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Internal Quality Control of Blood Components: A Five Year Experience of Hospital Based Blood Centre of Surat

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Abstract: ***Background &Aims: Blood centers have the responsibility of providing safe, pure, efficacious & adequate blood & its components to all the needy patients. Internal quality control (IQC)is the backbone of quality assurance program. The main objective of this study was to analyze the IQC of blood components as an indicator of blood bank performance. Material and Method: An observational study was conducted at the blood center of tertiary level hospital in Surat from year 2018 to 2022.Selection criteria were 1% of total collection or minimum 4 bags per month as per National Accreditation Board for Hospital & healthcare provider (NABH) guidelines. Result: The quality control data for all blood components were found to be within range for standard criteria. Conclusions: The IQC of blood products at the blood center was in overall compliance and met recommended international standards. Periodic re-assessment and quality checking should be a departmental protocol and care should be made to use standard and relevant techniques and criteria for quality assessment.***

Keywords: Internal quality control, blood components, quality assurance, NABH

1. Introduction

Blood component therapy became the one of the standard of care in patient treatment throughout the world in the latter half of 20thcentury. 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 other means of donor screening[1].

Transfusion services must have standard obligation to endorse the optimal usage of blood components and to ensure that the final product causes minimal to zero risk to the potential recipient.

The present study was done to check whether Quality Control (QC) testing results of blood units fulfil the standard guidelines given by the D & C act 1940 (and rules there under) & 3rd edition (with amendments) of National Accreditation Board for Hospital & healthcare provider (NABH) standard[2]. During the study, blood components tested were Red Cell Concentrates (RCC), Fresh Frozen Plasma (FFP), Platelet Concentrates (PC) and Cryoprecipitate.

2. Material and Method

An Observational study was conducted at the blood center of tertiary care hospital, from year 2018-2022.In this period, blood units were collected in sterile bags, from healthy blood donors after taking written consent & following guidelines provided by the D & C act 1940 (and rules there under)

During the study, 1% of total collection or minimum 4 units per month were checked as per 3rd edition (with amendments) of NABH standard. All products were evaluated at the day near of expiry which had different collection dates. Details of all Internal Quality Control (IQC) parameters tested are shown in Table 1.

For blood unit QC testing Hematology Analyzer used was ABX Micros 60 (Horiba, France) & Factor assay with other coagulation tests were done on Semi-automatic Coagulometer (CoA state -1, Tulip diagnostics, India).

Data were collected from blood bank software, register & ruff-records. Data were analyzed using the Excel Sheets (Microsoft office 2007)

3. Result

A total of 398 red cell units were tested for QC during the study period. The mean Hct of red cell units (RCC) prepared from 350 ml of bags without additive solution was 70.72% & 61.43% for bags with additive solution. While mean Hct of RCC units prepared for 450 ml of bags were 71.1% for bags without additive solution & 60.81% for bags with additive solution. The mean volume & Hct of all type of red cell units (350/450 ml parent bag with/without additive solution) are shown in table 1.

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Table 1: Criteria for Quality Control of Blood Component along with their values achieved during the study

Components	Quality Requirement	MEAN±SD	Frequency
Red Cell Concentrates			
Volume	350 ml:175-272 ml 450 ml:225-350 ml	350 ml: 250.28±25.35 450 ml: 301.76±51.68	1% of all units
Hematocrit	65-75%	350 ml: 70.72±4.82 450 ml: 71.10±4.73	1% of all units
Red Cell concentrates with Additive solution			
Volume	350 ml:245-325 ml 450 ml:300-400 ml	350 ml: 273.46±27.42 450 ml: 340.89±33.60	1% of all units
Hematocrit	55-65%	350 ml: 61.43±3.90 450 ml: 60.81±3.73	1% of all units
Fresh Frozen Plasma			
Volume	>180 ml	227.15±36.03	4 units per month
PT	11-14 sec	13.57±2.18	4 units per month
Aptt	21-35 sec	29.87±4.55	4 units per month
Factor VIII	>0.7 units/ml	1.12±0.47	4 units per month
Fibrinogen	>200 mg	342.99±97.79	4 units per month
Platelet Concentrates			
Volume	50-70 ml	56.78±4.71	All units
Platelet yield	350 ml - $\geq 3.5\times 10^{10}$ 450 ml - $\geq 4.5\times 10^{10}$	350 ml – $5.21\pm1.61\times 10^{10}$ 450 ml – $6.24\pm2.04\times 10^{10}$	4 units per month
Ph	>6	7.35±0.33	4 units per month
RBC Contamination	Traces to <0.5 ml	0.23± 0.21 ml	4 units per month
Cryoprecipates			
Volume	10-20 ml	24.30±2.69	1% of all units
Factor VIII	>80 units/ml	119.85±39.87	1% of all units
Fibrinogen	>150 mg	538.66±156.06	1% of all units

A total of 228 units of FFP were tested for QC during the study. The mean factor VIII & fibrinogen levels were found to be 1.12 IU/ml & 342.99 mg/dl for FFP respectively. All FFP units had fibrinogen ≥200 mg/dl, while only 6.14% of units had factor VIII below the desired level. Stable-coagulation factors were checked by Prothrombin time (PT) & Activated Partial Thromboplastin Time (aPTT). Mean value of PT & aPTT were 13.57 second & 29.87 second respectively.

A total of 218 random donor platelets units (RDPs) were tested for IQC. The mean platelet yield was of 5.210×10^{10}per bag (RDPs prepared from 350 ml of bags) & 6.245×10^{10}per bag (RDPs prepared from 450 ml of bags). Only 12.84% units had low platelet yield &1.83% units had RBC contamination of >0.5 ml. The culture test of all units was negative.

For Cryoprecipitate, mean factor VIII & Fibrinogen level were 119.85 units/bag & 538.66 mg/dl respectively. 90.62% units were in conformity with the norms concerning the fibrinogen & Factor VIII.

All units selected for IQC were non reactive for HIV 1 & 2, HBV, HCV by Enzyme-linked immunosorbent assay (ELISA) & were non reactive for syphilis & malaria by rapid test.

Table 2 shows Percentage of blood units not fulfilling QC standards during the study period.

Table 2: Percentage of blood units not fulfilling QC standards in the present study along with their comparison with other studies[3,4].

Component	Percentage of blood units not fulfilling QC standards (%)		
	Sultan S et al	Patel S et al (2013-2014)	Present study
RCC	2	8.51	16
RCA			8.06
PC	6	5	14.67
FFP	5	16.47	6.57
Cryoprecipitate	4	19	9.38

4. Discussion

Blood centers have the responsibility of providing safe, pure, efficacious & adequate blood & its components to all the needy patients. **"**Zero risk blood supply" is the ultimate manufacturing goal of transfusion medicine[3].

For safe & effective preparation of blood & its components, IQC plays a very important role. Quality concept comprises of a triad of quality control, quality assurance & quality management & their maintenance[5]. Introducing Quality management in transfusion services includes all requisites of blood supply chain including blood donation, appropriate blood collection, screening testing, component preparation, product storage, transportation and safe transfusion to the recipients.

In the present study, the overall QC results met the standards & within permissible limits as per national guidelines which means less than 25 % of blood units showed not acceptable QC results. Table 2 shows the percentage of blood units which were not fulfilling the standard guidelines in the present study & studies done by Sultan S et al & Patel S et

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al.[3,4] The table shows that IQC results were overall better for Red cell concentrates & platelet concentrates in the studies by Sultan S.et al[3]& Patel S.et al[4] while IQC results of FFP & cryoprecipitate were better in the present study. All studies had IQC results which were out of range within permissible limits.

The mean yield of platelets concentrate was $5.21\pm1.61\times 10^{10}$ per bag for 350 ml of parent bags while $6.24\pm2.04\times 10^{10}$ per bag for 450 ml of parent bags. Table 3 shows that the present study had low yield in comparison to other studies except study by Raturi M et al[6].The mean pH of the present study was in agreement with the study done by Sultan S et al[3]. The mean volume of platelet concentrate was comparable with all other studies.

Table 3: Results seen in various studies in comparison to present study for platelet concentrates

Sr. No.	Study	Volume (ml)	Platelet Count (/unit)	pH
1	Sadia sultan et al.,[3]	-	$8.87\pm3.40\times10^{9}$	7.5±0.8
2	Fijnheer R et al.,[7]	67.8±4	$7.0\pm1.0\times10^{10}$	-
3	Hirosue A et al.,[8]	41±2	$7.62\pm 1.8\times10^{10}$	-
4	Singh RP et al.,[9]	62.3±22.68	$7.6\pm2.97\times10^{10}$	-
5	Raturi M et al.,[6]	58.4±9.5	$5.9\pm1.28\times10^{10}$	-
6	Present Study	56.78±4.71	350ml-$5.21\pm1.61\times10^{10}$ 450ml-$6.24\pm2.05\times10^{10}$	7.35 ±0.33

IQC results of Fresh frozen plasma were within normal range as per standard guidelines. All the mentioned studies in table 4 had evaluated quality control parameters as done in the present study. Mean factor VIII level & mean fibrinogen level were higher in the present study in comparison to other studies.

Table 4: Results seen in various studies in comparison to present study for FFP

Sr. No.	Study	Volume (ml)	Fibrinogen (mg/dl)	Factor VIII
1	Sadia sultan et al.,[3]	-	247.17±49.69	84.24±15.01 (/unit)
2	Gunjanbala et al.,[10]	217±9.58	304.31±53.68	0.8±0.086 (IU/ml)
3	Dogra M et al.,[11]	-	270.66±69.64	117.20±29.01 (/unit)
4	Present Study	227.15±36.03	342.99±97.79	1.12±0.47 (IU/ml)

In the present study, 94 % of total cryoprecipitate units met the desired criteria. Results similar to this study have been observed in study done by Sultan S et al with mean fibrinogen & Factor VIII values of 420.7±75.32 & 178.75±86.30 respectively. The present study had per unit fibrinogen level higher as compare to study done by Sultan S et al & factor VIII level lower than the same study[3]. The Factor VIII & fibrinogen level were 99.25±5.37 IU/ml & 217.5±51.37 mg/dl in the study done by Arora et al[12].

All RBCs units checked had volume and hematocrit well within criteria given in standard given by NABH 3rd edition with amendment. Results similar to this study have been observed in study done by Upadhyay S et al. in which mean volume of RCC units with additive solution was 285±24.3 ml with a range of 198-350 ml and hematocrit of 54±4.2% with a range of 41-69%[5]. While Arora et al found mean volume of 238±26.25 ml & mean Hct of 65.75±7.42 %[12]. As per third edition of Transfusion Medicine Technical Manual published by Director General of Health Services *(*DGHS*)* in the year 2022, 06 RCC units prepared from 350 ml of parent blood bag without additive solution did not meet the volume criteria given in the present study[13].

The blood center of the present study had done root cause analysis for the units which did not fulfil standard. The root cause analysis was done taking into consideration the technical person involved, process & equipment used for such not fulfilling blood component. During the study, RCC & PC had more units with not fulfilling the standard. The main reason for volume related non conformance of RCC was that the blood collection monitors were not used as per process defined during blood collection in blood donation camps. The reason behind the red cell contamination of the PC was that the technical person were not preparing PC as per the process defined & imbalance error in the blood bag centrifuge.

5. Conclusion

From the results, it can be concluded that the quality of blood components being prepared at blood bank met the standard given by NABH.

Safe blood transfusion is universal human right and should be made available through proper quality management for all processes in blood collection, preparation of components and issuing to the recipients.

It can be concluded that if the blood center performs regular IQC & takes required corrective actions after doing root cause analysis, the non-conformance in QC of blood components can be prevented before it will be too late to be noticed by other ways like feedback from clinicians.

Declaration

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Conflict of interest: Nil

Ethical approval: done

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