Quality of Blood Components for Transfusion in Blood Transfusion Centre, Faculty of Medicine, Khon Kaen University, Thailand.

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Background and Objective : There are recommendations for the quality of blood components from the Council of Europe (EU), American Association of Blood Banks (AABB) and National Blood Centre, Thai Red Cross Society (TRC). We analyzed the quality control (QC) of blood components processed by the routine method used in our blood bank. This study aimed to test whether the components reached the recommended quality.

Methods : Packed red cells (PRC), leukocyte poored red cells (LPRC) and leukocyte depleted red cells(LDB) were measured hematocrit, weights and volumes were calculated based on specific gravity. Plasma were measured for volumes. Random platelet concentrates(RDP), leukocyte poored platelet concentrates(LPPC) were measured for volumes and platelet content. Cryoprecipitate were measured factor VIII and fibrinogen. For counting residual leukocytes, they were performed in LPRC, LDB, RDP and LPPC. Sterility test were done by sampling from all types of blood components.

Results : Red blood cell concentrates volume was 150-330 mL (refer to method used), with 50-80% of hematocrit. More than 90% of leukocyte poored red cells had fewer than $1.2X10^9$ white blood cells/unit and more than 90% of leukocyte depleted red cells(LDB) had fewer than $1X10^6$ white blood cells/unit. Plasma volume was $\geq$ 150 mL. Cryoprecipitate showed more than 80 IU/unit of factor VIII and more than 150 IU/unit for fibrinogen. Random platelet concentrates(RDP) had content more than $5.5X10^{10}$ cells/unit. Leukocyte poored platelet concentrates(LPPC) were more than $24X10^{10}$ cells/unit and had fewer than $1X10^9$ white blood cells contamination. Sterility test were no growth 100%.

Conclusions : Our QC data of blood components provides reached the recommended quality of EU, AABB, TRC.

Keywords: Blood components ; Quality control(QC)

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Proceeding

Introduction

It has long been recognized that blood bank institutions have provided safe blood products for their patients. Donors and products safety have improved significantly over the last decade as a consequence of the introduction of measures such as evidence-based blood donor selection criteria, which take into account the precautionary principal where appropriate and improved screening of blood donations for infectious agents. However, the implementation of underpinning quality assurance program based on good manufacturing practice has also played a key role in improving safety and quality of blood and blood components[1,6-9].

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Quality control activities are designed to monitor variations in manufacturing processes and product quality. The data will demonstrate whether the process is in control or not. This analysis is a far more powerful and sensitive tool .It can identify a trend much earlier, allowing for timely investigation and resolution of quality problems before they become significant.

There are recommendations of the Council of Europe (EU)[8], American Association of Blood Banks (AABB)[9] and National Blood Centre, Thai Red Cross Society (TRC)[6] for the quality of blood components. We analyzed the quality control (QC) of blood components processed by the routine method used in our blood bank. The objective of this study was to test whether our components reached the recommended quality of EU, AABB and TRC.

Methods

Whole blood (WB) was high-speed centrifuged before separation by manual separator or automated system. Platelet concentrate (PC) was prepared by pooling four isogroup buffy-coat (BC) units before low-speed centrifugation, and transferring the supernatant (LPPC) to a 5-days storage bag. An alternative approach involved PC preparation from a single BC unit by adding approximately 50-70 mL of plasma before centrifugation, followed by transfer of the platelet concentrate (RDP) to a 300 mL transfer bag. Both LPPC and RDP were stored in a flat agitator at 20-24 °C for up to 5 days after collection. Weights, platelet yields were measured and volumes were calculated based on specific gravity. The pH was determined on day 5 at 20-24 °C. Packed red cells (PRC), leukocyte poored red cells (LPRC) and leukocyte depleted red cells (LDB) were measured hematocrit, weights and volumes. Plasma were measured volumes. Cryoprecipitate were measured factor VIII and fibrinogen. For counting residual leukocytes were performed in LPRC, LDB, RDP and LPPC by automate; Mythic 22 hematology analyzer. Sterility test were done by sampling from all types of blood components[2-5].

The quality control (QC) data of blood components processed by the routine method used in our blood bank were analyzed from January 2016 to August 2016 by following the recommended quality of EU, AABB and TRC are presented in Table 1.

Results

From June to August 2016, Red blood cell concentrates volume was 150-330 mL(refer to method used), with 50-80% of hematocrit. More than 90% of leukocyte poored red cells had fewer than $1.2X10^9$ white blood cells/unit and more than 90% of leukocyte depleted red cells(LDB) had fewer than $1X10^6$ white blood cells/unit. Plasma volume was $\geq$ 150 mL. Cryoprecipitate showed more than 80 IU/unit of factor VIII and more than 150 IU/unit for fibrinogen. Random platelet concentrates(RDP) had content more than $5.5X10^{10}$ cells/unit. Leukocyte poored platelet concentrates (LPPC) were more than $24X10^{10}$ cells/unit and had fewer than $1X10^9$ white blood cells contamination. Sterility test were no growth 100%.

On March the QC program not done because of our work had annual turned. From January to February, hematocrit of our LPRC not reached the KPI (78% and 64% respectively) and on January to May the content of platelet not reached the KPI, too. We reviewed the data and changed some mehods in routine work examples, speed and time for centrifugation, volume of BC and plasma adding. Finally we found the appropriate methods for our routine works. The last three months, our results reached the recommended quality of EU, AABB and TRC that are show in Table 2.

Discussion

The data are stratified according to preparation process for analysis of Key performance criteria-residual leukocytes and hematocrit or platelet content. This study revealed that the analysis is a far more powerful and sensitive tool .It can identify a trend much earlier, allowing for timely investigation and resolution of quality problems before they become significant.

Conclusion

After changed some methods, our QC data of blood components provides reached the recommended quality of Council of Europe(EU), American Association of Blood Banks(AABB) and National Blood Centre, Thai Red Cross Society(TRC).

Table 1 The criteria of quality control in blood components and KPI for our Blood Transfusion Centre

Component (Standard References)	Quality control	Target Value	Key Performance Indication (KPI)
Whole Blood (TRC)	Volume Bag 350 ml. Volume Bag 450 ml.	364-434 ml. 468 – 558 ml.	100 %
Pack Red Cell: PRC (AABB,TRC)	Volume Hematocrit	150-200 ml. 65% - 80%	≥95%
Leukocyte poor red blood cell : LPRC (AABB,EU,TRC)	Volume Hematocrit Residual leukocyte	200-330 ml. 50% - 70% < 1.2×10^9 cells/unit	≥ 90%
Leukocyte depleted red blood cell: LDB (EU,TRC)	Volume Hematocrit Residual leukocyte	280-330 ml. 50% - 70% < 1×10^6 cells/unit	≥90%
Fresh Frozen Plasma/Frozen Plasma: FFP/FP (TRC)	Volume	≥150 *ml.*	≥90%
Cryoprecipitate: Cryo (AABB)	Factor VIII Fibrinogen	> 80 IU/unit > 150 IU/unit	≥90%
Random Platelet concentrates: RDP (AABB,TRC)	Volume Total platelet count Red blood cell ontamination Residual leukocyte pH	50 -70 *ml.* ≥ 5.5×10^{10}cells /unit < 1.2×10^9cells/unit < 0.12×10^9cells/unit ≥6.2 in the end of storage	≥ 90%
Leukocyte poor platelet Concentrates: LPPC (AABB,EU)	Volume Total platelet count Residual leukocyte pH	250-350 *ml.* ≥ 24×10^{10}cells /unit < 1×10^9 cells/unit ≥ 6.2 in the end of storage	≥90%
Sterility test	All components	No growth	100 %

Table 2 Key Performance Indication (KPI) and the successful of quality control in blood components

Key Performance Indication(KPI) Blood components	Target	successful							
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
1.Packed red cells : PRC	100%	100%	100%	ND	100%	100%	100%	100%	100%
2.Leukocyte poor red blood cells : LPRC	≥ 90%	78%	64%	ND	100%	100%	100%	100%	100%
3. Platelet concentrates(PC)									
3.1 Random plt.conc: RDP	≥90%	60%	75%	ND	38%	75%	93.8%	90.2%	100%
3.2 Leukocyte poor PC: LPPC	≥90%	ND	56%	ND	89%	89%	94%	93%	90%
4.Cryoprecipitate : Cryo									
4.1 Factor VIII	100%	ND	ND	ND	100%	100%	100%	100%	100%
4.2 Fibrinogen	100%	ND	ND	ND	100%	100%	100%	100%	100%
5. Sterility test	100%	100%	100%	ND	100%	100%	100%	100%	100%

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