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An insight to the internal quality control of blood components separated using the latest whole blood collection and processing systems: Experience from a tertiary care hospital blood transfusion service in Eastern India

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Abstract:

BACKGROUND: With blood component therapy becoming the standard of care in transfusion medicine globally, the quality control (QC) of these components has become a routine and mandatory program in all blood centers. Extensive utilization of blood components has been observed in our multidisciplinary tertiary care hospital. We use quadruple bag systems and automated component extraction facilities for collection and processing of whole blood (WB). In this study, we analyzed our data relating to QC of all blood components which we prepare and issue for transfusion.

MATERIALS AND METHODS: The retrospective 5-year study comprised 47,430 WB collections which were separated into blood components using quadruple bags and automated component extraction machine. A total of 90 units of WB were processed into blood components for the machine calibration and validation. Routine use of the system was started once the calibration and validation results were acceptable. At least 1% of each component prepared was subjected to QC as per departmental standard operating procedures. Statistical analysis was done using the SPSS statistical package.

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%, 0.93×10^{11}, and 3.12×10^{9} and 507.75 mL, 40.72%, 1.13×10^{11}, and 3.45×10^{9}, 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

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Introduction

Quality control (QC) activities are designed to monitor variations in manufacturing processes and product quality and ensure that manufacturing steps meet defined criteria for acceptance. Moreover, such activities generate substantial volumes of data, which can show that individual components have met quality specifications as per the national and international standards. While blood component therapy became the standard of care in transfusion medicine globally, QC has also become a routine and mandatory program in all blood centers.[1-3] While criteria for blood component QC are more stringent and parameters more elaborate in many nations, others have minimum QC mandates. Blood centers in India follow the program as depicted in the Drugs and Cosmetics (D and C) Act and include all important parameters that determine the quality of blood components optimally.[4] Not many blood centers in India have dedicated settings and machines for QC program and most either depend on the hospital laboratory or any outsourced facility. In addition, the present-day component separation systems have established their efficacy in terms of productivity. However, efficacy in terms of quality is explored less optimally.[5,6] The widespread adoption and retention of component therapy were driven by innovations in refrigeration, blood bag design, anticoagulant and preservative solution composition, infectious disease testing, and various means of donor screening.[7] In recent times, blood centers even in the developing nations including India have switched over to "triple," "quadruple," or "in-line leukocyte filter" bag systems to balance the productivity in terms of quantity, quality, and safety. To enhance good manufacturing practices (GMPs), many blood centers have now adopted the automated blood component separation facilities which have now become an essential tool of the quality assurance system.[5,8,9]

Elaborate data and facts from developing countries including India that describe QC of various blood components manufactured in blood centers are sparse in the literature. We developed a systematic QC program relating to blood and blood components at our center, and data obtained from the program have been analyzed and shared in this study.

Materials and Methods

The retrospective study from January 2015 to December 2019 comprised 47,430 whole blood (WB) collections. All collections were separated into blood components following the departmental standard operating procedure (SOP). WB was collected in 350 or 450 mL volume quadruple bags (Terumo Penpol, India) and separated into specific blood components using the automated component extraction system TACE II+ (Terumo Europe N. V., Belgium) following manufacturer's instruction.[10] While all WB collections were separated into various blood components such as packed red blood cells (PRBCs), random donor platelets (RDPs), and fresh frozen plasma (FFP), component like cryoprecipitate (cryo) was prepared from 450 mL collections only.

Whole blood collection and processing

WB was collected from screened, healthy donors in the "350 mL top-and-top" and "450 mL top-and-bottom" quadruple bag systems (Terumo Penpol, India). The system comprised a primary bag containing 49/63 mL citrate–phosphate–dextrose (CPD) as the anticoagulant, two satellite bags, one empty for the collection of plasma, and another containing 80/100 mL of saline–adenine–glucose–mannitol (SAGM) as an additive for the PRBC preservation. A small fourth bag is dedicated for the collection of buffy coat (BC). All WB units allocated for preparation of PRBC, FFP, and RDP or PRBC, FFP, and cryo were stored at 22°C ± 2°C or 4°C ± 2°C, respectively, and then separated into components within 6 h of collection. For processing, WB units were subjected to recommended centrifugation (Cryofuge 6000i, Heraeus, Germany) followed by loading centrifuged units onto the TACE II + automated component extraction system.[10]

Installation and validation of separation system

The TACE II + automated component extraction system is functional in our blood for the last 6 years. In short, this equipment consists of a series of optical detectors that monitors the interface between the plasma and red cell layers and regulates the fluid flow rate. The machine detects fluctuations in the BC volume during the separation process and is equipped with both clamping and sealing systems to facilitate plasma extraction at the top, SAGM PRBC collection in the primary bag/SAGM bag and BC-platelet mixture in the dedicated BC satellite bag.[10]

At the time of placement, the TACE II + automated component extraction system was subjected to quality analysis for calibration of the equipment and validation of results.[6,10] For these, a total of 90 units of WB were processed into blood components, namely PRBC, FFP, and RDP, over a period of time using the equipment. Samples of all these components were sent to the blood center QC laboratory. QC results thus obtained were used as guide for the system calibration and validation. Routine use of the system was only started once the calibration and validation results were acceptable.[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 component prepared was subjected to QC.[4,11] As per SOP every week, 3–4 units each of PRBC, FFP, and RDP and 2 units of cryo were randomly selected from their site of storage and subjected to analysis. Each Monday, Tuesday, and Wednesday were, respectively, dedicated for QC of PRBC, RDP, and plasma products (FFP and cryo). WB units were only analyzed for the calibration and validation of the T-ACE machine at the time of its installation. For all units subjected to quality testing including WB, sampling was performed only after proper homogenization of the bag to make sure that sample in the segment represents the actual content of the bag. Samples from WB were collected within 6 h of collection before separation. PRBC, RDP, FFP, and cryo were, respectively, tested within 28–42 days, 3–5 days, 2–6 months, and 1–3 months of their preparation.

Measurements

QC details against each component unit number have been duly documented in the respective QC register. Volume, date of collection/preparation, date of expiry, and physical examination findings were documented at the time of sample collection. All hematological values, namely hemoglobin (Hb), platelet (PLT) count, hematocrit (Hct) %, white blood cell (WBC), and RBC counts, were obtained using a routinely calibrated automated cell counter (iCount 3CP, IRIS Healthcare Technologies Private Limited, India). The pH of platelet units was measured by using a calibrated portable pH meter (EUTECH Instruments, Thermo Fisher Scientific, Singapore). Swirling in platelet units was assessed visually and documented as "present" or "absent." Serum potassium (K+) in PRBC supernatant was measured using indirect ISE method (Beckman Coulter Inc., California, USA) in the biochemistry facility. Coagulation parameters such as prothrombin time, activated partial thromboplastin time, fibrinogen, and Factor VIII (FVIII) were measured by automated coagulometer (STA Compact Max, Diagnostica Stago, France). Both aerobic and anaerobic cultures of PRBC and RDP were performed in the microbiology department using 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%, 0.93×10^{11}, and 3.12×10^{9} and 507.75 mL, 40.72%, 1.13×10^{11}, and 3.45×10^{9}, 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.

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.

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 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.

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.[4,11-13] While 91.4% of PRBC units

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 (×10^{12})	PLT (× 10^{11})	WBC (×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 (×10^{11})	PLT recovery (%)	WBC (×10^{9})	WBC recovery (%)	RBC (×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

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 (×10^{12})	RBC recovery (%)	WBC (×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	<1.2×10^{9}	NA
AABB standards (range/mean)	NA	55-65	≥45	NA	>85	<5×10^{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

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.[4,11-13]

Discussion and Conclusion

The QC program plays a vital role in blood transfusion safety and significantly mitigates the risks associated with blood and component therapy.[11] The last few decades have observed an impressive development in the safety and quality of blood and its components. Knowledge of clinical blood transfusion practices, advent of automation, technological advancements in blood banking, GMPs, good laboratory practices, availability of quality manual, and guidelines have ensured optimization in quality assurance program in blood centers.[7] Now processes are extremely focused on producing high-quality blood components that maximize the therapeutic benefits of blood transfusion.[3]

Owing to process improvement in blood component preparation and processing coupled with easy accessibility of automated component extractor and facilities of engineering and application support, we planned to shift to the quadruple bag system and their automated processing in our blood center.

The bags and machine were employed for routine use after proper and complete calibration, validation, and

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 ($\times10^{10}$)	PLT recovery (%)	WBC ($\times10^{9}$)	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	≥3.5×10^{10}	NA	NA	≥6
NABH (India) standards (range/mean)	50-90	NA	≥5.5×10^{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	>6×10^{10}	NA	<1×10^{9}	>6.4
AABB standards (range/mean)	40-70	1	≥5.5×10^{10}	NA	NA	≥6.2
D and C standards (range/mean)	70-90	NA	≥4.5×10^{10}	NA	NA	≥6
NABH (India) standards (range/mean)	50-90	NA	≥5.5×10^{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: 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		<50×10^{9}/L	<0.1×10^{9}/L	<6×10^{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

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

standardization of the system as per recommendation of the manufacturer and previous authors.[6,10] A total of 90 units of WB were subjected to initial QC as a part of calibration and validation study of the automated component extractor [Table 1]. BC units so obtained were expected to contain the optimum quantity of different cells as per the final set program. Accordingly, the expected recovery of WBC and PLT was ≥70% and ≥95%, respectively, with as low as 10% RBCs in a 100 mL BC.[10]

The authors in the past observed a mean platelet and WBC recovery of 91.7% and 62.7%, respectively, and mean red cell loss of 19% in BC units using

automated "top-and-top" blood processing system.[6] Variable recovery rates of platelets and WBC and loss of red cells in BC units were reported by others using different blood processing systems.[5,9] Causes of these deviations could not be ascertained, but the authors believed some unrecognizable fault in the working protocol or fault in the technical operation of machines. Platelet and WBC recoveries and red cell loss in BC in the present study were found comparable with the previous studies. While in more than 70% instances (66 out of 90, 73.3%), platelet recovery was observed to be ≥95%, WBC recovery of ≥70% was found in 71 (78.9%) units of BC irrespective of their separation from 350 or 450 mL WB.

After the completion of calibration and validation study, the final set program was used to separate 47430 units of WB into various components following SOP and manufacturer's instruction. Approximately 2% of the blood components prepared were subjected to QC analysis and compared with set guidelines.[4,11-13]

A total of 1013 (2.13%) PRBC units were subjected to QC [Table 3]. Over 90% (926/1013, 91.4%) of units tested for Hct could meet the national and international recommendations.[4,11-13] Hb level was found to comply in 100% units and 93.9% units when compared with the CE and AABB standards, respectively.[11,12] As per the D and C standards, all PRBC units except one tested in the current study showed RBC recovery of ≥70%.[4] A total of 884 (87.3%) units tested showed a WBC load of $<1.2 \times 10^9$/unit and $<5 \times 10^9$/L in accordance with the CE and AABB criteria, respectively.[11,12] Previous authors observed poor leukocyte depletion in PRBC units and attributed this to retention of leukocyte in the primary bag during separation of BC units using the "top-and-top" blood processing system.[6] The current study found satisfactory leukocyte depletion (97.5%, 581/596) using the "TAB" blood processing system. The mean Hct and Hb ranging from 54% to 60.87% and 52.5–54.9 g/bag, respectively, were observed by previous studies.[5,6,9] These findings were comparable to the current data and found to be compliant with recommended guidelines.[4,11-13]

Hurtado *et al*. found 59.7% of their tested platelet concentrates at par with the CE standards.[5,12] We observed a mean platelet yield of 3.97×10^{10} and 5.19×10^{10} in mean volume of 56.29 and 62.45 mL in RDP units prepared from 350 and 450 mL WB, respectively. Out of 404 and 575 units of RDP subjected to QC and separated from 350 and 450 mL WB, respectively, 356 (88.1%) and 536 (93.2%) complied with the D and C Act standards.[4] On further investigation, we found that platelet yield of 434 (75.5%) and 467 (81.2%) RDP units prepared from 450 mL WB fulfilled the CE standards and AABB or NABH standards, respectively [Table 4].[11-13] Low platelet yield in our study may be attributed to lower normal platelet count in our donor population as investigated previously.[14] The authors in the past observed a mean platelet yield of $\geq 6 \times 10^{10}$ in platelet concentrates and >90% of products complied with the CE standards.[5,9] In the present study, a total of 453 (78.8%) RDP units prepared from 450 mL WB could fulfill the CE criteria of $<0.05 \times 10^9$ residual WBC/40 mL.[12]

Studies on quality of FFP are sparse in the literature. With the advent of various recombinant or factor concentrates, FFP is less utilized in the developed countries. While the AABB has limited discussion on QC of FFP, the CE standards elaborately depicted the preparation and QC of plasma and plasma products.[11,12] Uses of plasma and plasma products are immense in the developing countries for one or the other indications.[3] The mean fibrinogen and FVIII values in the present study 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 FFP units prepared from 350 and 450 mL WB, respectively. All these values were observed to conform to the national and international standards.[4,11-13] Cellular contamination in the products was acceptable and was in accordance with the CE criteria.[12] Sultan *et al*. concluded that 95% of their FFP units conformed to the local guidelines.[3] Reports from other authors were also found convincing and comparable to the current study.[15-17]

A total of 578 units of cryo were subjected to QC in the present study. While 93.2% (n = 539) of units conform to the national or international value of >150 mg fibrinogen per bag, FVIII of >80 IU/bag was observed in 82.9% (n = 479) units tested.[4,11,13] Sultan *et al*. found that QC of 96% of the cryo units was in accordance to their local guidelines.[3] As discussed before, a number of factors influence the quality of cryo prepared from WB. FVIII being a labile factor is even more affected if deviations from SOP and manufacturer's instruction occur.[18] As FVIII level in 99 (17.1%) units of cryo could not conform to any of the described standards despite adherence to protocols and instructions, therefore more stringent vigil is needed in the entire process of preparation and quality assurance of cryo to improve its quality in terms of FVIII quantity. In a large study, the French Blood Service followed and analyzed the data of 5 years (2001–2006) on the quality of the BC prepared by the various blood centers. The QC data showed an overall compliance with the requirements for cellular BC and helped the transfusion service to analyze supplier claims, tender invitations, and quality deviations and take appropriate corrective actions.[19]

We conclude that QC data and facts generated in this study will provide invaluable information about the

performance of the latest WB collection and processing systems available commercially. More than 90% of PRBC units subjected to QC and tested for Hct and Hb could meet the national and international standards. Residual WBC of $<1.2 \times 10^9$/unit or $<5 \times 10^9$/L as mandated by the CE and AABB guidelines was observed in over 87% PRBC units. Over 88% RDP units showed acceptable platelet yield as described in the D and C standards. Quality values of all FFP units tested in the study complied with the national and international guidelines. Approximately 83% of cryo units contained FVIII of ≥80 IU/bag as mandated by both the Indian and international standards. Although we found the latest blood collection and processing system suitable to provide blood components of high standards, strict adherence to departmental protocols and manufacturer's instructions are key factors to successful quality assurance program.

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Conflicts of interest

There are no conflicts of interest.

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