reliable identification and labelling, Evidence-based collection technique, Controlled transport and storage, Interference and integrity screening, Standardisation and training, and Evaluation through quality indicators — offers a structured, interprofessional approach to pre-analytical quality management. For Saudi Arabia, as laboratory services are modernised under Vision 2030, investing in pre-analytical quality represents one of the most effective ways to ensure that laboratory medicine fulfils its essential role in accurate diagnosis and safe, effective patient care.

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