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RESEARCH ARTICLE

QUALITY CONTROL OF BLOOD COMPONENTS-A STEP TOWARDS EFFICIENT SUPPLY OF BLOOD PRODUCTS.

Dr Swapnil N Patel (M.B.B.S), Dr Mustafa Ranapurwala (M.D. Pathology), Dr Menka Shah (M.D., D.C.P, Pathology).

Pramukh Swami Medical College & Shree Krishna Hospital, Karamsad, Gujarat-388325, India.

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Corresponding Author

Dr Mustafa Ranapurwala

Abstract

Introduction: -Quality Control describes steps taken by Blood 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, blood components. The aim of study was to ensure supply of safe and efficient blood transfusion to patient and to prevent Transfusion Transmitted Diseases.

Material & Methods: - All donor blood bags at A.D. Gorwala Blood Bank in Pramukh Swami Medical College & Shree Krishna Hospital, Karamsad, collected in between year 2012-2014 were included in our study. Monthly Quality control (QC) of this blood bags were done. Selection criteria were 1% of total collection or minimum 4 bags per month.

Results:-There was decreasing trend in the percentage of QC out of range in subsequent years.

Conclusion: -At present era Quality Control is very important step in maintaining quality of blood bank. So that we ensure most efficient blood transfusion to patient

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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. In order to improve the standards of blood banks, well equipped blood centers with infrastructure and man power is an essential requirement[2]. Red Cell Concentrate, Fresh Frozen Plasma, Platelet Concentrate, Cryoprecipitate, Platelet Apheresis are the important components which require Quality.

Objectives:-

To ensure availability of a sufficient 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:-

All Blood Bags which were donated in A.D.Gorwala Blood Bank were selected in our study. However blood bags which were collected as therapeutic phlebotomy were excluded in the study. Red Cell Concentrate(RCC), Fresh Frozen Plasma(FFP), Platelet Concentrate(PC), Cryoprecipitate (CP), Platelet Apheresis were studied. 1% of each or minimum 4 Bags per month were taken for study in between April 2012 to March 2014. Data were collected from online blood bank software available at A.D.Gorwala Blood Bank, Karamsad.

Criteria used for Quality Control(QC) were according to National Accreditation Board for Hospitals and Healthcare Providers[1]. These were included in table 1, 2,3,4,5.

Results:-

Table 6: List of QC out of range.

Component	2012-2013	2013-2014
RCC	11.57%	8.51%
FFP	28.35%	16.47%
PC	8%	5%
CP	41%	19%
Apheresis*	-	0%

(*Apheresis was not in scope of our blood bank in year 2012-2013.)

In red cell concentrate, the main cause of failure of QC was due to high packed cell volume in collected blood bag which was 67.5% of all QC. Other reasons were low packed cell volume and positive sterility test in blood bags which were 25% and 7.5%, respectively.

In fresh frozen plasma, the main cause of failure was due to low volume of plasma which wasthe reason in 43% cases. The other reasons were low fibrinogen levels (33%) and low factor VIIIlevels (24%).

In platelet concentrate, the main cause of failure was low platelet count in 58% cases, in 17% cases each ofRBC contamination and positive sterility tests, while in 8% cases the cause was WBC contamination.

In cryoprecipitate, the main cause of failure was deranged factor VIII level which was the cause in 90% of cases while low fibrinogen was the cause in 10% of cases.

Discussion:-

In our study, we found decrease in frequency of QC out of range in subsequent year. However we didn't get any study for comparison of our results.

Root Cause Analysis was performed whenever QC was out of range. Some corrective measures were also taken under consideration.

We checked our equipment calibration, which were found well calibrated. So, emphasis was given on proper storage, transport and Lab personnel training.

In RCC we found problem with PCV content, so we advised our technicians to make sure that at least 50ml plasma remain present at the end of 1st rotation during separation. So that RCC do not get too much concentrated or diluted.

In FFP proper blast freezing was not occurred. So, the technicians were advised to keep one surface of FFP bag in direct contact with deep freeze -80° and proper transport of FFP from -80° to -40°.

In cryoprecipitate, main cause were low factor VIII and fibrinogen levels. Dilution of segment might be the cause of that. The technician were advised proper stripping of segment before performing QC.

Whenever we found low platelet count in QC, the clinicians were informed regarding that and they were advised to issue platelet concentrate as per clinical requirement.

In apheresis we found all the QC within the range. The reason being very strict criteria of donor selection which include checking of Hemoglobin, packed cell volume and platelet count before donation.

Conclusion:-

Quality Control is an important tool to ensure,

1. Effective and safe supply of blood components.
2. Tests which are done in blood bank are performed correctly.
3. Maximum benefit to patient with minimum cost and maximum advantage.
4. Minimizing requirement of transfusion to patient and Prevention of risk of Transfusion Transmitted Diseases.

Quality control activities are designed to monitor variations in manufacturing processes and product quality and ensure that manufacturing steps meet defined criteria for acceptance.[2]
Quality control activities generate substantial volumes of data, which can show that individual components have met quality specifications.

List of tables:-

Table 1: QC of Red Cell Concentrate.

	RCC			**RCC with Additive Solution**		
	Quality Requirement		**Frequency of control**	**Quality Requirement**		**Frequency of control**
	450 ml	**350 ml**		**450 ml**	**350 ml**	
Volume	225-350 ml	175-272ml	1% of all units	300-400 ml	245-325 ml	1% of all units
Hematocrit(HCT)	65-75%	65-75%	1% of all units	55-65%	55-65%	1% of all units
Sterility	By culture	By Culture	1% of all units	By culture	By Culture	1% of all units

Table 2: QC of Fresh Frozen Plasma.

	Quality Requirement	**Frequency of control**
Volume	200-220 ml (450 ml) 155-172 ml(350 ml)	1% of all units
Stable coagulation factors	PT & APTT	1% of all units
Factor VIII	0.7 units/ml	1% of all units
Fibrinogen	200-400 mg	1% of all units

Table 3: QC of Platelet Concentrate.

Parameters	**Quality Requirement**	**Frequency of control**
Volume	>200 ml	1% of all units
Platelet Count	$>3.0*10^{11}$	1% of all units
pH	>6.0	1% of all units
RBC contamination	Traces to <0.5 ml	1% of all units

Table 4: QC of Cryoprecipitate.

Parameter	**Quality requirement**	**Frequency of control**
Volume	10-20 ml	1% of all units
Factor VIII	80-120 units	1% of all units
Fibrinogen	150-250 mg	1% of all units

Table 5: QC of Platelet Apheresis.

Parameters	**Quality Requirement**	**Frequency of control**
Volume	>200 ml	1% of all units
Platelet Count	$>3.0*10^{11}$	1% of all units
pH	>6.0	1% of all units
RBC contamination	Traces to <0.5 ml	1% of all units

Reference:-

1. Standards on Blood Banks/Blood Centers and Transfusion Services, 1st edition.
2. Issued on November 2007, National Accreditation Board for Hospitals andHealthcare Providers, 6.11.1 Quality Control, Annexure-D.
3. Dr.R.N. Makroo, Compendium of Transfusion Medicine, 1st edition, Alps Printer, 1999, Quality Assurance in Blood Transfusion Services.