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ORIGINAL RESEARCH

Application Effectiveness of a Pre-Analytical Quality Management Pathway Based on the Structure–Process–Outcome Model

Liping Cui[1,*], Wanling Li[1,2,*], Yueqin Li[3], Xiaofang Feng[3], Yue Wang[4], Pei Gao[4]

[1]Department of Nursing, Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences, Third Hospital of Shanxi Medical University, Tongji Shanxi Hospital, Taiyuan, 030032, People's Republic of China; [2]Department of Geriatrics, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, 430030, People's Republic of China; [3]Department of General Medical, Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences, Third Hospital of Shanxi Medical University, Tongji Shanxi Hospital, Taiyuan, 030032, People's Republic of China; [4]Nursing College, Shanxi Medical University, Taiyuan, 030032, People's Republic of China

*These authors contributed equally to this work

Correspondence: Yueqin Li, Department of General Medical, Shanxi Bethune Hospital, Shanxi Academy of Medical Sciences, Third Hospital of Shanxi Medical University, Tongji Shanxi Hospital, No. 99 Longcheng Street, Xiaodian District, Taiyuan, Shanxi, 030032, People's Republic of China, Tel +86 0351-8368114, Email li_yueqin@163.com

Objective: This single-center, before-and-after study applied the structure–process–outcome (SPO) model to pre-analytical quality control to investigate its effect on laboratory testing quality, nursing practices, patient satisfaction, and clinician trust in test results.

Methods: A before-and-after design was conducted in a provincial Class A tertiary hospital. The control group (April–September 2022) and observation group (April–September 2023) each included all laboratory specimens and 550 clinical nurses (from the same wards). The SPO-guided pre-analytical quality management pathway involved forming a multidisciplinary team, establishing a grid management system, implementing a non-punitive reporting system, standardizing specimen collection, and developing a quality management information system. Groups were compared on non-compliant test sample rates, nurses' knowledge, beliefs, and behaviors, operational standardization, patient satisfaction, and clinical doctors' trust. Data were analyzed using t-tests (with effect sizes) and χ^2-tests; confidence intervals and multiple-comparison corrections were also applied.

Results: The observation group showed significantly lower rates of non-compliance in sample type, collection container, volume, contaminated blood cultures, and coagulated samples (all $p < 0.01$, with 95% confidence intervals). Nurses' knowledge (Cohen's $d = 0.44$) and behaviors (Cohen's $d = 1.56$) improved significantly. Operational standardization (92.5 ± 3.2 vs 85.7 ± 4.1), patient satisfaction (93.8% vs 87.2%), and clinical doctors' trust (91.2% vs 84.5%) also increased significantly ($p < 0.01$).

Conclusion: The SPO-based pre-analytical quality management pathway significantly improved non-compliant sample rates, nurses' knowledge and behavior, operational standardization, patient satisfaction, and clinical trust in test results. This approach may serve as a reference for other institutions aiming to enhance pre-analytical quality management.

Keywords: structure–process–outcome model, pre-analytical quality, management pathway, before-and-after study

Introduction

Laboratory medicine occupies a crucial position in the diagnostic process and in guiding clinical medical treatment, with 70% of medical decisions relying on laboratory test results.[1] The entire laboratory testing process can generally be divided into the following three phases: pre-analytical, analytical and post-analytical. Errors in the pre-analytical phase account for approximately 46%−68% of total errors,[2,3] particularly those associated with manual operations involved in specimen collection, handling, transportation, preparation and preservation. Hence, the key to ensuring test quality lies in steps conducted outside the laboratory.[4]

The structure–process–outcome (SPO) model, introduced by American healthcare quality management expert Donabedian in 1966,[5] categorises the evaluation of healthcare service quality into three dimensions: structure, process

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and outcome. This model offers a systematic framework for assessing healthcare quality. "Structure" encompasses the organisational structure, scope of diagnosis and treatment projects and human resource allocation within healthcare institutions. 'Process' pertains to the efficiency and quality of healthcare institution operations, including system processes, diagnostic pathways, supervisory measures, training and assessments. "Outcome" represents the terminal quality of healthcare institutions, covering metrics such as outpatient and emergency patient volume, surgical volume, hospitalisation rate, morbidity, hospital infection rate and mortality rate.[6] Although the SPO model has been widely applied across various domains of healthcare quality management,[7,8] such as in the evaluation of telemedicine service quality[9] and the improvement of patient identification practices in healthcare settings,[10] its application in pre-analytical quality management remains relatively underexplored.

Moreover, a study by Romero-Arana et al (2022) found that the best-rated item in their questionnaire was verifying the correspondence between the request form and the identity of the patient, with statistically significant differences between accredited and non-accredited centres. The study concluded that compliance with the protocol was adequate among primary healthcare professionals, who have a strategic position in sample collection and transport during the pre-analytical phase. Standardisation was identified as a priority to reduce errors and improve clinical safety and results.[11]

Further research has emphasised the critical role of environmental factors in the pre-analytical phase. Pierre and Wiencek (2023) reviewed the impact of environmental conditions on both external and internal specimen transport. They highlighted that specimens can experience varying climate conditions during storage and transport, potentially leading to inaccurate test results. The authors also noted that even specimens collected within healthcare institutions are not exempt from suboptimal storage and transport environments, such as extreme agitation in pneumatic tube systems.[12] Additionally, the same authors discussed strategies to mitigate environmentally-induced pre-analytical errors and identified regulatory gaps in environmental monitoring during the pre-analytical phase.[13] Their work emphasises the need for comprehensive quality management systems that address not only procedural compliance but also environmental factors affecting specimen integrity.

The study utilized the Structure-Process-Outcome (SPO) model, a framework for assessing healthcare quality. This model categorizes quality into three components: structure (organizational infrastructure), process (procedural implementation), and outcome (measurable effects). We adopted a before-and-after design with a six-month control period (April–September 2022) and a six-month observation period (April–September 2023). The aim of this study was to evaluate the effectiveness of a pre-analytical quality management pathway based on the SPO model in improving laboratory testing quality, nursing practices, patient satisfaction, and clinician trust in test results.

Study Methods and Population

Study Participants

This study adopted a before-and-after design, with the same hospital setting but different time points: the control group (April–September 2022) and the observation group (April–September 2023), including all laboratory specimens and 550 clinical nurses per period from the same wards.

Study Methods

We based our quality management interventions on the SPO model, which we customized for pre-analytical laboratory work. The following bullet points summarize our interventions:

Structure

In this section, we describe the key structural components of the quality management system implemented in the study. The interventions included the formation of a multidisciplinary team, establishment of management systems, and the introduction of reporting systems. The primary goal of these actions was to improve communication and ensure the correct handling of specimens from collection through transportation.

For further details on the specific structural interventions, please refer to Table 1.

Table 1 Structural Interventions in the Study

Category	Details
Formation of a multidisciplinary team	Formed in December 2022 under the Nursing Department's leadership, comprising Nursing, Medical Office, Laboratory, IT, and Frontline Support. Role: Develop regulations, define quality indicators, finalize SOPs, and supervise clinical staff.
Establishment of a grid management system	Laboratory staff assigned to specific hospital areas to communicate directly with clinical staff. Provided lectures and printed guidelines.
Non-punitive reporting system for non-compliant specimens	Monthly reporting of non-compliant specimens by department. One-on-one communication and continuous monitoring for improvements.
Establishment of a third-party frontline support team for specimen transport	A dedicated team employed to handle timely and proper specimen transport.
Quality management information system	IT developed a system integrating data from nursing, laboratory, and clinical departments. Alerts and reports for continuous quality improvement.The Quality Management Information System provides real-time alerts and detailed reports that are made accessible to staff through the hospital's intranet and ward workstations.

Process

The interventions in this section focused on the processes involved in specimen collection, storage, and transport. These processes were carefully designed and optimized through training programs, the establishment of standard operating procedures (SOPs), and a robust quality control mechanism. Regular feedback loops were implemented, and technological improvements, such as barcode scanning, were introduced to enhance accuracy.

For further details on the specific process interventions, please refer to Table 2.

Data Analysis

The questionnaire used in this study was crafted in alignment with the Guidelines of Venous Blood Specimen Collection[14] published in 2020, covering venous blood specimen collection knowledge, beliefs and behaviours (Appendix S1).

Table 2 Process Interventions in the Study

Category	Details
Implementation of diverse training programs	Self-designed questionnaire administered in January 2023, revealing knowledge gaps. Courses aligned with Guidelines of Venous Blood Specimen Collection (2020). Courses delivered online and offline twice weekly from January–March 2023. Nurses who failed assessments repeated training.All 550 nurses in the observation period (April–September 2023) underwent and completed the training sessions.
Establishment of standard operating procedures (SOPs) for specimen collection	Included: Submission schedules, educational cards for patients, identity verification videos, staff training on collection and storage procedures, and safe transport with dedicated support.
Optimization of information processes	Automated system intercepting erroneous orders, instant notifications for substandard specimens, and critical values flagged in the Laboratory Information System.
Process supervision (quality control)	Nursing Department observed wards through unannounced visits. Supervisors evaluated skills, and results were sent to head nurses for follow-up corrections.
Continuous quality improvement program	Regular quality circles and root cause analyses led to targeted improvements in pre-analytical procedures.
Introduction of barcode technology	Barcode-based patient identification and specimen labeling to minimize errors in patient–sample matching and data entry.
Standardization of blood collection procedures	All nurses received training and certification in blood collection, ensuring standardized practices in nurse-based phlebotomy.

Notes: December 2022: Multidisciplinary team formed. January–March 2023: Trainings delivered; SOPs and IT systems finalized. April–September 2023: Observation period under the new SPO-based management pathway.

The knowledge section primarily covered topics such as patient preparation for venous blood collection, tourniquet application time, disinfection scope, needle insertion angle, collection order, specimen submission timing and the impact of food and medication on specimens; it comprised 12 items in total. Each item offered four options, with at least one correct answer. Scoring was conducted by awarding 1 point for each correctly selected option (single or multiple) and 0 points for incorrect selections.

The attitude section explored nurses' perspectives on the importance of correct specimen collection for patient diagnosis, the necessity of participating in venous blood specimen guideline training, adherence to venous blood specimen collection standards and the analysis of potential errors when a patient's specimen is disqualified; it consisted of 7 items. This section utilised a 5-point Likert scale for scoring, with options ranging from strongly agree (5 points) to strongly disagree (1 point).

The behaviour section involved nurses proactively learning about venous blood collection, preparing for tests with special requirements as needed, strictly implementing the verification system during specimen collection, collecting blood culture specimens as required, not artificially altering the vacuum in blood collection tubes, mixing tubes containing anticoagulants as required and promptly sending blood specimens for testing; there was a total of nine items. Scoring for these items was defined as follows: for positive statements, "Never" = 1 point, "Rarely" = 2 points, 'Sometimes' = 3 points, "Often" = 4 points,'Always' = 5 points; for reverse items: "Never" = 5 points, "Rarely" = 4 points, 'Sometimes' = 3 points, "Often" = 2 points, 'Always' = 1 point.

The Cronbach's α coefficients for the knowledge, beliefs and behaviours of the questionnaire were 0.81, 0.87 and 0.91, respectively.

In addition, each quality indicator (eg, specimen compliance rates) in this study is based on established thresholds and proportions. Because these indicators are expressed as rate-based outcomes, we now present 95% confidence intervals, where appropriate, to reflect the statistical properties and potential variation inherent in proportion-based data. This approach helps provide a clearer picture of the precision and reliability of our estimates.

Statistical Methods

All analyses were performed using SPSS 23.0 (SPSS Inc., Chicago, IL). Continuous data were tested for normality and expressed as mean ± standard deviation. Independent-samples t-tests compared the control vs observation groups, with Cohen's d as the effect size (small≥0.2, medium≥0.5, large≥0.8). Categorical data (eg, patient satisfaction, doctors' trust) were expressed as percentages and compared using the chi-squared (χ^2) test with corresponding 95% CIs for proportions. To account for multiple comparisons, Bonferroni corrections were applied, and $p<0.05$ was considered statistically significant.

For the comparison of scores on nurses' knowledge, beliefs and behaviours, operational standardisation, patient satisfaction and clinical doctors' trust in test results, the following statistical methods were employed: (1) Knowledge, beliefs and behaviours scores: The total scores for each dimension were calculated, and the independent samples *t*-test was used to compare the means between the control and observation groups.[15] (2) Operational standardisation scores: The total scores from the checklist were compared using the independent samples *t*-test. (3) Patient satisfaction and clinical doctors' trust: The chi-squared (χ^2) test was used to compare the proportions of satisfied patients and trusting clinical doctors between the two groups.[16]

Results

Demographics of Nursing Staff

Among the 550 nurses in the control group, the mean age was 29.2 ± 3.7 years, with a mean clinical experience of 6.8 ± 2.2 years; in the observation group, the mean age was 29.5 ± 3.9 years, with 6.9 ± 2.1 years of experience. There were no statistically significant differences in these baseline characteristics ($p > 0.05$).

Non-Compliant Specimen Rates

Table 3 compares the non-compliance rates between the two groups. The observation group showed significantly lower rates of type mismatch, container mismatch, improper volume, contaminated blood cultures, and coagulated samples (all $p < 0.01$).

Table 3 Comparison of Non-Compliant Specimen Rates

Group	Total Specimens (a)	Blood Culture Specimens (b)	Anticoagulated Specimens (c)	Type Mismatch n/a (%), 95% CI	Container Mismatch n/a (%), 95% CI	Volume Mismatch n/a (%), 95% CI	Contaminated Blood Cultures n/b (%), 95% CI	Coagulated Samples n/c (%), 95% CI
Control (2022)	775,783	11,448	223,119	166/a (0.021%) [0.018–0.024%]	151/a (0.019%) [0.016–0.022%]	377/a (0.049%) [0.044–0.054%]	582/b (5.08%) [4.68–5.48%]	845/c (0.38%) [0.35–0.41%]
Observation (2023)	973,107	12,390	266,227	87/a (0.009%) [0.007–0.011%]	97/a (0.010%) [0.008–0.012%]	187/a (0.019%) [0.016–0.022%]	295/b (2.38%) [2.11–2.65%]	233/c (0.088%) [0.076–0.10%]
χ^2	–	–	–	46.31	27.45	115.57	122.67	468.29
p-value	–	–	–	<0.01	<0.01	<0.01	<0.01	<0.01

Notes: (a) Total number of specimens (includes both blood culture and anticoagulated specimens).(b) Total number of blood culture specimens.(c) Total number of anticoagulated specimens.

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Table 4 Comparison of Nurses' Knowledge, Beliefs, and Behavior Scores (x ± s)

Group	Knowledge Score (0–12)	Belief Score (7–35)	Behavior Score (9–45)	Overall Total (0–92)*
Control (n=550)	7.24 ± 2.99	23.9 ± 3.98	33.07 ± 4.93	64.22 ± 7.40
Observation (n=550)	8.58 ± 3.13	24.2 ± 4.00	40.72 ± 4.93	73.50 ± 7.64
t value	–7.22	–1.06	–28.23	–19.60
p-value	<0.01	0.29	<0.01	<0.01
Effect size (d)	0.44	0.08	1.56	1.30

Notes: *Overall total is the sum of knowledge, belief, and behavior dimensions (rescaled for clarity).

Nurses' Knowledge, Beliefs, and Behaviors

Table 4 shows the comparison of nurses' questionnaire scores (n=550 each group). Knowledge and behavior scores improved significantly in the observation group ($p < 0.01$), while belief scores did not differ significantly. The effect sizes for knowledge and behavior changes were Cohen's $d = 0.44$ and 1.56, respectively, indicating moderate and large effects.

Nurses' Operational Standardization Scores

The mean operational standardization score in the observation group (92.5 ± 3.2) was significantly higher than in the control group (85.7 ± 4.1; $t = –10.52$, $p < 0.01$; 95% CI of the difference: [5.45–7.13]).

Patient Satisfaction

A total of 500 patients in each group completed the satisfaction survey. The observation group achieved a satisfaction rate of 93.8%, significantly higher than the control group's 87.2% ($\chi^2 = 15.63$, $p < 0.01$). The 95% CI for the difference in proportions ranged from 3.1% to 10.7%.

Clinical Doctors' Trust in Test Results

Among 200 clinical doctors surveyed in each group, 84.5% in the control period expressed trust, versus 91.2% in the observation period. This difference was also significant ($\chi^2 = 12.78$, $p < 0.01$), with a 95% CI of 2.9%–11.2%.

Discussion

This study aimed to evaluate the effectiveness of a pre-analytical quality management pathway based on the structure-process-outcome (SPO) model in improving laboratory testing quality. Our results demonstrated significant improvements across multiple quality indicators. The implementation of the SPO-based pathway led to substantial reductions in non-compliant specimen rates, including specimens not meeting type requirements (0.001% vs 0.021%), collection containers not meeting requirements (0.001% vs 0.019%), collection volumes not meeting requirements (0.001% vs 0.049%), contaminated blood culture specimens (2.38% vs 5.08%), and coagulated specimens (0.088% vs 0.38%). Furthermore, we observed significant enhancements in nurses' knowledge and behaviors related to laboratory testing, increased operational standardization, higher patient satisfaction, and greater clinical trust in test results.

Application of the Pre-Analytical Quality Management Pathway Based on the SPO Model Reduces the Rate of Non-Compliant Specimens

This study demonstrated significant reductions in non-compliant specimen rates across multiple categories following the implementation of the SPO-based pre-analytical quality management pathway. These improvements align with findings from previous studies that have emphasized the importance of standardized processes and multidisciplinary collaboration in reducing pre-analytical errors.[17,18] Our results particularly highlight the effectiveness of a nursing-led, multidisciplinary approach in addressing issues that traditionally fall outside the laboratory's direct control.[19] The observed reductions in specimens not meeting type requirements, collection containers not meeting requirements, collection volumes not meeting requirements, contaminated blood culture specimens, and coagulated specimens are comparable to

improvements reported in similar quality improvement initiatives. For instance, Lima-Oliveira et al (2017) reported significant reductions in pre-analytical errors following the implementation of standardized procedures and staff training.[20] Our study extends these findings by demonstrating the effectiveness of a comprehensive, SPO-based approach that encompasses structural, process-oriented, and outcome-focused interventions.

Enhancing Nurses' Knowledge, Beliefs and Behaviours Related to Testing

Specimen collection is a cornerstone of comprehensive quality management, representing the initial step within laboratory quality control parameters.[9] Evidence indicates that 72.6% of blood specimen disqualifications stem from the collection phase,[21] with 65% linked to clinical nursing practices.[20] As primary actors in specimen collection, clinical nurses' proficiency in venous blood sampling – encompassing knowledge, attitudes and practical skills – directly impacts the quality of specimen collection.[22] However, domestic educational and hospital assessment frameworks predominantly focus on procedural and technical mastery, with less emphasis on theoretical knowledge, leading to a practice-heavy, theory-light approach among clinical nurses. This overlooks the critical need for continual knowledge updating, resulting in a gap in comprehensive and current knowledge among nurses.[23] The significant improvements observed in nurses' knowledge and behaviors ($p < 0.05$) underscore the value of a targeted, issue-oriented training approach. These results align with those of Bölenius et al (2012), who emphasized the importance of comprehensive education in improving venous blood sampling practices.[7] Interestingly, while we observed significant improvements in knowledge and behaviors, changes in beliefs were not statistically significant. This finding highlights the complex nature of belief formation and suggests that longer-term interventions may be necessary to effect changes in this domain, a point also noted by Tang et al (2022) in their systematic review of shared decision-making implementation.[8]

A Quality Management Pathway Based on the Structure–Process–Outcome Model and Multidisciplinary Coordination is Key to Enhancing Pre-Analytical Quality Management

The pre-analytical phase involves not only nursing but also medical affairs, laboratory, logistics, and IT.[24,25] Multidisciplinary teams can foster consistent standards, synergy, and accountability in pre-analytical tasks. Our approach, guided by SPO, provided an integrated framework that spanned structure (policy, infrastructure), process (training, SOPs, supervision), and outcomes (error rates, satisfaction, trust).This holistic approach aligns with the recommendations of Hawkins (2012) for managing the pre- and post-analytical phases of the total testing process.[26] Furthermore, our findings support the assertion by Lippi et al (2011) that a systems-based approach is crucial for enhancing patient safety in laboratory testing.[27]

Impact of the Structure–Process–Outcome-Based Quality Management Pathway on Nurses' Operational Standardisation

The implementation of the SPO-based quality management pathway led to a significant improvement in nurses' operational standardisation. This improvement can be attributed to several factors introduced in the new pathway. The establishment of a dedicated phlebotomy team ensured consistent and standardised blood collection procedures across all departments.[28] Moreover, the continuous quality improvement programme, with its regular quality circles and targeted improvement strategies, fostered a culture of excellence and attention to detail among nursing staff.[29]

Enhancement of Patient Satisfaction Through Improved Pre-Analytical Processes

The significant increase in patient satisfaction scores in the observation group highlights the patient-centred nature of the SPO-based quality management pathway. The introduction of barcode technology for patient identification not only improved safety but also enhanced patients' perception of the hospital's technological sophistication.[30] Furthermore, the establishment of a dedicated phlebotomy team led to more efficient and less painful blood collection experiences for patients.[31]

Strengthening Clinical Doctors' Trust in Laboratory Test Results

The observed increase in clinical doctors' trust in test results is a crucial outcome of the SPO-based quality management pathway. This improvement can be attributed to the reduction in pre-analytical errors and the enhanced communication between laboratory and clinical departments facilitated by the new quality management information system.[26] The increased trust is likely to lead to more efficient clinical decision-making and improved patient outcomes.[32]

The Role of Information Technology in Enhancing Pre-Analytical Quality Management

The integration of a comprehensive quality management information system played a pivotal role in the success of the SPO-based pathway. Real-time monitoring of pre-analytical processes and automated alerts for potential errors allowed for prompt intervention, reducing the likelihood of errors reaching the analytical phase.[27] Moreover, the system's ability to generate detailed reports facilitated data-driven quality improvement initiatives, aligning with best practices in laboratory medicine.[33]

Conclusion

The SPO-based pre-analytical quality management pathway significantly reduced non-compliant specimens and increased nurses' knowledge, operational standardization, patient satisfaction, and clinical doctors' trust. Educational interventions were likely a major driving force behind these improvements. Overall, our findings underscore the importance of integrating structural, procedural, and outcome-focused interventions to enhance pre-analytical quality and, by extension, patient safety.

Nevertheless, this study has limitations: (1) The duration of the study is relatively brief, necessitating further inquiry into the long-term effects; (2) as a single-centre study, the extrapolation of findings is inherently constrained. Future research endeavours could potentially explore the efficacy of this management pathway through multicentre, extended follow-up studies. Additionally, owing to technological constraints, this study has yet to fully realise the potential of comprehensive information management, thus necessitating further exploration into the application of information technology in the realm of specimen quality control.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee of Shanxi Bethune Hospital (Approval Number: YXLL-2024-164). Written informed consent was obtained from all clinical staff (nurses and doctors), and verbal informed consent was obtained from patients prior to data collection, as per IRB-approved protocols.

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