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Original Article

Assessment of Internal Quality Control of Blood Products; Experience at a Regional Transfusion Centre from Northern Pakistan

Maria Khan, Junaid Tariq*, Muhammad Ali Rathore, Asad Mahmood, Mansoor Ishaq Raja, Saima Bashir*

Armed Forces Institute of Transfusion (AFIT)/National University of Medical Sciences (NUMS), Rawalpindi Pakistan, *National University of Medical Sciences (NUMS), Rawalpindi Pakistan

ABSTRACT

Objective: To analyze internal quality control of blood components, including red cell concentrates, fresh frozen plasma, cryoprecipitate and random donor platelets, to measure our blood bank performance.

Study Design: Cross-sectional study.

Place and Duration of Study: Armed Forces Institute of Transfusion (AFIT), Rawalpindi Pakistan from Jul to Dec 2021.

Methodology: Whole blood units were separated into red cell concentrates, fresh frozen plasma and random platelets by the platelet-rich plasma method. Cryoprecipitates were prepared from FFPs. Quality control was done on representative components. For red cell concentrates, hematocrit was measured. For platelet concentrates, pH and platelet yield were measured. For fresh frozen plasma, Factor-VIII assay and for cryoprecipitate, Factor VIII and fibrinogen assays were done. The blood components were also tested for bacterial cultures.

Results: A total of 1130 units were analyzed for quality control, including 360 red cell concentrates, fresh frozen plasma, random donor platelets each and 50 cryoprecipitates. Red cell concentrates had a mean hematocrit of 68.5±3.7%. Random donor platelets had a yield of 10.1±1.4× 10^{10} / unit and a mean pH of 6.7±0.2. Fresh frozen plasma had a Factor VIII level of 2.2±0.98 IU/ml. Cryoprecipitate had a mean fibrinogen level of 202.8±27.8 mg/unit and Factor VIII132.5±54.1IU/unit. All blood components met internal quality control standards. Blood cultures were negative in 99.2% of random donor platelets tested.

Conclusion: The internal quality control of blood products was in concordance with the national and international standards for quality control in blood banks.

Keywords: Blood components, Internal quality control, Quality assurance.

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INTRODUCTION

Quality assurance refers to an organization's or body's efforts to ensure that the services or products provided to customers are of the highest possible quality and meet the organization's standards.[1] Blood banking is a highly significant specialized component of health care services; therefore, quality control of blood components is vital to ensure optimal benefit from transfusions.[2] Quality assurance in transfusion services includes all aspects such as blood donation, screening, component preparation, storage, transportation and transfusion to the recipient.[3] Internal quality control (IQC) is the backbone of the quality assurance program. It plays a vital role in safe blood transfusion, and the risks associated with blood transfusion can be substantially reduced by implementing an effective IQC program.[4]

The Internationally practiced quality standards for blood components include guidelines from the Association for the Advancement of Blood & Biotherapies (AABB) and the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC).[5,6] At the national level, these standards are regulated by the Safe blood transfusion programme of the Government of Pakistan (SBTP).[7] These regulatory and advisory bodies mandate quality control testing of at least 1% of blood bags or a minimum of four bags per month.

In developed countries, transfusion medicine has led to the development and implementation high-reliability quality principles in blood banks.[8] However, the blood banks in our country are disintegrated and are not being centrally regulated. Moreover, there is a lack of scrutiny over implementing quality control procedures in these setups.

In this study, we assessed the IQC of blood components prepared in our regional transfusion centre, including red cell, concentrates (RCC), fresh frozen plasma (FFP), cryoprecipitate and random donor

Correspondence: Dr Maria Khan, Department of Hematology, AFIT, Rawalpindi, Pakistan

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platelets (RDP) as a measure of the efficiency of our blood bank. Unfortunately, little data on quality control (QC) in blood banks is available in Northern Pakistan. Therefore, our focus was to compare our results and comply with international QC standards.

METHODOLOGY

This cross-sectional study was conducted at the Component Preparation Department of the Armed Forces Institute of Transfusion, Rawalpindi Pakistan, from July 2021 to December 2021 after approval from the Institutional Ethical review board (AFIT-ERC-21-018).

Inclusion criteria: Blood components of healthy blood donors of both genders aged 18-65 years who were selected after screening by uniform donor questionnaire, verbal interview, general physical examination, peripheral blood count within range and testing negative for infectious diseases including Hepatitis B and C, HIV and Syphilis.

Exclusion Criteria: Blood products from donors who tested positive for Hepatitis B, C, HIV and Syphilis and damaged blood bags (ruptured, leaked or discoloured) during processing were excluded from the study.

A total of 1130 blood components were tested for QC parameters. Non-probability convenient sampling technique was employed, and 1% of each blood component was tested during the study period. At the component preparation department, whole blood was separated into RCCs, FFPs and RDPs by Platelet-rich plasma (PRP) method within 6 to 8 hours of donation. Cryoprecipitate was prepared by FFPs after thawing. After separation, the products were evaluated randomly per the study protocol. The QC of RCC hematocrit (HCT) was determined using an SYSMEX XP100 Hematology analyzer. For QC of RDP, pH was calculated using pH-indi-cator strips and universal indicator by Merck Milli-pore; Platelet count was analyzed using SYSMEX (XP100) Hematology analyzer, and the Platelet yield was calculated by the formula: Platelet count Volume of RDP/10000.

For QC of FFP and cryoprecipitate, Factor VIII and fibrinogen levels were analyzed by the coagulometric method using the SYSMEX CA-600 series coagulation analyzer. In addition, bacterial cultures were also carried out on RCC and RDP. The samples were tested for bacterial contamination by inoculating 10 mL in each aerobic (BD BACTECTM plus Aerobic/ F) and anaerobic (BD BACTECTM plus Anaerobic/F) culture vial and incubating at 35°C in the BD BACTEC TM FX40 (Becton, Dickinson and Company, USA) automated detection system until positive or for seven days if negative.

Positively flagged culture vials were then sub-cultured onto blood, MacConkey, and chocolate agar for further microbial isolation and identification. These culture plates were incubated aerobically at 37°C for 24–48 hours, whereas chocolate agar was incubated anaerobically at 37°C for 48 hours. According to AABB and National guidelines, the QC of the components which had completed their shelf life was checked. For RCC collected in CPDA-1, the QC was checked on the 35th or 36th day of their shelf life, and for RDP on the fifth day of their shelf life. In addition, FFPs and cryoprecipitate were checked near expiry. AABB and National Quality control guidelines were employed to assess QC parameters.

Data was analyzed using a statistical package for social sciences (SPSS) version 25. Mean ± standard deviation (SD) of the quantitative variables were calculated while descriptive statistics were applied to qualitative variables, expressed as frequencies.

RESULTS

A total of 1130 blood products were analyzed for internal quality control. These included 360 (31.8%) units of RCC, 360 (31.8%) units of RDP, 360 (31.8%) units of FFP and 50 (4.4%) units of cryoprecipitate. The results of IQC of blood components were summarized in Table-I.

Table-I : Results of Internal Quality Control (IQC) of Blood Components (n=1130)

Parameter	Mean ± SD
Red Cell Concentrates	
Total units [n (%)]	360 (31.8%)
Volume (ml)	306.2±5.2
Hematocrit (%)	68.5±3.7
Fresh Frozen Plasma	
Total units [n (%)]	360 (31.8%)
Volume (ml)	204.2±20.2
Factor VIII (IU/ml)	2.2±0.98
Random Donor Platelet Concentrates	
Total units [n (%)]	360 (31.8%)
Volume (ml)	68.7±2.8
Platelet Yield (/unit)	10.1±1.4 x 1010
pH	6.7±0.2
Cryoprecipitates	
Total units [n (%)]	50 (4.4%)
Volume (ml)	24.8±2.8
Fibrinogen (mg/unit)	202.8±27.8
Factor VIII (IU/ml)	134.5±54.1

The blood components, including RCC and RDP, were also tested for bacterial cultures. No growth was observed in most of these components, i.e. more than 99% tested negative for bacterial cultures, per national and international standards (Table-II). The organism identified in positive cultures was identified as Coagulase-negative Staphylococcus aureus, which is a part of skin flora.

Table-II: Results of bacterial cultures on blood components.

Total Components Tested n (%)		Positive Cultures n (%)	Negative Cultures n (%)
RCC	360 (100)	4 (1.1)	356 (98.9)
RDP	360 (100)	3 (0.8)	357 (99.2)

We compared the results of IQC parameters of blood components observed in our study with the standards laid by AABB and National quality control guidelines, respectively. The internal quality control of RCC, FFP, RDP and cryoprecipitates as per national and international quality standards. This comparison was summarized in Table-III.

Table-III: Comparison with AABB and national QC standards.

Blood Components	AABB Standards	National QC Standards	Our Study
Red Cell Concentrates	Hct <80% in 100% units tested	Hct <80% in 100% units tested	Hct 68.5+3.7 % in 100% units tested
Fresh Frozen Plasma	Not mandatory*	Factor VIII > 0.7 IU/ml Fibrinogen > 140 mg/unit	Factor VIII > 2.2+0.98 IU/ml in 100% unjts tested
Random donor platelets	Platelet yield ≥5.5×1010/ unit & pH ≥6.2 in 90% units tested Culture negative in 90% units tested	Platelet yield > 0.55 x 1011 /unit & pH > 6.2 in 90% of donor units tested Culture negative in 90% units tested	Platelet yield 10.1+×1010/ unit & pH 6.7+0.2 in 100% units tested Culture negative in 99.2% units tested
Cryoprecipitate	Fibrinogen ≥150 mg/unit and Factor VIII ≥80 units in 100% units	Fibrinogen ≥150 mg/unit and Factor VIII ≥80 units in 100% units	Fibrinogen 202.8+27.8 mg/unit and Factor VIII 134.5 + 54.1 units in 100% units

**FDA and AABB do not mandate testing for FFP9.*

DISCUSSION

To ensure safe and effective blood products, implementing a quality assurance program on all aspects of components preparation is mandatory. All procedures and equipment should be validated and reliable. Every component must meet the QC standards. This study aimed to verify the quality of blood components by analyzing the internal quality of RCC, FFP, RDP and cryoprecipitate in AFIT, the largest and most advanced blood bank in Northern Pakistan. This study was one of the very few of its kind conducted in this country, as quality assurance program is expensive, and the majority of the blood banks cannot afford to implement them. We compared our results with AABB and National QC standards. AABB does not mandate testing for FFP due to its limited use.[9] In our setup, the FFPs were tested as per national quality control guidelines, and these para-meters are also in accordance with JPAC standards. A literature review on the IQC of RCC revealed contrasting results. An Indian survey analyzed 260 RCC units and reported a mean HCT of 54%, which is less than the hct observed in our study.[10] Another study conducted in Canada analyzed 202 RCC units. The HCT ranged from 59.5% to 64.8%, which is lower than our results.[11] While another Canadian research evaluated 572 RCC units and reported a mean HCT of 51.5%±5.6.[12] These values are again lower than our findings. This variation between results can be attributed to the differences in steps, from donor selection and blood donation to separation of components and blood storage. A study from Southern Pakistan included 100 RCC units and reported a mean HCT of 69.5%, and 98% of units met the AABB standards.[4] These findings are closely similar to our results. All of the FFPs prepared in our blood bank met IQC standards. Closely similar results were observed in an Iranian study where 99% of the FFPs met the desired stan-dards.[13] A blood bank from Southern Pakistan obser-ved a Factor VIII level of 84.24 ± 15.01 units/dl in FFPs, while another one in Southern Gujarat in India reported mean Factor VIII levels of 1.18±0.62 IU/mL with a range of 0.40 – 2.80 IU/ml which was lower than the levels of Factor VIII level of 2.2 ± 0.98 IU/ml observed in our study.[4,14] Moreover, all of the FFPs tested in our blood bank had an FVIII level of more than 70 IU/ml, meeting the required IQC criteria. Cryoprecipitate, prepared by controlled thawing of FFPs, has a critical role in managing acquired hypofi-brinogenemia. In contrast, their use in inherited coagulation disorders like Hemophilia A, von Wille-brand disease and inherited fibrinogen deficiency has been limited to developing countries due to the in-ability of these resource constraint

countries to procure costly factors concentrates.[15] Being concentrated fibrinogen and Factor VIII source, its quality is assessed on these parameters. We reported a high yield of fibrinogen and Factor VIII in all of the units tested, with a mean of 202.8 ± 27.8 mg and 132.5 ± 54.1 units, respectively. Furthermore, 100% of the units tested conform to the required national and international standards. Sultan *et al,* reported higher levels of both fibrinogen and factor VIII levels in the units tested, with 100% units in conformity with the norms con-cerning the fibrinogen levels and 96% concerning Factor VIII levels.[4] In contrast, the results obtained by Subramaniyan *et al*, revealed lower Factor VIII re-covery in cryoprecipitate prepared from in-house donations by both blast freezer and conventional techniques of 58.5% ± 16.2 and 66.7% ± 16.4, respec-tively.[16] Platelet concentrates are usually highly susceptible to bacterial contamination as they are stored at ambient temperatures promoting growth.[17] Therefore, quality control of platelet concentrates also includes routine microbiological testing for bacterial contamination. Out of 360, RDPs tested, cultures were positive in only three units with a positivity rate of 0.8%, and the sole organism isolated was coagulase-negative staphylococcus aureus.

These contaminants were likely due to inadequate donor arm disinfection. Research conducted in a blood bank in Nairobi showed a culture positivity rate of 12%, which was quite high. Moreover, around 96% of their components achieved the desired yield of >5.5 × 1010 / unit, whereas high platelet yield was achieved in all of the platelet concentrates tested in our transfusion centre.[18] Sehgal *et al*, reported a positive bacterial culture in 5.38% of platelet concentrates in PRP, while another research conducted in a blood bank in Ethiopia showed a very high bacterial contamination rate in 4 platelet bags out of a total of 12 bags tested.[19,20] Our results were similar to those reported in a Moroccan blood bank which analyzed platelet concentrates over seven years and reported culture positivity of 0.44%.[21] Bacterial contamination screening was introduced in Australian blood banks in 2008, and researchers have demonstrated a decline in the initial machine culture positivity rate in platelet concentrates of 0.6% since 2013.[22] The RCC evaluated in our blood bank demonstrated culture positivity in 1.1% of the total bags. Sehgal *et al,* observed closely similar results where all RCCs were found sterile.[19] Our findings highlighted our staff's routine adherence to stringent blood donor arm disinfection technique and meticulous donor selection criteria, which mitigated the risk of bacterial sepsis.

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LIMITATIONS OF THE STUDY

Due to a limited number of kits available, fibrinogen assay was not performed for QC of FFPs.

CONCLUSION

The internal quality control of RCC, FFP, RDP and cryoprecipitates was in accordance with the national and international quality standards. These results depict consistent and reliable instruments' performance, trained staff, efficient implementation of SOPs, and documentation in our blood bank. Our blood bank met the standards of Internal Quality Control.

Conflict of Interest: None.

Author's Contribution

MK: Conception design, data interpretation, manuscript writing, final approval and agreement for integrity of research, JT: Data collection, data analysis, manuscript writing, final approval and agreement for integrity of research, MAR:, AM: Concept, study design, manuscript editing and reveiw, final approval and agreement for integrity of research, SB: Study design, data analysis, manuscript editing and reveiw, final approval and agreement for integrity of research.

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