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Evaluation of the impact of PDCA cycle management on heparin anticoagulation specimen quality rate in neurorespiratory care units

Ying Shen[1], Dahong Zhai[1], Yang Li[1], Tingting Gui[1] and Dengqin Zuo[2]*

[1]Department of Nursing, Shanghai Sixth People's Hospital, China

[2]Gynaecologic Department of Traditional Chinese Medicine, Changhai Hospital, The First Affiliated Hospital of Naval Medical University, Shanghai, China

Abstract: **Background**: The quality of heparin-anticoagulated specimens is of paramount importance for the delivery of highly accurate diagnostic results in neurorespiratory settings. However, pre-analytical factors such as hemolysis, clotting, and labeling errors often threaten this quality. This paper explores if the use of a Plan-Do-Check-Act cycle management would improve the quality of the heparin anticoagulation specimen. **Objectives**: To evaluate the effectiveness of managing the PDCA cycle to improve the quality of heparin anticoagulation specimen samples in a neurorespiratory care unit through error reduction and work process optimization. **Methods**: This was a pre-post intervention study that took place in the 47-bed neuro-respiratory care unit of Shanghai Sixth People's Hospital. A total of 2,000 samples were screened from June 2020 to June 2021. Overall, 108 samples (54 pre-PDCA implementation and 54 post-PDCA implementation) were selected for analysis of specimen quality, delivery time, and pre analytical errors. Employee training was carried out, as well as process improvement through regular audits. Data collection took place in terms of specimen quality, delivery times, staff compliance, and staff knowledge from January to March 2023, with intervention phases from April to June 2023. **Results**: Following the PDCA intervention, there was a great improvement in specimen quality, with the percentage of qualified specimens rising from 68.5% to 94.4% ($p < 0.001$). Hemolysis decreased from 18.5% to 3.7% ($p < 0.001$), clotting from 11.1% to 1.9% ($p < 0.001$), and incorrect labeling from 9.3% to 0%. Mean delivery time reduced from 53.4 ± 11.8 minutes to 34.6 ± 7.3. **Conclusion**: A substantial improvement in the quality of anticoagulation specimens of heparin was achieved through the effective management of the PDCA cycle. It is evident that the PDCA cycle method possesses beneficial applications in optimizing laboratory practices for ensuring patient safety in neurorespiratory care units.

Keywords: Heparin anticoagulation; Laboratory quality management; Neurorespiratory care; PDCA cycle; Pre-analytical error; Quality of the specimen; Workflow optimization

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INTRODUCTION

The quality of heparin anticoagulation specimens is very critical in neurorespiratory practice and proper coagulation testing directly impacts diagnosis, treatment and outcomes in acute disorders such as ischemic stroke, pulmonary embolism, deep vein thrombosis and ventilator-associated complications (Dieplinger *et al.,* 2018). In such high-acuity settings, subtle failures in specimen handling threaten test validity, leading to delayed treatment, inappropriate anticoagulant dosing, or complications (Northam *et al.,* 2023; Dixon *et al.,* 2021; Mahto *et al.,* 2024). High-quality specimens, therefore, are vital to patient safety and successful intervention.

Pre-analytical errors, nevertheless, remain prevalent. They include hemolysis, inappropriate heparin quantity, inadequate mixing, clotting, mislabeling and delayed transport (Aggarwal *et al.,* 2021). National Chinese studies note that up to 85% of specimens rejected for anticoagulation are due to clotting, sample volume insufficiency, or mislabeling, with neurorespiratory units being particularly vulnerable due to their time-sensitive interventions and critically ill patients (Lin *et al.,* 2023; Gardiner *et al.,* 2021; Kushnir *et al.,* 2021). Evidence indicates that discrepancies with phlebotomy practice, irregular compliance with guidelines and inadequate staff training are the main reasons for these errors, often resulting in repeated sampling, increased healthcare cost and unnecessary patient distress. With the exception of individual cases, compromised specimen integrity also impairs hospital performance measures, laboratory productivity and accreditation. Solving these problems calls for a systematic, evidence-based approach to address both human and organizational issues (Bodley *et al.,* 2023; Gupta *et al.,* 2021).

The Plan-Do-Check-Act (PDCA) cycle, conceived initially for industrial quality assurance, offers just such a framework. PDCA facilitates ongoing improvement by detecting failures, taking corrective action, assessing the effect of the action and standardizing best practices. In the field of medicine, PDCA has been effectively applied to infection control, surgical safety briefing, medication reconciliation and patient satisfaction (Northam *et al.,* 2023). When applied to heparin specimen collection, PDCA-back mechanism can standardize phlebotomy procedures, ensure precise anticoagulant-to-blood ratios, streamline transport activities and maximize staff

**Corresponding author:* e-mail: 13761991813@163.com

compliance with evidence-based guidelines (Gupta *et al.,* 2021; Ebadi, 2025a).

While the potential of PDCA is clear, its application in Chinese tertiary hospitals remains uneven. Some managers are unaware of the entire methodology or fail to incorporate the "Act" step, thus limiting long-term impact. Contributing hindrances are limited institutional resources, insufficient full-time quality teams and competing clinical priorities. In heparin specimen collection, these hindrances perpetuate avoidable errors and jeopardize patient safety (Li and Liu, 2025; Cook *et al.,* 2021; Beriault *et al.,* 2021; Ebadi, 2025b; Ebadi and Selamoglu, 2025a). This study evaluates the impact of PDCA cycle management on heparin anticoagulation sample quality in Shanghai Sixth People's Hospital's neurorespiratory department, a Class III Grade A hospital. By applying systematic cause and effect finding for pre-analytical mistakes, evidence-based focused interventions and implementing compliance with training and supervision, this study seeks to create an efficient, replicable model of quality improvement. The findings must be able to demonstrate reductions in specimen rejection, improved workflows and enhanced staff competency, ultimately improving immediate patient care and long-term organizational results.

MATERIALS AND METHODS

Study design and setting

We conducted a before-and-after interventional observational study in Shanghai Sixth People's Hospital neurorespiratory ward, a 47-bed tertiary comprehensive hospital with a specialty in complex neurological and respiratory diseases. The ward receives patients requiring invasive or non-invasive ventilation, many of whom receive intensive heparin anticoagulation for the prevention or treatment of thromboembolic complications. The study evaluated the effect of PDCA cycle management on the quality of heparin anticoagulation specimens. Between June 2020 and June 2021, 2000 cases of heparin-related coagulation tests were screened. Of these, 108 specimens (54 pre-intervention and 54 post-intervention) were chosen for statistical comparison and in-depth analysis. The hospital's laboratory information system (LIS) is interfaced with the hospital information system (HIS), allowing systematic surveillance of specimen quality indicators (Li *et al.,* 2022; Kang *et al.,* 2024; Zonsius and Milner, 2021).

Study population and inclusion criteria

Eligible cases were patients aged ≥18 years who were admitted to the neurorespiratory ward and were receiving heparin therapy or undergoing heparin-related coagulation tests. Complete records of specimen collection, labeling, transport and laboratory processing were requirements for inclusion. Samples included activated partial thromboplastin time (APTT), prothrombin time (PT), international normalized ratio (INR), fibrinogen and D-dimer tests. Exclusion criteria included incomplete records, non-heparin therapy-related samples, or unavoidable hemolysis/clotting due to patient-related factors such as fragile veins or excessive trauma.

Baseline quality problems

Prior to the implementation of the PDCA cycle, the following issues were identified:

- 20% hemolysis, mainly due to poor venipuncture technique or unsuitable needle gauge.
- 15% clotting, frequently due to poor inversion of sodium citrate tubes or heparin-blood mixing.
- 10% labeling errors, resulting in specimen rejection or misidentification.
- 18% delayed transport, transport time >60 minutes, with potential for compromised heparin monitoring accuracy.

These problems decreased the percentage of qualified specimens, resulted in repeated collections, delayed anticoagulation adjustments and put patients at greater risk (Iqbal *et al*., 2023).

PDCA cycle implementation strategy

In January 2021, a root cause analysis using Ishikawa diagrams was conducted by an error-control committee comprising quality managers, head nurses, senior clinical nurses, and laboratory technicians. The analysis identified key issues such as insufficient staff training, the absence of standard operating procedures (SOPs), poor awareness of specimen transport times, and lack of supervision. In response, the Plan phase involved developing SOP manuals for specimen collection, labeling, handling, and transport. Additionally, theoretical and practical training sessions were delivered by senior nurses and laboratory experts, with a focus on maintaining correct blood-to-anticoagulant ratios. To reduce labeling errors, visual aids, flowcharts, and barcoded wristbands with bedside scanning were implemented. During the Do phase, these changes were actively implemented, and weekly error-tracking checklists along with laboratory rejection reports were used to monitor improvements. In the Check phase, the quality control team conducted monthly trend analyses to identify any ongoing issues. Finally, in the Act phase, continuous feedback was provided to staff, with rewards given to high performers and refresher training offered to those who made recurring errors. This ongoing cycle of improvement helped enhance specimen handling practices and minimize errors in the laboratory (Hétu *et al.,* 2021; Balasubramanian *et al.,* 2024).

Staff training and participation

16 nurses directly engaged in venous blood collection were put through a structured program that included:

- Simulation-based venipuncture on mannequins.
- Case-based discussion of common pre-analytical errors.
- Pre- and post-training knowledge assessment to ascertain learning.

- Certification of trainees who went through PDCA training.

All sessions were run under the supervision of nursing educators and department managers to ensure consistency and participation.

Data collection and monitoring

Specimen quality data were obtained from the LIS (receipt time, hemolysis, clotting, labeling errors, rejection causes) and collection times, transport times and SOP compliance audits were provided by the HIS and nursing records. Qualified specimen rate, hemolysis, clotting, labeling error, delayed transport, mean transport time and staff compliance with SOPs were the main quality indicators.

Statistical analysis

Data were analyzed with SPSS version 22.0. Categorical data (i.e., error rates, qualified specimen rates) were compared according to the Chi-square (χ^2) test. Continuous data (i.e., transport times) were compared using independent-samples t-tests. Results are presented as mean ± standard deviation or percentages. Statistical significance was set at $p < 0.05$.

RESULTS

Baseline and post-intervention comparison

2,000 heparin-associated coagulation specimens were screened and 108 specimens were selected for detailed analysis. Patients were randomized to the pre-PDCA group (n = 54) and the post-PDCA group (n = 54). All patients were adults (≥18 years) who were hospitalized in the neurorespiration ward and were receiving heparin therapy for prevention or treatment of thromboembolic complications. Baseline demographic factors, including age and sex, were similar between groups. The qualified rate of heparin anticoagulation specimens was significantly increased from 68.5% in the pre-PDCA group to 94.4% following PDCA ($\chi^2 = 13.62$, $p < 0.001$), indicating that the management of PDCA cycles was effective at optimizing specimen quality. (Table 1).

Comparison of specific error types

There were considerable reductions in pre-analytical errors after PDCA implementation. Hemolysis decreased from 18.5% to 3.7%, clotting from 11.1% to 1.9%, labeling errors from 9.3% to 0% and delayed delivery from 22.2% to 5.6%. These are significant improvements for valid APTT and anti-Xa assay results. Reductions in errors for each type of pre-analytical problem are given in fig. 1.

Improvement in specimen delivery time

The mean time from specimen collection to laboratory arrival decreased from 53.4 ± 11.8 minutes to 34.6 ± 7.3 minutes ($t = 9.88$, $p < 0.001$), reflecting quicker transport and improved sample integrity. (Table 2).

Staff knowledge and compliance audit

Compliance with SOPs and knowledge scores by staff were substantially improved after PDCA training. Compliance with SOPs increased from 73.2% to 98.1% and average knowledge scores from 68.7 to 91.4 ($p < 0.001$ for both). Enhanced staff competency directly resulted in proper specimen handling, proper mixing and timely tube inversion. (Table 3).

DISCUSSION

The current study shows how the use of the PDCA cycle in a department of neurorespiration significantly improved pre-analytical quality of heparin-monitoring samples. The percentage of qualified samples was raised from 68.5% to 94.4%, thereby demonstrating the ability of systematic quality management to improve anticoagulation monitoring (Johnson, 2024). Since APTT and anti-factor Xa testing are unduly susceptible to pre-analytical variation, even minor errors such as hemolysis, clotting, or delayed transport can affect results and negatively impact patient safety. Through the application of standardized collection practice, continuous staff training and reduced logistics, PDCA reduced bias and increased reliability in heparin monitoring (Weiss *et al.,* 2022; Northam *et al.,* 2021; Slade *et al.,* 2020).

The most significant gains were in reduction of hemolysis from 18.5% to 3.7% and elimination of labeling errors from 9.3% to 0%. These findings are in accord with previous studies by Mankar *et al.* (2024) and Marques-Garcia (2020), who also reported similar reductions in pre-analytical errors following quality efforts planned for. Elimination of clotting errors, reflective of better mixing practices and compliance with heparin-contaminated line avoidance, was also of great utility. Together, these innovations not only reduce laboratory workload via reduction of specimen rejection but also enhance direct patient care by better dosing control. Time for transport of specimens was decreased from 53.4 ± 11.8 minutes to 34.6 ± 7.3 minutes, an improvement that is particularly of interest to heparin, the half-life of which is so short that it can easily become neutralized by platelet factor 4 upon delay. Rapid delivery minimized falsely normalized APTT results and thereby improved clinical decision-making accuracy. Comparable benefits from PDCA-optimized logistics are reported in pathology processes elsewhere (Mohammadi Aria *et al.,* 2019).

Another significant accomplishment was staff compliance with SOPs rising from 73.2% to 98.1% and knowledge scores from 68.7 to 91.4. This reflects the cyclical repetition of training, feedback and audit of performance built into the PDCA cycle. In life-or-death scenarios where anticoagulant doses are being changed each hour, enhanced staff competence translates to fewer dosing errors and lower threat of bleeding or thrombosis. Wehner *et al.*

Table 1: Pre- and post-PDCA qualified rate of heparin anticoagulation specimens

Group	Total specimens	Qualified	Unqualified	Qualified rate (%)	χ^2	p-value
Pre-PDCA	54	37	17	68.5		
Post-PDCA	54	51	3	94.4	13.62	<0.001***

Note: The rise in qualified specimens following the implementation of PDCA was statistically significant.

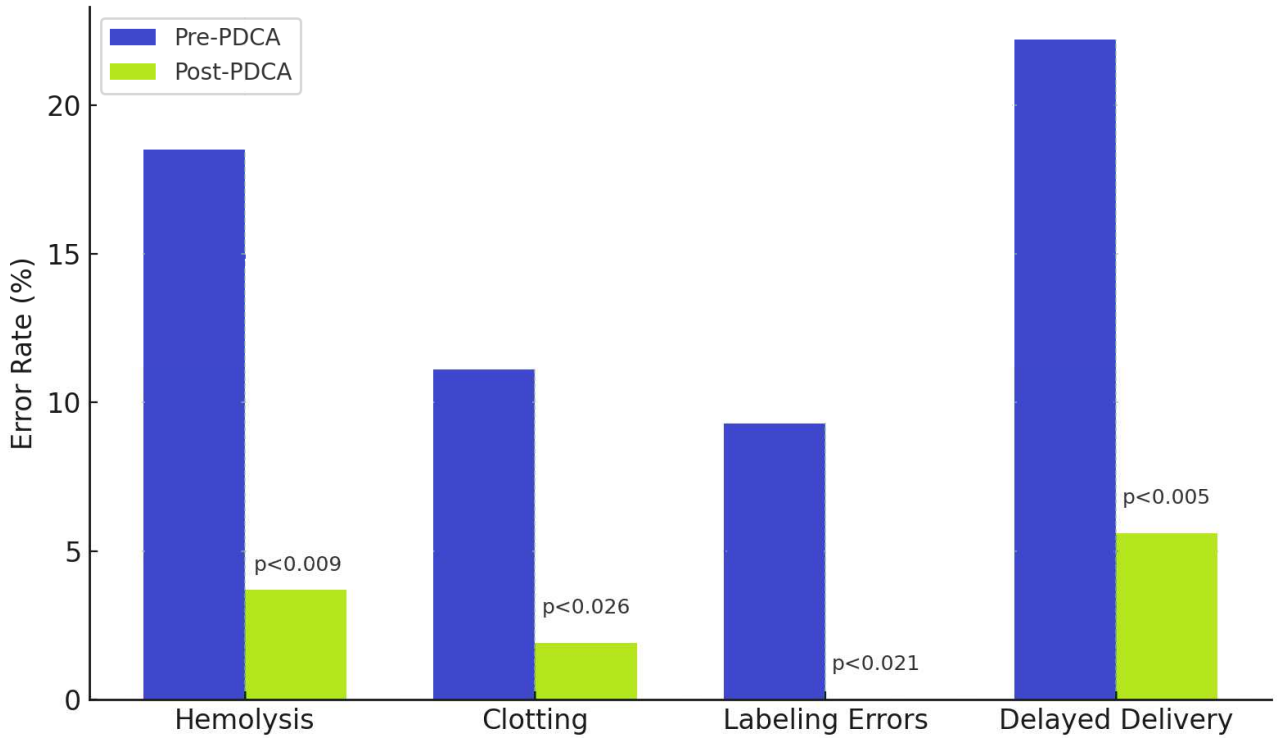

Fig. 1: Pre- and post-PDCA error rates for heparin anticoagulation specimens; Rates of hemolysis, clotting, labeling errors, and delayed delivery before and after PDCA cycle management implementation. Most significant improvements were in delivery times and labeling accuracy, which have a direct effect on sample stability and heparin monitoring reliability.

Table 2: Mean collection-to-arrival time for heparin specimens

Group	Mean ± SD (minutes)	t-value	p-value
Pre-PDCA	53.4 ± 11.8		
Post-PDCA	34.6 ± 7.3	9.88	<0.001***

Note: Reduced transit time improved sample stability and heparin monitoring result validity.

Table 3: Staff compliance and knowledge scores

Indicator	Pre-PDCA	Post-PDCA	F-value	p-value
SOP Adherence (%)	73.2%	98.1%	12.62	<0.001***
Average Knowledge Score (/100)	68.7	91.4	28.43	<0.001***

Note: Post-intervention, SOP compliance was >98% at all times, with a marked increase in staff knowledge of pre-analytical variables affecting heparin test reliability.

(2020). also reported that PDCA not only reduced the rate of rejection but also fostered a consistent culture of error prevention in coagulation testing. The evidence shows that PDCA is an effective and scalable method for enhancing the quality assurance of laboratories. By bridging procedural, educational and logistic disparities, PDCA offers a systematized path to more standardized anticoagulation monitoring that ultimately translates to safer and earlier therapeutic choices (Thakur *et al.,* 2023; Ro *et al.,* 2024). Another advantage of adopting PDCA is the enhancement of interdisciplinary cooperation. The cycle entailed coordination among nurses, lab personnel

and clinicians to streamline specimen handling, training and reporting. This kind of collaboration not only ensured compliance with protocols but also provided a collective responsibility for patient safety. Interdisciplinary teamwork from other healthcare settings suggests that it makes the system as a whole robust and reduces repeated error occurrence (Liu *et al.,* 2021; Patel *et al.,* 2022). Moreover, the PDCA cycle offers continuous feedback, allowing departments to identify emerging issues early and adjust interventions accordingly, with long-term sustainable gains in quality.

Finally, while the research was done on heparin monitoring, PDCA concepts can be used extensively in laboratory as well as clinical settings. Its systematic problem-solving approach for problem-definition, intervention, appraisal and cycle-breeding is a template that can be replicated to improve other high-risk processes, such as blood culture processing, transfusion practice and complex pharmacologic monitoring. Demonstrating measurable improvements in specimen quality, staff competence and logistical efficiency, the study provides data that PDCA can be a central part of laboratory quality management systems everywhere.

There are certain limitations, however, which must be factored. It was a single-center audit of a single ward of a single tertiary hospital and the sample size, although sufficient for statistical comparison, was extremely small. The retrospective before–after design is not able to adjust for confounding factors such as variations in staffing or patient case mix. Moreover, important influences such as patient nutritional status—which can directly affect coagulation profiles and specimen integrity—were not assessed (Salwa *et al.,* 2025; Ebadi and Selamoglu, 2025b). In addition, follow-up was minimal and outcome measures were limited to specimen quality and not patient outcome in and of itself such as bleeding or thrombotic event. Despite these limitations, the results provide evidence that PDCA can potentially have a profound influence on the integrity of heparin anticoagulation specimens and justify its widespread application in laboratory medicine.

CONCLUSION

Implementation of the PDCA cycle in the collection and handling of heparin-monitoring anticoagulation samples in the neurorespiration unit enhanced specimen quality considerably, reduced pre-analytical mistakes, reduced turnaround time and enhanced staff conformity to SOPs. As the therapeutic index is narrow with heparin and the precision of APTT and anti-Xa results depends on the quality of the sample, the improvement has critical patient safety implications. By systematically identifying and eliminating the underlying causes through systematic planning, concentrated training, controlled execution and continuous feedback, PDCA enhanced operational performance and facilitated consistent clinical decision-making. These findings are in line with more recent literature that demonstrates PDCA has the potential to reduce coagulation specimen error rates, reduce turnaround times and facilitate a sustainable quality culture. The technique is adaptable and scalable, making it suitable for broader use in monitoring anticoagulation in more widespread settings, particularly high-dependency areas where precise and timely heparin measurements are critical. It would be worthwhile to investigate further multicenter trials examining clinical outcomes and cost compared with conventional methods to further clarify the role of PDCA in optimizing heparin therapy and treatment in different hospital settings.

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Authors' contributions
Ying Shen and Dahong Zhai contributed to study design and data collection. Yang Li performed data analysis. Tingting Gui assisted with clinical coordination and specimen management. Dengqin Zuo supervised the research, provided methodological guidance, and revised the manuscript. All authors reviewed and approved the final version.

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Data availability statement
The datasets generated and analyzed during the current study are not publicly available due to patient confidentiality and institutional policies but are available from the corresponding author on reasonable request. De-identified data supporting the findings of this study may be shared upon approval by the Ethics Committee of Shanghai Sixth People's Hospital with no funding.

Ethical approval
The study was approved by the Ethics Committee of Shanghai Sixth People's Hospital (Approval No: 2022-KY-050(K)). Since it was a quality improvement project with non-invasive interventions and de-identified data, informed consent was not necessary.

Conflict of interest
There is no conflict of interest for any authors.

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