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To analyze Internal and External Quality Controls in Blood Bank

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ABSTRACT

Most quality control programs in blood banking are concerned exclusively with control of research center testing and staff and don't assess different region of the blood donation center or decide the capability of all work force in the presentation of administrative assignments. To accomplish the last objectives in our quality control program, during a 15-month time frame, 1,143 purposeful mistakes were placed into routine parts of all blood donation center exercises and afterward painstakingly checked and controlled. Of 498, 400, and 245 mistakes shipped off the workplace, nursing, and lab regions, separately, 12 (2.4%), 58 (14.5%), and 29 (11.8%) blunders were not recognized. Presentation of this program was likewise joined by a huge expansion in the quantity of genuine blunders that were distinguished and probably had not recently been perceived. The quantity of genuine blunders identified expanded from 4 to 43 to 73 during months 0 to 6, 7 to 12, and 13 to 15 of this review. Examination and recording of every blunder on an Error Report Form has allowed assessment of both faculty and frameworks and ensuing execution of restorative activity.

Key Words- Blood Bank, Quality Control, Blood Products, PRBC, FFP,PRP, Total quality management.

INTRODUCTION

Quality management is an integrated system of quality assurance covering all matters which individually or collectively influence the components in order to guarantee their quality. This describes all the steps taken both inside and outside the Blood Bank to achieve safest possible blood for the recipient.[1] there are various components of blood such as packed red blood cells, fresh frozen plasma, platelet concentrate and cryoprecipitate. [1]

The first successful transfusion of blood to a patient for the treatment of post partum hemorrhage was performed in by British obstetrician James Blundell. The Red Cross calls for national blood policy, which the federal government has set up in supporting standardized practices.[2]

Blood transfusion services (BTS) are fundamental part of health care system. Deficiency of such may cause impractical overall medical management. Blood transfusion is suggested only when there is a necessity to it as such practices may involve greater risks

of infections due to human factors.[3]

Internal Quality control (IQC) is the rigid background of quality management program in the blood bank system.[4, 5]To reduce various risks involved in these transfusions we need to follow manuals strictly to be more effective and safer to both donor and recipient.[6] The main part of this quality control system comprises of blood donation, which can be collected from donors of various age groups belonging to different demographic region, health profiles or with risk behaviors.

These donated blood units are later processed for initial screening, later stored or transported under different environments.[6]In the last decade due to increase in prevalence of infectious diseases there is huge necessity of quality control management as it may be hazardous to the donor/recipient/technician, which provides a solid framework for quality in BTS.

Blood component are Red cell concentrate, Fresh frozen plasma and Platelet concentrate. These components require different method of separation and preparation to maintain quality. The important aspect in QC is high packed cell volume, of low volume of plasma and low platelet concentrate.

A well-organized Blood Transfusion Service (BTS), with quality system in all areas, is a pre- requisite for the safe and effective use of blood and blood products. This is a vital component of any health care delivery system.The blood banks should establish and maintain a quality assurance system based on international standards.External quality assurance must be complemented regularly with internal quality control. One of the programmes followed is participation in a proficiency testing. These proficiency testing programme consist of codes like normal and problematic blood samples. These programtest are distributed from any national/seasonal laboratories to participants, which are usually performed twice a year.[3]The present study was undertaken to assess the internal and external quality control proceduresin our blood bank [3].

MATERIALS AND METHODS

Study Design:

A hospital based study was conducted in Department of Pathology Subharti Medical College and associated blood bank of Chhatrapati Shivaji Subharti Hospital (CSSH), Meerut.

Study Subjects:

- **Inclusion Criteria:**

All Donated units in blood bank

- **Exclusion criteria:**

Donated blood tested positive for Transfusion Transmitted Infection.

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Materials:

Blood was collected in sterile bags which contain CPDA-1 (citrate phosphate dextrose adenine-1) as anticoagulant. These units were collected from healthy blood donors. Consent forms from each donor were taken. For retrospective period the information regarding blood donors, screening for TTI, Internal QC of reagents and blood components and proficiency testing results will be taken from archive of Blood bank transfusion services. For prospective period, blood was collected from blood donors after taking complete history in CPDA containing blood bags and sample for their testing will be collected in EDTA and plain vial. All donor samples were analyzed for Hemoglobin, blood group typing and for TTI viz, HIV, HBV, HCV, Syphilis and malaria.

Methodology:

For hematological testing of blood components

- Hematocrit in PRBC, Platelet and RBC contamination in Platelet Concentrate (PC) count was analyzed on Yumizen/XL-80 Hematology analyzer.
- PT and APTT were analyzed on fully automated Stago coagulation analyzer
- PH for Platelet concentrate (PC) was measured by strip method.
- Culture of PRBC, PC and FFP was done in microbiology Laboratory on by Blood agar, Chocolate agar, Mac Conkey's agar.
- HIV, HCV, HBsAg, testing was done by ELISA
- Syphilis test was done by RPR
- Malaria was done by Rapid card test Following parameters will be recorded and analyzed
- Monthly details of Transfusion Transmitted Disease (TTD) – HIV, HCV, HBsAg, Syphilisand malaria will be recorded

2. Internal Quality Assurance for blood products and reagents

- **IQC of Reagents** – Antisera A, Antisera B, Antisera AB, Antisera D IgM. Appearance, Specificity, Avidity, Titer, Intensity
- **IQC of blood products**

-Packed Red Blood Cells (PRBC)

1. Volume
2. Hematocrit (HCT)
3. Culture

-Platelet Concentrate

1. Volume
2. PH
3. RBC Contamination
4. Culture

-Fresh frozen Plasma (FFP)

1. Volume
2. Prothrombin Time (PT)

3. Activated partial thromboplastin time (APTT)

Reference range / cut off each parameter for 450 ml

Table 1: Quality Parameters for PRBC

Parameter	Quality Requirement
Volume	280 ml ±40 ml
PCV (Hematocrit)	55-75%
Sterility	By Culture

Table 2: Quality Control of Fresh Frozen Plasma

Parameter	Quality Requirement
Volume	200-250 ml
Stable Coagulation	200 units
Factors	0.7 unit/ml

Table 3: Quality Control of Platelets

Parameter	Quality Requirement
Volume	40-70 ml
Platelet Count/Unit	5.5×10^{10}
pH	>6 in all units at the end of max day of storage

The IQC was done at or near maximum day of storage Analysis of External Quality Assurance Program.

TTI 1- Sample for HIV, HCV & HBV testing

- Antibodies to HIV
- Antibodies to HCV
- Hepatitis B antigen

These samples are lyophilized serum/Plasma sample prepared using pooled patient sample/donor sample.

TTI 2- and Donor hemoglobin screen.

- Syphilis (PRP) – [Lyophilized plasma 750 µl each]
- Malaria (Slide) – [2 unstained tired blood smear]- Leishman Stain.
- Hemoglobin (donor screening) –[2 tubes of stabilized blood sample 1 ml each]

Sample for program A, B, D blood group
Patient 1- History Group & Type, compatibility testing
Patient 2- No History; Group Type, DAT, IAT

Program C

1. ABO & Rh on Patient
2. ABO & Rh on donor
3. Compatibility testing
4. DAT (Direct Antiglobulin Test)
5. IAT (Indirect Antiglobulin Test)

RESULT

A retrospective and prospective study was conducted in blood bank, Subharti Medical College and CSSH Hospital from January 2019 to June 2020.Analysis of internal and external quality assurance was done. In internal quality of blood components Packed cells (PRBC), platelet concentrate (PC) and Fresh Frozen Plasma (FFP) and quality of reagents.

A total collection of 10,273 units of blood was done in CPDA, which included 2,920 Voluntary (28.42 %), and Replacement 7,353 (71.57%).During this period transfusion transmitted diseases were detected in , with HIV in 11(0.1%), HBsA 176 (1.7%). (HCV 208 (2.0%), Syphilis 5 (0.04%), and malaria in 1(0.01%)

Total PRBC units extracted were 9042 (88.01%). FFP extracted was 9472 (92.20%), PC extracted was 2025 (19.71%).Quality analysis of PRBC 72 units, FFP 25 units and PC 16 units was done

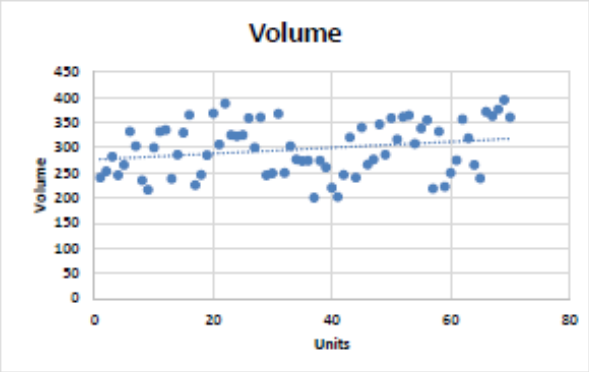
Quality control for PRBC units in our data:

Mean volume of PRBC was 297.47and haematocrit level was 62.72. There was no growth on culture.

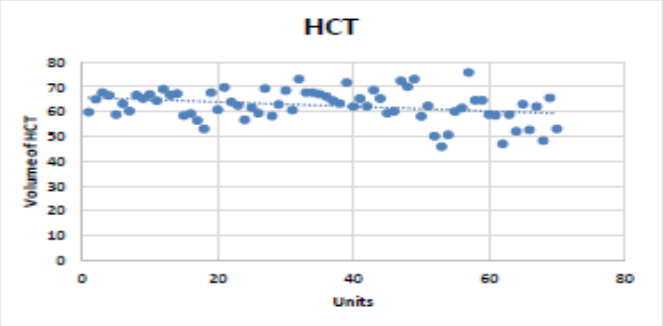
Table4: Quality control of Packed Red Blood Cells.

Parameters	Volume Concentration	HCT
Median	300	63.1
Mean	297.47	62.49
SD	52.19	6.37
Mean ± SD	245.48-349.09	56.2-69.2
Range	245.28-349.66	56.12- 68.86

Graph 1: Scatter diagram showing distribution of volume of packed red cells.



Graph 2: Scatter diagram showing distribution of hematocrit in PRBC.



Volume of PRBC was within range of 200 to 355ml, HCT was 45.9% to 75.9% for 5 (6.9%) units it was below the cut off volume, while 6 (8.3%) units it was more than the cut off volume (Graph 1, 2)

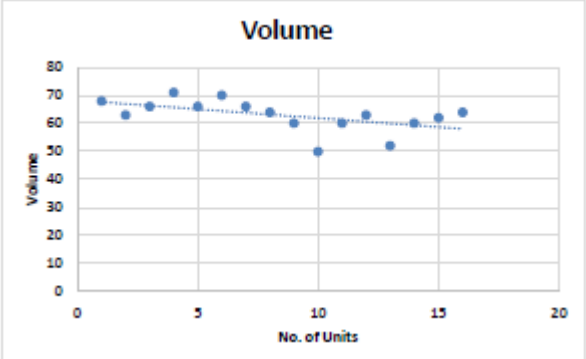
Quality control for Platelet Concentrate: 16 units were assessed for IQC. Mean platelet count 5.5×10^6 /cumm with Mean pH of 6.95, and Mean RBC contamination in platelet concentrate 0.48%.There was no growth on culture

Table5: Quality control of Platelet Concentrate

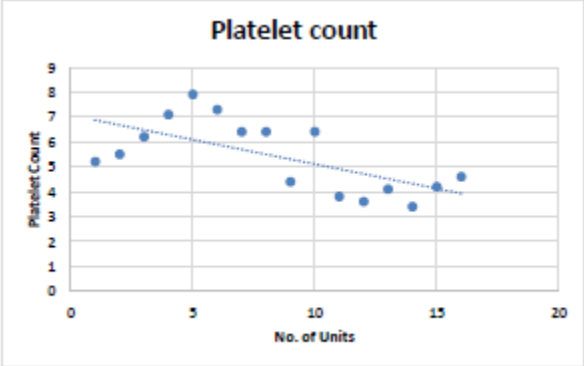
Parameters	Volume	Platelet Count	pH	RBC Contamination
Median	63	5.5	7	0.5
Mean	62.81	5.4	6.95	0.48
SD	5.68	1.43	0.24	0.10
Mean±SD	57.13-68.49	3.97-6.83	6.71-7.19	0.38-0.58
Range	21 (50-71)	4.3 (3.6-7.9)	1.0 (6.4-7.4)	0.4 (0.2-0.6)

All units were within specified range of volume. However, 7 (28%) units showed platelet count below 5.5×10^3/cumm. pH of all units was above 6.5 and RBC contamination was slightly high in 3 units with volume of (0.6 and 0.7). [Graph 3-6].

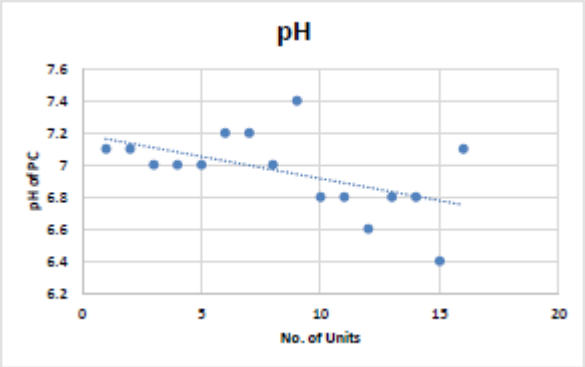
Graph 3: Scatter diagram showing distribution of volume in platelet concentrate.



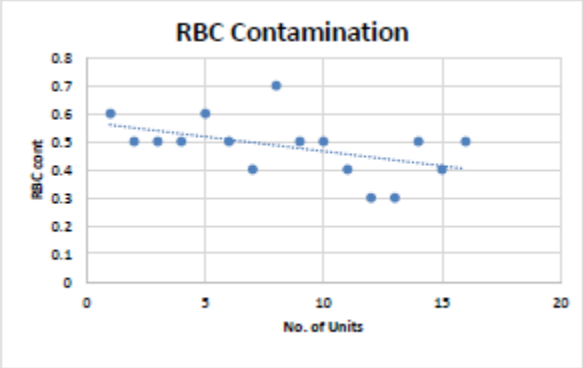
Graph 4: Scatter diagram showing distribution of platelet count in platelet concentrate.



Graph 5: Scatter diagram showing distribution of pH in Platelet concentrate.



Graph 6: Scatter diagram showing distribution of RBC contamination in Platelet Concentrate.



Quality control for Fresh Frozen Plasma units in our data was found to be in satisfactory range Mean volume was 189.59 ml, Mean PT (Prothrombin Time) was 11.92, and APTT (Activated Partial Thromboplastin Time) was 27.02.

Table.6: Quality control for Fresh Frozen Plasma

Parameters	**Volume**	**PT (Prothrombin Time)**	**APTT (Activated Partial Thromboplastin Time)**
Median	176	11.6	27.2
Mean	189.59	11.92	27.02
SD	48.66	1.12	1.96
Mean±SD	140.93-238.25	10.8-13.04	25.06-28.98
Range	170 (130-300)	4.0 (10.2-14.2)	7.5 (22.9-30.4)

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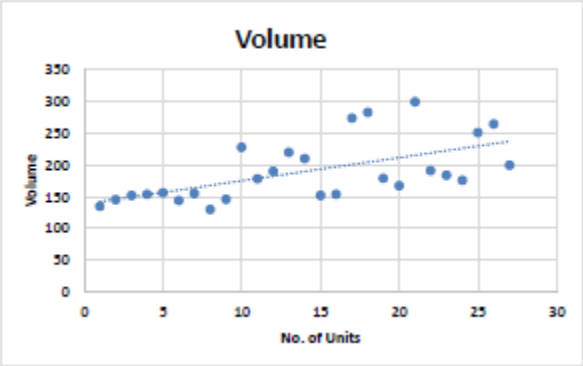
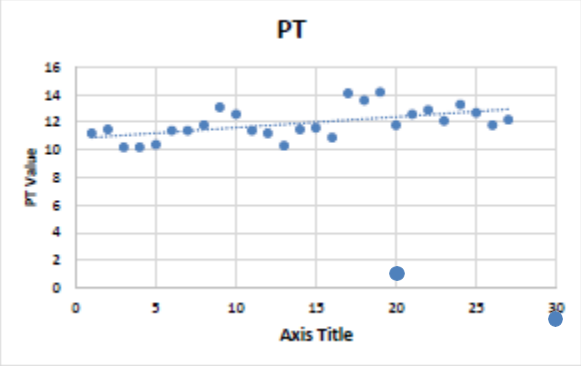
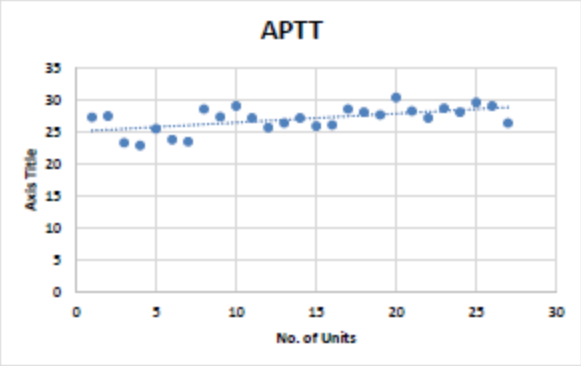
Graph 7: Scatter diagram showing distribution of volume of FFP



Graph 8: Scatter diagram showing distribution of Prothrombin timein FFP.



Graph 9: Scatter diagram showing distribution of APTT in FFP.



Internal quality control of all reagents for blood group and typing is performed daily by assessment of appearance, specificity, avidity, titer and intensity. All Parameters were within satisfactory limits.

Daily assessment was done on Q.C formats.

Lot no. of Reagent, Date of expiry and manufacturing company was recorded.

- There was no turbidity or precipitate in 100% reagents.
- Specificity for antisera A, B, AB and D IgM was positive with A,B,A and B cells and Ocells respectively.
- Avidity ranged from 6 to 7 seconds.

- Positive reaction was observed uptotitre of 1:256.
- Intensity of reaction was 3+ to 4+.

Also both positive and negative controls were run with each batch of HIV, HBsAg and HCV were satisfactory.

External Quality Assurance (EQAS)

EQAS in transfusion medicine is being done by CMC with assessment of performance in 3 rounds. The results received are analyzed for for any outlier and corrective measures taken. EQAS samples are lyophilized serum/plasma samples prepared using pooled patient sample / donor sample.

The program comprises of following parameters -

Program C

1. ABO & Rh on Patient
2. ABO & Rh on donor.
3. Compatibility testing.
4. DAT (Direct Antiglobulin Test)
5. IAT (Indirect Antiglobulin Test)A, B, D blood group

Patient 1- History Group & Type, compatibility testingPatient 2- No history; Group type, DAT, IAT

TTI – 1

- Antibodies to HIV
- Antibodies to HCV
- Hepatitis B surface antigen

TTI 2- and donor hemoglobin screen.

- Syphilis (PRP)- [lyophilized plasma 750 µl each]
- Malaria (Slide) – [2 unstained blood smear and Leishman Stain slide]
- Hemoglobin (donor screening)- [2 tubes of stabilized blood sample 1 ml each]

The results (score) for EQAS sample for 3 Rounds were conducted in 2019 is as follow programs

- Blood group & typing of both patient and donor samples, compatibility testing, DAT andIAT 1500/1500(100%)
- TTI-1

  HIV 30/30(100%)

  HBsAg 30/30(100%)

  HCV 30/30(100%)

Accuracy for screening of All TTI-1 was 100%.

- TTI-2 and donor hemoglobin screen.

Syphilis 28/30 (93.3%)
Malaria 30/30 (100%)
Hb estimation 60/60 (100%)

Among TTI-2, one case of syphilis was reported as negative, accuracy for screening was therefore 93.3% [It had low titers, which was not detected by RPR. Thereby, other testing Methods like ELISA or chemiluminence is recommended].
For malaria and Hb estimation score was 100%

Table7: Analysis of EQAS for 2019

Parameter	Score	%
Blood group & typing of Pt. & Donor Compatibility testing, DAT, IAT	1500/1500	100
HIV	30/30	100
HBsAg	30/30	100
HCV	30/30	100
Syphilis	28/30	93.3
Malaria	30/30	100
Hb estimation for donor screening	60/60	100

CONCLUSION

Quality management is an integrated system of quality assurance covering all matters which individually or collectively influence the components in order to guarantee their quality. This describes all the steps taken both inside and outside the Blood Bank to achieve safest possible blood for the recipient. There are various components of blood such as packed red blood cells, fresh frozen plasma, platelet concentrate and cryoprecipitate.
Internal Quality control (IQC) is the rigid background of quality management program in the blood bank system. To reduce various risks involved in these transfusions we need to follow manuals strictly to be more effective and safer to both donor and recipient. The main part of this quality control system comprises of blood donation, which can be collected from donors of various age groups belonging to different demographic region, health profiles or with risk behaviors.

Due to increase in prevalence of infectious diseases there is huge necessity of quality control management as it may be hazardous to the donor/recipient/technician, which provides a solid framework for quality in blood transfusion service.

External quality assurance must be complemented regularly with internal quality control. One of the programmes followed is participation in a proficiency testing. These proficiency testing programme consist of codes like normal and problematic blood samples. These programme test are distributed from any national/seasonal laboratories to participants, which are usually performed twice a year.

CONFLICT OF INTEREST

There is no conflict of interest.

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