Section: Pathology

Original Research Article

EVALUATION OF INTERNAL QUALITY CONTROL OF BLOOD COMPONENTS PROCESSED THROUGH ADVANCED WHOLE BLOOD COLLECTION SYSTEMS

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Received *: 16/04/2026*
Received in revised form *: 22/05/2026*
Accepted *: 09/06/2026*

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DOI: 10.70034/ijmedph.2026.2.587

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2026; 16 (2); 3559-3566

ABSTRACT

Background: As blood component therapy has emerged as the global standard of care in transfusion medicine, the quality control (QC) of these components has become a routine and essential program in every blood center. We employ quadruple bag systems and automated facilities for the extraction of components during the collection and processing of whole blood (WB). In this study, we examined our data concerning the QC of all blood components that we prepare and issue for transfusion.

Materials and Methods: The retrospective study conducted over 2 years included 10,500 whole blood (WB) collections, which were divided into blood components utilizing quadruple bags and an automated component extraction machine. For the purpose of machine calibration and validation, a total of 90 units of WB were processed into blood components. The system was routinely employed once the calibration and validation outcomes met the acceptable criteria. According to departmental standard operating procedures, a minimum of 1% of each prepared component underwent quality control (QC). Statistical analysis was performed using the SPSS statistical software.

Results: The mean volume, hematocrit (Hct), platelet (PLT), and white blood cell (WBC) in 350 and 450 mL WB units were 394.63 mL, 39.43%, 0.93 × 1011, and 3.12 × 109 and 507.75 mL, 40.72%, 1.13 × 1011, and 3.45 × 109, respectively, with mean recovery of PLT and WBC in buffy coat being 95.54% and 68.63% and 97.87% and 74.51%, respectively. As high as 89.91% RBC recovery was noted in the packed red blood cell units which were subjected to QC. QC of random donor platelets was performed in 979 (2.36%) units with acceptable results. The mean fibrinogen and FVIII values were estimated to be 469.17 mg and 217.34 IU (1.07 IU/mL) and 600.21 mg and 273.39 IU (1.11 IU/mL) in fresh frozen plasma units prepared from 350 and 450 mL WB, respectively. A total of 578 (1.62%) units of cryoprecipitate were investigated for QC with favorable results.

Conclusion: We conclude that QC data generated in this study will provide invaluable information about the performance of the latest blood collection systems. QC of all blood components under study complied with both national and international standards. We opine that all blood centers should establish a complete QC program and adhere to departmental protocols and manufacturer's instructions for its execution and effective outcome.

Keywords: Automated component separation, blood bag, blood component, quality assurance, quality control.

INTRODUCTION

Quality control (QC) activities are intended to oversee variations in manufacturing processes and product quality, ensuring that manufacturing steps adhere to established acceptance criteria.

Furthermore, these activities produce significant amounts of data, demonstrating that individual components comply with quality specifications according to national and international standards. Although blood component therapy has become the global standard of care in transfusion medicine, QC has also evolved into a routine and obligatory program in all blood centers.[1,2,3] While the criteria for blood component QC are more rigorous and the parameters more detailed in many countries, others impose only minimal QC requirements. Blood centers in India adhere to the program outlined in the Drugs and Cosmetics (D and C) Act, incorporating all critical parameters that optimally determine the quality of blood components.[4] A limited number of blood centers in India possess dedicated facilities and equipment for the QC program, with most relying on hospital laboratories or outsourced services. Additionally, contemporary component separation systems have proven their effectiveness in terms of productivity; however, their efficacy regarding quality is less thoroughly examined.[5,6] The widespread implementation and maintenance of component therapy have been propelled by advancements in refrigeration, blood bag design, the composition of anticoagulant and preservative solutions, infectious disease testing, and various donor screening methods.[7] Recently, blood centers, even in developing countries like India, have transitioned to using "triple," "quadruple," or "in-line leukocyte filter" bag systems to optimize productivity concerning quantity, quality, and safety. To improve good manufacturing practices (GMPs), many blood centers have now embraced automated blood component separation facilities, which have become a vital component of the quality assurance system.[5,8,9]

Comprehensive data and information regarding the quality control of different blood components produced in blood centers, particularly from developing nations such as India, are limited in existing literature. At our facility, we established a systematic quality control program for blood and its components, and the data collected from this initiative have been analyzed and presented in this study.

MATERIALS AND METHODS

The retrospective analysis conducted from January 2024 to January 2026 included a total of 10,500 whole blood (WB) collections. Each collection was processed into blood components in accordance with the departmental standard operating procedure (SOP). WB was collected in quadruple bags with volumes of either 350 or 450 mL (Terumo Penpol, India) and was subsequently separated into specific blood components utilizing the automated component extraction system TACE II+ (Terumo Europe N. V., Belgium) as per the manufacturer's guidelines.[10] While all WB collections were divided into various blood components, including packed red blood cells (PRBCs), random donor platelets (RDPs), and fresh frozen plasma (FFP), the component known as cryoprecipitate (cryo) was exclusively prepared from the 450 mL collections only.

Whole blood collection and processing

Whole blood (WB) was obtained from screened, healthy donors using the "350 mL top-and-top" and "450 mL top-and-bottom" quadruple bag systems (Terumo Penpol, India). This system included a primary bag that contained 49/63 mL of citrate–phosphate–dextrose (CPD) as the anticoagulant, along with two satellite bags: one was empty for plasma collection, and the other held 80/100 mL of saline–adenine–glucose–mannitol (SAGM) as an additive for the preservation of packed red blood cells (PRBC). Additionally, a small fourth bag was designated for the collection of buffy coat (BC). All WB units intended for the preparation of PRBC, fresh frozen plasma (FFP), and random donor platelets (RDP) or PRBC, FFP, and cryoprecipitate were stored at temperatures of 22°C ± 2°C or 4°C ± 2°C, respectively, and were separated into components within 6 hours of collection. For processing, WB units underwent the recommended centrifugation (Cryofuge 6000i, Heraeus, Germany) before being loaded onto the TACE II + automated component extraction system.

Installation and validation of separation system

The TACE II + automated component extraction system has been operational for the past six years. In summary, this apparatus comprises a series of optical detectors that monitor the interface between the plasma and red blood cell layers while regulating the fluid flow rate. The machine identifies variations in the blood component volume during the separation process and is equipped with clamping and sealing systems to facilitate plasma extraction from the top, collection of SAGM PRBC in the primary bag/SAGM bag, and the BC-platelet mixture in the designated BC satellite bag.[10]

Upon installation, the TACE II + automated component extraction system underwent a quality analysis to ensure the calibration of the equipment and the validation of results.[6,10] For this purpose, a total of 50 units of whole blood were processed into blood components, specifically PRBC, FFP, and RDP, over a designated timeframe using the equipment. Samples of all these components were forwarded to the blood center quality control laboratory. The quality control results obtained were utilized as a reference for the system's calibration and validation. Routine operation of the system commenced only after the calibration and validation results were deemed satisfactory.[6,10]

Separation of blood components by TACE II + automated component extraction system and their storage

All WB units were subjected to component separation using the BC method. Following primary separation, PRBC concentrates were refrigerated at 4°C ± 2°C, plasma was stored at − 80°C, and BC–platelet mixtures were subjected to low-speed centrifugation after a resting period of minimum 2 h. Platelet concentrates were then obtained by automated extraction and stored on flat agitator at 22°C ± 2°C.

Quality analysis of whole blood, packed red blood cell, fresh frozen plasma, random donor platelet, and cryoprecipitate

Sampling of units

At least 1% of each prepared component underwent quality control (QC).[4,11] In accordance with the standard operating procedure (SOP), every week, 3–4 units each of packed red blood cells (PRBC), fresh frozen plasma (FFP), and random donor platelets (RDP), along with 2 units of cryoprecipitate, were randomly chosen from their storage location for analysis. Each Monday, Tuesday, and Wednesday was specifically allocated for the QC of PRBC, RDP, and plasma products (FFP and cryo), respectively. Whole blood (WB) units were analyzed solely for the calibration and validation of the T-ACE machine during its installation phase. For all units undergoing quality testing, including WB, sampling was conducted only after the bag had been properly homogenized to ensure that the sample taken from the segment accurately represented the actual contents of the bag. Samples from WB were collected within 6 hours of collection prior to separation. PRBC, RDP, FFP, and cryo were tested within 28–42 days, 3–5 days, 2–6 months, and 1–3 months of their preparation, respectively.

Measurements

Quality control details for each component unit number have been accurately recorded in the corresponding QC register.The volume, collection/preparation date, expiry date, and findings from the physical examination were noted at the time of sample collection.All hematological parameters, including hemoglobin (Hb), platelet (PLT) count, hematocrit (Hct) %, white blood cell (WBC), and red blood cell (RBC) counts, were measured using a routinely calibrated automated cell counter (iCount 3CP, IRIS Healthcare Technologies Private Limited, India).The pH of the platelet units was determined using a calibrated portable pH meter (EUTECH Instruments, Thermo Fisher Scientific, Singapore).The presence of swirling in platelet units was evaluated visually and recorded as either "present" or "absent."Serum potassium (K+) levels in the supernatant of PRBC were assessed using the indirect ISE method (Beckman Coulter Inc., California, USA) within the biochemistry facility.Coagulation parameters, including prothrombin time, activated partial thromboplastin time, fibrinogen, and Factor VIII (FVIII), were evaluated using an automated coagulometer (STA Compact Max, Diagnostica Stago, France).

Both aerobic and anaerobic cultures of PRBC and RDP were conducted in the microbiology department utilizing the BACT/ALERT system (BioMerieux Inc., France).

Statistical Analysis

Statistical analysis was done using the SPSS statistical package (IBM, 2015, Armonk, New York, USA). Mean, standard deviation, and range were the frequency descriptive statistics employed for quality analysis.

RESULTS

The current study performed QC of blood components prepared from 350 and 450 mL of WB collected in our blood center. A total of 90 units each of WB and BC were subjected to QC for calibration and validation of the installed automated component extractor. Tables 1 and 2 show the QC of WB and BC, respectively. While the mean volume, Hct, PLT, and WBC in 350 and 450 mL WB units were 394.63 mL, 39.43%, 0.93 × 1011, and 3.12 × 109 and 507.75 mL, 40.72%, 1.13 × 1011, and 3.45 × 109, respectively; the mean recovery of PLT and WBC in BC prepared from 350 and 450 mL WB was found to be 95.54% and 68.63% and 97.87% and 74.51%, respectively. The mean RBC losses in BC separated from 350 and 450 mL WB were calculated to be 12.89% and 13.91%, respectively.

Table 1: Quality control of whole blood units for validation of automated component extractor (*n*=90)

Parameters (per bag)	Volume (mL)	Hct (%)	Hemoglobin (g)	RBC ($\times 10^{12}$)	PLT ($\times 10^{11}$)	WBC ($\times 10^{9}$)
QC of 350 mL whole blood units in 49 mL CPD anticoagulant (*n*=36)						
Mean±SD	394.63±8.36	39.43±3.97	51.14±4.89	1.74±0.19	0.93±0.42	3.12±0.69
Range	371-412	35.75-47.83	47.11-59.03	1.63-2.12	0.61-1.37	2.05-4.09
QC of 450 mL whole blood units in 63 mL CPD anticoagulant (n=54)						
Mean±SD	507.75±11.81	40.72±4.1	55.39±5.43	1.89±0.33	1.13±0.47	3.45±0.89
Range	478-526	36.3-49.9	49.36-62.23	1.74-2.26	0.72-1.64	2.48-4.45

QC=Quality control, SD=Standard deviation, CPD=Citrate-phosphate-dextrose, WBC=White blood cell, RBC=Red blood cell, Hct=Hematocrit, PLT=Platelet

Table 2: Quality control of buffy coat units for validation of automated component extractor (n=90)

Parameters (per bag)	Volume (mL)	PLT ($\times 10^{11}$)	PLT recovery (%)	WBC ($\times 10^{9}$)	WBC recovery (%)	RBC ($\times 10^{12}$)	RBC loss (%)
QC of BC units prepared from 350 mL WB (*n*=36)							
Mean±SD	85.35±7.22	0.73±0.52	95.54±7.31	2.09±0.55	68.63±12.09	0.56±0.13	12.89±6.68
Range	74-98	0.55-0.91	68.43-97.88	1.21-3.26	62.56-78.87	0.33-0.73	8.56-21.93
QC of BC units prepared from 450 mL WB (*n*=54)							
Mean±SD	98.25±5.29	0.83±0.59	97.87±7.03	2.56±0.31	74.51±13.27	0.59±0.09	13.91±7.11
Range	88-108	0.63-0.97	76.19-98.75	1.69-3.87	67.25-81.93	0.39-0.76	9.35-24.37

QC=Quality control, SD=Standard deviation, WBC=White blood cell, RBC=Red blood cell, Hct=Hematocrit, PLT=Platelet, WB=Whole blood, BC=Buffy coat

A total of 1013 (2.13%) units of PRBC were investigated for QC [Table 3]. The mean volume, Hct, and WBC content in PRBC units prepared from 350 and 450 mL WB were observed to be 200.55 mL, 56.63%, and 1.19×10^{9} and 258.61 mL, 62.18%, and 1.39×10^{9}, respectively. Considering all PRBC units under evaluation, as high as 89.91% RBC recovery was noted.

Table 3: Quality control of packed red blood cell prepared from 350 mL and 450 mL whole blood units (n=1013)

Parameters (per bag)	Volume (mL)	Hct (%)	Hemoglobin (g)	RBC ($\times 10^{12}$)	RBC recovery (%)	WBC ($\times 10^{9}$)	K+ (mmol/L)
QC of PRBC prepared from 350 mL WB units (*n*=417)							
Mean±SD	200.55±17.88	56.63±5.89	50.76±4.93	1.47±0.32	76.28±7.68	1.19±0.35	26.93±8.09
Range	187-214	53.37-62.34	44.3-55.17	0.98-1.89	69.72-79.83	0.45-1.99	16.9-41.66
CE standards (range/mean)				NA			
AABB standards (range/mean)				NA			
D and C standards (range/mean)	150±10%	50-60	NA	NA	≥70	NA	NA
NABH (India) standards (range/mean)	245-345 (non BC PRBC)	55-65	NA	NA	NA	NA	NA
QC of PRBC prepared from 450 mL WB units (*n*=596)							
Mean±SD	258.61±28.95	62.18±6.02	55.73±5.59	1.87±0.53	84.37±7.16	1.39±0.67	35.43±8.16
Range	212-307	56.63-66.92	48.92-59.88	1.48-2.21	76.24-89.91	0.77-2.63	23.78-48.7
CE standards (range/mean)	250±50	50-70	≥43	NA	NA	$<1.2\times10^{9}$	NA
AABB standards (range/mean)	NA	55-65	≥45	NA	>85	$<5\times10^{9}$/L	50
D and C standards range/mean)	250±10%	50-60	NA	NA	≥70	NA	NA
NABH (India) standards (range/mean)	300-400 (non BC PRBC)	55-65	NA	NA	NA	NA	NA

RBC units for culture (n=635): All negative on the 14th day of incubation. NA=Data not available, QC=Quality control, SD=Standard deviation, WBC=White blood cell, RBC=Red blood cell, Hct=Hematocrit, WB=Whole blood, PRBC=Packed red blood cell, NABH=National Accreditation Board for Hospitals and Healthcare Providers, BC=Buffy coat, CE=Council of europe, AABB=American association of blood banks

QC of RDP was performed in 979 (2.36%) units between days 3–5 of storage [Table 4]. The mean volume, PLT yield, and residual WBC in RDP units prepared from 350 and 450 mL WB were found to be 56.29 mL, 3.97×10^{10}, and 2.07×10^{9} and 62.45 mL, 5.19×10^{10}, and 1.86×10^{9}, respectively. Considering all RDP units under QC study, the mean PLT recovery was 62.71% with the highest recovery of 78.11%.

Table 4: Quality control of random donor platelets prepared from 350 mL and 450 mL whole blood units (n=979)

Parameters (per bag)	Volume (mL)	Hct (%)	PLT ($\times 10^{10}$)	PLT recovery (%)	WBC ($\times 10^{9}$)	pH
QC of RDP prepared from 350 mL WB units (*n*=404)						
Mean±SD	56.29±8.61	0.68±0.39	3.97±3.53	61.19±18.43	2.07±1.94	7.09±0.28
Range	36-63	0.5-1.3	1.77-7.12	46.24-72.71	0.02-9.63	6.9-7.2
CE standards (range/mean)	NA					
AABB standards (range/mean)	NA					
D and C standards (range/mean)	70-90	NA	$\geq3.5\times10^{10}$	NA	NA	≥6
NABH (India) standards (range/mean)	50-90	NA	$\geq5.5\times10^{10}$	NA	NA	>6

QC of RDP prepared from 450 mL WB units (*n*=575)						
Mean±SD	62.45±10.41	0.57±0.25	5.19±4.09	67.24±14.22	1.86±2.47	7.13±0.12
Range	47-69	0.3-1.4	2.89-10.56	54.51-78.11	0.04-10.27	6.8-7.4
CE standards (range/mean)	>40	0.8	$>6\times10^{10}$	NA	$<1\times10^{9}$	>6.4
AABB standards (range/mean)	40-70	1	$\geq5.5\times10^{10}$	NA	NA	≥6.2
D and C standards (range/mean)	70-90	NA	$\geq4.5\times10^{10}$	NA	NA	≥6
NABH (India) standards (range/mean)	50-90	NA	$\geq5.5\times10^{10}$	NA	NA	>6

RDP units for culture (n=613): All negative on the 3rd day of incubation. Swirling present for all units tested. NA=Data not available, QC=Quality control, SD=Standard deviation, WBC=White blood cell, Hct=Hematocrit, WB=Whole blood, NABH=National Accreditation Board for Hospitals and Healthcare Providers, RDP=Random donor platelets, CE=Council of europe, AABB=American association of blood banks

Table 5 depicts the QC of FFP performed in 892 (2.04%) units. The mean fibrinogen and FVIII values were estimated to be 469.17 mg and 217.34 IU and 600.21 mg and 273.39 IU in FFP units prepared from 350 and 450 mL WB, respectively. The mean volumes were 183.31 and 224.59 mL, respectively, in units prepared from 350 and 450 mL WB respectively

Table 5: Quality control of fresh frozen plasma prepared from 350 mL and 450 mL whole blood units (n=892)

Parameters (per bag)	Volume (mL)	Fibrinogen (mg)	FVIII (IU/bag) FVIII (IU/mL)	PLT ($\times10^9$)	WBC ($\times10^9$)	RBC ($\times10^9$)
QC of FFP prepared from 350 mL WB units (*n*=377)						
Mean±SD	183.31±25.67	469.17±102.29	217.34±56.21 1.07±0.16	13.25±2.35	2.03±0.47	1.44±0.45
Range	168-213	425-529	163-298 0.87-1.39	6.71-16.73	1.69-3.12	0.73-1.81
CE standards (range/mean)	NA					
AABB standards (range/mean)	NA					
D and C standards (range/mean)	180-220	200-400	≥0.7	NA	NA	NA
NABH (India) standards (range/mean)	>180	>200	≥0.7	NA	NA	NA
QC of FFP prepared from 450 mL WB units (*n*=515)						
Mean±SD	224.59±17.26	600.21±77.53	273.39±43.13 1.11±0.32	11.36±4.15	2.31±0.27	1.25±0.87
Range	193-242	462-718	199-390 0.98-1.63	7.75-17.19	1.77-3.22	0.79-1.92
CE standards (range/mean)	240%±10%	NA	≥0.7	$<50\times10^9$/L	$<0.1\times10^9$/L	$<6\times10^9$/L
AABB standards (range/mean)	225-275	NA	NA	NA	NA	NA
D and C standards (range/mean)	220-300	200-400	≥0.7	NA	NA	NA
NABH (India) standards (range/mean)	>180	>200	≥0.7	NA	NA	NA

Cell count (RBC, PLT, and WBC) done on 437 units (202 and 235 units from 350 mL and 450 mL WB, respectively) of FFP on day of preparation before freezing. NA=Data not available, FFP=Fresh frozen plasma, QC=Quality control, SD=Standard deviation, WBC=White blood cell, RBC=Red blood cell, WB=Whole blood, NABH=National Accreditation Board for Hospitals and Healthcare Providers, PLT=Platelet, CE=Council of europe, AABB=American association of blood banks

A total of 578 (1.62%) units of cryo were investigated for QC [Table 6]. The mean volume, fibrinogen content, and FVIII level were observed to be 19.93 mL, 166.19 mg, and 85.37 IU, respectively. For each blood component, the QC parameters with their observed values were compared with values described in international and national standards.[4,11,12,13] While 91.4% of PRBC units tested for Hct% could meet the national and international recommendations, 882 (90.1%) units of RDP complied with the D and C Act standards. FVIII of >80 IU/bag was observed in 82.9% units of cryo tested.[4,11,12,13]

Table 6: Quality control of cryoprecipitate (n=578)

Parameters (per bag)	Volume (mL)	Fibrinogen (mg)	FVIII (IU)
Mean±SD	19.93±2.62	166.19±47.33	85.37±19.31
Range	17-26	133.43-264.1	69.35-131.62
CE standards (range/mean)	30-40	≥140	≥70
AABB standards (range/mean)	15 (approximately)	>150	>80
D and C standards (range/mean)	15-20	≥150	≥80
NABH (India) standards (range/mean)	10-20	>150	>80

All cryoprecipitate units prepared from 450 mL WB as per SOP. NA=Data not available, SD=Standard deviation, NABH=National Accreditation Board for Hospitals and Healthcare Providers, WB=Whole blood, SOP=Standard operating procedure, CE=Council of europe, AABB=American association of blood banks.

DISCUSSION AND CONCLUSION

The Quality Control (QC) program is essential for ensuring the safety of blood transfusions and plays a significant role in reducing the risks linked to blood and component therapy.[11] Over the past few decades, there has been remarkable progress in the safety and quality of blood and its components. An understanding of clinical blood transfusion practices, the introduction of automation, advancements in blood banking technology, Good Manufacturing Practices (GMPs), adherence to good laboratory practices, and the availability of quality manuals and guidelines have all contributed to the enhancement of quality assurance programs in blood centers.[7] Currently, processes are highly concentrated on producing superior quality blood components that optimize the therapeutic advantages of blood transfusion.[3]

Due to advancements in the preparation and processing of blood components, along with the enhanced accessibility of automated component extractors and the support facilities for engineering and application, we have decided to transition to the quadruple bag system and its automated processing at our blood center.

The bags and machinery were utilized for routine operations following thorough calibration, validation, and standardization of the system in accordance with the manufacturer's recommendations and previous studies.[6,10] A total of 90 units of whole blood (WB) underwent initial quality control as part of the calibration and validation study of the automated component extractor [Table 1]. The blood component (BC) units obtained were anticipated to possess the optimal quantities of various cells as outlined in the final program. Consequently, the expected recovery rates for white blood cells (WBC) and platelets (PLT) were set at ≥70% and ≥95%, respectively, with a maximum of 10% red blood cells (RBCs) in a 100 mL BC.[10]

In previous studies, the authors noted a mean recovery of platelets and white blood cells (WBC) at 91.7% and 62.7%, respectively, along with an average red cell loss of 19% in blood component (BC) units processed using an automated "top-and-top" blood processing system.[6] Other researchers reported varying recovery rates for platelets and WBC, as well as red cell loss in BC units, utilizing different blood processing systems.[5,9] Although the reasons for these discrepancies could not be determined, the authors speculated that there might be an unidentifiable error in the operational protocol or a malfunction in the machinery. The recoveries of platelets and WBC, along with the red cell loss in BC, observed in the current study were found to be consistent with those of earlier studies. Notably, in over 70% of cases (66 out of 90, 73.3%), platelet recovery was recorded at ≥95%, while WBC recovery of ≥70% was achieved in 71 (78.9%) BC units, regardless of whether they were separated from 350 or 450 mL of whole blood.

Upon concluding the calibration and validation study, the finalized program was employed to segregate 10,500 units of whole blood into different components in accordance with the standard operating procedures and the manufacturer's instructions. Roughly 4% of the prepared blood components underwent quality control analysis and were evaluated against established guidelines.[4,11,12,13]

A total of 1013 (2.13%) PRBC units underwent quality control [Table 3]. More than 90% (926/1013, 91.4%) of the units evaluated for Hct met both national and international guidelines.[4,11,12,13] The Hb levels were compliant in 100% of the units and in 93.9% of the units when assessed against the CE and AABB standards, respectively.[11,12] According to the D and C standards, all PRBC units, with the exception of one, demonstrated RBC recovery of ≥70% in this study.[4] A total of 884 (87.3%) units tested exhibited a WBC load of <1.2 × 10^9/unit and <5 × 10^9/L, aligning with the CE and AABB criteria, respectively.[11,12] Previous research indicated inadequate leukocyte depletion in PRBC units, attributing this issue to the retention of leukocytes in the primary bag during the separation of BC units via the “top-and-top” blood processing system.[6] In contrast, the current study achieved satisfactory leukocyte depletion (97.5%, 581/596) utilizing the “TAB” blood processing system. Previous studies reported mean Hct and Hb levels ranging from 54% to 60.87% and 52.5–54.9 g/bag, respectively.[5,6,9] These results were consistent with the current findings and were found to comply with the recommended guidelines.[4,11,12,13]

Hurtado et al. reported that 59.7% of the platelet concentrates they tested met the CE standards.[5,12] Our analysis revealed a mean platelet yield of 3.97 × 10^10 and 5.19 × 10^10, with mean volumes of 56.29 mL and 62.45 mL for RDP units derived from 350 mL and 450 mL of whole blood (WB), respectively. Among the 404 and 575 RDP units that underwent quality control (QC) and were separated from 350 mL and 450 mL of WB, 356 units (88.1%) and 536 units (93.2%) were found to be compliant with the D and C Act standards.[4] Further analysis indicated that the platelet yield of 434 (75.5%) and 467 (81.2%) RDP units prepared from 450 mL of WB met the CE standards as well as the AABB or NABH standards, respectively [Table 4].[11,12,13] The low platelet yield observed in our study may be linked to a lower normal platelet count within our donor population, as previously investigated.[14] Previous authors noted a mean platelet yield of ≥6 × 10^10 in platelet

concentrates, with over 90% of products adhering to the CE standards.[5,9] In this study, a total of 453 (78.8%) RDP units prepared from 450 mL of WB were able to meet the CE criteria of <0.05 × 10^9 residual white blood cells (WBC) per 40 mL.[12]

Research regarding the quality of Fresh Frozen Plasma (FFP) is limited in existing literature. Due to the introduction of various recombinant factors and concentrates, the use of FFP has diminished in developed nations. Although the AABB provides minimal discussion on the quality control (QC) of FFP, the CE standards offer a detailed account of the preparation and QC of plasma and its derivatives.[11,12] In developing countries, the applications of plasma and its products are extensive for various medical indications.[3] In the current study, the average fibrinogen and FVIII levels were found to be 469.17 mg and 217.34 IU (1.07 IU/mL) for FFP units derived from 350 mL of whole blood, and 600.21 mg and 273.39 IU (1.11 IU/mL) for those from 450 mL of whole blood, respectively. All these measurements were consistent with both national and international standards.[4,11,12,13] The level of cellular contamination in the products was deemed acceptable and aligned with CE criteria.[12] Sultan et al. reported that 95% of their FFP units met local guidelines.[3] Additionally, findings from other researchers were also found to be credible and comparable to the results of the present study.[15,16,17]

A total of 578 units of cryoprecipitate were evaluated for quality control in this study. Of these, 93.2% (n = 539) met the national or international standard of >150 mg fibrinogen per bag, while FVIII levels exceeding 80 IU/bag were found in 82.9% (n = 479) of the tested units.[4,11,13] Sultan et al. reported that 96% of the cryoprecipitate units complied with their local guidelines for quality control.[3] As previously mentioned, several factors affect the quality of cryoprecipitate derived from whole blood. FVIII, being a labile factor, is particularly susceptible to variations from standard operating procedures and manufacturer instructions.[18] Notably, FVIII levels in 99 (17.1%) units of cryoprecipitate did not meet any of the established standards, despite following protocols and instructions. This indicates a need for more rigorous oversight throughout the preparation and quality assurance processes to enhance the FVIII content of cryoprecipitate. In a comprehensive study, the French Blood Service monitored and analyzed data over a five-year period (2001–2006) regarding the quality of blood components prepared by various blood centers. The quality control data indicated overall compliance with the requirements for cellular blood components, enabling the transfusion service to evaluate supplier claims, tender invitations, and quality discrepancies, and to implement necessary corrective measures.[19]

We conclude that the quality control (QC) data and findings produced in this study will offer essential insights into the efficacy of the most recent commercially available whole blood (WB) collection and processing systems. More than 90% of packed red blood cell (PRBC) units that underwent QC and were tested for hematocrit (Hct) and hemoglobin (Hb) met both national and international standards. A residual white blood cell (WBC) count of <1.2 × 10^9/unit or <5 × 10^9/L, as required by the CE and AABB guidelines, was noted in over 87% of PRBC units. Furthermore, over 88% of random donor platelet (RDP) units demonstrated an acceptable platelet yield in accordance with the D and C standards. The quality metrics for all fresh frozen plasma (FFP) units evaluated in this study adhered to national and international guidelines. Approximately 83% of cryoprecipitate (cryo) units contained factor VIII (FVIII) levels of ≥80 IU/bag, as stipulated by both Indian and international standards. While we determined that the latest blood collection and processing systems are capable of producing high-quality blood components, it is crucial to strictly follow departmental protocols and the manufacturer's instructions to ensure the success of the quality assurance program.

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