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Performance Assessment Of Quality Control Of Blood And Blood Products In Blood Bank At A Tertiary Care Hospital- A Cross Sectional Study

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Abstract

Introduction:

Blood transfusion services form an important part of health care system. The aim is always directed at providing quality blood and blood products which are safe and should be standardized to meet patients needs.[1]

The number of blood donations can never fulfil the ever increasing demand for blood and blood products and the quality should never be compromised in doing so.

Assurance of a quality product includes issues of safety of patients and blood donors, reagent quality control, monitoring of equipment maintenance and repair, competence of personnel and testing of a defined number of units of each product for the appropriate parameters and biomedical waste management.[1]

The safety, availability of and access to adequate blood supplies are constant challenges.

Aim:

To determine the various parameters on the whole blood and red cell concentrates and compare with the quality requirements laid down by WHO[World Health Organisation].[1,2]

Materials &Methodology:

This is a cross-sectional study in which data was collected from the blood bank of a Tertiary Care Hospital for a period of 1 year as a part of quality control. A total of 6256 units of blood bags were collected and analysed for the various parameters like Hemoglobin[Hb] and hematocrit[Hct] estimation. The samples from blood bags were screened for Hepatitis B Surface Antigen[Hbs Ag], Hepatitis C Virus[HCV] and Human Immunodeficiency virus[HIV] I and II antibodies.

Results:

The results of the quality control study were found to be within the acceptable range for the criteria laid down by the WHO and there should be a continuous effort to achieve the standards/ reach the criteria laid down.

Keywords: Blood Bank, Quality Control, p-RBC, Whole Blood

Introduction

Blood transfusion services form an important part of health care system. The aim is always directed at providing quality blood and blood products which are safe and should be standardized to meet patients needs.[1]

'Blood transfusion' is a medical treatment in which donated blood is administered to the patient being treated, in the form of whole blood or blood components/derivatives.[3]

'Blood transfusion service' deals with various aspects of the blood transfusion chain- from the potential donor to the potential recipient and should link to the clinical interface and patient follow-up.[3].

Extensive screening of donors and donations are a part of the quality management and quality assurance operations.[3]

WHO promotes an integrated strategy for blood transfusion safety and recommends quality management systems to be uniformly applied in all areas.

In India, NACO [National AIDS Control Organisation] has been primarily responsible for ensuring provision of safe blood for the country since 1992.NACO also recommends establishment and maintenance of a quality assurance system based on any current international standard. Government of India adopted the National Blood Policy in April 2002 which aims to develop a nationwide system to ensure easy access to adequate and safe and good quality blood supply [4].

Aim:

To determine the various parameters on the whole blood and red cell concentrates and compare with the quality requirements laid down by WHO[World Health Organisation].

Materials & Methodology:

This is a cross-sectional study conducted in Blood Bank Centre of Osmania General Hospital, Hyderabad. The data was collected for a period of one year. The quality control of whole blood and packed red blood cell concentrates (p-RBC) which form the major part of blood bank as well as of demand from the clinician. Voluntary blood donations form the source of blood.

All the whole blood bags and p-RBC bags of the entire year were included in the study. Whole blood collected from the donors at the Blood Bank, Osmania General Hospital, Hyderabad and also from voluntary blood donation camps conducted within and outside the hospital premises under the initiative taken by local NGOs. Samples were collected from p-RBC bags after processing of the whole blood.

The Ethical clearance for the study was obtained from the Institutional Ethics Committee of Osmania Medical College,Koti,Hyderabad,Telangana.[IEC/OMC/2022/M.No.(5)/Acad-37].

Informed consent from all the donors was taking before the donation of blood.

Inclusion Criteria:

All voluntary blood donors who are found to be physically fit [weight > 50kgs] satisfy the criteria laid down.

Exclusion Criteria:

1. Professional blood donors.

2. Blood bags where the collected blood was less than 300ml.

3. Leaky blood bags.

A total of 6256 units/bags were included in this study.

After the donor has been selected by the above laid down inclusion and exclusion criteria, the process of blood donation and adverse effects if any arising at the time of the procedure were explained to the donor and a consent was obtained before bleeding the donor.

Whole blood units were collected in a single bag (capacity of 350ml) with 49ml of anticoagulant[CPDA- Citrate Phosphate Dextrose Adenine]-with shelf life of35 days when stored at 2-60C. To prepare p-RBC's, blood was collected in double bags (capacity of 350ml) with 63ml of anticoagulant. After collection the bags were centrifuged for 10 minutes at the rate of 2500g. The plasma thus formed was transferred to the satellite bag and the p-RBC bag was separated from the satellite bag.

Blood samples from the blood bags of whole blood and p-RBC's were collected in to K3-EDTA [Tri Potassium Ethylene Diamine Tetraacetic Acid] vacutainers. The vacutainers were labelled by the corresponding bag number, the date of collection and type of the blood bag from which the sample had been taken(whole blood or p-RBC) and care was taken not to disclose the name and identity of the donor. These samples were analysed in a SYSMEX [XN-1000model, serial number-24256] 5-part haematology analyser. The haemoglobin estimation in this analyser is done by the Colorimetric technique using the Cyanide-free Sodium Lauryl Sulphate Hb estimation method. The Hematocrit is calculated by the analyser using the Cumulative Pulse Height method.

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All samples were tested for HbsAg, Anti- HCV, Anti-HIV I and II by ELISA method; Syphilis by VDRL method and Malaria by Direct microscopy of the blood smears. Every 100th bag of whole blood and p-RBC's was selected and sample from it was analysed for the various parameters laid down by WHO. One in every 100 bags of whole blood was sent for microbiological analysis.

The quality control parameters assessed on whole blood include- Volume of blood, volume of anticoagulant, Hematocrit, HbsAg Antigen, Anti-HCV Antibodies, Anti- HIV I and II Antibodies, Syphilis by VDRL and Sterility.

The quality control parameters assessed on red cell concentrates i.e. p-RBC are volume and Hct [Hematocrit].

The entire data collected was tabulated using Microsoft Excel sheets [version 2007] and L-J charts were plotted for the samples analysed.

Results:

A total number of 6256 units of blood were collected over a period of 1 year, of which 2525 units were single bag or whole blood collections and 3731 were p-RBC's.

All the units were screened for the transfusion transmissible infection panel according to the guidelines laid down by the WHO & result is as in Table 1.

One percent of the whole blood units (25 bags) were sent to the microbiological lab for culture and all the bags (100%) were found to be sterile.

One percent of all whole blood (25 bags) and p-RBC's units (37 bags) were analysed for the parameters.

The volume of the whole blood units were found to be 350 ml +/- 20ml. The volume of anti-coagulant (CPDA) was 49ml.

The volume of the p-RBC units were found to be 240ml +/- 20ml.The volume of the anti-coagulant was 63ml.

The haemoglobin [Hb] content of the whole blood units was estimated and 2 values were found to be below the accepted haemoglobin of 12.5gm/dl[Fig 1]. Correspondingly a low hematocrit (<40%) was found in these 2 units. When looked retrospectively in to the donations it was found that both the units of the blood were collected in blood donation camps where the screening method used for estimation of haemoglobin was Copper Sulphate Specific Gravity method.

The Hematocrit values for the p-RBC units (37 units) was analysed. A total of 5 units were found to be above the acceptable value of 80.[Fig 2].

Table 1 : Result of the screening of bags

Total no.of blood bags	6256
Single bags	2525[40.36%]
p-RBC's	3731[59.63%]
Units positive for HbsAg antigen	50[0.79%]
Units positive for HIV1&2 antibodies	32[0.51%]
Units positive for HCV Antibodies	14[0.22%]
Units positive for Syphilis	0

Table 2 : Most common factors to be considered during blood donation & how to overcome

FACTORS[5,7]	PRECAUTIONS
Donor Selection	Strict selection criteria

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a- AGE	18-60 years
b- Donation interval	3 months
c- Intake of alcohol	24hr deferral
d- COVID Vaccine	15 days deferral
e- Tatoo/skin piercing	6 months- 1 year deferral
f- Dental procedure	72 hr deferral
g- Viral hepatitis	1 year deferral
h- HbsAg/ Anti- HCV +	Lifelong deferral
i- HIV/High risk population	Lifelong deferral
j- Malaria	3 months deferral after treatment
k- Co-morbidities [DM,HTN,Epilepsy,Asthma]	Lifelong deferral if on medication and if uncontrolled
l- Medication history	Depending on the type of medication72 hrs to life long deferral
m- History of surgery/recipient of blood	1year deferral
n- Pregnancy/lactation[female donor]	1 year deferral
Type of Anti-coagulant/Quality of blood bag	CPDA- shelf life 35 days @2-6^{0}C
Technique of Phlebotomy	
a- site	Cubital fossa- antecubital vein
b- time	8-10mins
c- clot-?	Use of Automated blood mixers
d- under/over collection of blood	Use of Blood collection monitors
Transit temperature	2^0 C-24^{0}C not more than 8 hrs
Time period of separation of components	Within 8hrs of collection
Storage temperature	As per the type of product
Instruments/Equipments	Calibration, Validation, Maintenance
QC	Minimum Standards, Regulatory requirements, SOP's

Table 3 : Comparison of present study with other similar studies.

Study/Parameter	Sultan S et al[6]	Arora R et al[8]	Gupta A et al[9]	Present study
Whole blood Hb%	-	-	-	>12.5gm/dl in 92 % of units.
p-RBC's – Hct%	< 80% in 98% units	< 80% in 100% units	56.3% -80.9% [mean- 69.5%]	< 80% in 86.5% 0f units

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Fig 1 : Hb% plotted in Y-axis against the units of whole blood in X-axis

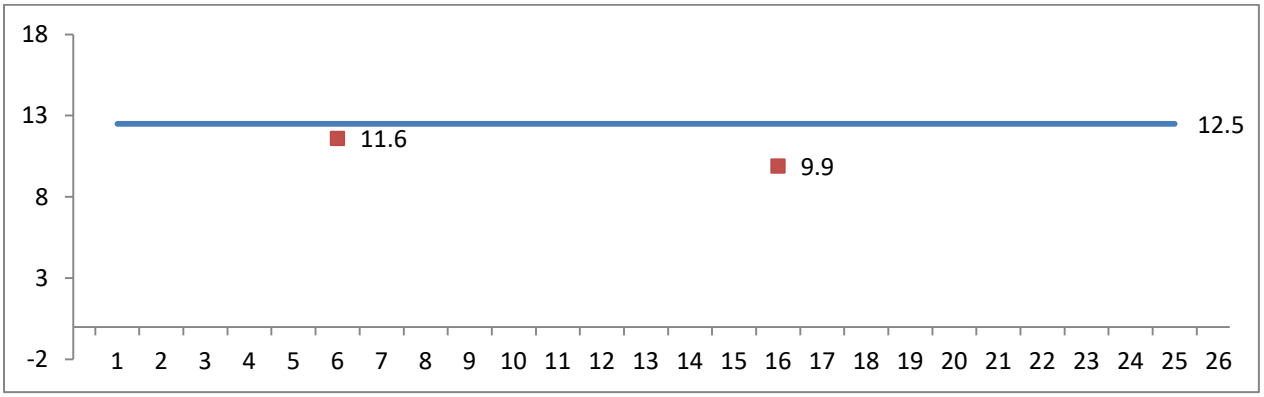
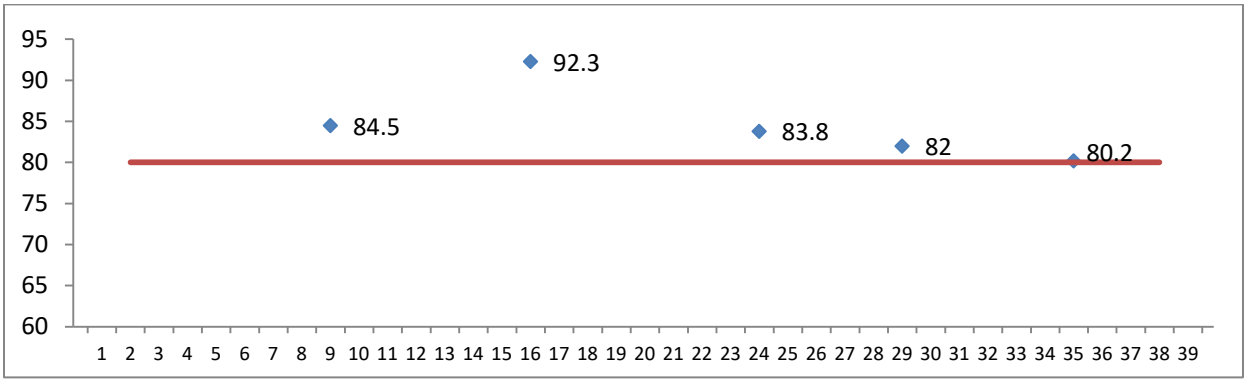


Fig 2 : Hct plotted in Y-axis against the units of p-RBC in X-axis



Discussion:

The present study was a cross –sectional study taken up as part of quality control in a blood centre at a tertiary care hospital. The aim of the study was to determine the various parameters on the whole blood and red cell concentrates and compare with the quality requirements laid down by WHO and also to compare with similar such studies conducted in a low resource setting of developing countries.

Voluntary blood donors were included in this study- "A Voluntary non-remunerated blood donor gives blood, plasma or cellular components of his or her own free will and receives no payment, either in the form of cash or kind which could be considered a substitute for money.[4].

There are various factors and precautions to be considered during the selection of these donors. Table 2 enumerates some of the most common factors and how these can be overcome.In this study these factors were taken in to consideration while selecting the donors.

Quality Control:

Quality control of blood components forms an integral part of the blood bank quality management system thus ensuring proper yield and efficacy of the components for patient care.[5].

IQC[Internal Quality Control] is the set of procedures undertaken for continuously and concurrently assessing blood bank work and the results, to decide whether the performance is up to the mark. IQCs play a vital role in blood transfusion safety, and risks allied with blood transfusion can be substantially reduced by the implementation of IQC.[6].

Need For Quality Control:

QC of blood products is the available tool to assess the viability of product, and consequently, it can adjust production techniques when necessary.[6].It involves the testing of random components to ensure that they achieve reliably specific standards. Analysis of test results and detection of irregularities to identify deficiencies in production of blood and blood components.[5].

Volume Of Blood Bags:

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The volume of the whole blood units were found to be 350 ml +/- 20ml, which is well within the range of the 10% criteria. The collection volume was well maintained within the range with the help of the blood collection monitors [Terumo Penpol- D601].

The volume of the p-RBC units were found to be 240ml +/- 20ml, which is well within the range of the 10 % criteria. The collection of volume was well maintained within the range indicating the adequate centrifugation [Heraeus cryofuge 6000i centrifuge-Thermo Electron Corporation].

Haemoglobin Content Of Whole Blood Bags:

The haemoglobin [Hb] content of the whole blood bags was estimated and 2 values were found to be below the accepted haemoglobin of 12.5gm/dl[Fig-1]. Correspondingly a low hematocrit (<40%) was found in these 2 units. When looked retrospectively in to the donations it was found that both the units of the blood were collected in blood donation camps where the screening method used for estimation of haemoglobin was Copper Sulphate Specific Gravity method which has a low sensitivity because of it being only a screening test and operator dependent. So, it is better to use a more sensitive screening method for estimation of haemoglobin in blood donation camps.

Haematocrit Of P-Rbc Bags:

The Hematocrit values for the p-RBC bags (37 units) was analysed. A total of 5 units were found to be above the acceptable value of 80.The reason for the outliers could be the faulty technique of centrifugation or excess squeezing out of the plasma in to satellite bag or improper mixing of the contents of the bag before collection of the sample for analysis. Also clerical errors need to be considered. Faulty technique of collection of blood in to vacutainers without proper mixing was found to be the most common cause. The technician collecting the sample has to be trained regarding the procedure/ technique of collection.

In Comparison With Similar Studies:

The findings are depicted in Table 3.

The Hct% in p-RBC bags in the present study was found to be within the desirable range in 86.5% of units which is higher than the mean value of 69.5% found in the study conducted by Gupta A et al and lower than the values when compared with the study done by Sultan S et al [98%] and Arora R et al [100%].

Haematocrit % of less than 80% in the p-RBC units ensures adequate mixing of the blood and anticoagulant and thus ensures adequate preservative for support of red cells.[7]

The studies tabulated above had not measured the Hb% in the whole blood, while in the present study the desirable value of Hb% of >12.5 gm/dl was found in 92% of the units.

The cut off value of Hb% of more than 12.5 gm/dl at the time of selection of donors is to be strictly followed as this will ensure the donor safety [7] and reasonable benefit to the recipient.

The sero-prevalence of the transfusion transmissible infections also could be estimated [10] in the asymptomatic donors by these quality control studies and the changing trends in the disease in asymptomatic individuals, the behavioural risks could also be estimated.

Conclusions:

Quality control is an integral part of functioning of the blood bank and there should be a continuous effort to achieve the standards or reach the criteria laid down. This can be achieved by scrutinizing each step involved in the blood bank services right from the donor selection to issue of the appropriate blood products requested and also monitoring for any post-transfusional reactions.

Regular training programmes, constant motivation of the staff, Adherence to the SOP's[Standard Operating Protocol], Equipment standardization, calibration, maintenance, repair, Effective trouble-shooting and backup plan, Good quality kits, Efficient supervision, Documentation and record of all events, Evaluation, Assessment and above all the Corrective actions taken/implemented help us in achieving the Quality Standards.

Limitations:

The study did not include the quality control of other blood components like FFP, RDP and SDP.

Our present work is only a preliminary analysis over a short period of time on limited samples.

Acknowlegement:

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