

# Application Analysis of Quality Control Management in Blood Component Preparation at Blood Stations

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**Abstract:** Objective: To analyze the application effect of quality control management in blood component preparation at blood stations. Methods: A total of 1,984 blood samples prepared at the blood station from January 2024 to March 2025 were selected and divided into a control group (991 samples) and an experimental group (993 samples). The control group implemented routine preparation management, while the experimental group implemented full-process quality control management on this basis. The qualification rate of blood components, rejection rate, incident rate at key control points, and work quality were compared between the two groups. Results: The qualification rate of blood components in the experimental group was higher than that in the control group, and the rejection rate was lower than that in the control group ( $P < 0.05$ ). The incident rate of abnormalities at each control point in the experimental group was significantly lower than that in the control group, and the disposal time in the experimental group was  $9.35 \pm 2.84$  minutes, significantly shorter than that in the control group ( $23.41 \pm 4.62$  minutes) ( $P < 0.05$ ). The experimental group scored significantly higher than the control group in terms of work quality ( $P < 0.05$ ). Conclusion: Full-process quality control management can effectively improve the standardization and qualification rate of blood component preparation, contributing to the systematic and refined development of quality management at blood stations.

**Keywords:** Blood station; Blood component preparation; Quality control management; Full-process management

**Online publication:** January 30, 2026

## 1. Introduction

Blood stations are non-profit public health and medical institutions established by the state, responsible for collecting, testing, preparing, and supplying blood, with the collected blood primarily used for the continuous supply of clinical blood<sup>[1]</sup>. Since the quality of blood used clinically directly relates to the transfusion safety and treatment outcomes of patients, strict quality control management of blood quality is required in the workflow of blood stations<sup>[2]</sup>. Typically, after collecting blood, blood stations prepare blood components, a process that mainly involves physically separating the collected whole blood into various types of component blood for

targeted clinical use<sup>[3]</sup>. To enhance the quality of blood component preparation at blood stations, it is necessary to implement comprehensive quality control management measures to ensure the safety of the blood supply from blood donation institutions<sup>[4]</sup>. Therefore, this study will compare the changes in the qualification rate, discard rate, critical control point incident rate, and work quality scores of blood components under two management models, thereby providing a basis for the standardization, refinement, and continuous improvement of quality management in blood component preparation at blood stations.

## **2. Materials and methods**

### **2.1. General information**

A total of 1,984 blood component samples prepared and subjected to quality testing at a central blood station from January 2024 to March 2025 were included in the study. These samples were randomly divided into a control group and an experimental group using a random number table method, with 991 samples in the control group and 993 samples in the experimental group. In the control group, there were 991 blood component samples; among the blood donors, there were 556 males and 435 females; the age range was 18 to 54 years, with an average age of  $31.62 \pm 7.15$  years; there were 617 first-time donors and 374 repeat donors; the average single donation volume was  $392.46 \pm 48.73$  mL; the pre-donation hemoglobin level was  $146.27 \pm 11.63$  g/L, systolic blood pressure was  $117.85 \pm 9.18$  mmHg, and diastolic blood pressure was  $74.33 \pm 7.26$  mmHg. In the experimental group, there were 993 blood component samples; among the blood donors, there were 552 males and 441 females; the age range was 18 to 55 years, with an average age of  $31.48 \pm 7.22$  years; there were 610 first-time donors and 383 repeat donors; the average single donation volume was  $393.21 \pm 49.15$  mL; the pre-donation hemoglobin level was  $145.96 \pm 11.72$  g/L, systolic blood pressure was  $118.02 \pm 9.07$  mmHg, and diastolic blood pressure was  $74.52 \pm 7.11$  mmHg. There were no statistically significant differences in gender ratio, age distribution, or donation volume between the two groups of blood donors and prepared samples ( $P > 0.05$ ). The study was approved by the ethics committee of the central blood station.

### **2.2. Inclusion and exclusion criteria**

Inclusion criteria: (1) Blood donors met the physical and laboratory examination criteria outlined in the “Health Examination Requirements for Blood Donors”<sup>[5]</sup>; (2) Aged between 18 and 55 years, with a body weight of  $\geq 50$  kg for males and  $\geq 45$  kg for females, and a hemoglobin concentration of  $\geq 120$  g/L; (3) Complete collection and component preparation process; (4) Blood donors provided informed consent for their samples to be used in this study.

Exclusion criteria: (1) Positive results in any of the serological tests (HBsAg, anti-HCV, anti-HIV, Treponema pallidum antibody) for blood donors; (2) Hemolysis, lipemic blood, or other conditions occurring during blood collection or preparation; (3) Incomplete sample test results or missing data records; (4) Other abnormal conditions that affect blood quality assessment.

### **2.3. Methods**

The control group adopted a conventional management model during the blood component preparation process. The preparation process was divided into stages such as blood collection, packaging, centrifugation, separation, rapid freezing, and storage, with each position carrying out corresponding work tasks according to established operational standards. After blood reception, the receiving personnel verified the donor number, label, and volume,

and registered the blood into inventory after confirming that there was no damage, clotting, or hemolysis in appearance. Subsequently, preliminary stratification of whole blood was completed through conventional single-stage centrifugation. During the separation process, the operator segmented the plasma, red blood cell, and platelet layers, and immediately sealed and labeled them after separation. If any broken bags, poor sealing, or abnormal blood appearance were found during the preparation process, they were manually removed by the operator and reported to the quality inspector for registration. Plasma rapid freezing was completed within 6 hours after blood collection, with the rapid freezing temperature set at  $-30^{\circ}\text{C}$ . After the finished blood products were packaged, they were stored in dedicated low-temperature refrigerators according to component types, and the temperature was recorded twice daily, in the morning and evening.

The experimental group implemented total process quality control management on the basis of conventional preparation. All personnel on duty were required to pass pre-job theoretical and practical assessments, and their operational error rates were assessed monthly. Before each shift, the quality control personnel verified the status of the instruments and environmental parameters, and filled out the equipment operation logs simultaneously. After blood collection, the information is double-checked, and an appearance inspection is conducted by two individuals to verify whether the blood bag seal, tubing, and labels are intact and clearly visible. Blood separation is completed within 4 hours of collection using a two-stage centrifugation method (initial centrifugation at 2000 r/min for 10 minutes, followed by secondary centrifugation at 3800 r/min for 10 minutes), and the blood is immediately transferred to the separation station after centrifugation. During the separation process, each bag of blood is weighed individually, with a balance tolerance of no more than  $\pm 2$  g. After plasma separation, the bag is sealed immediately, and the blood cell layer is processed through a leukocyte filtration device. Before thermo-sealing, the voltage and temperature of the sealing machine are checked. After thermo-sealing the catheter connectors, the operator reviews each one individually and records the serial numbers. Plasma is flash-frozen by distinguishing thickness according to specifications and placed flat on freezing plates. The start and end times of all operational steps, operator signatures, equipment serial numbers, and batch numbers are simultaneously recorded in the preparation quality control record form. Temperature and humidity are checked twice daily, and airborne microbial monitoring is conducted weekly. The surfaces of workstations and equipment are wiped and disinfected at least once daily. Consumables are received by the quality control personnel according to batch numbers, with checks for production dates, expiration dates, and packaging integrity. Any remaining consumables after use are sealed and stored separately. After each batch preparation, quality inspectors independently sample and test the suspended red blood cells, plasma, and platelet samples for quality. The tests include physical and chemical indicators, plasma clarity, platelet recovery rate, and bacteriological results, with all test items passing considered as qualified. The pass rate = (number of qualified products  $\div$  total number of tested products)  $\times$  100%. Discarded samples refer to those that cannot be placed into inventory due to issues occurring during collection, centrifugation, separation, thermo-sealing, flash-freezing, storage, or testing.

## **2.4. Observation indicators**

### **2.4.1. The qualification rate and rejection rate of blood component preparation**

Quality inspections are conducted on prepared suspended red blood cells, plasma, and platelet samples. The inspections encompass various physicochemical indicators of the products, plasma clarity, platelet recovery rate, and bacteriological results. Samples that pass all inspection items are deemed qualified.

Pass rate = Number of qualified products ÷ Total number of inspected products × 100%.

Discarded samples refer to those that cannot be placed into inventory due to issues occurring during collection, centrifugation, separation, thermo-sealing, flash-freezing, storage, or testing.

Scrap rate = Number of scrapped samples ÷ Total number of samples entering the preparation process × 100%.

#### **2.4.2. Event rate and handling time for key control points**

Monitoring is conducted at six nodes: blood reception, centrifugation, component separation, catheter heat sealing, rapid freezing, and storage/transportation. Abnormal events at each node are recorded, including inconsistent information, unbalanced centrifugation, poor layering, sealing defects, failure to meet the target temperature at the center during rapid freezing, and temperature deviations during storage and transportation.

Event rate = Number of abnormal events ÷ Total number of operations at the node × 100%

Handling time refers to the duration (in minutes) from the discovery of an abnormal event to its correction or completion of handling.

#### **2.4.3. Work quality**

The quality of work is assessed using a self-developed quality evaluation scale for blood component preparation positions. The scale consists of 12 indicators across four dimensions: blood source collection management, preparation operation standards, equipment maintenance, and material and storage/transportation management, with a total score of 100 points. Scoring is based on a 5-level scale (20, 40, 60, 80, 100 points), and the average score is taken as the total score. The Cronbach's  $\alpha$  of the scale is 0.92.

### **2.5. Statistical analysis**

Data are imported into statistical software (SPSS version 24.0) for analysis. Measurement data are verified for distribution characteristics using the Shapiro-Wilk test. Data conforming to a normal distribution are expressed as mean  $\pm$  standard deviation (Mean  $\pm$  SD), and comparisons between two groups are made using the independent samples t-test. Data not conforming to a normal distribution are expressed as median (interquartile range), and comparisons between groups are made using the Mann-Whitney U test. Count data are expressed as frequency and composition ratio "[n/(%)]", and comparisons between groups are made using the  $\chi^2$  test. When the theoretical frequency is  $<5$ , Fisher's exact probability method is used instead. All tests are two-sided, and a  $P$ -value  $<0.05$  is considered statistically significant.

## **3. Results**

### **3.1. Comparison of blood component preparation quality between two groups**

The qualification rate of blood component preparation in the experimental group was significantly higher than that in the control group, while the rejection rate was significantly lower than that in the control group ( $P < 0.05$ ) (Table 1)



**Table 1.** Comparison of blood component preparation quality between the two groups [%, Case (n)]

Group	Samples (n)	Qualified (n)	Qualified Rate (%)	Rejected (n)	Rejection Rate (%)
Control Group	991	904	91.22 (904/991)	91	9.18 (91/991)
Experimental Group	993	985	99.19 (985/993)	8	0.81 (8/993)
$\chi^2$ -value		69.166			73.417
<i>P</i> -value		<0.001			<0.001

Note: The qualification rate was calculated based on the products that completed testing, while the rejection rate was calculated based on the samples that entered the preparation process

### 3.2. Comparison of event rates and response times at key control points between the two groups

The experimental group had lower abnormal event rates at six key nodes, namely blood reception, centrifugation, component separation, catheter heat sealing, rapid freezing, and storage/transportation, compared to the control group, and the response time was significantly shortened ( $P < 0.05$ ) (Table 2).

**Table 2.** Comparison of event rates and response times at key control points between the two groups

Group	Information Mismatch n (%)	Centrifugal Imbalance n (%)	Poor Stratification n (%)	Sealing Defect n (%)	Inadequate Core Freezing Temp. n (%)	Storage/Transport Temp. Excursion n (%)	Processing Time (min, $\pm$ s)
Control Group (n=991)	12/991 (1.21)	18/991 (1.82)	11/991 (1.11)	13/991 (1.31)	9/991 (0.91)	8/991 (0.81)	23.41 $\pm$ 4.62
Experimental Group (n=993)	2/993 (0.20)	1/993 (0.10)	3/993 (0.30)	1/993 (0.10)	2/993 (0.20)	1/993 (0.10)	9.35 $\pm$ 2.84
$T/\chi^2$	7.214	15.392	4.620	10.383	4.494	5.483	81.676
<i>P</i> -value	0.007	<0.001	0.032	0.001	0.034	0.019	<0.001

### 3.3. Comparison of work quality scores between the two groups

The experimental group had significantly higher scores in all dimensions and overall scores compared to the control group ( $P < 0.05$ ) (Table 3).

**Table 3.** Comparison of work quality scores between the two groups (points, mean  $\pm$  SD)

Group	Blood Collection Management	Preparation Operation Standardization	Equipment Maintenance	Material and Storage/Transport Management	Comprehensive Score
Control Group (n=991)	86.35 $\pm$ 2.26	84.71 $\pm$ 2.83	82.93 $\pm$ 2.94	83.52 $\pm$ 3.18	84.38 $\pm$ 2.79
Experimental Group (n=993)	95.64 $\pm$ 1.84	96.18 $\pm$ 1.56	94.83 $\pm$ 1.97	95.33 $\pm$ 1.65	95.50 $\pm$ 1.71
t-value	100.411	111.824	105.927	103.857	107.054
<i>P</i> -value	<0.001	<0.001	<0.001	<0.001	<0.001

## 4. Discussion

Blood component preparation is one of the most technically demanding processes in blood station operations

and has a direct impact on blood utilization <sup>[6]</sup>. After collection, blood must undergo separation and rapid freezing within a specified time frame, and variations in operator proficiency, equipment performance, ambient temperature, and humidity control can all affect the quality of the final blood products <sup>[7]</sup>. Although blood stations have implemented strict testing procedures in the preparation process, their management mechanisms have primarily relied on post-event control, lacking comprehensive norms for real-time supervision during the process. While this approach can achieve certain results, it struggles to provide real-time warnings and corrections for process fluctuations in a timely manner. As the public's demand for the safety of blood transfusion rises today, the quality management of preparation also needs to be improved accordingly. In this regard, the current whole-process quality control management involves setting standardized parameters and recording requirements in processes such as collection, separation, heat sealing, quick freezing, storage, and transportation. The application of this model helps eliminate differences caused by human factors and enhances the consistency and stability of finished products <sup>[8]</sup>.

The results of this study show that the qualification rate of the experimental group implementing quality control management increased from 91.21% to 99.19%, while the rejection rate decreased from 9.18% to 0.81% compared to the control group under conventional quality management ( $P < 0.05$ ). By comparing the specific measures of the two management models, it is not difficult to identify the reasons for this improvement. Due to the adoption of dual parameter confirmation and balance verification during the centrifugation process in quality control management, the stratification of red blood cells in the blood becomes more stable. Meanwhile, equipment such as heat sealers and quick freezers is maintained and calibrated as planned, which largely avoids leakage and contamination caused by temperature deviations or poor heat sealing. Additionally, operators improve their adherence to execution standards through systematic training and assessment, significantly reducing subjective randomness in the preparation process. These results are consistent with the research conclusions of Mao Qichao et al., who believed that adjusting the quality control plan for blood component preparation can effectively improve the qualification rate of spot checks <sup>[9]</sup>. Furthermore, the results also show that the abnormal event rate at each control point in the experimental group was significantly lower than that in the control group, and the handling time was significantly shortened ( $P < 0.05$ ). This may be because a real-time recording and quality control feedback mechanism is established in quality control management, enabling operators to promptly identify and handle abnormalities at the early stage of problems, greatly reducing event accumulation and cross-impact. Finally, the results also indicate that the experimental group scored higher overall in work quality evaluations ( $P < 0.05$ ), suggesting that the effects of quality control management not only improve preparation results but also further enhance the overall execution capability and management maturity of the team. This result is consistent with the research findings of Li Yingping et al., both concluding that the adoption of quality control management in blood component preparation at blood stations can effectively improve work quality <sup>[10]</sup>.

In summary, quality control management throughout the entire process of blood component preparation can reduce waste caused by human errors and equipment failures at the source, enhance preparation efficiency and consistency of finished products, and improve the overall quality of blood products. In the future, it is essential to integrate information technology or tools to conduct real-time monitoring and trend analysis of key parameters involved in the process, thereby gradually establishing an intelligent quality control system and providing more reliable technical support for the safety of clinical blood transfusions.

## Disclosure statement

The authors declare no conflict of interest.

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