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ORIGINAL RESEARCH

Quality control of blood components-a step towards efficient supply of blood products

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ABSTRACT

Objective: The aim of study was to ensure supply of safe and efficient blood transfusion to patient and to prevent Transfusion Transmitted Diseases.

Methods: The present study included data of routine monthly analysis of whole blood and blood components which was collected from archives of blood bank from the period of 1st January 2018 to 31st December 2019. Data was collected for the above mentioned period in which blood was collected from 2520 healthy donors in sterile single, double or triple blood bags with anticoagulant Citrate Phosphate Dextrose Adenine 1 (CPDA 1) after taking written consent.

Result: Mean volume was 65.5 mL with range of 50-70 mL. Mean WBC contamination was 1.4×10^{8}/unit with a range of $0.15\text{-}5.5\times10^{8}$/unit. Mean RBC contamination was 0.077×10^{12}/liter with a range of $0.05\text{-}\ 0.14\text{x}10^{12}$/liter.

Conclusion: Quality indicators should be well-defined, regularly monitored and properly documented. Quality Control is an important tool to ensure maximum benefit to patient with minimum cost and maximum advantage and minimizing requirement of transfusion to patient and Prevention of risk of Transfusion Transmitted Diseases.

Keywords: blood components, quality, plasma, transfusion, safety

INTRODUCTION

Blood component therapy became the standard of care in transfusion medicine throughout the industrialized world in the latter half of the twentieth century.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]Whole blood is processed by centrifugation, predominantly by one of two main protocols which generate different intermediates: platelet-rich plasma (PRP) or a buffy coat (BC).[2]White blood cells may be removed from blood components through the use of leukoreduction filters, often during blood processing and before storage.[3]

Quality assurance is defined as the consistent and reliable performance of services, procedures and products in conformance to the standard specifications.[4] Blood banking is a vital part of health care services, therefore quality analysis of whole blood and blood components is imperative for the assurance of optimal benefit to the recipients.[5] Blood

component transfusion therapy has become the standard of care in transfusion medicine throughout the world in present times. The widespread and judicious use of blood transfusion therapy has been possible by the new innovations and advancements in blood collection, anticoagulant compositions, component separation equipments, storage, refrigeration, screening of transfusion transmissible diseases, and other means of donor selection and screening. Quality control of whole blood and PRBCs involves estimation of volume and haematocrit.[6] Quality of platelet concentrate is assessed by parameters like swirling movement, volume, platelet yield, and RBC and WBC counts per unit and pH changes.[7]
The aim of study was to ensure supply of safe and efficient blood transfusion to patient and to prevent Transfusion Transmitted Diseases.

MATERIAL AND METHODOLOGY

The present study included data of routine monthly analysis of whole blood and blood components which was collected from archives of blood bank from the period of 1st January 2018 to 31st December 2019. Data was collected for the above mentioned period in which blood was collected from 2520 healthy donors in sterile single, double or triple blood bags with anticoagulant Citrate Phosphate Dextrose Adenine 1 (CPDA 1) after taking written consent. Out of these 2520 units, 1200 units were utilised as whole blood (350 mL of whole blood from donors weighing 45-60 kg) and 1320 units collected in double or triple bags (450 mL blood) from healthy donors weighing more than 60 kg were processed for component preparation in a refrigerated centrifuge (Cryofuge 5500i) by Heraeus.After 2-4 hours of holding time, units were centrifuged at 3800 (4400xg) rotations per minute at 4°C for 9 minutes for separation into PRBCs and FFP. For separation of whole blood into PRBCs, FFP and platelet concentrate units were centrifuged at 2 spin centrifugation at 1500 rpm for 9 minutes at 22°C followed by 2500 (4400 x g) rpm for 15 minutes at 22°C.
Criteria used for Quality Control (QC) were according to National Accreditation Board for Hospitals and Healthcare Providers.[9]These were included in table 3 and 4

RESULTS

A total of 2520 units of blood were collected from healthy screened donors, out of which 1200 were utilised as whole blood and 2320 units were separated into components (FFP and PRBCs; FFP, PRBCs and PC).

Table 1: Quality control results of whole blood and PRBCs

	Whole blood			Packed red blood cells		
Parameters	**Recommended**	**Mean**	**Range**	**Recommended**	**Mean**	**Range**
Volume (in mL)	350±10%	350	345-375	280±60	320	250-370
Hematocrit	>30%	45.7%	33.5-47%	>55%	65.5%	55.9%-78.9%

The samples of total whole blood collection in the present study were analyzed for quality control of haematological parameters.

Table 2: Quality control results of platelet concentrate

Parameter	Quality requirement	Mean±SD (mL)	Range
Volume	50-70 mL/bag	65.5±4.56	50-70 mL
Inspection	Swirling movement of platelets	Present in all units	
Platelet count	$8.3\pm1.50\times10^{10}$/unit	$>5.9\times10^{10}$/bag in 75% of bags	5.7-14.9×10^{10}/unit
RBC Contamination	$<0.3\times10^{12}$/liter	$0.077\pm0.09\times10^{12}$/liter	0.05-0.14×10^{12}/liter

WBC contamination	5.5×10-5×10^8 in 450 mL bag.	$1.40\pm1.37\times10^8$/unit	0.15-5.5×10^8/unit

Mean volume was 65.5 mL with range of 50-70 mL. Mean WBC contamination was 1.4×10^8/unit with a range of 0.15-5.5×10^8/unit. Mean RBC contamination was 0.077×10^{12}/liter with a range of 0.05- $0.14x10^{12}$/liter.

Table 3: QC of Platelet Concentrate

Parameters	Quality Requirement	Frequency of control
Volume	>200 ml	1% of all units
Platelet Count	>3.0*1011	1% of all units
pH	>6.0	1% of all units

Table 4: QC of Fresh Frozen Plasma

	Quality Requirement	Frequency of control
Volume	200-220 ml (450 ml) 155-172 ml(350 ml)	1% of all units
Stable coagulation factors	PT & APTT	1% of all units
Stable coagulation factors	PT & APTT	1% of all units
Factor VIII	0.7 units/ml	1% of all units
Fibrinogen	200-400 mg	1% of all units

DISCUSSION

Blood banks have the dual responsibility of providing safe blood/components with maximum efficacy to the recipients as well as maintaining adequate stock and blood supply.[10]

Blood banks have a dual liability primarily to meet the adequate blood supply for the community and essentially to ensure maximum blood recipient safety. Improved quality testing over the period has resulted in safer transfusion practices and decrease adverse outcomes.[11]The aim of study was to ensure supply of safe and efficient blood transfusion to patient and to prevent Transfusion Transmitted Diseases.

Internal Quality Control is the integral part of quality assurance in all laboratory services. It is the pre-defined set of procedures that are done for continuous assessment of routine work, so as to assess the performance standards.[12] Maintaining quality control standards in blood banks help in decreasing the number of adverse blood reactions. Regular periodic quality analysis of blood components is designed to monitor variations in manufacturing processes, product quality and ensure that manufacturing steps meet defined criteria for acceptance.[13]

The recommended volume for whole blood was 350±10 mL with haematocrit of >30%, and recommended volume of PRBCs was 280±60 mL with haematocrit of >55% as per standard guidelines.[7] In present study, the mean volume of whole blood units was 350 mL with a range of 345-375 mL and the mean volume of PRBCs was 320 mL with a range of 250-370 mL. The mean haematocrit of whole blood units was 45.7% with a range of 33.5-47%, whereas mean haematocrit of PRBCs was 65.5% with a range of 55.9 to 78.9%. All the whole blood and PRBCs units checked had volume and haematocrit well within standard criteria thus establishing the quality of our blood bank. Results similar to this study have been observed in study done by Upadhyay S et al., in which mean volume of whole blood units was 410±8.1 mL with a range of 391-522 mL and haematocrit of whole blood units was 43.7±3.2% with range of 38-52.5%.[6]

Raveendran R. et al., also studied the various haematological parameters of platelet concentrate. Volume and WBC contamination in their study corroborated with the present study, however, their mean platelet count was more than this study, both meeting normal

standard criteria.[14]As patients with thrombocytopenia need transfusion of platelet concentrates for prevention/ stoppage of bleeding, platelet transfusion should provide good quality for adequate benefit.

CONCLUSION

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. Quality indicators should be well-defined, regularly monitored and properly documented. Quality Control is an important tool to ensure maximum benefit to patient with minimum cost and maximum advantage and minimizing requirement of transfusion to patient and Prevention of risk of Transfusion Transmitted Diseases.

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