



Original Article

Study of Quality Control of Blood Components in a Tertiary Care Hospital Blood Centre in Navi Mumbai

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ABSTRACT

Background: Quality control in blood banking is essential for transfusion safety and component efficacy.

Methods: This observational cross-sectional study assessed 72 blood component units, including 12 packed red blood cell units each 350ml and 450 ml with SAGM (Saline, Adenine, Glucose, Mannitol). 12 platelets concentrate units (Random donor platelet RDP) 350ml and 450 ml each were tested. 12 FFP prepared each from 350 ml and 450 ml blood bag were also studied. The study was conducted in a tertiary care blood centre in Navi Mumbai and results are evaluated against DGHS/NACO standards.

Results: PRBC (n = 24) showed volumes of 252.50 ± 12.65 ml and 345.00 ± 14.32 ml with stable hematocrit (~54.5%) and 100% sterility. RDP (n = 24) had volumes of 59.67 ± 3.47 ml and 82.17 ± 3.49 ml, with platelet counts of $3.93 \pm 0.29 \times 10^{10}$ and $5.23 \pm 0.40 \times 10^{10}$, and minimal contamination. FFP (n = 24) showed volumes of 209.17 ± 7.93 ml and 256.67 ± 28.39 ml with consistent freezing (4.75 ± 0.75 h), coagulation factors, and 100% sterility.

Conclusion- Abbreviations- DGHS- Director General of Health services, NACO- National Aids Control Organization.

Keywords: Whole blood, packed red blood cells, platelet concentrates, quality control, blood centre, DGHS, NACO, tertiary care hospital.

INTRODUCTION

Blood transfusion is one of the most important therapeutic interventions in modern medicine, supporting patients with haemorrhage, severe anaemia, haematological disorders, coagulopathies, trauma, obstetric emergencies, and perioperative blood loss.¹ The modern practice of component therapy has improved transfusion efficiency by allowing a single donation to be separated into multiple products, each used for a specific clinical indication.² This approach improves resource utilization, reduces unnecessary exposure to non-essential blood elements, and supports safer patient care.

However, the therapeutic value of any blood component depends on quality at every stage of the collection-processing-storage chain.³ Substandard products may fail to achieve the intended haemostatic or oxygen-carrying effect and may also contribute to transfusion reactions, inadequate correction of anaemia, bacterial sepsis, or platelet refractoriness.⁴ In platelet components especially, quality is influenced by storage temperature, agitation, processing method, residual cellular contamination, and bacterial safety.⁵ Therefore, regular internal quality control is a core responsibility of blood centres and is central to transfusion safety, accreditation, and haemovigilance.

Tertiary care hospitals occupy a particularly important place in this framework because they handle high transfusion volumes and manage patients with limited physiologic reserve.⁶ They also act as referral centers and training institutions, so their blood-bank practices often influence broader regional standards. The present study was undertaken to evaluate the

quality of whole blood and selected components in a tertiary care blood bank and to compare the findings with DGHS/NACO standards.

MATERIALS AND METHODS

This was an observational, descriptive, cross-sectional study conducted in the tertiary care hospital attached blood centre at navi Mumbai. The study period extended from August 2018 to December 2018. This observational laboratory-based study was conducted in a blood component separation unit to evaluate quality control (QC) parameters of Packed Red Blood Cells (PRBC), Random Donor Platelets (RDP), and Fresh Frozen Plasma (FFP) prepared from whole blood collected in 350 ml and 450 ml blood bags. A total of 72 blood component units were analyzed, comprising 24 PRBC, 24 RDP, and 24 FFP units, with each component equally derived from 350 ml ($n = 12$) and 450 ml ($n = 12$) collections. Units marked for discard, fresh frozen plasma, cryoprecipitate, and leuco-reduced components were excluded.

Quality parameters assessed included volume, haematocrit, appearance, sterility, platelet count, pH, RBC contamination, WBC contamination, and swirling, depending on component type. Volume was determined gravimetrically, haematocrit and cellular counts were measured using automated methods, pH was assessed with calibrated equipment, and sterility was determined by microbiological culture. The study received institutional ethics approval, and informed consent was waived because testing was performed on blood component units without direct patient contact.

Statistical analysis was performed using standard descriptive and inferential methods. Continuous variables were summarized as mean, standard deviation, median, interquartile range, and range.

RESULTS

This study provides a comprehensive evaluation of quality control parameters for Packed Red Blood Cells (PRBC), Random Donor Platelets (RDP), and Fresh Frozen Plasma (FFP) derived from 350 ml and 450 ml whole blood collections. PRBC, RDP, and FFP: 24 units each (12 from 350 ml bags and 12 from 450 ml bags) were studied in our study. PRBC units from both bag sizes demonstrated consistently high quality, with mean volumes of 252.50 ± 12.65 ml and 345.00 ± 14.32 ml for 350 ml and 450 ml collections (Figure 1), respectively. Hematocrit values remained stable at approximately 54.5% across both groups, indicating uniform red cell concentration irrespective of initial collection volume. All PRBC units showed 100% compliance in terms of visual inspection and sterility, with no evidence of hemolysis or contamination. RDP units exhibited proportional increases in volume, measuring 59.67 ± 3.47 ml in the 350 ml group and 82.17 ± 3.49 ml in the 450 ml group. The mean platelet yield was $3.93 \pm 0.29 \times 10^{10}$ per unit for 350 ml collections. In the 450 ml group, after correcting a significant outlier, the mean platelet count was $5.23 \pm 0.40 \times 10^{10}$ per unit, reflecting improved yield with higher volume collection. pH levels remained within acceptable physiological limits in both groups. Residual RBC and WBC contamination were minimal, and all units demonstrated appropriate platelet swirling, confirming functional integrity, along with complete sterility.

FFP analysis revealed mean volumes of 209.17 ± 7.93 ml and 256.67 ± 28.39 ml for 350 ml and 450 ml collections, respectively, with greater variability noted in the higher volume group. Freezing times and storage temperatures were consistent, ensuring preservation of coagulation factors. FFP analysis revealed average Factor VIII (90 IU) and fibrinogen (300 mg) levels, and demonstrated optimal visual clarity (clear, pale yellow, no hemolysis, no clots or leakage) and sterility (no growth after 14 days culture).

Overall, blood component quality was maintained across both collection volumes, with predictable scaling of component yield and consistent adherence to transfusion quality standards.

Average Volume by Component and Bag Size

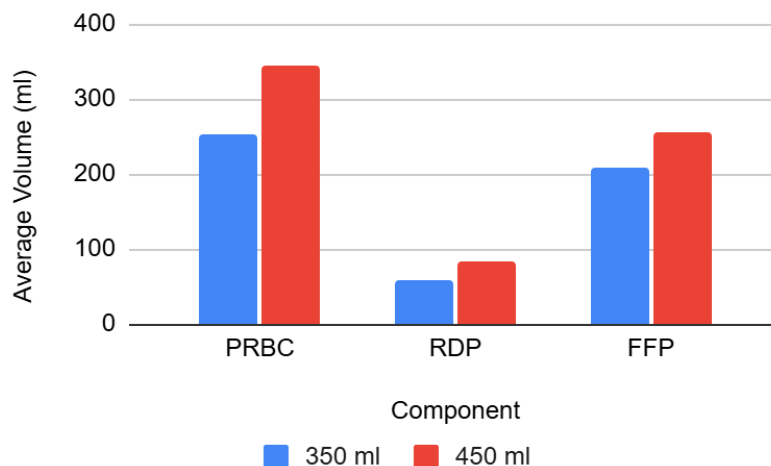


Figure 1- Average volumes by component of PRBC, RDP and FFP from 350 and 450 ml whole blood bags.

DISCUSSION

The present study evaluated internal quality-control performance for PRBCs and platelet concentrates in a tertiary care blood centre. The principal finding was that PRBCs showed high conformity with DGHS standards⁷, whereas platelet concentrates showed comparatively greater variability, especially with respect to platelet yield and WBC contamination. This pattern suggests that the blood centre's collection and red cell processing systems were functioning well, but platelet preparation still requires closer process monitoring.

Proper whole blood volume is essential because underfilling or overfilling can alter the blood-to-anticoagulant ratio and affect downstream component quality. The 100% compliance for appearance and sterility further supports adequate aseptic collection and storage practices.

The PRBC findings were especially strong, with complete compliance for haematocrit, appearance, and sterility. This indicates effective separation, expression, and storage of red cell components in the study centre. The variation in PRBC volume and haematocrit across subtypes is expected and reflects technical differences rather than quality failure.

These results compare favourably with several Indian studies. Akhtar et al. reported acceptable PRBC haematocrit and haemoglobin values but noted lower-than-expected volume in some units.⁸ Warke et al. found that all PRBC units met haematocrit and haemoglobin standards, though a small proportion developed excessive haemolysis near expiry.⁹ In contrast, Das et al. reported that more than half of red cell concentrate units failed national standards, although many would have passed European or British criteria.¹⁰ The present study aligns more closely with the higher-performing reports and suggests good local process control.

Platelet concentrates were the most variable component in this study, which is consistent with the broader transfusion literature. Platelets are biologically fragile and technically demanding because they require storage at $22 \pm 2^\circ\text{C}$ with continuous agitation and are more vulnerable than red cell products to processing error and bacterial contamination. In the present study, pH and sterility were excellent, which is reassuring because platelet metabolic deterioration and bacterial contamination are among the most clinically relevant threats to platelet safety. However, platelet count compliance was only 90%, and WBC contamination compliance was lower at 84%, identifying the main process gap in this component group.

The lower WBC compliance is particularly important because residual leucocyte contamination reflects incomplete separation during PRP processing and may affect product quality and recipient response. The PRP method is known to be more sensitive to technical variation than other platelet preparation methods, and studies comparing preparation techniques have consistently shown that buffy coat or apheresis methods may yield better leucocyte reduction and lower red cell contamination. Toora et al. demonstrated better overall platelet quality compliance with buffy coat and apheresis methods than with PRP-derived units, which supports the interpretation that the PRP method may be the main reason for residual contamination in the present study.¹¹

The comparison of platelet units from 350 mL and 450 mL whole blood is also informative. The 450 mL group had significantly higher platelet volume and count, which is expected because a larger source collection generally provides a higher total platelet mass. However, this did not translate into a significant difference in overall compliance, suggesting that source volume alone is not enough to ensure optimal platelet quality. Processing conditions, centrifugation settings, plasma expression technique, donor characteristics, and operator expertise likely contribute substantially to final product quality.

The findings are also consistent with the work of Priya et al., who showed that platelet QC failure remains a common concern even in accredited tertiary care blood banks.^{11,12} Gnanaraj et al. likewise documented quality gaps in key performance indicators, including platelet and FFP-related parameters, and demonstrated that corrective and preventive actions could improve outcomes.¹³ Taken together, these studies support the concept that platelet quality deserves component-specific monitoring rather than reliance on aggregate blood-bank performance measures.

In our study, FFP results demonstrated mean volumes of 209.17 ± 7.93 ml (350 ml bags) and 256.67 ± 28.39 ml (450 ml bags), with consistent freezing times (4.75 ± 0.75 hours) and Factor VIII ≥ 90 IU and fibrinogen ≥ 300 mg across all units, meeting international standards. These findings align with Umesh et al.'s study, which reported FFP quality parameters remained within acceptable limits even after extended storage.¹⁴

Our study demonstrated comparable FFP quality with average Factor VIII ≥ 90 IU/bag and fibrinogen 300 mg/bag (100% compliance, $n = 24$), compared to the Loganathan et al study's means of 68.42 IU (in-house) and 75.39 IU (outdoor), with 75% of units in the > 4 h processing group at 67.69 IU/unit. Our mean volumes were 209.17 ml (350 ml) and 256.67 ml (450 ml) versus 217 ± 9.58 ml (range 192–235 ml) in Loganathan et al study. Fibrinogen in our study was average of 300 mg/bag (100% at ≥ 200 mg/dl) versus Loganathan et al average of 255.02 mg (in-house) and 264.70 mg (outdoor), all 155 units at ≥ 200 mg/dl.¹⁵

The time-dependent processing you achieved (4.75 hours) is comparable to studies showing that FFP prepared within 4 hours maintains labile factors as per DGHS criteria.¹⁶

From a programmatic perspective, the present findings have practical implications. Regular calibration of centrifuges, stricter review of PRP separation technique, staff retraining, and periodic audit of platelet QC data may help reduce WBC contamination and improve platelet yield consistency. Since platelets are often prepared and stored under time pressure, process standardization is likely to produce measurable benefits. Incorporating these data into a quality-management dashboard would also allow trend analysis by operator, processing day, or source volume.

The study's strengths include assessment of multiple common blood components, use of objective laboratory parameters, and direct comparison of different PRBC and platelet subtypes. Its main limitations are the cross-sectional design and relatively modest sample size, which limit assessment of long-term trends and seasonal variation. In addition, cryoprecipitate and fresh frozen plasma were not included, so the findings cannot be generalized to all blood components prepared at the centre.

CONCLUSION

PRBC components in this tertiary care blood centre showed high compliance with accepted quality criteria, demonstrating good collection and processing standards. Platelet concentrates were the most vulnerable component, with lower compliance for platelet count and especially WBC contamination. Regular audits, process refinement, required changes in SOP and stronger monitoring of platelet preparation were conducted after results of this study to improve product quality and transfusion safety.

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