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Internal quality control in blood and component bank in a tertiary healthcare center in Northern India

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ABSTRACT

Introduction: Quality control describes steps taken by blood and component bank to ensure that tests are performed correctly. Primary goal of quality control is transfusion of safe quality of blood. It is to ensure availability of efficient supply of blood and blood components. Internal quality control is the backbone of quality assurance program.

Aims and Objectives: To analyze 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 and Component Bank, JN Medical College and Hospital from 2018 to 2020. Each blood component was arbitrarily chosen during the study on monthly basis. Selection criteria was 1.0% of total collection or minimum 4 bags per month. Packed red cells were evaluated for hemoglobin, hematocrit, RBC count; platelet concentrates for pH, 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 65.75+7.42%, volume was 238+26.25ml, Hb was 20.5+0.15g/dL and RBC count of $5.89x10^{12}$+$0.30x10^{12}$. The mean platelet yield was $5.7x10^{10}$, pH was ≥6.8+0.175 and volume was 82.5+13.75ml; cultures were negative and swirling was present in all the platelet units tested. Mean factor VIII and fibrinogen levels were found to be 95.25 +7.37and 307.5+41.37gm/l for FFP respectively. Mean volume, PT and APTT were 215+32.5ml, 14.15+0.325 sec and 29.50+1.5 sec 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.

1. Introduction

Blood Banking is a vital part of the health care 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 order to improve the standards of blood banks, well equipped blood centers with infrastructure and man power is an essential requirement. Red Cell Concentrate, Fresh Frozen Plasma, Platelet Concentrate, Cryoprecipitate, Platelet Apheresis are the important components which require quality control. Internal quality control (IQC) is the

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backbone of the quality management program in the blood bank.[4,5]

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. Processes and manuals are needed to be highly focused on generating quality blood components that are more efficacious and safe.[6]

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 high‑quality manufacturing practices have been redefined to provide the framework for quality in BTSs. This drive causes significant improvement in processes and blood component quality.[2]The purpose of this study is to determine the IQC on various blood products in a tertiary care center.

2. Materials and Methods

An observational cross sectional study was conducted at the Blood and Component Bank of Jawaharlal Nehru Medical College Hospital from 2018 to 2020. Total units of each blood component was arbitrarily chosen during the study. Packed red cell units were evaluated for hemoglobin, hematocrit, RBC count; platelet concentrates were evaluated for pH, yield and culture; fresh frozen plasma and cryoprecipitates were evaluated for unit volume, factor VIII and fibrinogen concentrations. 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.

3. Observations

Table 1: Quality assurance parameters of RBC Concentrate

Parameters	No. of Units	Mean	Range
Volume (ml)	140	238+26.25	185-290
Hemoglobin (g/dl)	140	20.5+0.15	20.3-20.9
Hematocrit (%)	140	65.75+7.42	50.9-80.6
RBC Count	140	$5.89x10^{12}$ $+0.30x10^{12}$	5.29-$6.50x10^{12}$

Mean volume and hematocrit per unit was 238+26.25ml and 65.75+7.42% respectively and hemoglobin and RBC Count was 20.5+0.15g/dl and $5.89x10^{12}$+$0.30x10^{12}$respectively. (Table 1)

Mean volume, pH and platelet count was 82.5+13.75ml, 6.8+0.175 and $5.7x10^{10}$respectively for 68 platelet concentrates studied**.** (Table 2)

Table 2: Quality assurance parameters of platelet concentrate

Parameters	No of Units	Mean	Range
Volume (ml)	68	82.5+13.75	55-110
pH	68	6.8+0.175	6.4-7.1
Platelet Count	68	$5.7x10^{10}$	3.4-8$x10^{10}$
Culture	68	Sterile	Sterile
Swirling	68	present	present

Table 3: Quality assurance parameters of fresh frozen plasma

Parameters	No of Units	Mean	Range
Volume (ml)	76	215+32.5	150-280
Factor VIII (IU/unit)	76	95.25+7.37	80.5-110.0
Fibrinogen (gm/L)	76	307.5+41.375	225.0-390.5
PT (sec)	76	14.15+0.325	13.5-14.8
INR	76	1.20+0.11	0.97-1.44
APTT (sec)	76	29.50+1.5	26.5-32.5

The Mean volume, Factor VIII levels, Fibrinogen concentration, PT and APTT of 76 units was 215+32.5 ml/unit, 95.25+7.37 IU/unit**,** 307.5+41.375 gm/l,14.15+0.325 sec and 29.50+1.5 sec respectively. (Table 3)

Table 4: Quality assurance parameters of cryoprecipitate

Parameters	No. of Units	Mean	Range
Volume (ml)	76	56+32.5	51-70
Factor VIII (IU/unit)	76	99.25+5.37	88.5-115.0
Fibrinogen (gm/L)	76	217.5+51.37	201.0-291.4

The Mean volume, Factor VIII levels, Fibrinogen concentration of 76 units was 56+32.5 ml/unit, 99.25+5.37 IU/unit**,** 217.5+51.37 gm/l respectively. (Table 4)

4. 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.[5,7] This blood collection process mainly depends on manual procedures which may have operator

Table 5: Comparative assessment parameters of our study with known world-wide standards

Components	Requirements of AABB	Requirements of NACO	Present Study
Packed Red Cells	Hematocrit <80% in 100% units tested.	Hematocrit <70% in 100% units tested.	Hematocrit <80% in 100% units tested.
Platelet Concentrate	Platelet yield >$5.5x10^{10}$ pH > 6.2 culture negative	Platelet yield >$4.5x10^{10}$ pH > 6.4 culture negative	Platelet yield >$5.7x10^{10}$ pH > 6.8 culture negative
Cryoprecipitate	Fibrinogen >150 mg/dl Factor VIII >80/ unit	Fibrinogen >150 mg/dl Factor VIII >80/ unit	Fibrinogen 217.5+51.37 mg/dl Factor VIII 99.25+5.37/ unit

variations. Subsequently, these donations are screened, stored, and transported under variant environmental circumstances. These variants may compromise the critical control points which are designed to improve the quality of blood components.[7–9] Our study assessed the mean volume, hematocrit, hemoglobin and RBC count of PRBCs. The mean volume of PRBCs was 238 ml with the range of 185-290ml. Haematocrit was 65.75% with a range of 50.9-80.6%, hemoglobin was 20.5g/dl with a range of 20.3-20.9g/dl and RBC count was $5.89x10^{12}$/L with a range of $5.29\text{-}6.50x10^{12}$/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 with a range of 198-350 mL and mean haematocrit of 54±4.2% with a range of 41-69%.[10] Singh et al in 2009 found the Mean volume of RBCs as 310 mL with range of 270-390 ml and mean hematocrit as 69.5% with range of 56.3-80.9%.[10]

Our study also assessed the volume, pH, platelet count and culture of platelet concentrates. Mean volume of platelet was 82.5 ml with a range of 55-110ml, pH was 6.8 with a range of 6.4-7.1, mean platelet count was $5.7x10^{10}$ with a range of $3.4\text{-}8x10^{10}$and all the cultures were sterile. Similar results were observed by Gupta et al, Fijnheer et al and Hirosue et al.[11–13]

Our study also assessed the volume, levels of factor VIII, fibrinogen, PT and APTT. Mean volume of 76 units tested was 215ml with a range of 150-280 ml, mean factor VIII levels were 95.25 with a range of 80.5-110.0% and mean fibrinogen levels were 307.5 mg/dl with a range of 225.0-390.5 mg/dl. PT and APTT had a mean value of 14.15 sec and 29.50 sec respectively. 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.[8]

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 with a range of 0.66-1.47 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]

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6. Conflicts of Interest

There are no conflicts of interest.

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