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Quality of Transfusion Products - An internal quality control in tertiary care blood center.

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Abstract

Background: The primary aim of transfusion medicine is to provide improved quality standards of blood com ponents to promote patient care and safety. The blood component transfusion therapy seeks to reduce morbidity and specially to improve quality of life in the patients. Our study summarizes the current knowledge of the quality control of blood components, including red blood cells, platelets, and fresh frozen plasma.

Methods: Quality control of blood components prepared at the blood center of Sawai Man Singh Medical College, Jaipur from January 2021 to December 2022. As per National guidelines set by Govt. of India (DGHS), 1% of components prepared shall be tested for Quality Control out of which 75% shall match the acceptable ranges. Packed red cell units were evaluated for hematocrit (HCT); random platelet concentrates were evaluated for pH, yield, and culture; fresh frozen plasma (FFP) and cryoprecipitate (CP) were evaluated for unit volume, factor VIII, and fibrinogen concentrations.

Results: A total of 244 units were tested for IQC. The mean hematocrit of RBC was 62.6%. In PLT, mean yield was 6.9 × 1010/cu mm. Mean factor VIII and fibrinogen levels were found to be 84.7 IU/ bag and 310.2 mg/bag in FFP respectively.

Conclusion: In the current era, Quality Control plays a pivotal role in upholding the quality of blood components and achieving the quality objectives of a blood center. By prioritizing efficient blood transfusion to patients, Quality Control ensures the highest level of effectiveness and safety. The Internal Quality Control (IQC) of blood components demonstrates overall compliance and adhe rence to recommended national standards. This accom plishment is a result of the implementation of standar dized ope rating procedures, adherence to established guidelines, meticulous documentation practices, regular audits, and ensuring staff competencies.

Keywords: Quality control, Blood products, Patient care, Blood safety.

Introduction

Blood transfusion service is an integral part of health care system as it ensures safe blood and transfusion practices (1). Also, it is crucial to maternal health because haemo rrhage and anaemia are leading causes of maternal death in India (2). Blood is collected from the donor either as whole blood, which is subjected to component pro

cessing, or through the use of apheresis devices where one (or more) component is retained and the remaining constituents are returned to the individual (3). Quality assurance is defined as the consistent and reliable performance of services, procedures and products in conformance to the standard specifications (4). Thus, quality control is an integral part of quality assurance. In the modern blood banking, quality controls of blood products ensure the timely availability of a blood com ponent of high-quality yield with maximum efficacy and minimal risk to potential recipients (1). There have been advancement and progression in international standards for blood components, and principles of high-quality manufacturing practices have been redefined to provide the framework for quality in Blood Transfusion Services (5). This drive causes significant improvement in processes and blood component quality. The purpose of this study is to determine the IQC on various blood components in obstetric patients in tertiary care center (6).

Material and Methods

An observational cross-sectional study was conducted in the Department of Immuno hematology and Transfusion Medicine at Mahila Chikitsalay attached to SMS Hospital in Jaipur, Rajasthan from January 2021 to December 2022. Total units of each blood component was arbitrarily chosen during the study. Packed red cell units were evaluated for hemoglobin, hematocrit, RBC count; platelet con centrates were evaluated for pH, yield and culture; fresh frozen plasma and cryoprecipitates were evaluated for unit volume, factor VIII and fibrinogen con centrations. Monthly Quality control (QC) of the donated blood bags was performed and the selection criteria was 1.0% of the total collection or minimum 4 bags per month. During this period, after adequate screening, 9480 whole bloods from healthy blood donors were collected in 350- or 450-mL volume quadruple bags (Top & Top con figuration) and separated into specific blood components using manual component expressor. While all WB collec tions were separated into various blood components such as packed red blood cells (PRBCs), random donor platelets (RDPs), and fresh frozen plasma (FFP) (7). Criteria used for Quality Control (QC) were according to the DGHS manual, 3rd edition. **Results**

During the study period 9480 units of whole blood collected and 8326 units of blood separated in the components. Components prepared comprised of 8326 units of RBC, 8198 units of FFP, 8176 units of Platelets and 3954 units of cryoprecipitates. Total RBC (83) units, and FFP (81) units, PLTs (80) out of which 32 from 350 ml bag and 48 from 450 ml bag were randomly selected for internal Quality control. All components were evaluated on the day of expiry or near expiry (PLTs).

The Internal Quality Control results obtained for every component separated are shown in the following tables (11).

Table 1: Quality control results of PRBCs.

Parameter	IQC results obtained
Appearance	No hemolysis, no turbidity, no visible clots, no frothing
Volume (Range)	315-385 ml (Mean-349.60ml) for 450ml 225-275 ml (Mean-247.03ml) for 350 ml
Hematocrit	52.6%-72.9%
Sterility	No growth

Table 2: Quality control results of RDP prepared from PRP method from 350 ml of whole blood.

Parameter	IQC results obtained
Appearance	Swirling movements of platelets, no visual RBC contamination
Volume (Range)	50-70ml (mean-59.62ml)
Platelet Count	3.5- 6×10^{10}/unit
pH	6.0-7.3
RBC contamination	$<0.05\times10^{8}$/unit
WBC Contamination	$5\text{-}6\times10^{8}$/unit
Sterility	No growth

Table 3: Quality control results of RDP prepared from PRP method from 450 ml of whole blood.

Parameter	IQC results obtained
Appearance	Swirling movements of platelets, no visual RBC contamination
Volume (Range)	70-90 ml (mean-81.54ml)
Platelet Count	$5.5\text{-}8\times10^{10}$/unit
pH	5.7-8
RBC contamination	$<0.05\times10^{8}$/unit
WBC Contamination	$5\text{-}6\times10^{7}$/unit
Sterility	No growth

Table 4: Quality control results of FFP prepared from 350ml and 450 ml whole blood.

Parameter	IQC results obtained
Appearance	No icteric, lipemia, discoloration present
Volume (Range)	180-220 ml from 350 ml bag 220-300 ml from 450 ml bag
Factor VIII	70-100 IU/bag (Mean-84.7)
Fibrinogen	190-430 mg (Mean-310.2 mg)

Discussion and Conclusion

The Quality Control (QC) program plays a crucial role in ensuring blood transfusion safety and effectively reduces the risks associated with blood and component therapy (10). A deep understanding of clinical blood transfusion practices, coupled with the advent of automation and technological advancements in blood banking, has led to significant improvements in the quality assurance program within blood centers (12).

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. In present study, the mean volume of PRBCs was 315-385 ml (Mean-349.60ml) for a 450 ml bag while for 350 ml bag, it was

225-275 ml (Mean-247.03ml). The mean haematocrit of PRBCs was 62.6% with a range of 52.6%-72.9%. All the PRBCs units checked had volume and haematocrit well within standard criteria thus establishing the quality of our blood bank.

During IQC testing, 100% components for sterility matched the defined standards. In case of FFP, 100% FFP match for fibrinogen level and 99.2% of FFP could match the defined standard for factor VIII. As per regulatory guidelines, at least 75% of components should match or surpass the baseline quality standards (11).

The implementation of Good Manufacturing Practices (GMPs), adherence to Good Laboratory Practices, and the availability of comprehensive quality manuals and guidelines have all contributed to optimizing the processes involved in producing high-quality blood com ponents. These advancements are aimed at maximizing the therapeutic benefits of blood transfusion, ensuring the utmost safety for patients (1).

Safe blood transfusion is not only a fundamental human right but also an essential healthcare service that should be accessible to all individuals. To achieve this, proper quality management must be implemented across all processes involved in blood collection, preparation of components, and issuance to recipients. Well-defined quality indicators should be established, Table 4: Quality control results of FFP prepared from 350ml and 450 ml whole blood Parameter IQC results obtained Appearance No icteric, lipemia, discoloration present Volume (Range) 180-220 ml from 350 ml bag 220-300 ml from 450 ml bag Factor VIII 70-100 IU/bag (Mean-84.7) Fibrinogen 190-430 mg (Mean-310.2 mg) regularly monitored, and thoroughly documented to ensure the highest standards of safety and efficacy (4).

Quality Control plays a crucial role in achieving these objectives by serving as a vital tool in maximizing the benefits to the patient while minimizing costs and transfusion requirements. By implementing rigorous quality control measures, the risk of Transfusion Transmitted Diseases can be significantly reduced, safeguarding the health and well-being of patients.

Through robust quality management practices, including quality control protocols, blood banks and transfusion services can ensure the optimal use of available resources while maintaining the highest standards of safety and quality. By doing so, they not only fulfill their duty to provide safe transfusions but also contribute to the overall well-being of the healthcare system and society as a whole.

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