Jurnal Riset Kesehatan, 11 (1), 2022, 21 - 27
DOI: 10.31983/jrk.v11i1.8506

Jurnal Riset Kesehatan

http://ejournal.poltekkes-smg.ac.id/ojs/index.php/jrk

QUALITY CONTROL OF PACKED RED CELL (PRC) PRODUCT IN BLOOD DONATION UNIT

Silvi Astitiningtiyas[a]*; Luthfi Rusyadi[b] ; Yeti Kartikasari[c]

[a]Blood Donation Unit Red Cross Banjarnegara District ; Letjend Suprapto No. 73 Wangon; Banjarnegara 53417 ; Indonesia
[b,c] Poltekkes Kemenkes Semarang ; Tirto Agung ; Pedalangan ; Banyumanik ; Semarang 50268 ; Indonesia

Abstract

Blood Transfusion Service Standards aim to ensure the safety high quality and sufficient blood services sufficient blood reserve. The standard for blood requirements for each country according to WHO is at least 2% of the total population. The population in Indonesia has increased every year so the need for blood is also increasing causing demands for causing the quality of blood services to be better. One of the demands for the quality of blood services by knowing is to know the quality control of the blood produced. One of the blood products produced is PRC. PRC Packed Red Cells quality control checks must be carried out to determine the quality of the PRCs produced. This study aims to determine the overall quality control of PRC and the results of PRC quality control based on (volume, hemoglobin, hematocrit, hemolysis, and bacterial contamination) in the Blood Donation Unit of Banyumas Regency in 2020. This type of research is descriptive. Sampling technique with a sample quota as much as the total sample quality control packed red cell test obtained 1% of the total production of PRC components every month in the Blood Donation Unit of Banyumas. The QC research results were obtained from 430 PRC samples that met the passing standards: 426 samples (99%) volume, 426 samples (99%) hemoglobin, 380 samples (88%) hematocrit, 429 samples (99.7%) hemolysis, and 426 samples (99%) passed from bacterial contamination. The number of QCs who qualified was 373 samples (87%). These results indicate that the 2020 PRC QC obtained good and satisfying results.

Keywords: *quality control*; *packed red cell*; *blood transfusion service*

1. Introduction

Blood transfusion is essentially the giving of blood or blood components from one individual (donor) to another (recipient) (Eldest, 2018). Blood transfusion service is a health service effort that utilizes human blood as a basic primary material for humanitarian purposes and not for commercial purposes so that blood cannot be traded. Blood transfusion services as one of the health efforts in the context of healing disease and restoring health so that it requires the availability of blood or blood components that are safe, easily accessible, and affordable by the community. The government is responsible for the implementation of blood transfusion services that are safe, useful, and easily accessible, both the needs of the community (Permenkes No. 91, 2015).

Blood Transfusion Service Standards are needed to ensure safe, quality, and sufficient blood supply. Blood transfusion service standards include blood service quality management system; blood transfusion services in the Blood Transfusion Unit; blood transfusion services at plasmapheresis centers; blood transfusion services at the Hospital Blood Bank; giving blood transfusions to patients; and blood service information system (Permenkes No. 91, 2015). All elements must be implemented properly to create a good standard of blood service quality.

*) Corresponding Author (Silvi Astitiningtiyas)
E-mail: silviastutiningtiyas@gmail.com

Permenkes (2015), quality control is a critical function (a function that determines whether or not the quality is good) of the production of blood components and is evidence that blood components meet specifications. Quality control (QC) is usually carried out on the final blood component and often problems will be identified after they occur Process control is a broader activity that monitors all production processes against established requirements to ensure that processes are monitored. This provides a mechanism for early identification of potential problems and increases the assurance that the quality of the final blood component will meet specifications.

According to the Center for Health Data and Information of the Republic of Indonesia in 2014, the national production of Whole Blood and blood components was 4,644,863 bags. By WHO guidelines blood production is at least 2% of the population. If the total population in Indonesia in 2014 was 252,124,458 people, then ideally the need for blood is 5,042,489 bags of blood, so 397,626 bags are still lacking. Meanwhile, in 2016 the production of Whole Blood and blood components was 4,201,578 bags. By the WHO guidelines that the need for blood is at least 2% of the total population. If the total population in Indonesia in 2016 was 258,704,986 people, then ideally the need for blood is 5,174,100 bags of blood, so there is still a shortage of 972,522 bags or 18.8% The population of Banyumas in 2020 is 1,780,000 people, so the need for blood is around 35,600 bags. The demand for increased service quality is seen in the need for blood in Indonesia every year with the hope of being able to reduce mortality due to blood events and other blood disorders. Blood supply services in Indonesia are carried out by the Blood Transfusion Unit/UTD managed by the Government, Regional Government, and PMI which found 379 UTD in 2014 and increased to 421 UTD in 2016 (Data And Information Center Of The Ministry Of Health Of The Republic Of Indonesia, 2018). One of the Blood Donor Units that have GMP (Good Manufacturing Product) and CPOB (How to make good medicine) certification is PMI Banyumas Regency.

Based on data on blood production and needs in Indonesia, every blood product produced by the Blood Transfusion Unit must be ensured to be safe and free from IMLTD (Infectious Infection Through Blood Transfusion) and meet the QC stipulated in Permenkes No. 91 of 2015. Based on this, the author wants to review the results of Quality Control of Packed Red Cell Products at the Blood Donation Unit of Banyumas Regency in 2020.

2. Method

The type of this research is descriptive research with the scope of managing the quality of blood services. The study population includes the total number of red blood cell production in the Blood Donation Unit, Indonesian Red Cross of Banyumas Regency 2020 ran 48,000 blood bags. The sampling technique used is the total sample quota of the PRC quality control test which is obtained as 1% of the total production of PRC components every month at the Blood Donation Unit, Indonesian Red Cross of Banyumas Regency in 2020. The number of samples obtained based on inclusion and exclusion criteria. PRC production every month is about 4,000 blood bags, and the QC population every month is about 40 bags.

Inclusion criteria are data quality control of PRC in Blood Donation Unit, Indonesian Red Cross of Banyumas Regency 2020. The exclusion criteria are incomplete data quality control of PRC in Blood Donation Unit, Indonesian Red Cross of Banyumas Regency 2020. The data obtained from the study were then processed using the percentage calculation formula in the database to the quality percentage of the PRC specifications (volume, hematocrit, hemoglobin, hemolysis, and bacterial contamination with the same sample n) with the same sample and based on the overall results of the QC PRC, they were presented and analyzed so that conclusions could be drawn.

3. Results and Discussion

The research was conducted at the Blood Donation Unit of Banyumas Regency on March 26, 2021. The results of the study have been conducted through secondary data resulting from quality control packed red cells at Blood the Donation Unit of Banyumas Regency in 2020 with a total sample of 430 blood bags taken based on inclusion and exclusion criteria. The sample in the quality control study came from 1% of the PRC blood component production (Permenkes No. 91, 2015) in the Blood Donation Unit of Banyumas Regency. The amount of PRC blood components produced in the Blood Donation Unit of Banyumas Regency every month is around 4,000 bags of PRC blood, so the estimated QC PRC samples each month are 40 samples with a total QC PRC one year of as many as 480 samples. The number of samples

obtained from the study were 430 samples. This amount is not in line with estimates because the amount of PRC production in the Blood Donation Unit of Banyumas Regency in certain months, namely in March-May decreased by only around 1,000 to 3,000 bags caused by a decrease in the number of donors due to the phenomenon of the covid-19 pandemic around the world.

The PRC quality control inspection process begins with the preparation of samples and worksheets, then proceeds with a physical examination (identification of bags, pouches, and pouch volumes), hemolysis examination using a low HB system/ HemoCue plasma, examination of bacterial contamination (aerobic and anaerobic) inoculated in BPA sample bottles. (aerobic) & BPN (anaerobic) then incubated for 5 days in bact/alert, and hematological examination to determine the results of hemoglobin and hematocrit (Blood Donation Unit of Banyumas Regency).

Results of Quality Control Volume of Packed Red Cell Products at Blood Donation Unit of Banyumas Regency Year 2020

The results of research that have been conducted on the quality control of the volume of packaged red cell products in table 1 (PRC QC P results to volumes) test the specifications of a total of 430 peer samples 426 (99%), passed of the highest volume of 40 samples (100%) in January, February, May, July, September, October, November, December, December and as low as 9 samples (90%) of the total 10 samples in April.

Table 1. PRC QC Passed by Volume

Volume	month												Total
	1	2	3	4	5	6	7	8	9	10	11	12	
number of samples	40	40	30	10	30	40	40	40	40	40	40	40	430
Sample pass	40	40	29	9	30	39	40	39	40	40	40	40	426
The sample did not pass	0	0	1	1	0	1	0	1	0	0	0	0	4
Passed Percentage (%)	100	100	97	90	100	98	100	98	100	100	100	100	99
QC accepted	75%(Passed QC in PMK No. 91, 2015)												

The results of the QC volume obtained the graduation of 426 samples (99%) out of a total of 430 samples. The results are by the QC volume standard (218 ± 39 (179-257ml)) received by 75%. This result indicates that the PRC volume QC in the Blood Donation Unit of Banyumas Regency is satisfactory, and the blood.

Results of Quality Control of Hemoglobin for Packed Red Cell Products at Blood Donation Unit of Banyumas Regency Year 2020

The results in table 2 QC PRC passed on hemoglobin from a total of 430 samples as many as 426 (99%), the highest hemoglobin graduations (100%) in January-December except in November 39 samples (98%), March 29 samples (97%) and the lowest hemoglobin pass in May was 28 samples (90%) out of a total of 30 samples.

Table 2. QC PRC Passed based on Hemoglobin

Hb 45gr/ unit	Month												Total
	1	2	3	4	5	6	7	8	9	10	11	12	
Number of samples	40	40	30	10	30	40	40	40	40	40	40	40	430
Sample pass	40	40	29	10	28	40	40	40	40	40	39	40	426
Sample did not pass	0	0	1	0	2	0	0	0	0	0	1	0	4
Passed Percentage (%)	100	100	97	100	93	100	100	100	100	100	98	100	99
QC accepted	75%(Passed QC In PMK No. 91, 2015)												

The results of QC PRC hemoglobin with acceptance criteria that is 45gr/unit and accepted QC standard is 75% (Permenkes No. 91, 2015) the results obtained pass rate of 426 samples (99%) of a total of 430 samples and did not pass were 4 samples (1%). QC samples that did not pass were then carried out for internal repairs by the Blood Donation Unit of Banyumas regency. These results indicate that the hemoglobin QC of PRC in the Blood Donation Unit of Banyumas Regency obtained satisfactory results. These results are not much different from Saloni Upadhyay's research conducted at the Hospital of Kumaon Region of Uttarakhand, India, which obtained a hemoglobin QC passing result of 92.9% meeting the criteria of the European Council and considered satisfactory.

Results of Quality Control Hematocrit for Packed Red Cell Products at Blood Donation Unit of Banyumas Regency Year 2020

Table 3 data shows the results of the QC PRC passed on the hematocrit from a total of 430 samples as many as 380 (88%) with the highest hematocrit passing in April as many as 10 samples (100%) from a total of 10 samples and the lowest 80% from the total sample.

Table 3. PRC QC Passed on Hematocrit

Ht 65-75%	Month												Total
	1	2	3	4	5	6	7	8	9	10	11	12	
Number of samples	40	40	30	10	30	40	40	40	40	40	40	40	430
Sample pass	36	39	27	10	28	33	32	32	36	34	36	37	380
The sample did not pass	4	1	3	0	2	7	8	8	4	6	4	3	50
Passed Percentage (%)	90	98	90	100	93	83	80	80	90	85	90	93	88
QC accepted	75%(Passed QC in PMK No. 91, 2015)												

The results of QC hematocrit with the criteria for acceptance of the hematocrit are 65-75% (Permenkes No. 91, 2015) The results of the graduation rate were 380 samples (88%) from a total of 430 samples and those who did not pass were 50 samples (12%). QC samples that did not pass were then carried out for internal repairs by the Blood Donation Unit of Banyumas Regency. These results are not much different from Saloni Upadhyay's research conducted at the Hospital of Kumaon Region of Uttarakhand, India, which obtained a QC hematocrit passing result of 85.1% meeting the criteria of the European Council and considered satisfactory. This shows that the results of the QC hematocrit at the Blood Donation Unit of Banyumas Regency are satisfying.

Results of Quality Control of Hemolysis for Packed Red Cell Products at Blood Donation Unit of Banyumas Regency Year 2020

Table 4 the QC PRC passed for hemolysis are 429 samples (99.7%) from a total of 430 samples with the highest hemolysis passing in January-December as many as 40 samples (100%) from a total of 40 samples, except March as many as 30 samples (100 %) from a total of 30 samples, April there were 10 samples (100%) from a total of 10 samples and the lowest was 29 samples (97%) from a total of 30 samples in May.

The results of the QC hemolysis obtained a passing rate of 429 samples (99.7%) out of a total of 430 samples. The results of the standard hemolysis QC accepted are 75% with the acceptance criteria 0.8% (Permenkes No. 91, 2015). These results indicate that the QC hemolysis of PRC in the Blood Donor Unit of Banyumas Regency obtained a satisfactory QC by the standards set. QC sample hemolysis that did not pass were then carried out internal repairs by the Blood Donation Unit of Banyumas Regency.

Table 4. PRC QC Graduation based on Hemolysis

Hemolysis 0.8%	Month												Total
	1	2	3	4	5	6	7	8	9	10	11	12	
Number of samples	40	40	30	10	30	40	40	40	40	40	40	40	430
Sample pass	40	40	30	10	29	40	40	40	40	40	40	40	429
Sample did not pass	0	0	0	0	1	0	0	0	0	0	0	0	1
Passed percentage (%)	100	100	100	100	97	100	100	100	100	100	100	100	99.7
QC accepted	75%(Passed Qc in PMK No. 91, 2015)												

Results of Quality Control of Bacterial Contamination of Packed Red Cell Products at Blood Donation Unit of Banyumas Regency Year 2020

The QC PRC passed against bacterial contamination in table 5 are 100% samples free from bacterial contamination, namely in January-December except in August and October for 39 samples (98%) and the lowest in November 38 samples (95%).

Table 5. PRC QC passed based on Bacterial Contamination

Contamination Bacteria	Month												Total
	1	2	3	4	5	6	7	8	9	10	11	12	
Number of samples	40	40	30	10	30	40	40	40	40	40	40	40	430
Sample pass	40	40	30	10	30	40	40	39	40	39	38	40	426
The sample did not pass	0	0	0	0	0	0	0	1	0	1	2	0	4
Passed Percentage (%)	100	100	100	100	100	100	100	98	100	98	95	100	99
QC accepted	Refer to the bacteria statistics chart												

Jurnal Riset Kesehatan, 11 (1), 2022, 25 - 27
DOI: 10.31983/jrk.v11i1.8506

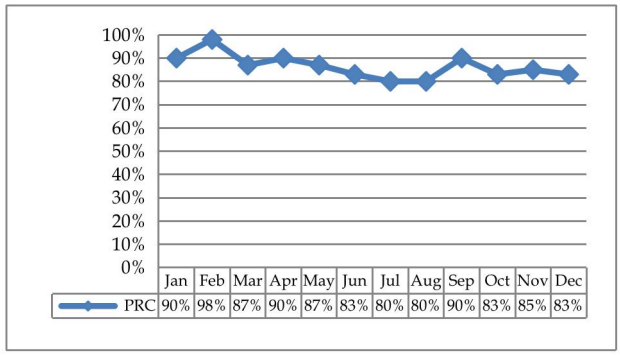

Figure 1. *Passed Percentage QC PRC bacterial contamination 2020*

The results of QC of bacterial contamination were obtained with a passing rate of 246 samples (99%) from a total of 430 samples. The standard of acceptance of bacterial QC results does not yet have a standard specification set, but the results must refer to the statistical graph of bacterial growth (Permenkes No. 91, 2015). In Permenkes No. 91, 2015 the results of bacterial contamination refer to the statistical graph of bacterial growth). In Figure 1, the QC graph of bacterial contamination shows consistent results, although in November it decreased by 85%, the graph is still consistent. These results indicate that the QC of bacterial contamination in the Blood Donation Unit of Banyumas Regency is satisfying.

Final Result of Quality Control of Packed Red Cell Products at Blood Donation Unit of Banyumas Regency Year 2020

Table 6 data shows that the final results of QC passed for PRC products were highest in February with 39 samples (98%) and the lowest in July and August with 32 samples (80%). While the data in table 7 states that the total QC PRC graduations in 2020 were 373 samples (87%), while the total QC PRC years did not pass or did not meet the criteria as many as 57 samples (13%) from a total of 430 samples.

Overall PRC QC results, 373 samples (87%) passed QC results and 57 samples (13%) did not pass from a total of 430 samples indicating the quality of PRC products at the Blood Donation Unit of Banyumas Regency is quite good and satisfying and overall QC is by the standards set by Permenkes No. 91, 2015.

The results of QC inspections must be regularly discussed to ensure that investigations and corrective actions are carried out if the results of the inspection indicate a trend or indicate the process is outside the requirements (Permenkes No. 91, 2015). QC results do not pass, it is necessary to know the cause and take corrective actions to improve the QC of the products produced.

Table 6. PRC QC Passed Final Results

	Month											
	1	2	3	4	5	6	7	8	9	10	11	12
Passed	36	39	26	9	26	33	32	32	36	33	34	37
Not pass	4	1	4	1	4	7	8	8	4	7	6	3
% Passed	90 %	98 %	87 %	90 %	87 %	83 %	80 %	80 %	90 %	83 %	85 %	83%
Percentage												
N	430 Samples											

The results of the QC PRC study at the Blood Donor Unit of Banyumas Regency in terms of specifications (volume, hemoglobin, hematocrit, hemolysis, bacterial contamination) and terms of final QC obtained satisfactory results and by the standards set by the Minister of Health. The results of QC PRC who passed in 2020 were 83%, this indicates that the quality of blood products produced by the Blood Donation Unit of Banyumas Regency is very good and safe. There is no doubt that the Blood Donation Unit of Banyumas Regency is one of the Blood Donation Units in Indonesia that already has GMP (Good Manufacturing Product) and CPOB (Good Manufacturing Practices) certificates because the blood products produced are safe and of high quality.

Table 7. Total Percentage (%) of QC PRC

	Passed	Not pass
PRC	373	57
Percentage	87%	13%
N	430 Samples	

Factors that affect blood in the blood bag include storage time and temperature. Erythrocytes will experience destruction if the processing or storage is not correct. One way to minimize erythrocyte damage is to store PRC blood at a low or standard temperature of 2°C - 6°C. Proper storage of PRC is one-way metabolism can be slowed down. Above this temperature, erythrocytes will experience rapid destruction (Zuherni, 2019). This can affect the results of QC PRC on hemoglobin, hematocrit, hemolysis, and bacterial contamination.

4. Conclusion and Suggestions

The QC results in the Blood Donation Unit of Banyumas Regency are by accepted standards in Permenkes No. 91, 2015. QC PRC who pass or meet the standards of Permenkes No. 91 in 2015 as many as 373 samples (87%). This shows that the results of the QC PRC in the Blood Donor Unit of Banyumas Regency have good quality and satisfactory results.

Suggestions for Blood Donation Unit, Indonesian Red Cross of Banyumas Regency, there is a need for further investigation and corrective action against QC that does not pass either based on volume, hemoglobin, hematocrit, hemolysis or bacterial contamination, as well as QC PRC assessment, needs to be done regularly to find out differences in product quality. This is related to the quality of transfusion services which is very important for setting the goals of good and safe transfusion practices. Meanwhile, the suggestion for further researchers is that the research should be carried out more complexly because the blood component is not only PRC.

5. Acknowledgments

Thanks to the Blood Donation Unit of Banyumas Regency who has given permission and helped carry out the research, as well as the Department of Blood Bank Technology, Health Analyst, Poltekkes Kemenkes Semarang, the author's parents, and friends who have provided support so that the research can be completed smoothly.

6. References

Asryani, T., Yaswir, R., & Rofinda, Z. D. (2018). Perbandingan Kadar Kalium Packed Red Cell Berdasarkan Lama Penyimpanan Di Bank Darah RSUP Dr. M. Djamil Padang. *Jurnal Kesehatan Andalas*, *7*, 10. https://doi.org/10.25077/jka.v7i0.862

BPOM. (2018). *Petunjuk Operasional Penerapan Pedoman Cara Pembuatan Obat Yang Baik Di Unit Transfusi Darah Dan Pusa Plasmaferesis*.

Committee, E. (2017). *Guide to the preparation, use, and* Quality Assurance Of Blood Components. European Committee (Partial Agreement) on Blood Transfusion.

Install, T., Card, E., Cause, P., Action, C., & Sample, I. (nd). Operator' S Manual Operator' S Manual. 53–56.

Irawan, A. D. R. (n.d.). 2015. Mengenal CPOB Untuk Produk Darah. Jurnal vol. 3, No. 2, November. Jambi. Fakultas Ilmu Kedokteran dan Ilmu Kesehatan Universitas Jambi.

Meganada, Sukini, Yodong. 2017. Mikrobiologi. Jakarta: Pusat Pendidikan Sumber Daya Manusia Kesehatan.

PEMERIKSAAN KUANTITATIF DARAH : BC-2600 / BC-2800 AUTO HEMATOLOGY ANALYZER By : Dosendoktor. (n.d.).

Peraturan Menteri Kesehatan Republik Indonesia Nomor 83 Tahun 2014 Tentang Unit Transfusi Darah, Bank Darah Rumah Sakit, Dan Jejaring Pelayanan Transfusi Darah. Jakarta.

Permenkes. 2015. Permenkes No 91 Th 2015 Tentang Standar Pelayanan Transfusi Darah. Jakarta.

PUSAT DATA DAN INFORMASI KEMENTERIAN KESEHATAN RI. 2018. Infodatin Pelayanan Darah Di Indonesia (p. 156). Jakarta

Saragih, P. (2019). Pengaruh Waktu Simpan PRC Terhadap Perubahan Hemoglobin, Hematokrit, dan Plasma Glukosa di RSUP H. Adam Malik

Medan. *Universitas Sumatra Utara*.https://pdfs.semanticscholar.org/a5f2/ddc1039d33b7848e160b65b581172ce2f845.pdf

Studi, P., Laboratorium, T., & Binawan, U. 2019. Analisa Quality Control Hematologi Di Laboratorium Rumah Sakit An-Nisa Tangerang Analysis Of Hematology Quality Control In An-Nisa Tangerang Hospital. 1, 80–85.

Sultan, S., Zaheer, HA, Waheed, U., Baig, MA, Rehan, A., & Irfan, SM 2018. Internal quality control of blood products: An experience from a tertiary care hospital blood bank from Southern Pakistan. Journal of Laboratory Physicians, 10(01). https://doi.org/10.4103/jlp.jlp_97_17

Sulung, N. 2018. Perbedaan Reaksi Pemberian Transfusi Darah Whoole Blood (Wb) Dan Packed Red Cell (Prc) Pada Pasien Sectio Caesare. Human Care Journal, 1(3). https://doi.org/10.32883/hcj.v1i3.29

Upadhyay, S., & Pangtey, T. 2016. Quality Analysis Of Blood Component (Prbc And Platelet Concentrates): A Study From A Tertiary Care Teaching Hospital Of Kumaon Region Of Uttarakhand. Journal of Evolution of Medical and Dental Sciences, 5(23). https://doi.org/10.14260/jemds/2016/282