



Assessment Of Quality Control Of Blood Component In A Regional Blood Bank At Tertiary Care Hospital

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Abstract

Introduction:

Blood Banking is a vital part of the health care service. This study is a step towards the safe and adequate supply of blood & blood products at right time to right person

Objective –

1. To ensure availability of adequate supply of blood component with high quality and minimum risk to both donors and patients.
2. To determine problems in whole transfusion chain and to solve it.

Methods:

1. Healthy screened donors (>50 kg and above 18yrs) selected as per standard blood donation criteria during period of Jan 2018 to June 2019 through voluntary blood donations
2. Blood components are separated through standard procedures.
3. All collected blood samples were tested for Transfusion Transmitted Diseases by ELISA
4. Parameters like hemoglobin and haematocrit were tested for RBC components. Platelet count was tested for platelet concentrate. Factor VIII activity and fibrinogen were tested for fresh frozen plasma as well as cryoprecipitate. Along with it volumes of components were included in study.

Study was conducted at Regional Blood Bank, B.J.Government Medical College and Sassoon General Hospital, Pune

Result:

91% of Red Cell Concentrate (273 out of 300), 86% of Fresh frozen plasma (258 out of 300), 93% of platelets (93 out of 100) and 85% of cryoprecipitate (64 out of 75) were found within range as per standard criteria.

Conclusion:

To ensure efficient and adequate supply of blood & blood components, periodic assessment of quality control is an essential step to be undertaken.

Key Words: Quality Control, Red cell concentrate, Fresh Frozen Plasma, Cryoprecipitate, Platelet Concentrate.

Keywords: NIL

Introduction

Blood Banking is a backbone of health care service.

Recent advances in the field of transfusion medicine have been enforcing measures to ensure quality of blood and blood components.

In order to improve the standards of blood banks, well equipped blood centres with infrastructure and man power is an essential requirement¹

The transfusion practices are based on providing right blood to right person at right place and time²

Component separation plays important role to make judicious use of blood units

Temperature maintenance is mandatory for viability and longevity of blood and its components under various parameters³

Quality includes three concepts- quality control, quality assurance, quality management as well as their maintenance. Quality control involves steps to ensure quality of blood product for its specific indications⁴

Red Cell Concentrate, Fresh Frozen Plasma, Platelet Concentrate and Cryoprecipitate are the important components which require Quality.

This is a step towards the safe and adequate supply of blood and blood components.

Aims and Objectives

To ensure availability of adequate supply of blood, blood components of high quality with maximum efficacy and minimum risk to both donors and patients.

To determine problems in the whole transfusion chain and to solve it.

Materials and Methods

Nature of study: Cross sectional study

Sample size: One % of blood components prepared or minimum 4 bags of blood components prepared per month (WHO)⁵

1. Red Cell Concentrates-300 units
2. Fresh Frozen Plasma-300 units
3. Platelets-100 units

4. Cryoprecipitate-75 units

Through voluntary blood donation camps, healthy screened donors (more than 50kg and above 18 years) were selected as per standard blood donation criteria⁵ during period of Jan 2018 to June 2019.

Donor forms were filled completely along with consent.

Blood components were separated as per standard procedures.

All collected blood samples were tested for transfusion transmitted diseases by Enzyme Linked Immunosorbent Assay (ELISA).

Following parameters were checked

For Red cell concentrate – volume, hemoglobin and hematocrit.

For platelet concentrate – volume and platelet count.

For Fresh frozen plasma – volume, factor VIII and fibrinogen

Cryoprecipitate – volume, factor VIII and fibrinogen

Selection of cases

Inclusion Criteria:

Blood components which were prepared within 6-8 hours of blood collection were included in our study.

Exclusion Criteria:

Blood bags separated after 8 hours of collection and having low volume of blood were excluded for study.

Blood bags which are positive for Transfusion Transmitted Diseases were excluded from study.

Equipments we used-

For Volume- Weighing scale (1.05 gm=1 ml)

For Hb, haematocrit and platelet on Sysmex XP-100 analyser- fully automated 3 part differential hematology analyser.



We tested Factor VIII and Fibrinogen on Erba ECL 412 which is 4 channel semi automated Coagulometer which performs all types of hemostasis assays.



Observation:

Total blood collection in our setup through voluntary blood donation during period of January 2018 to June 2019 is 28813. Depending on requirement and type of bag, components like red cell concentrate, platelet concentrate, fresh frozen plasma and cryoprecipitate were prepared

Measurement of parameters like hemoglobin, hematocrit, platelet count, fibrinogen and factor VIII activity along with volume of component included in study was done.

Expected Results

Table1. Quality Control of Red Cell Concentrate⁶

Parameter	Quality requirements
Volume	245-325ml

Hematocrit	55-65%
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Table2. Quality Control of Fresh Frozen Plasma⁶

Parameter	Quality requirement
Volume	155-172ml
Factor VIII activity	50-150%
Fibrinogen	200-400mg

Table3. Quality Control of Platelet concentrate⁶

Parameter	Quality requirement
Volume	50-70ml
Platelet count	>6 lakhs

Table 4. Quality Control of Cryoprecipitate⁶

Parameter	Quality requirement
Volume	10-20 ml
Factor VIII activity	80-120 units
Fibrinogen	150-250 units

According to standard guidelines, 75% units sampled and tested should have the values indicated above⁷

Results in present study

Components	% of components within expected range	Mean of parameter
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Red Cell Concentrate (RCC)	91	HCT-61.68%
Platelet Concentrate (PC)	93	Platelet count-6.95 lakhs
Fresh Frozen Plasma (FFP)	86	Factor VIII activity-89.77% Fibrinogen levels-265.05 mg/dl
Cryoprecipitate (CP)	85	Factor VIII activity-93.53% Fibrinogen levels-196.64 mg/dl

Comparison of out of range components with other similar studies

Component Out of range (%)	Patel et al, Gujarat, India (2013-14)	Upadhyay et al Uttarakhand, India (2015)	Present study
Red Cell Concentrate	8.5	14.9	9
Fresh Frozen Plasma	16.4	-	14
Platelet Concentrate	5	29	7
Cryoprecipitate	19	-	15

Discussion

Quality assurance is a standard procedure in a western countries, it still is a new concept in developing countries due to poor laboratory settings, non-standard improper devices and inadequate manpower⁸

The Food and Drug Administration (FDA) describes standards for quality and safety for transfusion services and blood banks through quality assurance programs.

National Accreditation Board for Hospitals and Healthcare Providers (NABH) is a constituent board of Quality Council of India (QCI), set up to establish

and operate accreditation programme for healthcare organizations⁹

These are regulatory and accrediting agencies for quality and safety.

Two similar studies conducted by Swapnil patel et al, Gujrat India and Saloni Upadhyay et al, Uttarakhand, India are available for comparison.

Root Cause Analysis was performed whenever QC was out of range.

Calibration of equipment and machines were checked time to time.

Whenever required corrective and preventive actions were taken

In Red Cell Concentrates, main problem was high Hct which might be due to hemoconcentration so technicians were advised to keep strictly at least 50 ml of plasma in it

In case of low platelets, it was informed to clinicians Emphasis was given to history taking like blood clotting history during prior donations and intake of NSAIDS

In FFP, main cause was lower Factor VIII activity, which is very labile factor, so emphasis was given on strict temperature maintenance during transport and storage

Conclusion

Periodic assessment of quality control is necessary for achieving objectives of good transfusion practice. Goal of National Blood Transfusion services is to provide safe and adequate supply of blood and blood components. To achieve this goal, implementation of quality control is important.

To implement quality control

1. Standard Operative Procedures have to be written for every procedure in blood bank, implemented and updated yearly or whenever there is change in procedure
2. Stringent criteria for blood donor selection is must and motivation of young population for blood donation is required
3. Temperature maintenance during transport and storage plays very important role
4. Maintenance and calibration of equipment is required

In present study, we found 91% of red cell concentrates, 93% of platelet concentrate, 86 % of fresh frozen plasma and 85% of cryoprecipitate were found within expected range. Thus results of present study in our setup are within expected range as per WHO and NABH guidelines.

In existing infrastructure, our blood bank is able to supply safe and adequate blood components to

patients at our tertiary care hospital. As we supply quality products, it minimises risk of transfusion to patients and ultimately benefits to patients.

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