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Internal Quality Control of Blood Products at Tertiary Health Care Centre

Dr. Khyati Patel[1] Dr. Krutika Ganvit[2] Dr. Atul Shrivastav[3] Dr. Meeta Parikh[4]
[1] 3rd Year Post Graduate Resident, Pathology Department, GMERS Medical College and Hospital Gandhinagar, India
[2] 2nd Year Post Graduate Resident, Pathology Department, GMERS Medical College and Hospital Gandhinagar, India
[3]Associate Professor, Pathology Department, GMERS Medical College and Hospital Gandhinagar, India
[4]Professor and Head of Department, Pathology Department, GMERS Medical College and Hospital Gandhinagar, India

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ABSTRACT:
INTRODUCTION: Internal quality control (IQC) is the backbone of quality assurance programme. In blood banking, the quality control of blood products ensures the timely availability of a blood component of high quality with maximum efficacy and minimal risk to potential recipients. Primary goal of quality control is transfusion of safe quality of blood and to analyse the IQC of blood products as an indicator of our blood bank performance.
AIMS AND OBJECTIVES: To analyse the internal quality control of blood components in modern blood banking as an indicator of our blood bank performance.
MATERIALS AND METHODS: An observational cross-sectional study conducted at the Blood Bank, GMERS Medical College and Hospital, Gandhinagar from July 2022 to December 2023. Each blood component was randomly chosen during the study on monthly basis. Selection criteria was minimum 4 bags per month. Packed red cells were evaluated for haemoglobin, haematocrit, RBC count and other indices like MCV,MCHand RDWCV, culture; platelet concentrates for yield and culture; fresh frozen plasma and cryoprecipitate were evaluated for unit volume, factor VIII and fibrinogen concentration.
RESULTS: The mean HCT of packed red cells was 62.09+6.56%, volume was 365.15+53.05 ml, Hb was 19.22+2.66 g/dL and RBC count of$7.20x10^{12}$+$1.09x10^{12}$. The mean platelet yield was $7.47x10^{10}$, and volume was 62.94+5.75 ml; cultures were negative and swirling was present in all the platelet units tested. Mean fibrinogen and factor VIII levels were found to be 271.23 +89.32 and 83.98+16.11 gm/l for FFP respectively. Meanfibrinogen and factor VIII levels were found to be 280.6 +69.83 and 81.83+17.23gm/l for cryoprecipitate respectively.
CONCLUSIONS: The quality control of blood components ensures the timely availability of a blood component of high quality with maximum efficacy and minimal risk to potential recipients.

I. INTRODUCTION:

Blood Banking is a vital part of the healthcare service. Increasing advancement in the field of transfusion medicine has been enforcing measures to ensure quality of blood and blood components.[1]Blood transfusion service (BTS) is the fundamental part of health care system; deficiency causes impractical overall medical management. However, the blood transfusion is not free of risks owing to human factors; thus, it should only be prescribed when patients clinical statuses really necessitate it.[2]Transfusion services must have a 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.[3] In the modern blood banking, quality controls of blood products ensure the timely availability of a blood component of high-quality yield with maximum efficacy and minimal risk to potential recipients.[4]

Processes and manuals are need to be highly focused on generating quality blood components that are moreefficacious and safer. The primary component in the quality control system is blood donation, which is collected from prospective donors of various ages with different demographics, health profiles, and risk behaviours. Subsequently, these donations will be screened, stored and provided when needed. These variants may compromise the critical control points which are designed to improve the quality of blood components. In recent years, there have been significant developments aimed at improving the quality of the blood components. There have been advancement and progression in international standards for blood components, and principles of

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high-quality manufacturing practices have been redefined to provide the framework for quality inblood transfusion system. This drive causes significant improvement in processes and blood component quality.

II. MATERIALS AND METHOD:

A prospective cross-sectional study was conducted in the blood bank, GMERS medical college Gandhinagar from July 2022 to December 2023. Material in this periodblood units were collected in sterile bags with an anticoagulant CPDA-1 (citrate phosphate dextrose adenine-1) having a volume of 63 ml, from healthy blood donors, who signed informed consent forms. Out of which, 100 units (a total of 400 units) of each blood components were arbitrarily chosen during the study, with the frequency ofIQC testing once weekly for each product. All products were evaluated at the day of expiry (packed red blood cells [PRBCs] and platelets) or near expiry (fresh frozen plasma [FFP] and cryoprecipitate [CP]).

The American Association of Blood Banks (AABB) set standards for quality control assessment of bloodcomponent which was used for products evaluation as shown in Table 1.[5]Packed red cell units were evaluated for haematocrit (HCT) which was determined by CELL-DYN SYSMEX Hematology analyzer. Random platelet concentrates were evaluated for yield, and culture; yield was calculated by standard formula (platelets count×volume×1000), and bacteriological culture analysis was achieved through the inoculation of samples in solid culture media (Nutrient agar, chocolate, and MacConkey agar). Culture plates were incubated at 37°C (±0.5) in Thermo Scientific incubator for 72 hrs. If no growth results were taken as negative, positive cultures further proceeded based on smear examination (Gram staining) and series of biochemical testing, which were performed to identify the bacterial species. FFP and CP were evaluated for unit volume, factor VIII, and fibrinogen concentrations; factor activities were evaluated by Sysmex® CA-1500-automated coagulation analyzer by clotting assay.

Table 1: American Association of Blood Banks standard for the quality control in blood components

Components	Requirements
Packed red cells	Haematocrit ≤80% in 100% units tested
Random donor platelets	Platelet yield ≥5.5×109/L pH ≥6.2 Culture negative in 90% units tested
Cryoprecipitate	Fibrinogen ≥150 mg/unit and Factor VIII ≥80 units in 100% units

OBSERVATIONS

Table 2: Quality assurance parameters of RBC concentrate

Parameters	No. of units	Mean	Standard Deviation
Volume (ml)	72	365.15	53.05
Haemoglobin (g/dl)	72	19.22	2.66
Haematocrit (%)	72	62.09	6.56
RBC count	72	7.20	1.09
MCV	72	87.81	7.96
MCH	72	27.94	2.36
RDW-CV	72	12.93	2.92

Mean volume and haematocrit per unit was 365.15+53.05ml and 62.09+6.56% respectively and haemoglobin and RBC Count was 19.22+2.66g/dl and $7.20x10^{12}$+$1.09x10^{12}$ respectively. (Table 2)

Table 3: Quality assurance parameters of Platelet concentrate

Parameters	No. of units	Mean	Standard Deviation
Volume (ml)	72	62.94	5.75
Platelet count	72	7.47	1.95
Culture	72	Sterile	Sterile
Swirling	72	Present	Present

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Mean volumeand platelet count was 62.94+5.75ml and$7.47x10^{10}$ respectively for 72 platelet concentrates studied. (Table 3)

Table 4: Quality assurance parameters of Fresh Frozen Plasma

Parameters	No. of units	Mean	Standard Deviation
Fibrinogen (gm/L)	40	271.23	89.32
Factor VIII (IU/unit)	40	83.98	16.11

Mean fibrinogen and factor VIII levels were found to be 271.23 +89.32 and 83.98+16.11 gm/l for FFP respectively. (Table 4)

Table 5: Quality assurance parameters of Cryoprecipitate

Parameters	No. of units	Mean	Standard Deviation
Fibrinogen (gm/L)	10	280.6	69.83
Factor VIII (IU/unit)	10	81.83	17.23

Meanfibrinogen and factor VIII levels were found to be 280.6 +69.83 and 81.83+17.23 gm/l for cryoprecipitate respectively.

III. DISCUSSION

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. [6] The aim of quality control measures is to ensure supply of safe and efficient blood transfusion to the patient and to prevent transfusion transmitted diseases. The primary component in the quality control system is blood donation, which is collected from prospective donors of various ages with different demographics, health profiles, and risk behaviors.[7,8]

Our study assessed the mean volume, haematocrit, haemoglobin and RBC count of PRBCs. The mean volume of PRBCs was 365.15 ml. Haematocrit was 62.09%, haemoglobin was 19.22g/dl and RBC count was $7.20x10^{12}$/L. Results similar to our study have been observed by Upadhyay et al in 2016, who found mean volume of PRBCs units as 285±24.3 mL and mean haematocrit of 54±4.2%.[9]Singh et al in 2009 found the Mean volume of RBCs as 310 mL and mean haematocrit as 69.5%.[9]

Our study also assessed the volume, platelet count and culture of platelet concentrates. Mean volume of platelet was 62.94 ml, mean platelet count was $7.47x10^{10}$ and all the cultures were sterile. Similar results were observed by Gupta et al, Fijnheer et al and Hirosue et al. [10-12]

Our study also assessed the levels of factor VIII and fibrinogen. Mean factor VIII levels were 83.98 and mean fibrinogen levels were 271.23 mg/dl.Sultan et al in 2016 tested 100 units for internal quality control. The mean factor VIII and fibrinogen levels were found to be 84.24±15.01 and 247.17±49.69 for FFP respectively. Almost all donors had fibrinogen ≥150mg/dl, while only five percent donors had factor VIII below the desired levels in their study. [13]

In another study done by Agus et al in 2012, 30 units of FFP prepared within 8 hours of collection were tested for factor VIII levels, who found the mean to be 1.0 IU/mL.[14] Dogra et al in 2015 also assessed the comparative analysis of Factors V and VIII and fibrinogen in 100 units of Fresh Frozen Plasma and reported the level of fibrinogen as 270.66±69.64 mg/dl and factor VIII as 117.205±29.01%. [15]

IV. CONCLUSION

From the results, it can be concluded that the quality of blood components being prepared at our blood bank meets the international standards. Safe blood management is absolutely essential, and it is a universal human right which can be achieved by all national health-care systems through well-trained, motivated staff, quality kits, equipment's, facilities, efficient supervision, error and risk assessment system, good manufacturing practice guidelines, and adherence to standard operating procedures. Nevertheless, for all processes in blood collection, quality indicators should be defined, regularly monitored, documented, collated, evaluated, accounted, and consequently implemented.

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