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Original Research Article

Internal quality control of blood & blood components - Two years study at a standalone blood centre, Ahmedabad

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ABSTRACT

Introduction: Internal Quality Control (IQC) describes steps taken by the blood centre to ensure that tests are performed correctly and as per the guidelines. Primary goal of Quality Control is transfusion of safe quality of blood components to give optimal benefit to patients.
Aims and Objective: The aim of study was to ensure supply of safe and efficient blood component to patients.
Materials and Methods: Quality control of blood components prepared between December 2019 to November 2021 were included in our study. Monthly Quality control (QC) of the blood components were done as per the national guideline, 1% of total components prepared or minimum 4 units. Packed red cell units were evaluated for haematocrit, random donor platelet concentrates for yield and fresh frozen plasma (FFP) and cryoprecipitate were evaluated for volume, factor VIII and fibrinogen concentrations.
Results: A total of 1302 units were tested for IQC. The mean hematocrit of RBC was 58.8%. In PLT, mean yield was 6.9×10^{10}/cu mm. Mean factor VIII and fibrinogen levels were found to be 377 IU/bag and 851.60 mg/bag in FFP respectively. Mean factor VIII and fibrinogen levels were found to be 311.81 IU/bag and 1694.4 mg/bag in cryoprecipitate respectively.
Conclusion: In the present era, Quality Control is very important step in maintaining quality of blood components and the quality objectives of the blood centre, so that we ensure most efficient blood transfusion to patient. The IQC of blood components at our blood centre is in overall compliance and met recommended national standards. Implementation of standard operating procedures, accomplishment of standard guidelines, proper documentation with regular audit and staff competencies can improve the quality performance of the transfusion services.

1. Introduction

Blood Transfusion service is the important part of health care system. However, the blood transfusion is not free of risks owing to human factors; thus, it should only be prescribed when patients' clinical status really necessitates it.[1] Internal quality control (IQC) is the backbone of the quality management program in the blood bank.[2,3] In the modern blood banking, quality controls of blood components ensure the high-quality yield with maximum efficacy to potential recipients.[4] Processes and manuals are need to be highly focused on generating quality. 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. This blood collection process mainly depends on manual procedures which may have operator variations. Subsequently, these donations will be screened, stored, and transported under variant environmental circumstances. In recent years, there have

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been significant developments to improve 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 Blood Transfusion Services.

Transfusion service is a vital part of the health care system. 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 centres, well equipped blood centres with infrastructure and manpower is an essential requirement.[5] All the blood components and the services provided by the blood centre should meet all quality criteria and as per guidelines.

The another most important for IQC is route cause analysis for IQC outliers.

2. Aims and Objectives

The aim of study is to highlight the importance of stringent donor screening to ensure safe and efficient blood transfusion to patients.

3. Materials and Methods

Quality control of blood components prepared between December 2019 to November 2021 were included in our study as per the prescribed guidelines. Monthly Quality control (QC) of the blood components were done as per the regulatory guideline. As per the same criteria, 1% of total RBCs, FFP and PLTs prepared and minimum 4 bags for Cryoprecipitate were carried out. Packed red cell units were evaluated for haematocrit, random donor platelet concentrates for yield and fresh frozen plasma (FFP) and cryoprecipitate were evaluated for unit volume, factor VIII, and fibrinogen concentrations. Data were collected from IBBMS software available at the Blood Centre. Criteria used for Quality Control (QC) were according to National Accreditation Board for Hospitals and Healthcare.

During this period, 43091 blood units from healthy blood donors were collected in sterile bags containing an anticoagulant CPD (citrate phosphate dextrose). All the donors were screened properly. After discarding less quantity and other non-eligible blood units, 42175 units of RBCs, 42250 units of FFP, 21809 units of PLTs and 5585 units of Cryoprecipitate were prepared as per institutional SOPs. Blood components which were used for products evaluation as shown in Table 1.

4. Results

During the study period 43091 units of whole blood collected and 42175 units of blood separated in the components. Components prepared comprised of 42175 units of RBC, 42250 units of FFP, 21809 units of Platelets and 5585 units of cryoprecipitates.

Total RBC (473) units, FFP (484) units, PLTs (255) units and Cryoprecipitate (90) units were randomly selected for internal Quality control. All components were evaluated on the day of expiry or near expiry (PLTs).

As mentioned in Table 1, during IQC testing, 95% of RBCs, 95% of PLT, 100% components for sterility matched the defined standards. In case of FFP, 100% FFP match for fibrinogen level and 99.2% of FFP could match the defined standard for factor VIII. For Cryoprecipitate, 100% Cryoprecipitate match for fibrinogen level and 91.2% of Cryoprecipitate could match the defined standard for factor VIII. As per regulatory guidelines, at least 75% of components should match or surpass the baseline quality standards.[Table 2]

4.1. Statistical analysis

All the data were compiled, tabulated and frequencies and percentages were calculated using Microsoft excel spreadsheet 2007 (12.0.4518.1014).

4.2. Ethical clearance

The current study was retrospective data analysis. The ethical clearance was taken from institutional ethical committee.

5. Discussion

Blood centres have a dual responsibility primarily to meet the adequate blood supply for the needy patients and essentially to ensure maximum blood recipient's safety.[6] The safety and quality of blood components have been owing to advancement in technology in all regions of the manufacturing processes, practices, and manuals. Processes are highly focused on producing high quality products that are efficacious and are as safe as possible. Recently, the Food and Drug Administration commenced the concept of a "zero risk blood supply" as the manufacturing goal.[7] IQC is the central component of quality assurance program in transfusion services. IQC is the 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.[8]

Our present work is only an analysis improved IQC in blood products and its methods need to be studied furthermore.

Root Cause Analysis was performed whenever IQC was out of range and corrective measures were also taken.

Ferreira et al observed and recommended that in RBC, the problem with HCT content, so the technicians were advised to make sure that at least 50 ml plasma left at the end of 1st rotation during separation. So that RBC do not

Table 1: IQC performed

Blood Component	No of Component selected for QC	QC passed	QC Outliers	QC Outliers Criteria
RBC	473	448 (95%)	25 (5%)	25%
PLT	255	241 (95%)	14 (5%)	25%
FFP-Factor VIII	484	480 (99.2%)	4 (0.8%)	25%
FFP-Fibrinogen	484	484 (100%)	00 (0%)	25%
Cryo-Factor VIII	90	82 (91.2%)	8 (8.8%)	25%
Cryo-Fibrinogen	90	90 (100%)	00 (0%)	25%
Blood culture & sterility	477-RBC 252-PLT	100 %	00 (0%)	NIL

Table 2: verage range of IQC

Blood Component	QC criteria[5]	IQC results obtained (Minimum)	IQC results obtained (Maximum)
RBC	HCT-50-65%	50 %	77.7 %
PLT	$4.5* 10^{10}$	$4.5 * 10^{10}$	$12.7 *10^{10}$
FFP- Factor VIII	70 IU/Bag	100 IU/Bag	2464 IU/Bag
FFP- Fibrinogen	>200-400 mg	247 mg	14408 mg
Cryo- Factor VIII	80 IU/Bag	82 IU/Bag	2967 IU/Bag
Cryo- Fibrinogen	>150 mg/Bag	196.74 mg/Bag	7294.95 mg/Bag
Blood culture & sterility	No Growth	No Growth	No Growth

get too much concentrated or diluted.[8] In the present study, authors also following same procedure since long.

In FFP, proper blast freezing was not occurred. So, the technical team was 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, dilution of segment might be cause for low factor VIII level. The technical team were advised proper stripping of segment before performing QC.

Whenever the authors found low platelet count in IQC, the clinicians were informed regarding that and they were advised to issue platelet concentrate as per clinical requirement. We are following same SOP.

6. Conclusion

From the results, it can be concluded that the quality of blood components being prepared at our blood centre meets the national 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. For all processes in blood collection, quality indicators and objectives should be defined, regularly monitored, documented, evaluated, accounted, analysed and consequently implemented.

7. Conflict of Interest

The authors declare no relevant conflicts of interest.

8. Source of Funding

None.

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