

EVALUATION OF BLOOD AND BLOOD PRODUCTS QUALITY AT CENTER FOR HEMATOLOGY - BLOOD TRANSFUSION, HAI PHONG VIETNAM - CZECH FRIENDSHIP HOSPITAL

Hoang Van Phong*, Ngo Manh Quan**,
Nguyen Ngoc Dung**, Nguyen Thi Thu Huyen***,

ABSTRACT.

The objective of research: Study the status of blood quality and blood products in Haiphong Hematology and blood transfusion Center in 2019. **The subject of research:** Whole blood units, erythrocyte volume, fresh frozen plasma, removed coagulation plasma, platelet volume pool, cold-clotting factor VIII. **Method of research:** Cross-sectional study. **Results of research:** The quantity of the blood production: erythrocyte volume produced from whole blood 250 ml and 350 ml that has hemoglobin amount 31.5 ± 4.9 g/unit and 43.5 ± 5.2 g/unit respectively. Fresh-frozen plasma has factor VIII concentrations is 1.86 ± 0.43 IU/ml, the amount of fibrinogen is 0.76 ± 0.03 mg/Unit and protein is 73.8 ± 6.1 g/l and the remained amount of white blood cells markedly reduced. Platelet volume pool has platelet numbers is $1.92 \pm 0.4 \times 10^{11}$ /unit. Cold-clotting factor VIII, that has factor VIII concentration is 325 ± 14 IU/unit, fibrinogen is 90 ± 1.6 mg/Unit

Key words: *Quantity, whole blood, erythrocyte volume produced, Fresh-frozen plasma, Platelet volume pool*

I. INTRODUCTION

Blood and blood products are increasingly

used in treatment and emergency, the goal of blood transfusion sector is supplying safely and adequately blood and blood products. In order to have enough qualified blood, we must have sufficient number of blood donors and the process of receiving, screening, producing blood products is consistently invested and improved. In developed countries, blood sources are mainly collected from donors; from receiving, screening, supplying to using blood products are in accordance with the process, so the quality of blood and blood products are guaranteed.

Blood transfusion in Vietnam has made remarkable progress in providing safe blood products recent years. Future of blood transfusion would focus on screening, preparation and supplying to ensure the quality of blood and blood products nationwide.

Hai Phong city has a population of 1,9 million people and about 4000 inpatient beds. In recent years, the quality of blood and blood products is constantly improved. In 2016, 100% of blood units was received and applied the standard blood product manufacture process under science and technology project at the state level 11-DA5, blood preparations were prepared within 8 hours after the end of blood reception. In order to understand the quality of blood and blood products in Hai Phong, we conduct this research with the purposes: *Evaluate the quality of blood and some blood products at*

*Center for Hematology - Blood Transfusion,
Vietnam- Czech friendship hospital

**National Institute of Hematology - Blood
Transfusion

***Internal medical department, Vietnam- Czech
friendship hospital

Responsible person: Hoang Van Phong

Email: phongkhaduy@yahoo.com

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Hai Phong Center of Hematology - Blood transfusion in 2016.

II. SUBJECT AND METHODOLOGY

2.1. Subject of the study

Complete blood units were received in 2016, blood products were prepared according to standard process and after 8 hours since the end of blood reception.

2.2. Time and site of the study

The study was conducted from January 2019 to December 2019 at Center of Hematology - Blood transfusion, Hai Phong Vietnam - Czech friendship hospital

2.3. Research methodology

2.3.1. Research design

The study was designed using cross-sectional descriptive method

2.3.2. Sample size and sample selection

2.3.2.1. Sample size

- Quality of blood and blood products: whole blood units, erythrocyte, fresh-frozen plasma, removed coagulation plasma, platelet volume pool, cold-clotting factor VIII. The number of samples in each group was selected according to one-estimate estimation formula:

$$n = Z_{(1-\alpha/2)}^2 \frac{pq}{d^2}$$

n: Sample size

$Z_{(1-\alpha/2)}$: Reliability coefficient at probability level 95% = 1,96

p: percentage of whole blood, erythrocyte, fresh-frozen plasma prepared, which meet the demand of quality in 2008 of the Hematology - blood transfusion hospital, Ho Chi Minh city was 93%, 92% and 92% [3]

q: Percentage of complete blood, erythrocyte, fresh-frozen plasma that not meet the demand of quality in 2008 of the

Hematology - blood transfusion hospital, Ho Chi Minh city [3]

d: Relevant error ($d = 5\% = 0,05$)

+ The sample size of complete blood $n = 101$; erythrocyte (the number of sample of each erythrocyte unit was prepared from whole blood unit of 250 ml, 350ml) $n = 114$; fresh frozen plasma (the number of real sample and intervention was the same) $n = 114$. Whole blood, erythrocyte, fresh frozen plasma were studied, each type consisted 200 samples.

+ Removed coagulation plasma, platelet volume pool, cold-clotting factor VIII, the production rate at the center stayed low, so we conducting sampling due to average value estimation, each type consisted of 50 samples.

2.3.2.2. Sampling method

The samples were randomly selected based on blood collection day and manufacturing date.

2.3.3. Research content

* Research index:

- Whole blood, erythrocyte: volume, hemoglobin / unit, hematocrite (l / l) and the number of white blood cells, the number of remaining platelets / unit.

- Fresh frozen plasma, removed coagulation: volume, factor VIII, left blood cells including hemoglobin, white blood cells, platelets and quantification of protein, fibrinogen, pH.

- Removed coagulation plasma: Volume, protein, pH

- Platelet volume pool: Volume, number of platelets, white blood cells, pH

All above parameters were calculated as average, then the percentage were compared with the standard of Vietnam and Europe.

III. RESEARCH RESULT

Indicators of blood and blood products quality

Table 3.1. Quality indicators of whole blood

Indicator	Unit	Unit 250ml (n= 200)		Unit 350 ml (n= 200)	
		Standard	Result $\bar{X} \pm SD$	Standard	Result $\bar{X} \pm SD$
Volume	ml	250 ± 25	238 ± 11	350± 35	334 ± 14
Hemoglobin	g/dv	≥ 25g	29,4 ± 5,2	≥ 35	41,2 ± 6,2
Screening		Negative	Negative	Negative	Negative
pH		6,4-7,4	7,35 ± 0,02	6,4-7,4	7,35 ± 0,02

Comments: The quality of the whole blood unit 250 ml had a volume of 238 ± 11 ml, the amount of hemoglobin was 29.4 ± 5.2 g / unit. Whole blood receiving 350ml had a volume of 334 ± 14 ml and hemoglobin volume of 41.2 ± 6.2 g / unit, which meets the standards in Circular 26/20013.

Table 3.2. Quality indicators of erythrocyte

Indicator	Unit	Unit 250ml (n= 200)		Unit 350 ml (n= 200)	
		Standard	Result $\bar{X} \pm SD$	Standard	Result $\bar{X} \pm SD$
Volume	ml	≥ 150	162 ± 11	≥ 220	223 ± 12
Hemoglobin	g/dv	23,8	31,5 ± 4,9	33,25	43,5 ± 5,2
Hematocrite	l/l	0,5-0,7	0,59 ± 0,11	0,5-0,7	0,59 ± 0,12
WBC count	G/dv	<1,2	0,48 ± 0,18	<1,6	0,52 ± 0,24
PLT count	G/l	<15	1,2 ± 0,7	<25	5,5 ± 0,3
Screening		Negative	Negative	Negative	Negative
pH		6,4-7,4	7,35 ± 0,02	6,4-7,4	7,35 ± 0,02

Comments: The quality of the erythrocyte mass prepared from a whole blood unit of 250 ml had a volume of 162 ± 11 ml, the hemoglobin volume was 31.5 ± 4.9 g/ unit. The red blood cell mass prepared from a whole blood unit of 350ml had a volume of 223 ± 12 ml and a hemoglobin count of 43.5 ± 5.2 g/ unit and the number of leukocytes and platelets remaining in red blood cell products all met the standards under Circular 26/20013.

Table 3.3. Quality indicators of fresh frozen plasma

Indicator	Unit	Plasma unit produced from 02 whole blood unit 250 ml (n=200)	
		Vietnamese standard	Result $\bar{X} \pm SD$
Volume	ml	230-270	230 ± 8
Factor VIII concentration	IU/ml	>0,7	1,86 ± 0,43
Number of red blood cell	G/unit	<9	0,49 ± 0,05
No of white blood cell	G/unit	<0,1	0,02 ± 0,005
No of platelets	G/unit	<15	20 ± 6,2
Protein	g/l	>60	73,8 ± 6,1
Fibrinogen	mg/unit	>0,62	0,76 ± 0,03
Screening		Negative	Negative
pH		6,4 - 7,4	7,25 ± 0,17

Comments: Indicators such as volume, factor VIII concentration, amount of fibrinogen, protein and blood cells such as the number of red blood cells, white blood cells, platelets were all within the allowable limits (meet the standards in Circular 26, 20013).

Table 3.4. Quality indicators of removed coagulation plasma from two whole blood units 250 ml

Indicator	Unit	Removed coagulation plasma (n= 200)	
		Vietnamese standard	Result $\bar{X} \pm SD$
Volume	ml	230-270	225 \pm 7
WBC count	G/unit	<0,1	0,04 \pm 0,005
PLT count	G/unit	<15	11 \pm 3
Protein	g/l	>60	67,5 \pm 4,4
Screening		Negative	Negative
pH		6,4 - 7,4	7,24 \pm 0,18

Comments: The indicators of volume, protein and blood cells such as number of leukocytes, platelets all met the quality requirements according to Circular 26/2013.

Table 3.5. Quality indicators of plate volume pool produced from 4 units of whole blood 250 ml

Indicator	Unit	Platelet volume pool (n=50)	
		Vietnamese standard	Result ($\bar{X} \pm SD$)
Volume	ml	120 - 200	162 \pm 18
PLT count	10 ¹¹ /unit	>1,3	1,92 \pm 0,4
WBC count	G/unit	<0,05	0,38 \pm 0,04
RBC count	G/unit	<2,0	0,72 \pm 0,06
Screening		Negative	negative
pH		6,4 - 7,4	7,24 \pm 0,15

Comments: Indicators such as volume, amount of platelets and blood cells as WBC, RBC count all met the standards according to Circular 26/2013.

Table 3.6. Quality indicators of cold-clotting factor VIII produced from 8 whole blood units 250 ml

Indicator	Unit	Cold-clotting factor VIII (n = 50)	
		Vietnamese standard	Result ($\bar{X} \pm SD$)
Volume	ml	50 -70	68 \pm 18
Factor VIII	IU/unit	>250	325 \pm 14
Fibrinogen	mg/unit	>75	90 \pm 1,6
Screening		Negative	Negative
pH		6,4 - 7,4	7,32 \pm 0,11

Comments: Indicators such as volume, volume factor VIII, fibrinogen all were in allowable limits according to the Circular 26/2013.

IV. DISCUSSION

The quality of whole blood received at Hai Phong center of Hematology - Blood transfusion is presented in table 3.1. Based

on the Circular 26/2013, Hai Phong mainly receives two types of volume: 250ml and 350ml for each blood donation, resulting in a volume equivalence to $V \pm 10\%$ ($V = 250\text{ml}$)

or 350ml). The amount of hemoglobin unit 250ml reaches $29.4 \pm 5.2\text{g/ unit}$ (over 25g/unit) and unit 350ml is $41.2 \pm 6.2\text{g/ unit}$ (over 35g / unit). This result is similar to the result of Pham Thi Thuy Nhung at the National Institute of Hematology and Blood Transfusion in 2010 [4] as well as the research result of Nguyen Duc Thuan in Vinh Phuc [5].

Quality of red blood cells prepared from whole blood units of 250ml and 350ml at Hai Phong Hematology and Blood Transfusion Center is presented in Table 3.2. Erythrocyte mass unit is produced from whole blood unit of 250ml with average volume of $162 \pm 11\text{ml}$, hemoglobin reaching $31.5 \pm 4.9\text{g/ unit}$, hematocrite reaching $0.59 \pm 0.11\text{l/l}$, the number of white blood cells to $0.48 \pm 0.18\text{G/ unit}$. The erythrocyte mass produced from whole blood unit 350ml of has volume of $223 \pm 12\text{ml}$, hemoglobin of $43.5 \pm 5.2\text{ g/unit}$, hematocrite of $0.59 \pm 0.12\text{ l/l}$ and the remaining leukocyte count of $0.52 \pm 0.24\text{G/ unit}$, these indicators meet the requirements in Circular 26/2013. This result is similar to that of Do Trung Phan [2], Tran Hong Thuy, Pham Quang Vinh and colleagues at the National Institute of Hematology and Blood Transfusion [6].

Quality of fresh-frozen plasma at Hai Phong center of Hematology - Blood Transfusion is presented in table 3.3. By pooling two plasma units of two whole blood units of 250ml, we get volume of $230 \pm 8\text{ml}$, factor VIII concentration of $1.86 \pm 0.43\text{IU/ml}$, RBC count, WBC count and PLT count are within the allowable limits. Indicators such as the amount of protein, the amount of fibrinogen meet the standard in Circular 26/2013. This result is similar to that of Do Trung Phan [2], of Tran Hong Thuy, Pham Quang Vinh of the National Institute of

Hematology and Blood Transfusion [6], of Nguyen Ngoc Minh at Hue Center for Hematology and Blood Transfusion [1]], of Mai Thanh Truyen, Truong Thi Kim Dung at Ho Chi Minh City Blood Transfusion Hospital [3]. Similarly, the quality indicators of removed coagulation plasma are presented in Table 3.4, including volume, protein concentration, and the remaining blood cell indicators such as erythrocytes, leukocytes, platelets all meet the standard of Circular 26/2013.

Platelet volume pool is produced from four whole blood units with a volume of 250ml. The results are presented in Table 3.5: the volume reaches $162 \pm 21\text{ml}$, the number of platelets reaches $1.92 \pm 0.4 \times 10^1\text{/unit}$, the number of red blood cells, the number of remaining WBCs meets the standard according to Circular 26/2013. Our results are similar to those of Do Trung Phan [2], Tran Hong Thuy, Pham Quang Vinh and colleagues at the National Institute of Hematology and Blood Transfusion in 2004 [6] and by Nguyen Ngoc Minh in Hue Blood Transfusion Center [1], by Truong Thi Kim Dung at Ho Chi Minh City Blood Transfusion Hospital [3]. With the development of Hai Phong Hematology and Blood Transfusion Center, we have produced cold-clotting factor VIII, which helps to treat patients with hemostatic disorders, especially patients with hemophilia A. Efficiency in treatment has been reached in the first steps. The quality of cold-clotting factor VIII presented in table 3.6 shows that the volume reaches $68 \pm 18\text{ ml}$, the factor VIII concentration $25 \pm 14\text{ IU/ unit}$, fibrinogen $90 \pm 1.6\text{ mg/unit}$. This result meets the standard in Circular 26/2013. This is similar to the results of study by Tran Hong Thuy et al. [6].

V. CONCLUSION

- Quality of whole blood of unit of 250ml has a volume of 238 ± 11 ml; hemoglobin of $29,4 \pm 5,2$ g/unit. Whole blood unit of 350ml has a volume of 334 ± 14 ml; hemoglobin of $41,2 \pm 6,2$ g/unit.

- Erythrocyte of 250ml has a volume of 162 ± 11 ml; hemoglobin $31,5 \pm 4,9$ g/unit, leukocyte $0,48 \pm 0,18$ G/unit; platelet $1,2 \pm 0,7$ G/unit. Erythrocyte of 350ml has a volume of $223 \pm$ ml; hemoglobin $43,5 \pm 5,2$ g/unit, leukocytes $0,52 \pm 0,24$ G/unit; platelets $5,5 \pm 0,3$ G/unit.

- Fresh-frozen plasma has volume of 230 ± 8 ml; factor VIII concentration $1,86 \pm 0,43$ UI/ml; leukocytes $0,02 \pm 0,005$ G/unit; protein $73,8 \pm 6,1$ g/l; fibrinogen $0,76 \pm 0,03$ mg/unit.

- Removed coagulation plasma has volume of 225 ± 7 ml; remaining leukocytes $0,04 \pm 0,005$ G/unit; protein $67,5 \pm 4,4$ g/l

- Platelet pool has volume of 162 ± 18 ml; amount of platelets $1,92 \pm 0,4$ G/l; remaining leukocytes $0,38 \pm 0,04$ G/unit.

- Cold-clotting factor VIII has volume 68 ± 18 ml; factor VIII concentration 325 ± 14 UI/unit; fibrinogen $90 \pm 1,6$ mg/unit.

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