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Effectiveness of Laboratory Interventions in Reducing Blood Sample Clotting and Specimen Rejection Rates

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ABSTRACT: Laboratory interventions such as staff training, standardized blood-collection procedures, appropriate tube selection, correct order of draw, and thorough but gentle tube mixing can reduce clotting in anticoagulated blood samples. Clear collection guidelines, competency assessments, and feedback help ensure these practices are applied consistently. Their effectiveness depends on identifying the causes of clotting in each setting, including collection difficulties, inadequate mixing, delays in handling, and equipment or workflow issues. Reducing clotting can also lower specimen rejection rates, minimize repeat collections, and support timely, reliable test results. Laboratories can evaluate progress by tracking clot-related rejections before and after interventions, reviewing trends by department or collection site, and providing ongoing feedback to staff. A continuous quality-improvement approach helps sustain improvements and identify new

problems, while recognizing that rejection rates may also be influenced by other factors, such as insufficient volume, hemolysis, or mislabeling.

INTRODUCTION

The clinical laboratory occupies a central position in modern healthcare, generating the objective data upon which a substantial proportion of diagnostic and therapeutic decisions are made. Laboratory testing influences a large share of medical decisions, making the quality of every step in the total testing process a matter of direct patient safety [1]. The total testing process is conventionally divided into pre-analytical, analytical, and post-analytical phases. Of these, the pre-analytical phase—encompassing test selection, patient preparation, sample collection, labeling, transport, and processing—has proven to be the most vulnerable. Up to 70% of all laboratory errors are estimated to originate in this phase, and the pre-analytical phase alone accounts for a large proportion of total laboratory errors [2]. Among the numerous pre-analytical failure modes, blood sample clotting occupies a uniquely prominent position. Clotted specimens are unsuitable for analysis, leading to rejection, repeated venipuncture, delayed diagnosis, increased patient discomfort, and avoidable expenditure of staff time and resources [3].

The Pre-Analytical Phase and the Problem of Specimen Rejection

The pre-analytical phase is a complex sequence of interdependent steps, each of which presents opportunities for error. Blood collection errors are among the most common causes of laboratory sample rejection, and clotted blood samples consistently emerge as the leading or second-leading cause of rejection across diverse laboratory settings. A cross-sectional study of 1,072,366 blood samples received by the hematology laboratory of the Philippine General Hospital between 2018 and 2022 found that 61,935 specimens were rejected, with clotted blood accounting for 86.31% of rejections in routine hematology and 44.43% in coagulation testing [3]. Similar patterns have been reported elsewhere. In a tertiary care hospital laboratory in Saudi Arabia, clotted specimens emerged as the most prevalent pre-analytical error, closely followed by insufficient specimen quantity, each representing roughly one-third of all cases [5]. Other hospital-based studies have identified clot as the major cause of rejection at 43.8%, followed by insufficient sample volume at 24%, while a Turkish university hospital reported clotted specimens at 55.8% of total rejections and a Cape Town tertiary laboratory reported inappropriate clotting as the main reason for rejection at 30% [6]. These figures, drawn from different countries and laboratory contexts, converge on a single conclusion: clotting is not a marginal or idiosyncratic problem but a systemic and persistent feature of pre-analytical practice.

The clinical and economic consequences of specimen rejection are substantial. Rejected specimens necessitate re-collection, which exposes patients to the discomfort and risks of repeated venipuncture, delays the availability of results, prolongs hospital stays, and increases healthcare costs. In critical care settings, where blood volumes are limited and vascular access is difficult, the cost of rejection is especially high. In neonatal intensive care units, repeated sampling for clotted specimens contributes to iatrogenic anemia and represents a significant burden on fragile patients [4]. For umbilical cord blood gas analysis, the specimen is irreplaceable and cannot be re-collected, so a clotted sample may entirely preclude the objective assessment of fetal acid–base status at birth. The reduction of clotting is therefore not merely a laboratory efficiency measure but a direct contribution to patient safety and clinical timeliness.

Causes and Mechanisms of Blood Sample Clotting

The formation of a clot in an anticoagulated blood specimen is a multifactorial event, but its immediate physiological mechanism is well characterized. The primary cause is typically the failure to adequately mix tubes immediately after collection, so that the anticoagulant—whether ethylenediaminetetraacetic acid, sodium citrate, or heparin—does not come into uniform contact with the blood before the coagulation cascade is activated. A regional laboratory network analysis encompassing 7.4 million specimens found that inadequate mixing was the attributable cause in 62.25% of clotting incidents [7]. Vacuum tube manufacturers and the Clinical Laboratory Standards Institute recommend gentle inversion of diagnostic blood specimens eight to ten times to ensure proper interaction between blood and additives [8]. When this step is omitted, abbreviated, or performed inadequately, microclots or macroscopic clots form.

Several contributing factors amplify the risk of clotting even when mixing is attempted. Overfilled vacuum tubes can leave insufficient airspace for adequate mixing, while underfilled citrate tubes disturb the critical 9:1 blood-to-anticoagulant ratio and may permit clot formation through relative anticoagulant deficiency [9]. Extended venipuncture with delayed transfer of blood into the collection tube is another recognized contributor. The choice of collection device matters: in neonatal practice, clotted

samples have been most frequently associated with needle use and intravenous cannula collection, with odds ratios of 4.14 and 3.11 respectively compared with other methods [4]. Delayed processing and inappropriate transport conditions further increase the likelihood that a specimen will arrive in the laboratory already clotted or will clot before analysis. Patient-related factors, including difficult venipuncture, fragile veins, and the use of catheters, interact with operator technique and workflow pressures to produce the observed variation in clotting rates across hospital locations and shifts. Evidence also indicates that mixing requirements vary by tube type: while tubes with liquid-based citrate buffer for coagulation testing must be mixed to avoid clotting, mixing may not be mandatory for all tube types [10].

The distribution of clotting errors across hospital settings is instructive. In the Philippine General Hospital study, the highest rejection rate was observed in the emergency department, followed by intensive care units, reflecting the combined effects of urgency, high workload, staffing pressures, and the complexity of obtaining blood from critically ill patients [3]. In a Saudi Arabian tertiary laboratory, clotting errors were more frequent in the emergency department and during the night shift, a pattern attributed to workload pressure, staff fatigue, reduced staffing levels, and disparities in training [5]. These observations indicate that clotting is not simply a technical failure of individual phlebotomists but a systems phenomenon that reflects the conditions under which blood collection occurs. Effective interventions must therefore address both the technical and the organizational dimensions of the problem.

Monitoring and Quality Indicators

The effectiveness of any intervention depends ultimately on the capacity of the laboratory system to measure, monitor, and respond to performance data. Monitoring sample rejections is a key quality indicator to identify critical points and guide improvement strategies, and continuous monitoring, targeted training, reinforcement of rejection criteria, and improved traceability during collection, labeling, storage, and transport are consistently recommended [11]. The development of integrated informatics platforms has substantially enhanced the feasibility and precision of this monitoring. A regional medical laboratory network implemented a web-based quality indicator management system with automated data collection, quality indicator calculation, visual analytics, and a corrective action implementation module. Across 7,437,716 specimens, 4,208 were rejected, with clotted samples accounting for 43.37% of total rejections and inadequate mixing accounting for 62.25% of clotting incidents [7]. The use of P-control charts enabled continuous rejection rate monitoring, and electronic forms supported collaborative non-conformity rectification. These metrics allow laboratories to benchmark their performance, prioritize interventions, and detect deterioration before it becomes entrenched.

Educational and Training Interventions

The most extensively evaluated category of laboratory intervention for reducing clotting and specimen rejection is targeted education and training of the personnel who collect blood. The rationale is straightforward: if inadequate mixing and deviations from standardized collection technique are the proximate causes of clotting, then improving knowledge and skills should reduce the error. A study of targeted training and education interventions at a single institution reported that the cumulative specimen rejection rate was 0.49% by the end of April 2022, improved from 0.57% in the same period of the previous year. After multiple training and education sessions conducted in May, the rejection rate fell to 0.24%, approximately half the earlier value, a difference that was highly statistically significant [12]. In an oncology setting, five educational sessions for nurses and physicians, combined with process modifications and improved communication protocols within a FOCUS-PDCA framework, reduced the sample rejection rate from 20.85% before the intervention to 6.05% afterward [13].

The effectiveness of education is not, however, uniformly sustained. A diagnostic laboratory affiliated with a teaching medical institute observed a significant reduction in rejections during the training phase, but the effect diminished when training ceased, leading the authors to recommend periodic redesign and reinforcement of phlebotomy training [14]. This finding is consistent with the broader quality improvement literature: educational interventions are necessary but rarely sufficient on their own, because knowledge decays and staff turnover erodes the gains achieved. The most successful programmes combine initial training with ongoing monitoring, feedback, and reinforcement.

Quality Control Circles and Structured Quality Improvement

Quality Control Circles represent a structured, team-based approach to process improvement that has been applied with considerable success to specimen rejection. The Quality Control Circle model engages frontline staff from the laboratory, nursing, and administration in a cyclic Plan-Do-Check-Act process, using tools such as flowchart analysis, Pareto analysis, and

fishbone diagrams to identify root causes and design targeted countermeasures. In a hospital clinical laboratory, a Quality Control Circle initiative conducted between July 2021 and August 2022 reduced the monthly specimen rejection rate from an average of 1.13% before the intervention to 0.27% afterward [15]. The most significant factors contributing to rejection were identified as lack of sample collection information and blood clotting; targeted interventions included appointing specimen collection liaisons, establishing a quality control team, and providing training on blood collection procedures. The Quality Control Circle approach was judged effective not only in reducing rejection but also in shortening the waiting time for patients to receive test results and in enhancing staff capabilities and workplace engagement [16].

Structured improvement methodologies more broadly have demonstrated substantial effects. A risk-based quality management initiative in a tertiary cancer center reduced pre-analytical error rates from 1.6% to 0.35%, a 78% reduction, and decreased sample rejection and re-collection by 40% [17]. The use of annual training programmes within a Six Sigma framework has been associated with a downward trend in specimen rejection rates over multiple years, demonstrating the value of sustained, metric-driven quality management [18]. In another analysis, clotted blood specimens were the top error at 67.34%, with a Sigma value of 4.42, followed by insufficient volumes at 8.22% and cancelled test requests at 6.28% [19]. These findings suggest that the most effective interventions are those that embed improvement in a systematic, iterative, and measurement-based organizational framework rather than relying on isolated training events.

Narrative Medicine and Communication-Centred Interventions

An innovative and conceptually distinct intervention is the integration of narrative medicine principles into laboratory quality improvement. The premise is that pre-analytical errors often reflect a systemic failure of communication and mutual understanding between laboratory staff and clinical staff, rather than a simple deficit of technical knowledge. By implementing parallel charts and fostering empathetic, contextualized communication about rejection notices—replacing impersonal directives with explanations of the "why" and offers of assistance—a laboratory sought to transform the relationship between the laboratory and the clinical units from adversarial to collaborative. The results were striking: the median coagulation specimen rejection rate declined from a baseline of 1.862% to 0.108% immediately following intervention initiation, a 94.2% reduction, and further declined to 0.026% in the long-term optimization phase, a 98.6% overall reduction from baseline [20]. The improvement was sustained over a 33-month period and persisted through a large-scale staff rotation, with a rapid return to low rejection rates after targeted re-education when a transient spike occurred [21]. This evidence indicates that the culture and mode of communication surrounding specimen rejection are not incidental but are themselves modifiable determinants of pre-analytical performance.

Technological and Device-Based Interventions

Technological interventions target the physical conditions of blood collection, transport, and analysis. One of the most clearly effective is the use of clot catchers for blood gas analysis. Umbilical cord blood gas specimens are particularly prone to clotting because heparinized cord blood forms small clots more readily than other blood sources, and the specimen is irreplaceable. Before intervention, the cancellation rate for umbilical cord blood gas specimens was 18.6%, compared with 0.7% for non-cord arterial and venous samples. After clot catchers were implemented for all cord specimens, the cancellation rate decreased approximately five-fold in the first month and remained below 5% a year after implementation [22]. Clot catchers have also been validated for clinical use with a bias of less than ±4% for all analytes, indicating that their analytical performance is acceptable [23].

Device selection and blood collection technique also influence clotting rates. The use of dedicated blood extraction equipment, heel lance devices designed for neonatal sampling, and standardized collection pathways have been associated with reductions in clotted specimens in neonatal intensive care. A three-year quality improvement programme in a 112-cot neonatal unit reduced the overall rate of clotted specimens from 4.8% in 2017 and 2018 to 2.4% in 2019, with statistically significant odds ratios across the successive years [4]. The interventions included awareness-raising and safe-sampling workshops, involvement of the neonatal vascular access team, development of a complete blood count sample collection pathway, review of collection equipment, introduction of a specialized heel lance, establishment of benchmarks, and provision of dedicated blood extraction equipment. These findings demonstrate that device-level and workflow-level changes can produce measurable reductions in clotting even in highly vulnerable patient populations.

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Procedural Standards: Mixing, Fill Volume, and Order of Draw

Procedural standardization forms the technical foundation of clotting prevention. Immediate and adequate mixing of anticoagulant tubes is the single most critical step. Recommendations consistently specify gentle inversion of EDTA and heparin tubes eight to ten times, serum separator tubes five times, and sodium citrate tubes three to four times [8]. However, evidence also indicates that mixing requirements vary by tube type: while tubes with liquid-based citrate buffer for coagulation testing must be mixed to avoid clotting, mixing may not be mandatory for all tube types [24]. The practical implication is that protocols should be tube-specific and that training must emphasize the tubes in which clotting risk is highest—namely, citrate and EDTA tubes used for coagulation and hematology testing.

Fill volume is a second critical procedural variable. Evacuated collection tubes must be filled to completion to ensure the correct blood-to-anticoagulant ratio; underfilling of citrate tubes results in an increased anticoagulant-to-blood ratio and can extend clot-based coagulation assays or permit clot formation. Overfilling can also cause problems by reducing the airspace available for mixing and by disturbing the anticoagulant ratio [9]. The acceptable minimum fill volume is assay-dependent: quality performance specifications indicate that the tube fill volume must be at least 70% for prothrombin time and activated partial thromboplastin time and 50% for fibrinogen, although some guidance recommends rejection of samples with less than 80% fill. The order of draw is a third procedural standard that influences clotting and contamination. Serum tubes containing clot activators may cause interference in coagulation testing, and only blood culture tubes, glass nonadditive serum tubes, or plastic serum tubes without a clot activator may be collected before the coagulation tube. Adherence to the recommended order of draw—blood culture, coagulation, serum with or without gel, heparin, and glycolytic inhibitor tubes—is therefore an integral component of clotting prevention [25].

Synthesis of Evidence and Comparative Effectiveness

The evidence reviewed above permits a comparative assessment of intervention types, although direct head-to-head trials are rare and most studies are single-centre before-and-after designs. The Table summarizes representative intervention studies and their reported effects.

Table 1. Representative Laboratory Interventions and Reported Reductions in Clotting or Specimen Rejection

Intervention category	Setting and design	Principal components	Reported effect on rejection or clotting	Reference
Targeted training and education	Single institution, pre–post	Workshops, webinars, practical sessions	Rejection rate from 0.49% to 0.24%	[12]
Educational sessions with FOCUS-PDCA	Oncology centre, quasi-experimental	Five sessions for nurses and physicians; process modification; communication protocols	Rejection rate from 20.85% to 6.05%	[13]
Quality Control Circle	Hospital clinical laboratory, pre–post	Plan-Do-Check-Act, Pareto and fishbone analysis, collection liaisons, quality team, training	Monthly rejection from 1.13% to 0.27%	[15]
Narrative medicine with Plan-Do-Study-Act cycles	Coagulation laboratory, longitudinal	Parallel charts, empathetic communication, just culture	Median rejection from 1.862% to 0.026%	[20]
Clot catchers	Umbilical cord blood gas, pre–post	Device implementation for all cord specimens	Cancellation from 18.6% to below 5%	[22]
Multimodal neonatal quality improvement	112-cot neonatal unit, retrospective observational	Workshops, vascular access team, collection pathway, equipment review, heel lance, benchmarks	Clotted specimens from 4.8% to 2.4% over three years	[4]

Targeted training alone	Diagnostic laboratory, pre–post	Phlebotomy training	Significant reduction during training, with decay after cessation	[14]

Several conclusions emerge from this synthesis. First, interventions that combine technical training with systems-level change—Quality Control Circles, FOCUS-PDCA, and multimodal neonatal programmes—tend to produce larger and more durable reductions than training alone. Second, the most dramatic reductions reported in the literature come from interventions that address the communication and cultural dimensions of specimen rejection alongside technical factors; the narrative medicine study achieved a 98.6% reduction and sustained it over years, whereas purely technical interventions typically report reductions in the range of 40%–80%. Third, device-based interventions such as clot catchers can be highly effective in specific contexts where the specimen is irreplaceable or particularly prone to clotting, but their generalizability to routine venous specimens is limited. Fourth, the durability of gains is contingent on continuous monitoring and reinforcement; programmes that cease training and monitoring see their effects decay, whereas those that embed quality indicators in routine practice sustain improvement.

Table 2. Common Causes of Specimen Rejection and Their Relative Frequency

Cause of rejection	Reported frequency	Context	Reference
Clotted specimen	86.31% in routine hematology; 44.43% in coagulation	Philippine General Hospital, 2018–2022	[3]
Clotted specimen	55.8% of total rejections	Turkish university hospital	[6]
Clot	43.8% of rejections	Porto Alegre university hospital	[6]
Inappropriate clotting	30% of rejections	Cape Town tertiary laboratory	[6]
Clotted specimen	Approximately one-third of pre-analytical errors	Saudi Arabian tertiary laboratory	[5]
Clotted sample	43.37% of total rejections; inadequate mixing in 62.25% of clotting incidents	Regional laboratory network, 7.4 million specimens	[7]
Clotted blood specimen	67.34% of top errors; Sigma value 4.42	Quality indicator analysis	[19]

Limitations and Considerations for Implementation

The evidence base for interventions against clotting has several limitations that warrant acknowledgment. Most studies are single-centre, before-and-after designs without concurrent controls, making them susceptible to secular trends, regression to the mean, and unmeasured confounding. The Quality Control Circle study itself noted that it was conducted during the COVID-19 pandemic, that it was a single-centre study, and that its duration was slightly over one year, limiting generalizability and the assessment of long-term sustainability [15]. The neonatal study was retrospective and observational, and although the interventions were associated with reduced clotting rates, the independent contribution of each component cannot be disentangled [4]. The narrative medicine study, while methodologically robust in its longitudinal design, was also conducted in a single laboratory, and its transferability to settings with different staffing models and organizational cultures remains to be established [20].

Implementation considerations are equally important. Educational interventions require sustained investment, and their effects decay without reinforcement [14]. Technological interventions such as clot catchers incur device costs and require validation before routine use [23]. Informatics platforms for quality indicator monitoring require upfront development and integration with laboratory information systems, although they enable scalable and automated surveillance that manual systems cannot match [7]. Procedural standards such as fill volume and order of draw require not only training but also the availability of appropriate collection tubes and the cooperation of clinical staff who may be under pressure to complete collections quickly

[9]. The most effective implementation strategies are therefore those that combine multiple intervention types, engage stakeholders across the laboratory–clinical interface, and establish feedback loops that make performance visible and actionable.

CONCLUSION

Blood sample clotting is a significant pre-analytical error that undermines laboratory efficiency and patient care. The essay highlights that clotting and rejection rates can be mitigated through various interventions, showing reductions in rejection rates via education and quality improvement methodologies. Notable strategies include the use of Quality Control Circles and communication-centered interventions, which yielded substantial decreases in specimen rejection. Additionally, technological solutions and procedural standardization enhance effectiveness. A multimodal approach combining training, systems redesign, and continuous monitoring is essential for sustained improvement. This evidence-based roadmap indicates that clotted samples are preventable, leading to improved turnaround times and diagnostic reliability.

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