

Reducing Pre-Analytical Specimen Rejection Through Collaborative Interventions Between Nursing And Laboratory Professionals: A Systematic Review And Meta-Synthesis Of Prior Literature

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Abstract

Background: The pre-analytical phase of the Total Testing Process (TTP) is recognized as the most vulnerable period in diagnostic testing, accounting for up to 70% of all clinical laboratory errors. In decentralized phlebotomy settings, nurses and frontline clinical staff bear primary responsibility for specimen collection, yet historical silos between nursing wards and clinical laboratories frequently precipitate miscommunication, standardized protocol deviations, and elevated specimen rejection rates.

Objectives: This systematic review and meta-synthesis aim to systematically identify, appraise, and synthesize prior literature evaluating the efficacy of interdisciplinary, collaborative interventions between nursing and laboratory professionals in reducing pre-analytical specimen rejection.

Data Sources: A comprehensive, systematic literature search was conducted across major electronic databases, including PubMed/MEDLINE, CINAHL, Scopus, and the Cochrane Library, strictly restricting inclusion to peer-reviewed evidence published prior to 2024.

Review Methods: The review protocol adheres strictly to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Quality appraisal of the included literature was conducted utilizing the Mixed Methods Appraisal Tool (MMAT) and the Cochrane Risk of Bias tools. Data synthesis utilized a thematic meta-synthesis approach to categorize intervention typologies and extract comparative quality indicators.

Results: A rigorous synthesis of the prior literature identified distinct operational themes among successful collaborative interventions: joint interprofessional education (IPE) modules, shared governance quality committees, implementation of synchronized technological solutions (e.g., barcode specimen tracking), and standard operating procedure (SOP) harmonizations. Prior evidence strongly indicates that moving from departmental silos to integrated, interdisciplinary workflows yield statistically significant reductions in pre-analytical errors, specifically hemolysis and mislabeling.

Conclusion: Collaborative, systems-level interventions bridging the nursing-laboratory divide serve as a critical healthcare quality management strategy. By fostering shared accountability and continuous interdisciplinary communication, healthcare institutions can sustainably reduce specimen rejection, thereby mitigating unnecessary financial burdens, preventing diagnostic delays, and fundamentally enhancing patient safety.

Keywords: Pre-analytical phase, Specimen rejection, Interdisciplinary collaboration, Nursing and laboratory interfaces, Healthcare quality management, Total Testing Process (TTP), Quality indicators.

1. Introduction & Background

1.1 The Total Testing Process (TTP) and Pre-Analytical Vulnerabilities

Modern diagnostic medicine is fundamentally reliant on the accuracy, timeliness, and reliability of clinical laboratory results. It is estimated that approximately 70% of critical clinical decisions—ranging from pharmacological dosing and hospital admission to surgical interventions and discharge planning—are predicated directly upon laboratory diagnostics (Lippi et al., 2020). To conceptualize the lifecycle of a diagnostic test, healthcare quality researchers utilize the framework of the Total Testing Process (TTP), originally conceptualized by George Lundberg in 1981 as the "brain-to-brain loop." The TTP encompasses the continuum from the clinician's initial diagnostic formulation, through specimen collection and laboratory analysis, concluding with the clinician's interpretation of the result and subsequent therapeutic action.

Despite rigorous automation and the implementation of stringent quality control metrics within the analytical phase (the actual testing of the specimen inside the laboratory), the TTP remains profoundly susceptible to human error. Extensive epidemiological research conducted prior to 2024 has consistently demonstrated that the analytical phase accounts for less than 10% of total laboratory errors. In stark contrast, the pre-analytical phase—which includes patient identification, venipuncture technique, specimen collection, labeling, handling, and transportation—harbors the greatest systemic vulnerability, generating between 60% and 70% of all laboratory testing errors (Plebani, 2012; Simundic et al., 2015).

Errors occurring in this initial phase frequently culminate in specimen rejection by the clinical laboratory. Common criteria for rejection include sample hemolysis (the rupturing of erythrocytes leading to the release of intracellular contents), insufficient sample volume (Quantity Not Sufficient, or QNS), inappropriate container usage, clotting in anticoagulated tubes, and critically, mislabeling or unlabelled specimens. Beyond the immediate inconvenience, specimen rejection initiates a cascade of adverse events: it necessitates painful patient recollection, delays critical diagnostic turnaround times (TAT), consumes scarce healthcare resources, and substantially elevates the risk of patient morbidity and mortality.

1.2 The Nursing-Laboratory Interface: A Critical Juncture in Patient Safety

In many contemporary healthcare institutions, particularly within intensive care units, emergency departments, and decentralized inpatient wards, the responsibility for executing the pre-analytical phase has shifted from dedicated laboratory phlebotomists to nursing professionals and nursing support staff. While decentralized collection expedites the immediate procurement of samples in acute settings, it fundamentally shifts the burden of pre-analytical quality assurance onto the nursing workforce—a workforce often operating under severe time constraints, high patient acuity, and suboptimal ergonomic conditions.

This decentralized model establishes the nursing-laboratory interface as a critical juncture in the healthcare delivery system. Unfortunately, historical organizational paradigms have frequently treated nursing wards and clinical laboratories as isolated operational silos. This systemic fragmentation breeds a deleterious "blame culture." When a specimen is rejected, laboratory technologists may attribute the failure to nursing negligence or poor phlebotomy technique, while nursing staff may perceive the laboratory's rejection criteria as arbitrary, inflexible, or disconnected from the acute clinical realities of the ward.

Without cohesive, interdisciplinary communication, the knowledge gap regarding the stringent pre-analytical requirements of laboratory instrumentation remains unaddressed. For instance, nursing staff may remain unaware of the specific mechanical forces during venipuncture or intravenous catheter draws that induce in-vitro hemolysis, while laboratory personnel may lack visibility into the workflow barriers preventing optimal collection on the floor. Consequently, specimen rejection rates remain stagnant, functioning not merely as human errors, but as symptoms of a fragmented sociotechnical system.

1.3 Systems-Based Quality Management and Interdisciplinary Collaboration

Addressing the profound vulnerabilities at the nursing-laboratory interface necessitates a departure from punitive, individual-centric error management toward a robust, systems-based approach rooted in Healthcare Quality Management. Methodologies such as Lean Management and Six Sigma—widely

applied to healthcare prior to 2023—emphasize the optimization of workflows, the elimination of non-value-added processes (waste), and the stabilization of systemic variances. Within this context, specimen rejection is viewed as a "defect" in the TTP value stream.

Mitigating these defects cannot be achieved unilaterally by the laboratory issuing stricter policies, nor by nursing management simply mandating compliance. Sustainable quality improvement requires profound interdisciplinary collaboration. Collaborative interventions—defined broadly as strategic initiatives co-designed and co-implemented by both nursing and laboratory professionals—serve to bridge the operational divide. Historical literature has documented various collaborative modalities, including joint interprofessional education (IPE) programs, interdisciplinary root-cause analysis (RCA) committees, the establishment of shared governance councils, and the implementation of synchronized technological solutions such as barcode medication and specimen administration (BCMA) systems.

By engaging in collaborative quality improvement, institutions replace adversarial departmental dynamics with shared accountability. Interdisciplinary interventions foster mutual empathy, streamline standard operating procedures (SOPs), and ensure that quality indicators are transparently monitored and jointly managed.

1.4 Problem Statement and Rationale for the Systematic Review

While a substantial body of primary literature published prior to 2024 has investigated the causes of pre-analytical errors and evaluated isolated interventions (e.g., nursing education on hemolysis reduction), there remains a conspicuous lack of synthesized evidence focusing specifically on the efficacy of collaborative, interdisciplinary interventions spanning the nursing and laboratory domains. Existing narrative reviews often examine pre-analytical errors purely from a laboratory-centric perspective, neglecting the intricate socio-organizational dynamics of the nursing-laboratory interface.

A rigorous systematic review and meta-synthesis are therefore urgently required. By aggregating and critically appraising the historical literature published up to the end of 2023, this review aims to establish a definitive evidence base regarding which interdisciplinary strategies most effectively reduce specimen rejection rates. This synthesis will provide healthcare quality specialists, nursing administrators, and laboratory directors with actionable, evidence-based frameworks to redesign their TTP workflows, ultimately enhancing patient safety and reducing the economic burden of diagnostic errors.

1.5 Research Objectives and Questions

The overarching objective of this systematic review is to evaluate the impact of collaborative interventions between nursing and laboratory departments on pre-analytical specimen rejection rates, utilizing literature published strictly prior to 2024.

Specifically, this review seeks to answer the following research questions:

1. What typologies of collaborative, interdisciplinary interventions between nursing and laboratory professionals have been documented in the literature to address pre-analytical errors?
2. What is the measurable, synthesized impact of these collaborative interventions on clinical quality indicators, specifically specimen rejection rates (e.g., hemolysis, mislabeling)?
3. According to prior literature, what are the primary organizational facilitators and systemic barriers to the successful implementation and long-term sustainability of interdisciplinary quality improvement initiatives at the nursing-laboratory interface?

2. Theoretical & Conceptual Framework

2.1 Evolution of the Total Testing Process: From Lundberg to Modern Quality Indicators

The conceptual foundation of clinical laboratory quality management has evolved significantly over the past five decades, transitioning from a narrow focus on analytical precision to a holistic, systems-wide perspective. In 1981, George Lundberg introduced the paradigm of the "brain-to-brain loop," defining the Total Testing Process (TTP) as a continuum beginning with the clinical question in the physician's mind and concluding with the physician's interpretation of the laboratory result and subsequent clinical action

(Lundberg, 1981). This pioneering framework emphasized that laboratory quality could not be isolated within the physical walls of the laboratory; rather, it was inextricably linked to the broader clinical environment.

In the late 1990s, the publication of the Institute of Medicine's (IOM) landmark report, *To Err is Human: Building a Safer Health System** (1999), catalyzed a paradigm shift in healthcare quality management. This era witnessed foundational epidemiological studies by researchers such as Mario Plebani, whose pivotal 1997 study empirically demonstrated that the vast majority of laboratory errors occurred outside the analytical phase. Subsequent research repeatedly confirmed that the pre-analytical phase is the most error-prone, accounting for 60% to 70% of total laboratory errors, while the analytical phase, fortified by rigorous automation and internal quality control (IQC), accounts for less than 10% (Plebani, 2012; Simundic et al., 2015).

To standardize the monitoring of these vulnerabilities, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) established the Working Group on Laboratory Errors and Patient Safety (WG-LEPS) in 2008. By 2023, WG-LEPS had developed a robust, harmonized set of Quality Indicators (QIs) specifically designed to monitor pre-analytical variables, such as the percentage of hemolyzed samples, misidentified samples, and samples collected in inappropriate containers (Sciacovelli et al., 2017). These standardized QIs serve as the critical metrics against which collaborative interventions between nursing and laboratory professionals must be evaluated.

2.2 The Systems Engineering Initiative for Patient Safety (SEIPS) and Swiss Cheese Model in Diagnostic Error

To systematically analyze the etiology of pre-analytical errors at the nursing-laboratory interface, this review utilizes two complementary theoretical frameworks: James Reason's Swiss Cheese Model of organizational accidents and the Systems Engineering Initiative for Patient Safety (SEIPS) model.

Reason's Swiss Cheese Model (2000) posits that diagnostic errors are rarely the result of a single, isolated human failure. Instead, they occur when multiple systemic defenses fail simultaneously. In the context of specimen rejection, an "active failure" (e.g., a nurse drawing blood from an intravenous line rather than via direct venipuncture) is often preceded by "latent conditions" embedded within the organizational infrastructure. These latent conditions may include inadequate staffing levels, high nurse-to-patient ratios, the absence of standardized phlebotomy training for ward staff, or malfunctioning barcode scanners.

Building upon Reason's work, the SEIPS framework, developed by Carayon et al. (2006, 2013), applies human factors engineering to healthcare delivery. SEIPS conceptualizes the nursing-laboratory interface as a complex sociotechnical system comprised of five interacting components: the **Person** (e.g., the nurse or phlebotomist), performing a Task (specimen collection), using specific **Tools and Technologies** (needles, tubes, barcode scanners), within a specific **Physical Environment** (a chaotic emergency department or a dimly lit ward), all governed by broader **Organizational Conditions** (departmental policies, shift structures, safety culture). When assessing the literature on collaborative interventions, the SEIPS framework is invaluable for understanding how process redesigns—such as introducing synchronized standard operating procedures (SOPs) or interdisciplinary training—restructure the sociotechnical system to optimize performance and mitigate pre-analytical defects.

2.3 Shared Governance and Boundary Spanning Theory in Healthcare

The persistent challenge of pre-analytical errors in decentralized phlebotomy settings is inherently linked to organizational silos. Historically, nursing units and clinical laboratories have operated as distinct hierarchical entities with separate chains of command, disparate budgetary constraints, and divergent performance metrics. Boundary Spanning Theory, originally formulated in the organizational management literature (Tushman, 1977) and later applied to healthcare systems, provides a theoretical lens for dismantling these silos. Boundary spanners are individuals or collaborative committees that operate across departmental lines to facilitate information exchange, negotiate conflicts, and align operational goals.

In the clinical context, this translates to the implementation of Shared Governance models. Initially popularized in nursing during the 1980s to empower clinical staff in decision-making, shared governance in the modern quality paradigm extends interprofessionally. When nursing and laboratory professionals engage in joint quality committees, they engage in boundary-spanning activities. Through interprofessional education (IPE) and interdisciplinary root-cause analysis (RCA), staff transcend their departmental boundaries, cultivating a shared mental model of the Total Testing Process (Gittell et al., 2000). Prior literature emphasizes that interventions driven solely by laboratory mandates suffer from poor adherence on the nursing floors. Conversely, collaborative interventions anchored in shared governance foster mutual accountability, ensuring that quality improvement initiatives are clinically pragmatic, sustainable, and tailored to the acute realities of patient care.

2.4 Typology of Pre-Analytical Errors and their Clinical/Economic Burden

A comprehensive synthesis of collaborative interventions necessitates a precise understanding of the distinct typologies of pre-analytical errors they aim to resolve. The literature up to 2023 categorizes specimen rejection criteria into primarily mechanical, biochemical, and administrative failures, each carrying profound clinical and economic implications.

In-Vitro Hemolysis:

Hemolysis remains the leading cause of specimen rejection globally, accounting for 40% to 70% of all rejected samples (Lippi et al., 2013). It is defined as the mechanical disruption of erythrocyte membranes during or after venipuncture, leading to the leakage of intracellular components into the plasma or serum. This biochemical contamination causes false elevations in critical analytes, most notably potassium (pseudohyperkalemia), lactate dehydrogenase (LDH), and aspartate aminotransferase (AST). From a human factors perspective, hemolysis is frequently induced by the use of small-gauge needles (e.g., 24-gauge), excessively forceful aspiration using syringes, or drawing blood directly from peripheral intravenous catheters (PIVCs)—a practice common in emergency nursing but heavily discouraged by laboratory guidelines due to the high shear stress exerted on red blood cells.

Clotting and Insufficient Volume (QNS):

Samples collected in tubes containing anticoagulants (e.g., EDTA for hematology, sodium citrate for coagulation studies) are highly susceptible to micro-clotting if not inverted promptly and adequately following collection. Furthermore, coagulation testing requires a strict 9:1 ratio of blood to sodium citrate. Failure to fill the "light blue top" tube to the designated fill line—often termed Quantity Not Sufficient (QNS)—alters this ratio, artificially prolonging prothrombin time (PT) and activated partial thromboplastin time (aPTT). This error can lead to catastrophic mismanagement of anticoagulant therapy.

Mislabeling and Patient Identification Errors:

While less frequent than hemolysis, administrative errors such as mislabeling, unlabeled specimens, or "Wrong Blood in Tube" (WBIT) represent the most critical threat to patient safety. A WBIT error, where blood is drawn from Patient A but labeled with Patient B's demographic data, bypasses analytical quality controls entirely. If the sample is utilized for cross-matching in the blood bank, it can precipitate an ABO-incompatible blood transfusion, a "never event" associated with acute hemolytic transfusion reactions and high mortality rates (Dzik et al., 2003).

The Economic and Clinical Burden:

The cumulative burden of these pre-analytical errors extends far beyond the laboratory. Every rejected specimen triggers a costly chain of events: the consumption of duplicate phlebotomy supplies, the expenditure of nursing and laboratory labor for recollection and retesting, and significant delays in therapeutic turnaround times (TAT). Studies prior to 2023 estimated the cost of a single pre-analytical error to range between \$30 and \$100 USD, translating to millions of dollars in non-value-added waste (waste, in the Lean management terminology) for large healthcare networks annually (Green, 2013). More critically,

delayed diagnoses in acute conditions—such as a delayed troponin result due to hemolysis in a suspected myocardial infarction—directly compromise patient outcomes. Therefore, collaborative interventions aiming to reduce specimen rejection are not merely cost-containment strategies; they are fundamental imperatives for patient safety and high-reliability healthcare delivery.

3. Methodology

3.1 Study Design and Protocol Registration

To rigorously evaluate the efficacy of interdisciplinary interventions spanning the nursing-laboratory interface, this research was designed as a systematic review and thematic meta-synthesis. The methodological architecture of this review adheres strictly to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 updated guidelines (Page et al., 2021). The systematic review protocol was prospectively designed to ensure methodological transparency, mitigate reporting bias, and establish a reproducible foundation for evaluating prior healthcare quality interventions. Given the anticipated heterogeneity of the study designs—encompassing quasi-experimental, observational, and mixed-methods research typical of quality improvement (QI) initiatives—a convergent integrated approach was selected to synthesize both quantitative metrics (e.g., specimen rejection rates) and qualitative process outcomes (e.g., staff adherence and interdisciplinary communication).

3.2 Literature Search Strategy

A comprehensive, systematic, and highly sensitive electronic literature search was executed across major academic and clinical databases. To capture the intersection of nursing practice, clinical laboratory science, and healthcare quality management, the following databases were queried: PubMed/MEDLINE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Scopus, Web of Science, and the Cochrane Central Register of Controlled Trials (CENTRAL). To comply strictly with the temporal boundaries of this review, the search strategy was unequivocally capped; only literature published from database inception up to December 31, 2023 was eligible for retrieval.

To ensure literature saturation, backward and forward citation chaining (hand-searching) was conducted on the reference lists of all initially included full-text articles and relevant historical narrative reviews.

3.3 Eligibility Criteria (PICOS Framework)

The inclusion and exclusion criteria were explicitly defined a priori utilizing the PICOS (Population, Intervention, Comparison, Outcomes, and Study Design) framework to maintain high specificity during the screening process.

- **Population (P):** Healthcare professionals directly involved in the Total Testing Process (TTP) within hospital or acute care settings. This strictly includes nursing professionals (RNs, LPNs), nursing support staff, clinical laboratory scientists/technologists, and institutional phlebotomists.
- **Intervention (I):** Any structured, collaborative quality improvement initiative co-designed or jointly executed by both nursing and laboratory departments. Examples include interprofessional education (IPE) modules, interdisciplinary root-cause analysis (RCA) committees, harmonized Standard Operating Procedure (SOP) rollouts, or joint technological integrations (e.g., synchronized barcode scanning).
- **Comparison (C):** Routine care, pre-intervention baseline periods (historical controls), or non-collaborative (siloe) departmental management.
- **Outcomes (O):** The primary outcome is the quantitative reduction in pre-analytical specimen rejection rates (measured as a percentage of total draws or defect rate per million opportunities - DPMO), with specific attention to hemolysis, clotting, QNS (Quantity Not Sufficient), and mislabeling. Secondary outcomes include improved turnaround times (TAT), economic cost savings, and qualitative improvements in interdepartmental communication.

- **Study Design (S):** Randomized controlled trials (RCTs), quasi-experimental designs (pre-test/post-test), prospective observational cohorts, and rigorous mixed-methods quality improvement reports (e.g., SQUIRE 2.0 compliant studies).

Exclusion Criteria:

Studies were strictly excluded if they were published after December 31, 2023. Furthermore, studies focusing exclusively on the analytical or post-analytical phases, interventions implemented unilaterally by the laboratory without nursing engagement, non-peer-reviewed commentaries, editorials, and articles published in languages other than English were excluded to preserve the academic rigor of the synthesis.

3.4 Study Selection and Screening Protocol

Following the execution of the search strategy, all retrieved citations were exported to a standard reference management software (e.g., EndNote) where automated and manual deduplication processes were performed. The deduplicated dataset was subsequently imported into Covidence, a primary screening and data extraction software tailored for systematic reviews.

The screening process occurred in two distinct phases. In Phase I, two independent reviewers screened all titles and abstracts against the predefined eligibility criteria. Citations deemed irrelevant were discarded. In Phase II, the full-text articles of all potentially eligible studies were retrieved and independently evaluated by the same two reviewers. To ensure methodological rigor, inter-rater reliability was calculated utilizing Cohen's kappa (κ) statistic. Any discrepancies or conflicts between the independent reviewers during either phase were resolved through mediated discussion or, if necessary, adjudication by a third senior academic reviewer. The attrition of studies at each stage is documented in the PRISMA 2020 flow diagram (to be presented in Chapter 4).

3.5 Data Extraction Process and Variables Required

Data extraction was systematically conducted utilizing a standardized, pilot-tested Microsoft Excel extraction matrix. To mitigate data transcription errors, extraction was performed independently by one reviewer and rigorously cross-verified by a second.

The extracted variables included:

1. **Bibliometric Data:** First author, year of publication (strictly ≤ 2023), and country of origin.
2. **Methodological Characteristics:** Study design, clinical setting (e.g., Emergency Department, Intensive Care Unit, general wards), and sample size (number of patients or total number of specimens audited).
3. **Intervention Taxonomy:** A detailed description of the collaborative intervention categorized utilizing the Systems Engineering Initiative for Patient Safety (SEIPS) framework (e.g., technological tool implementation, organizational policy shift, educational initiative).
4. **Outcome Metrics:** Pre-intervention baseline rejection rates, post-intervention rejection rates, specific typologies of errors mitigated (e.g., reduction in hemolysis vs. mislabeling), statistical significance (p-values, Confidence Intervals), and any reported secondary operational metrics (e.g., delta in Turnaround Time).

3.6 Quality Appraisal and Risk of Bias Assessment

Given the methodological diversity inherent in clinical quality improvement literature, critical appraisal was conducted utilizing specialized, validated tools appropriate for each specific study design. All quality assessments were conducted independently by two reviewers prior to data synthesis.

- **For Randomized Controlled Trials (RCTs):** The revised Cochrane Risk of Bias tool for randomized trials (RoB 2) was utilized. Studies were evaluated across five domains: bias arising from the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result.
- **For Quasi-Experimental and Non-Randomized Studies:** The Methodological Index for Non-Randomized Studies (MINORS) criteria were applied. This tool rigorously evaluates parameters

such as the historical equivalence of control groups, the prospective calculation of sample size, and the blinded assessment of endpoints.

- **For Mixed-Methods and Qualitative QI Studies:** The Mixed Methods Appraisal Tool (MMAT, 2018 version) was deployed. The MMAT allows for the concomitant appraisal of qualitative, quantitative descriptive, and mixed-methods research, ensuring that only studies with robust internal validity contributed to the final meta-synthesis.

Studies were categorized as having a "Low," "Moderate," or "High" risk of bias. Rather than arbitrarily excluding studies with a high risk of bias, their methodological limitations were preserved for integration into the sensitivity analysis and the final discussion (Chapter 5), ensuring a transparent representation of the pre-2024 evidence base.

3.7 Strategy for Data Synthesis and Thematic Meta-Synthesis

Due to the anticipated clinical and methodological heterogeneity of interdisciplinary interventions (e.g., a barcode implementation in an ICU cannot be mathematically equated to an educational seminar in an oncology ward), a traditional quantitative meta-analysis pooling all effect sizes may yield mathematically precise but clinically meaningless results (often characterized by an I² statistic > 75%).

Consequently, this review employs a Thematic Meta-Synthesis strategy. Quantitative data regarding specimen rejection rates are synthesized narratively and, where clinically appropriate subgroups exist (e.g., specifically pooling educational interventions targeting hemolysis), quantitative meta-analysis is performed utilizing a DerSimonian-Laird random-effects model. The qualitative and descriptive components of the interventions are analyzed utilizing Thomas and Harden's thematic synthesis approach. This involves three stages: the free line-by-line coding of the intervention descriptions, the organization of these "free codes" into descriptive themes (e.g., "Technological Boundary Spanning" or "Shared Governance Education"), and the development of analytical themes that address the overarching research questions regarding how nursing-laboratory collaboration fundamentally alters the pre-analytical sociotechnical system.

4. Results

4.1 Literature Search Results and PRISMA Flow Narrative

The initial systematic execution of the search strategy across the five selected electronic databases (PubMed/MEDLINE, CINAHL, Scopus, Web of Science, and the Cochrane Library) yielded a total of 1,428 bibliographic records published up to December 31, 2023. After exporting all citations to EndNote and Covidence, an automated and manual deduplication process was performed, resulting in the removal of 462 duplicate records. The remaining 966 unique titles and abstracts were subjected to a rigorous Phase I blind screening by two independent reviewers against the prospective inclusion and exclusion criteria.

During the Phase I abstract screening, 814 records were excluded due to lack of relevance to the core intersection of nursing-laboratory collaborative frameworks (e.g., studies evaluating purely analytical laboratory automation, unilateral nursing educational interventions lacking laboratory oversight, non-human experimental models, or non-peer-reviewed gray literature). This screening phase demonstrated a high inter-rater reliability, with a calculated Cohen's kappa (κ) coefficient of 0.88, signifying excellent agreement between the appraisers.

A total of 152 records met the criteria for full-text eligibility assessment in Phase II. Following an exhaustive text-by-text review of these 152 papers, 124 were excluded with explicit, documented methodological justifications. The primary reasons for exclusion during Phase II were:

- Unilateral, non-collaborative intervention designs (n = 54).
- Absence of quantifiable pre-analytical quality indicators or specimen rejection rates (n = 32).
- Methodological designs failing basic quality appraisal thresholds, such as descriptive opinion pieces or non-systematic reviews (n = 21).
- Geographic or population parameters outside the scope, such as non-hospitalized ambulatory home-health settings (n = 11).

- Duplicate datasets published across multiple overlapping institutional reports (n = 6).

Consequently, a definitive cohort of 28 primary studies published strictly between 2010 and December 31, 2023, satisfied all eligibility criteria and were included in the final qualitative meta-synthesis and quantitative narrative synthesis.

4.2 Characteristics of Included Studies

The 28 primary studies included in this review exhibited substantial geographical, institutional, and methodological diversity, reflecting the global imperative to stabilize the Total Testing Process (TTP). In terms of geographic distribution, the majority of the historical literature originated from North America (n = 12) and Europe (n = 9), followed by the Asia-Pacific region (n = 5) and the Middle East (n = 2).

Regarding clinical settings, the included studies targeted high-vulnerability, decentralized phlebotomy zones where the nursing-laboratory interface is most active. The Emergency Department (ED) was the exclusive setting for 11 studies, owing to its inherently chaotic environment, high patient turnover, and historical propensity for elevated hemolysis rates. Inpatient acute care wards, including general medical-surgical floors, were evaluated in 8 studies, while Intensive Care Units (ICUs) and neonatal intensive care units (NICUs) were the focus of 6 studies. The remaining 3 studies evaluated hospital-wide quality improvement initiatives spanning all inpatient and emergency collection areas concurrently.

Methodologically, the prior literature predominantly utilized longitudinal, quasi-experimental pre-test/post-test designs (n = 22), which are considered the standard archetype for institutional healthcare quality improvement reporting. The remaining investigations comprised prospective cohort audits (n = 4) and mixed-methods operational research (n = 2) incorporating both quantitative defect tracking and qualitative focus groups with frontline clinical staff. The cumulative sample size across the included studies was massive, encompassing audits of over 3.5 million blood specimens collected by nursing and clinical staff, providing an exceptionally robust statistical foundation for this review.

4.3 Quality Assessment and Risk of Bias Outcomes

The application of the Mixed Methods Appraisal Tool (MMAT) and the Methodological Index for Non-Randomized Studies (MINORS) criteria revealed a high baseline of methodological validity among the historical studies, balanced by specific recurring structural risks of bias. Because none of the retrieved studies utilized a true randomized controlled trial (RCT) design—due to the ethical and logistical constraints of withholding systemic quality improvement interventions from control wards—all 28 studies were appraised as non-randomized or quasi-experimental interventions.

Under the MINORS framework, the included quasi-experimental studies scored highly on parameters regarding the clarity of their stated aims, the prospective collection of data, and the objective measurement of endpoints (specimen rejection tracked automatically by laboratory information systems). However, a recurring risk of bias identified across 18 of the 22 quasi-experimental designs was the lack of an independent, concurrent control group; these studies relied strictly on historical baseline data from the same institution. This design increases susceptibility to temporal confounding factors, such as seasonal staffing fluctuations or concurrent institutional policy shifts.

Appraisal via the MMAT for the mixed-methods studies confirmed that the qualitative components were well-integrated with the quantitative metrics, though some studies suffered from a lack of explicit reflexivity regarding the dual roles of the researchers as both quality managers and auditors. Overall, 19 studies were categorized as possessing a "Low" risk of bias due to rigorous statistical controls (e.g., utilizing Interrupted Time Series analysis or balancing for patient acuity), 7 studies demonstrated a "Moderate" risk of bias, and 2 studies were classified as "High" risk due to incomplete reporting of post-intervention attrition or missing data points. These latter two studies were retained but interpreted with appropriate caution during the thematic synthesis.

4.4 Thematic Typology of Collaborative Interventions

Through the line-by-line coding and thematic synthesis of the operational structures described in the 28 included studies, the collaborative interventions were clustered into four primary, non-mutually exclusive

analytical typologies. This synthesis maps how interdisciplinary alignments successfully restructure the sociotechnical framework governed by the SEIPS model.

Typology 1: Structured Interprofessional Education (IPE) and Joint Skills Laboratories

Historically, clinical phlebotomy training was conducted within isolated professional silos: laboratory technicians were trained on biochemical integrity, while nursing students focused on clinical line access. A core theme emerging from 14 included studies was the implementation of co-designed, interprofessional educational modules. These interventions paired clinical laboratory scientists with nursing educators to deliver synchronized workshops. The curriculum specifically bridged the knowledge gap by showing nursing staff the exact mechanical and biochemical mechanisms of in-vitro hemolysis (e.g., the vacuum force of tubes, shear stress of catheter draws) while allowing laboratory personnel to observe the ergonomic and temporal constraints faced by frontline nurses during acute resuscitation events.

Typology 2: Interdisciplinary Shared Governance and Quality Committees

Moving away from a punitive "blame culture," 9 studies documented the establishment of permanent or semi-permanent joint quality committees. Comprising frontline nurse champions, laboratory quality supervisors, and institutional quality specialists, these committees functioned as cross-departmental boundary spanners. Their operational mandate included the collaborative execution of Root Cause Analyses (RCAs) for every major spike in specimen rejection, the joint rewriting of institutional standard operating procedures (SOPs) for blood collection, and the continuous monitoring of shared digital quality dashboards.

Typology 3: Technological Boundary Spanners and Process Synchronization

The integration of digital health technologies served as a mechanistic bridge in 11 studies. The primary intervention within this theme was the synchronized rollout of Barcode Medication and Specimen Administration (BCMA/BCSA) systems. Rather than the laboratory unilaterally mandating barcode adoption, these collaborative interventions involved joint workflow mapping. Nursing and laboratory teams co-designed the hardware placement (e.g., mobile bedside printers) and software alerts (e.g., real-time warnings on the electronic health record if a tube was scanned out of the correct order of draw), ensuring technology supported, rather than hindered, the clinical workflow.

Typology 4: Standard Operating Procedure (SOP) Harmonization and Fluid Material Redesign

A final structural theme found in 8 studies involved the physical and procedural modification of the collection value stream. This included collaborative agreements to eliminate high-risk collection practices, such as drawing diagnostic blood samples directly from peripheral intravenous catheters (PIVCs) during routine operations, replacing them with dedicated, direct venipuncture protocols. It also involved the joint implementation of "phlebotomy bundles," which standardized tube inversion techniques and mandated the use of specific engineering controls, such as straight-needle safety devices or blood transfer units, across all nursing departments.

4.5 Synthesized Impact on Pre-Analytical Quality Indicators

The quantitative synthesis of data extracted from the historical pre-2024 literature demonstrates a profound, statistically significant reduction in specimen rejection rates following the implementation of collaborative nursing-laboratory interventions.

Across the 28 included studies, the pooled baseline (pre-intervention) specimen rejection rate ranged from a high of 3.8% to 8.2% in emergency settings, and 1.2% to 3.5% in general inpatient wards. Following the execution of interdisciplinary collaborative interventions, post-intervention tracking revealed an institutional reduction in total specimen rejections, with rates dropping to a range of 0.4% to 1.9% in the ED, and down to <0.5% in general wards.

Specific Rejection Criterion	Pre-Intervention Pooled Rate Range (%)	Post-Intervention Pooled Rate Range (%)	Absolute Reduction Range (%)	Statistical Significance (p-value)
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In-Vitro Hemolysis	2.5% – 5.9%	0.3% – 1.2%	2.2% – 4.7%	p < 0.001\$
Specimen Mislabeling / Unlabeled	0.4% – 1.1%	0.01% – 0.05%	0.39% – 1.05%	p < 0.01\$
Quantity Not Sufficient (QNS)	0.6% – 1.8%	0.1% – 0.4%	0.5% – 1.4%	p < 0.05\$
Clotted Samples	0.3% – 1.4%	0.05% – 0.2%	0.25% – 1.2%	p < 0.01\$

The most dramatic improvements were observed in the mitigation of in-vitro hemolysis, particularly within Emergency Departments that transitioned from PIVC-derived draws to collaborative direct venipuncture bundles; several key historical studies reported a relative risk reduction exceeding 70% (RR < 0.30, 95% CI [0.22, 0.41]). Administrative errors, specifically specimen mislabeling, were almost entirely eliminated in institutions that co-implemented bedside barcode specimen scanning, with some large-scale audits showing a shift in Six Sigma quality levels from \$3.2\sigma\$ up to \$4.8\sigma\$ within twelve months of institutional adoption. Furthermore, these quantitative reductions were consistently associated with secondary operational benefits, including a synthesized reduction in diagnostic turnaround time (TAT) by an average of 14.5 minutes, and a substantial decrease in hospital non-value-added expenditure.

5. Discussion & Healthcare Quality Implications

5.1 Synthesis of Main Findings and Interpretation Against Theoretical Frameworks

The comprehensive meta-synthesis of the pre-2024 literature unequivocally establishes that pre-analytical specimen rejection is not fundamentally a manifestation of isolated individual incompetence, but rather a symptom of profound sociotechnical fragmentation within the healthcare delivery system. The quantitative outcomes demonstrated in Chapter 4—most notably the dramatic reduction in in-vitro hemolysis and specimen mislabeling following interdisciplinary interventions—validate the application of systems engineering principles, specifically the SEIPS (Systems Engineering Initiative for Patient Safety) model, to the clinical laboratory and nursing interface.

When interpreted through the lens of James Reason's Swiss Cheese Model (2000), traditional, siloed departmental structures create latent organizational conditions (the "holes" in the defensive layers). For example, when laboratory administration unilaterally defines a complex sequence for the "order of draw" without consulting the nursing units regarding the ergonomic realities of bedside acute care, a systemic vulnerability is established. The results of this systematic review demonstrate that collaborative interventions act as targeted corrective mechanisms that realign these defensive layers. By implementing joint interprofessional education (IPE) and shared governance committees, healthcare institutions effectively enact "Boundary Spanning." These boundary-spanning activities dismantle operational silos, fostering a shared mental model of the Total Testing Process (TTP) where both nursing and laboratory professionals possess mutual visibility into the constraints, requirements, and workflows of their counterparts.

Furthermore, the efficacy of technological boundary spanners, such as Barcode Medication and Specimen Administration (BCMA/BCSA), highlights a critical theoretical pivot. The literature reveals that technology alone is insufficient; its success is entirely contingent upon collaborative implementation. When nurses and laboratory technologists co-design the integration of barcode scanners into the clinical workflow, the technology transitions from being an imposed administrative burden to a seamlessly integrated cognitive aid, thereby drastically reducing the incidence of "Wrong Blood in Tube" (WBIT) errors.

5.2 The Role of Nursing Leadership and Healthcare Quality Management

The translation of interdisciplinary collaboration from a theoretical ideal into a sustained clinical reality is heavily dependent on robust nursing leadership and the rigorous application of Healthcare Quality

Management frameworks. Transformational nursing leadership is repeatedly identified in the historical literature as a primary catalyst for dismantling the adversarial "blame culture" that historically plagued the nursing-laboratory interface. Transformational leaders advocate for psychological safety, empowering frontline nurses to report near-misses and pre-analytical defects without fear of punitive retribution, thereby generating the transparent data required for continuous quality improvement (CQI).

From a quality management perspective, the successful interventions synthesized in this review align seamlessly with the principles of Lean and Six Sigma methodologies. Lean philosophy defines any rejected specimen as muda (non-value-added waste), which disrupts the value stream of patient care. The collaborative interventions identified—such as harmonizing Standard Operating Procedures (SOPs) and eliminating the practice of drawing diagnostic specimens from peripheral intravenous catheters (PIVCs)—are quintessential Lean Kaizen (continuous improvement) events. They strip away procedural variations and standardize the process to its most efficient, error-free state.

Simultaneously, the Six Sigma methodology, which seeks to reduce process variation and defect rates (striving for 3.4 defects per million opportunities), is deeply applicable to the mitigation of administrative pre-analytical errors. The historical data indicates that institutional implementation of collaborative barcode scanning alongside joint educational initiatives elevated pre-analytical labeling accuracy from baseline averages of approximately 3 to 4 Sigma, approaching 5 Sigma in highly optimized, interdisciplinary environments. This operational synergy underscores that quality improvement in diagnostics cannot be sequestered within the laboratory; it must be championed inter-departmentally by nursing leadership utilizing DMAIC (Define, Measure, Analyze, Improve, Control) cycles.

5.3 Facilitators and Barriers to Sustained Interdisciplinary Collaboration

While the immediate post-intervention results detailed in Chapter 4 are compelling, a critical evaluation of the prior literature reveals variable long-term sustainability. The thematic synthesis identified several core facilitators and systemic barriers that govern the longevity of collaborative quality initiatives.

Systemic Facilitators:

The primary facilitator for sustained success is the institutionalization of shared governance. Interventions that relied on a single, isolated educational workshop frequently succumbed to the "Hawthorne effect," where rejection rates temporarily declined during the study period but regressed to the mean within six to twelve months. Conversely, institutions that established permanent interdisciplinary quality committees—where nursing and laboratory champions reviewed monthly Quality Indicator (QI) dashboards together—maintained their reduced defect rates longitudinally. Furthermore, executive administrative sponsorship, providing protected, compensated time for frontline staff to engage in cross-departmental root-cause analysis (RCA), was critical to circumventing the constraints of chronic understaffing.

Operational Barriers:

The most pervasive barrier identified in the pre-2024 literature is extreme clinical workload and high nursing turnover. In acute care environments characterized by high patient acuity and critical understaffing, frontline nurses often resort to "workarounds" (e.g., bypassing barcode scanning or utilizing improper phlebotomy techniques to expedite collection). Additionally, cognitive overload and "alert fatigue" associated with poorly implemented electronic health record (EHR) warnings frequently undermined technological interventions. Finally, entrenched departmental tribalism and asynchronous budgetary structures—where the financial savings of reduced specimen rejection are realized by the laboratory, while the labor costs of the intervention are borne by the nursing department—often stymied collaborative momentum.

5.4 Economic and Patient Safety Impacts of Reduced Specimen Rejection

The implications of the synthesized data extend far beyond intra-institutional quality metrics, presenting profound economic and clinical consequences. To contextualize the financial impact, the Cost of Poor Quality (COPQ) framework is highly illustrative.

Direct COPQ encompasses the tangible losses associated with specimen rejection: the cost of duplicate evacuated tubes, sterile needles, laboratory reagents consumed by aborted analytical runs, and the non-productive labor hours of both phlebotomists and laboratory scientists. Historical estimates consistently placed the direct cost of a single pre-analytical error between \$30 and \$100 USD. However, the indirect COPQ is vastly more substantial. Delayed diagnostic Turnaround Times (TAT) resulting from recollection directly prolong emergency department boarding times and overall hospital Length of Stay (LOS). By reducing hemolysis and mislabeling through interdisciplinary collaboration, hospitals recapture massive operational capacity, accelerating patient throughput and optimizing bed utilization.

More critically, the impact on patient safety is absolute. The pre-analytical phase represents the most significant vulnerability for catastrophic diagnostic errors. Mismanagement of hyperkalemia due to undetected in-vitro hemolysis, or the administration of ABO-incompatible blood products due to a WBIT error, are sentinel events with high associated morbidity and mortality. Therefore, the collaborative reduction of these errors serves as a paramount risk management strategy, safeguarding patients from the iatrogenic harm associated with delayed or erroneous therapeutic interventions.

5.5 Direct Implications for Healthcare Quality Specialists and Policy Makers

The synthesis of the historical literature yields direct, actionable implications for Healthcare Quality Specialists, Clinical Risk Managers, and institutional policy makers.

First, quality specialists must transition institutional auditing from department-specific metrics to continuum-based Total Testing Process (TTP) Quality Indicators. Specimen rejection should not be recorded merely as a "laboratory failure" or a "nursing failure," but rather as an "interface defect."

Second, it is imperative to establish formalized boundary-spanning roles, such as Pre-Analytical Quality Coordinators, who operate seamlessly between the clinical wards and the diagnostic laboratory. These professionals must be empowered to facilitate Plan-Do-Study-Act (PDSA) cycles that require joint sign-off from both nursing directors and laboratory managers.

Finally, policy makers and accrediting bodies (such as the Joint Commission or CAP) must increasingly mandate evidence of interdisciplinary quality management as a prerequisite for institutional accreditation. By weaving interprofessional collaboration into the regulatory fabric of healthcare delivery, the reduction of pre-analytical errors transitions from an isolated departmental initiative to a fundamental standard of high-reliability patient care.

6. Conclusion

6.1 Summary of the Meta-Synthesis

The integrity of the Total Testing Process (TTP) is a fundamental pillar of modern clinical diagnostics, heavily dictating the trajectory of patient care and systemic healthcare outcomes. Through a rigorous systematic review and thematic meta-synthesis of literature published up to December 31, 2023, this research provides compelling, synthesized evidence that the pre-analytical phase remains the most vulnerable locus of diagnostic error, primarily due to the socio-organizational fragmentation of the nursing-laboratory interface.

The findings demonstrate unequivocally that decentralized phlebotomy performed by nursing staff—while necessary for acute clinical workflows—requires robust, systems-level support to prevent elevated specimen rejection rates. Unilateral mandates issued by clinical laboratories are historically ineffective and frequently precipitate adversarial interdepartmental dynamics. Conversely, the implementation of structured, collaborative interventions—categorized systematically in this review as interprofessional education (IPE), shared governance quality committees, technological boundary spanning (e.g., synchronized barcode integration), and harmonized standard operating procedures (SOPs)—yields profound clinical benefits.

The quantitative synthesis reveals that interdisciplinary collaboration leads to statistically significant reductions in pre-analytical defects. Specifically, the collaborative elimination of peripheral intravenous catheter (PIVC) blood draws in favor of direct venipuncture bundles reduced in-vitro hemolysis

by up to 70% in emergency settings. Furthermore, joint implementations of Barcode Medication and Specimen Administration (BCMA/BCSA) systems elevated labeling accuracy to near Six Sigma thresholds ($>4.8\sigma$), virtually eliminating catastrophic "Wrong Blood in Tube" (WBIT) errors. Ultimately, bridging the nursing-laboratory divide is not merely an operational efficiency metric; it is a critical healthcare quality management imperative that ensures diagnostic accuracy, minimizes non-value-added organizational waste (*muda*), and fundamentally protects patient safety.

6.2 Methodological Limitations of the Included Studies

While the synthesized evidence strongly supports collaborative quality improvement, a critical appraisal of the literature base utilizing the MMAT and MINORS criteria reveals several pervasive methodological limitations. Recognizing these limitations is essential for contextualizing the findings and avoiding the over-extrapolation of the data.

Firstly, the overwhelming majority of the included studies ($n=22$) utilized quasi-experimental, pre-test/post-test designs without concurrent, randomized control groups. While this is a recognized standard in operational healthcare quality improvement—where randomizing wards to standard, flawed care poses significant ethical dilemmas—it inherently introduces the risk of temporal confounding. Factors such as concurrent changes in hospital administration, seasonal variations in patient acuity, or unmeasured shifts in nursing-to-patient ratios may have influenced the observed reductions in specimen rejection independently of the collaborative interventions.

Secondly, the literature exhibits a pronounced deficiency in longitudinal follow-up. Many studies reported data spanning only three to six months post-intervention. This short observation window is highly susceptible to the "Hawthorne effect," wherein healthcare staff transiently alter their behavior (e.g., adhering strictly to tube inversion protocols) simply because they are aware they are being audited. The long-term sustainability of these interventions, particularly after the initial enthusiasm of the quality improvement campaign subsides and staff turnover occurs, remains inadequately documented in the historical evidence base.

Finally, geographic and institutional bias is evident. The vast majority of the synthesized literature originates from well-resourced, tertiary academic medical centers in North America and Western Europe. These institutions often possess advanced digital infrastructures (e.g., comprehensive electronic health records and mobile barcode scanners) and robust quality management departments. Consequently, the applicability and scalability of these highly resource-intensive, collaborative interventions to community hospitals, rural healthcare settings, or institutions in low-to-middle-income countries (LMICs) cannot be definitively established from the existing literature.

6.3 Recommendations for Future Research Agendas

Based on the synthesized gaps identified in the pre-2024 literature, several critical trajectories for future healthcare quality research are proposed:

1. **Longitudinal and Ethnographic Evaluation:** Future quality improvement studies must prioritize longitudinal tracking, extending post-intervention data collection to a minimum of 24 to 36 months to verify the true sustainability of reduced specimen rejection rates. Furthermore, embedding qualitative ethnographic research within these studies would provide a deeper understanding of how interdisciplinary cultural shifts at the nursing-laboratory interface are maintained despite high clinical turnover.
2. **Economic and Cost-Benefit Analysis:** While the direct costs of pre-analytical errors are well-documented, comprehensive health economic evaluations are scarce. Future research should utilize rigorous Time-Driven Activity-Based Costing (TDABC) to quantify the indirect economic benefits of collaborative interventions, specifically mapping the return on investment (ROI) derived from reduced diagnostic turnaround times (TAT) and optimized emergency department throughput.
3. **Advanced Predictive Modeling:** Building upon the robust historical data generated by quality indicators, future researchers should explore the integration of early machine learning (ML) algorithms with electronic health records (EHR). Research is needed to determine if predictive

models can analyze real-time variables (e.g., nurse-to-patient ratios, time of shift, patient vein condition) to proactively alert frontline staff to a high probability of specimen hemolysis prior to the physical phlebotomy event, thereby shifting the paradigm from retroactive defect tracking to proactive error prevention.

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