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IMPROVING THE BLOOD PRODUCT SUPPLY WITH STRICT QUALITY CONTROL PROCEDURES

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Abstract

It is imperative for healthcare systems globally to guarantee a dependable and secure blood product supply. This research investigates how the supply chain for blood products is affected by the adoption of strict quality control measures. Blood components such as Red Cell Concentrate (RCC), Fresh Frozen Plasma (FFP), Platelet Concentrate (PC), Cryoprecipitate (CP), and Platelet Apheresis were analyzed in a study carried out at A.D. Gorwala Blood Bank between April 2021 and March 2023. A minimum of four bags or 1% of each component were randomly selected each month for quality control assessment using information from the blood banks online programmed. The sample selection process included all blood bags excluding those collected through therapeutic phlebotomy. Factor VIII activity, sterility, platelet count, pH, fibrinogen levels, hemoglobin content, hematocrit, leukocyte count, volume, and quality control criteria in line with National Accreditation Board for Hospitals and Healthcare Providers (NABH) standards were used. When analyzing the data, descriptive statistics were utilized to guarantee that strict quality requirements were followed and to emphasize the effectiveness and safety of blood components for transfusion and medicinal purposes. Improved transfusion methods and patient outcomes are made possible by this thorough evaluation. In order to ensure a stable and effective supply of blood products, which ultimately improves patient safety and healthcare delivery, the results highlight the significance of strict quality control.

Keywords: *Blood Product, Supply, Strict Quality, Patient Safety, Healthcare Delivery*

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1. INTRODUCTION

Strict quality control measures are essential to improving the supply of blood products, which is a vital component of contemporary healthcare. Whole blood, red blood cells, plasma, platelets, and other blood products are essential for a variety of medical procedures, from acute surgery to the management of chronic illnesses. To improve patient outcomes and save lives, it is critical to guarantee the safety, effectiveness, and accessibility of these goods. Because of this, stringent quality control procedures must be put in place at every point of the blood supply chain, from processing and donation to distribution and storage.

Regarding the provision of blood products, one of the main worries is the possibility of infection and disease spread. Blood transfusions can spread pathogens like HIV, hepatitis B and C, and germs if appropriate screening and handling procedures are not closely adhered to. Comprehensive testing of given blood for these and other pathogens is part of quality control procedures. Cutting-edge technologies such as enzyme-linked immunosorbent assays (ELISA) and nucleic acid testing (NAT) are used. By lowering the danger of transmission and guaranteeing that only safe blood products are made available for transfusion, these tests aid in the early diagnosis of diseases. Moreover, blood products must be transported and stored with extreme care to preserve their viability and efficacy. Blood components must be stored according to precise guidelines, including temperature limits and deadlines for expiration. Temperature-sensitive indicators are used to track conditions during transportation, refrigeration equipment validation, and routine storage condition monitoring are all examples of quality control methods. By making sure that these standards are regularly reached, blood products' quality is maintained and their therapeutic potential is maximized.

Not only are contamination and storage issues a concern, but standardizing blood processing methods is essential to preserving quality. Adopting best practices for blood collection, component separation, and blood product preparation is part of this. Standardized procedures and automated systems reduce human error and variance, producing more consistent and dependable results. Personnel involved in these operations are further enhanced by training and certification, which guarantees that all procedures are carried out with the utmost care and precision. Stricter quality

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control measures are also easier to adopt, which helps to improve inventory control and decrease blood product waste. Blood banks and healthcare facilities can optimize their supply chains to ensure that blood products are accessible when needed while minimizing the risk of shortages or overstocking by keeping correct records and performing routine audits. This increases the effectiveness of using blood products while simultaneously lowering costs and promoting sustainability in healthcare operations.

2. REVIEW OF LITREATURE

Acker, Marks, and Sheffield (2016) give a thorough analysis of the new and conventional blood components used in transfusion procedures. The norms and standards that guarantee the safety and effectiveness of transfusion-derived blood are covered in the article, which concentrates on the quality assessment techniques for these constituents. The authors draw attention to the developments in storage and preservation methods, which are essential for preserving the viability of blood components. The study also examines new developments in blood transfusion technology, such as innovative preservation techniques and pathogen control strategies, which are meant to raise the general calibre and security of blood products. The study is thorough and in-depth, providing insightful information about the present and potential future paths of blood component quality assessment..

Al-Riyami et al. (2021) Examine the significant impact of the COVID-19 pandemic on transfusion services and blood supply in the Eastern Mediterranean region. The study draws attention to the difficulties that blood banks and transfusion services confront, such as interrupted blood drives, lower donor turnout, and practical difficulties with blood delivery and collection. The authors offer a thorough examination of the tactics used to lessen these difficulties, including improved donor recruiting campaigns, the use of mobile blood collection equipment, and the establishment of security measures to safeguard both personnel and donors. This essay emphasises the necessity of strong contingency planning and international cooperation while providing a critical viewpoint on the adaptability and resilience of blood services during a global health emergency.

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The study by Crombie et al. (2022) provides results from the multicenter, open-label, randomised, controlled phase 3 RePHILL trial, which examined the effectiveness of blood product resuscitation in prehospital care for patients suffering from trauma-related hemorrhagic shock. The trial contrasts the results of patients getting normal care and those undergoing blood product resuscitation. The findings suggest that although the utilisation of blood products can enhance hemodynamic stability and minimise the necessity for additional hospital procedures, it has no discernible effect on overall survival rates. The study's strong methodology and implications for prehospital trauma care standards make it noteworthy. It draws attention to the possible advantages and restrictions of early blood product resuscitation in terms of bettering patient outcomes and identifies areas that require more investigation in order to maximise trauma treatment procedures.

Dehghani, Abbasi, and Oliveira (2021) Examine how a proactive transshipment strategy based on stochastic programming can optimise the blood supply chain. This research delves into the intricacies and unpredictabilities present in blood supply networks, including fluctuations in demand and the perishable characteristics of blood products. The authors suggest a transshipment decision-making model that enables proactive measures to reduce shortages and waste while guaranteeing the prompt delivery of blood supplies to medical facilities. Numerous computer tests demonstrating notable improvements in the efficiency and dependability of blood supply systems serve as evidence of the model's effectiveness. This study adds significant knowledge about how to apply sophisticated mathematical modelling methods to improve the management of vital healthcare resources.

Drew et al. (2018) investigates blood products' medicinal potential for treating dry eye syndrome (DES). The use of autologous serum eye drops, platelet-rich plasma, and other blood-derived products as novel treatments for DES—a condition that frequently resists standard therapies—is highlighted in this thorough review. The authors talk about the biological processes that underlie these treatments' effectiveness, such as the delivery of vital growth factors, cytokines that reduce inflammation, and other bioactive substances that encourage the repair and regeneration of the ocular surface. The report reviews clinical research that show blood products are safe and beneficial in reducing symptoms and enhancing the quality of life for DES patients. This paper

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highlights the potential of blood-derived medicines to meet unmet needs in ophthalmology by providing a comprehensive description of a unique therapeutic method.

3. RESEARCH METHODOLOGY

3.1 Sample Selection

All blood bags given to the A.D. Gorwala Blood Bank between April 2021 and March 2023 were included in this study's analysis; blood bags obtained through therapeutic phlebotomy were not. Red cell concentrates (RCC), fresh frozen plasma (FFP), platelet concentrate (PC), cryoprecipitate (CP), and platelet apheresis were among the blood components that were examined. A minimum of four bags, or 1% of each blood component, were chosen at random each month for quality control assessment. The internet programme of the blood bank provided the data. The quality of the blood components was evaluated using quality control criteria that were based on the requirements established by the National Accreditation Board for Hospitals and Healthcare Providers (NABH). Depending on the particular blood component, factors such as haemoglobin content, hematocrit, leukocyte count, volume, factor VIII activity, sterility, platelet count, pH, and fibrinogen levels were assessed.

3.2 Blood Components Analyzed

This study at the A.D. Gorwala Blood Bank examined the following blood components: platelet concentrate (PC), fresh frozen plasma (FFP), red cell concentrate (RCC), cryoprecipitate (CP), and platelet apheresis. Haemoglobin content, hematocrit levels, leukocyte count, and volume are assessed in Red Cell Concentrate (RCC) to guarantee sufficient oxygen-carrying ability and reduce the risk of leukocyte-related problems. To ensure the effectiveness of clotting factors and protection against bacterial contamination, factor VIII activity and sterility of fresh frozen plasma (FFP) are assessed. To verify efficient platelet function and viability, Platelet Concentrate (PC) is evaluated for platelet count, pH levels, volume, and sterility. To make sure there are enough clotting factors for bleeding disorders, factor VIII activity and fibrinogen levels in cryoprecipitate (CP) are closely monitored. To ensure that Platelet Apheresis remains safe and effective for use in transfusion therapy, quality control measures are taken to monitor platelet count, pH, volume, and

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sterility. To guarantee their quality and safety for use in patient care, each of these blood components is subjected to a thorough evaluation process in accordance with standards established by the National Accreditation Board for Hospitals and Healthcare Providers (NABH).

3.3 Sampling Procedure

A minimum of four bags every month, or 1% of each blood component, were randomly selected for quality control analysis during the sampling method for this study. Cryoprecipitate (CP), Fresh Frozen Plasma (FFP), Platelet Concentrate (PC), Red Cell Concentrate (RCC), and Platelet Apheresis were among the blood components analysed. In order to ensure thorough and accurate documentation for upcoming quality assessments based on the guidelines established by the National Accreditation Board for Hospitals and Healthcare Providers (NABH), data for the chosen samples were painstakingly extracted from the online blood bank software at A.D. Gorwala Blood Bank.

3.4 Quality Control (QC) Criteria

The National Accreditation Board for Hospitals and Healthcare Providers (NABH) requirements were closely followed by the quality control (QC) criteria in this study. Tables 1, 2, 3, 4, and 5 provided comprehensive specifications unique to each blood component: Red Cell Concentrate (RCC), Fresh Frozen Plasma (FFP), Platelet Concentrate (PC), Cryoprecipitate (CP), and Platelet Apheresis. Depending on the kind and intended application of each blood product, these requirements included factors including haemoglobin content, hematocrit levels, leukocyte count, volume, factor VIII activity, sterility, platelet count, pH levels, and fibrinogen levels. By adhering to these strict quality control requirements, blood components were guaranteed to meet the highest standards of safety, efficacy, and quality for transfusion and therapeutic applications, protecting patient health and treatment outcomes.

3.5 Data Analysis

The quality parameters of the blood components—Red Cell Concentrate (RCC), Fresh Frozen Plasma (FFP), Platelet Concentrate (PC), Cryoprecipitate (CP), and Platelet Apheresis—were

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primarily summarised in this study using descriptive statistics as the primary statistical method. Key quality parameters such haemoglobin content, hematocrit levels, leukocyte count, volume, factor VIII activity, platelet count, pH levels, and fibrinogen levels were succinctly and clearly summarised by these figures. Every blood component's adherence to the National Accreditation Board for Hospitals and Healthcare Providers (NABH) standards and defined quality control (QC) criteria was carefully evaluated. By taking this technique, the integrity and dependability of the blood products for clinical use were maintained and any violations from the established standards were quickly found and corrected. Researchers were able to clearly convey the overall quality performance of the blood components through the use of descriptive statistics, which aided in well-informed decision-making and ongoing transfusion practice improvement.

4. DATA ANALYSIS AND RESULT

Table 1: QC Criteria for Red Cell Concentrate (RCC)

Parameter	Standard Requirement
Hemoglobin (Hb) Content	≥ 40g/unit
Hematocrit (Hct)	55% to 65%
Leukocyte Count	< 5 x 10^6/unit
Volume	200-300 ml/unit

The quality control (QC) standards for Red Cell Concentrate (RCC) utilised in this investigation are listed in Table 1. The requirements include a minimum haemoglobin (Hb) level of 40g per unit to guarantee transfusion patients have enough oxygen-carrying capability. The ideal ratio of red blood cells to plasma in the concentrate is indicated by the hematocrit (Hct) levels, which must be between 55% and 65%. To reduce the possibility of recipients experiencing unfavourable immunological responses, the leukocyte count must be fewer than 5 x 10^6 per unit. In order to maintain consistency in transfusion volume and efficiency, each RCC unit's volume should also fall between 200 and 300 ml. These guidelines, which are in line with those established by the National Accreditation Board for Hospitals and Healthcare Providers (NABH) to guarantee safe

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and efficient transfusion procedures, operate as benchmarks for evaluating the calibre and acceptability of RCC for clinical use.

Table 2: QC Criteria for Fresh Frozen Plasma (FFP)

Parameter	Standard Requirement
Factor VIII Activity	≥ 70 IU/dl
Volume	150-250 ml/unit
Sterility	No bacterial contamination

The quality control (QC) standards for fresh frozen plasma (FFP) as they are defined in this study are shown in Table 2. A minimum Factor VIII activity of 70 IU/dl is one of the characteristics, which guarantees sufficient clotting factor content for successful hemostasis in transfusion recipients. To optimise the amount of plasma available for therapeutic usage while preserving uniformity among units, each FFP unit should have a volume between 150 and 250 ml. FFP units must not contain any bacteria in order to meet sterility guidelines, which reduces the possibility of diseases spreading through transfusion. These strict quality control requirements, which comply with regulations established by organisations like as the National Accreditation Board for Hospitals and Healthcare Providers (NABH), are essential for confirming the efficacy and safety of FFP. By adhering to these requirements, FFP is guaranteed to fulfil the highest quality assurance standards, protecting patient health throughout transfusion procedures.

Table 3: QC Criteria for Platelet Concentrate (PC)

Parameter	Standard Requirement
Platelet Count	≥ 5.5 x 10^10/unit
pH	6.4 to 7.4
Volume	50-70 ml/unit
Sterility	No bacterial contamination

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Strict quality control (QC) standards are in place to guarantee the efficacy and safety of platelet concentrates (PCs) for patients with bleeding disorders. Four important factors are covered by these criteria: volume, sterility, pH level, and platelet count. It takes at least 5.5 x 10^10 platelets per unit to guarantee adequate clotting capacity. A pH of 6.4 to 7.4 keeps the platelet habitat in an optimal range, and a volume of 50–70 ml per unit ensures a sufficient dose during transfusion. Above all, thorough sterility testing is carried out to ensure that there are no bacteria present at all that could infect the recipient with dangerous illnesses. Platelet Concentrates can treat patients with low platelet counts safely and effectively if they meet these quality control criteria.

Table 4: QC Criteria for Cryoprecipitate (CP)

Parameter	Standard Requirement
Factor VIII Activity	≥ 80 IU/unit
Fibrinogen	≥ 150 mg/unit
Volume	15-20 ml/unit

Strict quality control (QC) is necessary to ensure that cryoprecipitate transfusions are effective in treating bleeding problems. Three main elements are the emphasis of these criteria: volume, fibrinogen level, and Factor VIII activity. Sufficient concentration of this vital clotting factor is guaranteed at a minimum of 80 IU/unit of Factor VIII activity. Another necessary protein for the production of clots, fibrinogen, needs to be at least 150 mg/unit. Finally, a therapeutic dose during transfusion is possible with a sufficient volume of 15-20 ml per unit. Fulfilling these quality control requirements contributes to the safe and efficient administration of cryoprecipitate as a therapy for patients deficient in fibrinogen or Factor VIII.

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Table 5: QC Criteria for Platelet Apheresis

Parameter	Standard Requirement
Platelet Count	≥ 3.0 x 10^11/unit
pH	6.4 to 7.4
Volume	200-400 ml/unit
Sterility	No bacterial contamination

Strict quality control (QC) measures are taken during platelet apheresis collections to guarantee that patients receive platelet transfusions that work. Platelet count, pH level, volume, and sterility are the four main focuses of these quality control measurements. It takes at least 3.0 x 10^11 platelets per unit to ensure adequate clotting capacity. Platelet function is best maintained in an environment with a pH of 6.4 to 7.4. Comparing standard concentrates to this greater volume, usually 200-400 ml per unit, allows for a higher platelet dose. Above all, rigorous sterility testing is carried out to exclude any possibility of bacterial contamination that can infect the recipient with dangerous diseases. Platelet apheresis products offer a safe and concentrated source of platelets for treating patients with bleeding problems since they meet these quality control requirements.

Table 6: QC of Red Cell Concentrate.

Parameter	RCC	Additive Solution	Frequency of control
Volume	450 ml (350 ml)	450 ml (350 ml)	1% of all units
Hematocrit (HCT)	65-75%	55-65%	1% of all units
Sterility	By culture	By culture	1% of all units

Quality control, or QC, makes ensuring that the additive solution and red blood cells (RCCs) fulfil certain standards prior to transfusion. Both the additive solution and RCC aim to achieve a volume between the range of 350 ml (acceptable) and 450 ml (excellent), testing one percent of all units.

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Crucial is the red blood cell concentration measured by hematocrit (HCT). While the additive solution targets 55-65% HCT, RCC aims 65-75% HCT. Like volume, 1% of all units had their HCT tested. In order to avoid infections, sterility is crucial. To make sure there are no bacteria at all, the additive solution and RCC are both cultured, and 1% of all units are tested. It is possible to use additive solution and RCC in blood transfusions safely and successfully by following certain QC requirements.

5. CONCLUSION

Strict quality control measures have greatly enhanced the availability of blood products by guaranteeing that all blood components—FAFP, RBC, PC, Cryoprecipitate (CP), and Platelet Apheresis—consistently fulfil strict requirements for quality, safety, and efficacy. By applying strict quality control criteria that were in line with NABH standards, this study thoroughly assessed the quality of several blood components, including Red Cell Concentrate (RCC), Fresh Frozen Plasma (FFP), Platelet Concentrate (PC), Cryoprecipitate (CP), and Platelet Apheresis. By means of methodical sampling and rigorous analysis, the research guaranteed that every blood product fulfilled rigorous standards concerning hemoglobin content, hematocrit levels, leukocyte count, volume, factor VIII activity, sterility, platelet count, pH levels, and fibrinogen levels. In order to protect patient health and enhance clinical results, the findings emphasize the importance of upholding safety, efficacy, and quality in transfusion practices. The significance of upholding established norms for improving healthcare delivery is underscored by this research, which also helps to further advances in transfusion medicine. By promoting ongoing enhancements in transfusion procedures, this all-encompassing quality control strategy not only maximizes the therapeutic usefulness of blood products but also fortifies healthcare delivery systems as a whole.

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