IMPROVING THE PERCENTAGE OF PLATELET CONCENTRATES THAT MEET PLATELET COUNT STANDARD

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Abstract

The platelet concentrates (PCs) is used for the treatment and prevention of bleeding in patients with reduced platelet number or function. The prepared platelet concentrates (PCs) must meet the specified quality control (QC) test standards. PCs that do not meet QC standards will reduce the efficacy of patient care and increase the need of repeated PC transfusion. According to the standards, at least 75% PCs tested should contain more than 60 x 10^9 per platelet count units. Hence, the objective of this study was to increase the percentage of PCs that meet the platelet count standard to more or equal to 75%.

A cross sectional study was conducted from May 2015 to March 2016. Data were collected and analysed through monthly PCs QC test results. A retrospective QC data review in March and April 2015 showed only 30% PCs achieved the platelet count standard for QC tests. Intervention package was implemented to tackle the identified risk factors that lead to platelet count problems that do not meet the standards.

The post remedial results showed an increase to 90% of PCs that meet platelet count standards in January to February 2016. The study also found that the rate of platelet count increment in patients after PCs transfusion increased from 5 x 10^9 per ml to 9 x 10^9 per ml after the study. Additionally, the repeated PC transfusion rate decreased from 22% to 18%. Achievements were successfully maintained after the study which was 89% in March to April 2017. Continuous monitoring need to be carried out to ensure the achievement remains in compliance with the established standards. This quality improvement method has facilitated successful platelet transfusion to patient by improving the quality and performance of PCs. The improvement strategies of this study have the potential to be implemented at other blood collection centers in order to improve the quality of healthcare services.

KEYWORDS: Platelet concentrate, cold chain, quality improvement

Problem

In our Blood Transfusion Unit, QC tests were conducted every month to assess the quality of PCs. These QC tests illustrate function and effectiveness of PCs transfusion to patients. Among the parameters evaluated were platelet count, residual leukocyte, pH value and sterility. All quality parameters of the PCs in our Blood Transfusion Unit had achieved the minimum standards except for platelet count parameter, which repetitively did not meet the standard since 2010. Only 30% of PCs had achieved the standard platelet count for QC tests in March and April 2015. A verification study conducted in May 2015 also found that only 40% of PCs achieved specified platelet standard count of more than 60 x 10^9 per unit. According to the "Transfusion Practice Guidelines for Clinical and Laboratory Personnel" 3rd Edition by the National Blood Centre, at least 75% of the tested platelets must contain platelet count more than 60 x 10^9 per unit (1). Average platelet count increment per unit PC transfused was at minimum level which is 5,000/mL only.

Our Blood Transfusion Unit is a clinical support unit in the Sultanah Nur Zahirah Hospital (HSNZ) located in the district of Kuala Terengganu on a 21.09 hectare with population of 343,284. HSNZ is a state general hospital and acts as a reference hospital for district hospitals and health clinics throughout the state of Terengganu with a total population of 1,207,700.

The Blood Transfusion Unit play an important role in supplying blood and blood components to patients who were in need. Our Unit processed about 4,500 units of PCs per year. We provided PCs not only for HSNZ patients, but also for all district hospitals in Terengganu. The Blood Transfusion Unit consisted of 43 members led by a transfusion physician and assisted by medical officers, science officers, medical laboratory technologists, assistant medical officers, trained nurses, assistant information officers and other support officers. Additionally we provided clinical and consultative diagnostic services pertaining to transfusion service in ensuring accurate treatment was given to the patients.

The aim of this study was to increase the percentage of PCs that meet the platelet count standard to more or equal to 75% within a year.

Background

The normal concentration of platelets in the blood is between 150 to 400 x 10^9/L and their main function is to promote a haemostatic surface in blood vessels (primary haemostasis) following the events of vasoconstriction, adhesion, secretion, and platelet aggregation. The PCs are used for the treatment and prevention of bleeding in patients with reduced platelet number or function for example in acute treatment of thrombocytopenia. PCs transfusions are a lifesaving adjunct to control and prevention of bleeding in cancer, hematologic, surgical, and trauma patients.

The PC supplied must meet the specified quality control (QC) test standards to ensure its therapeutic effects. PCs that do not meet QC standards will reduce the effectiveness of treatment and increase repeated PCs transfusion. Therapeutic effects were determined by the quality of PCs which were largely affected by preparation method and storage conditions such as duration taken from collection to processing, type of storage container, and storage solution (plasma or an additive solution) (2). The recommended shelf life of PCs in presently available platelet storage bags is 5 days. The yield of platelet also depend on the donor's platelet count. However, at the time of the study, there was no policy requiring platelet count measurement before blood donation, so the donor platelet count factor would not be addressed in this study (3).

It is important to understand the standard method of platelet preparation for clinical use and how they differed from the preparation for use as research samples in clinical chemistry. The separation of platelets from whole blood was based on the

differential densities of the various cellular elements when blood was subjected to defined centrifugation forces. The protocols for the preparation of platelets relied on this characteristic, including those used by blood transfusion services for the preparation of platelet concentrates (PCs) for clinical use. A quality monitoring programme (QMP) for PCs was implemented to improve standards and to better understand platelet products by performing routine quality control (QC). Randomly selected PCs were sent to a laboratory and tested on platelet count, residual leucocytes, pH, and sterility preferably on the day after the expiry date of the PCs. This quality check on components prepared from whole blood donations focused on the product's safety and compliance with regulatory standards (4).

Measurement

The general objective of the study was to increase the percentage of PCs that met the platelet count standard to more or equal to 75% within one year. The standard of 75% was in accordance with the Transfusion Practice Guidelines of Clinical and Laboratory Personnel (3rd edition 2008) by the National Blood Center. The specific objective was to identify the causes of platelet count not meeting the standards set. The study was also conducted to suggest and implement improvement strategies and subsequently evaluate the effectiveness of the strategies.

The indicator in this study was the percentage of PCs that met the specified platelet count standard (more than 60 x 10^9 per unit) calculated using the following formula:

The percentage of PCs that met the standard platelet count

$$= \frac{Number\ of\ PCs\ containing\ more\ than\ 60\ x\ 10^9\ per\ unit\ platelet\ count}{Number\ of\ PCs\ sampled\ in\ monthly\ QC\ test}\ x100\%$$

This indicator was collected monthly by our science officer using a standard QC format. Any expired PCs can be sampled for the monthly QC test but PCs with visible red blood cell contamination or leaked blood bags were excluded. A minimum 10 PCs were selected for the monthly QC check and full blood count (FBC) test was performed preferably on the day after the expiry date of PCs. The specified standard for platelet count was the count must be more than 60 x 10^9 per unit.

Verification study conducted in May 2015 found that only 40% PCs achieved specified platelet standard count of more than 60 x 10^9 per unit.

Initial Assessment of the Problem

Blood collected from blood donation mobile session or walk-in donor at HSNZ were brought to the laboratory for processing. Upon arrival at the laboratory, the blood bag was weighed. If it met the criteria of weight (within the normal range) and the blood collection time did not exceed 12 minutes, the PCs were produced. Otherwise, PCs will not be produced from the blood bag. The resulting PCs were weighed and stored until used or expired.

The processes involved in platelet concentrate production were as in Figure 1. Some contributing factors had been identified such as less efficient blood temperature monitoring system (blood cold chain system), non-optimal equipment performance such as blood bags spring scales and refrigerated centrifuges machine as well as under competent staff.

The results from preliminary study found that there were some problems in certain processes such as:

1. The blood cold chain is a system for storing and transporting blood and blood products within the correct temperature range (20-24°C) and conditions, from the point of collection from blood donors to the point of transfusion to the patient. Among the problems identified in cold chain implementation were inconsistent blood box temperature monitoring, inadequate storage due to blood

collection exceeding the target, suboptimal ice packs preparation during blood donation session, improper transportation and storage of triple and double bags blood and untrained staff.
2. The condition and performance of the refrigerated centrifuged machine used to produce PCs was non optimal.
3. Only 50% of spring weighing scale verification activities were carried out. The spring weighing scale used for weighing blood bag should be verified every 3 months and standard performance was at least 90%.
4. Non-standardised PCs processing methods and QC test sampling techniques were also found contributing to this problem as it relied on the staff's skill.

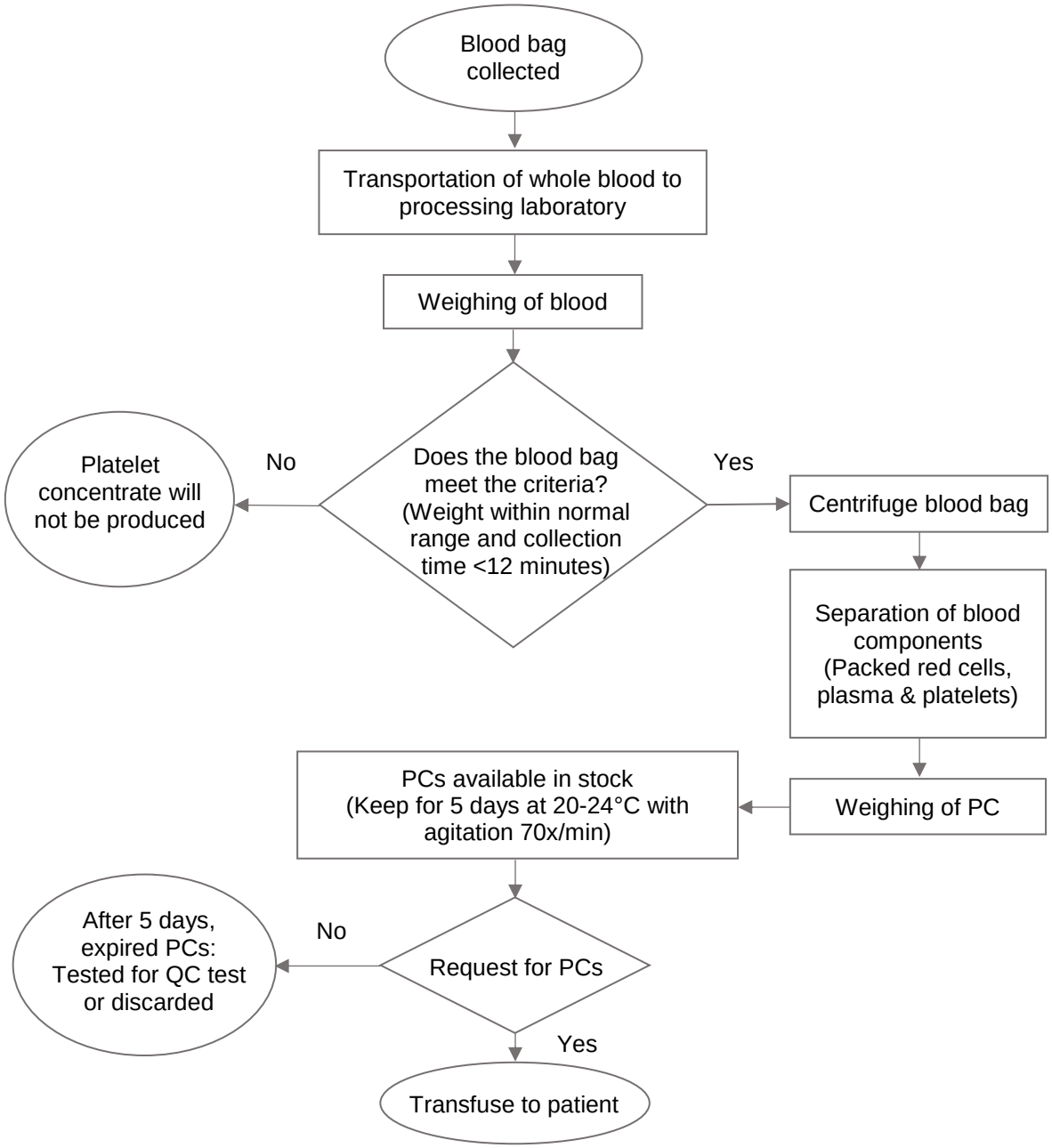


Figure 1: Process of platelet concentrate production.

Strategy for Change

Two phases of remedial actions had been implemented from June until September 2015 (first phase) and in December 2015 (second phase). Each strategy was implemented to address the identified contributing factors.

a) First phase:

The first step was to improve the blood cold chain monitoring system during the blood donation session and transportation to the laboratory. Transportation for triple blood bags blood collection for platelet processing and double blood bags for whole blood were separated in different blood boxes for proper temperature monitoring. The blood box temperature was strictly monitored for at least every 30 minutes. The type of ice pack used was also changed to a more durable and cold resistant one. Additionally, the Blood Box Temperature Monitoring Record Form had been modified to be more user-friendly, improving staff compliance to temperature monitoring requirement.

Secondly, to improve the accuracy of measured donated blood weight, the spring weighing scale was verified every 3 months. Verification training was conducted to all respective staffs which emphasised on the importance of equipment verification and the correct method of performing verification activities.

The third step of remedial action was to reorganise and optimise manpower involved during blood donation activities. The ratio of blood donor beds to phlebotomist was limited to 2 beds to 1 phlebotomist. If the blood collection target for the mobile session was high, additional staffs from another department would be requested as an additional phlebotomist. In addition, a skilled Medical Laboratory Technologist (MLT) had also been privileged as a phlebotomist. In this way, there were more human resource and less workload during the blood donation process and therefore could maintain the quality of donated blood.

Fourthly, the functional calibration of the refrigerated centrifuge for PCs processing was carried out to ensure it functions optimally and consistently. This was crucial in ensuring good quality PCs preparation. Functional calibration of the refrigerated centrifuge was usually performed in case of machine damage, machine relocation or when poor quality of PCs being produced. The calibration was carried out with several programme settings attempted. Post calibration, the programme on the centrifuge machine had been changed to the new settings and configurations that will give higher platelet count yield.

b) Second phase

A validation test for the ratio of ice packs number to blood bags in the blood box was also carried out. The test was carried out with different number of blood bags, ice pack and temperature logger during the validation process. The result showed that the best sufficient ratio of ice pack ratio to the blood bags was set to 2:1. This information was very crucial in ensuring optimal management of blood bag temperature monitoring during blood donation mobile sessions and transportation to the processing laboratory. Staffs on duty can plan quantity of ice packs needed according to the estimated number of blood donors.

In addition, CME, training and briefing sessions were held regularly to make sure all the strategies and actions were implemented by our staff. A briefing before the blood donation session began was given by a Blood Transfusion Unit staff to any additional staffs involved during blood donation session.

Results

The post-remedial PCs quality control test results had shown that the percentage of PCs that met the platelet count standards had increased from 46% to 56% (Oct – Nov 2015) and to 90% subsequently (Jan – Feb 2016) as shown in Figure 2. This showed that the interventions were successful in increasing the quality of PCs produced in the Blood Transfusion Unit. All other critical steps involved in processing of PCs that were identified in the Model of Good Care had also improved with the implementation of the remedial actions (Table 1).

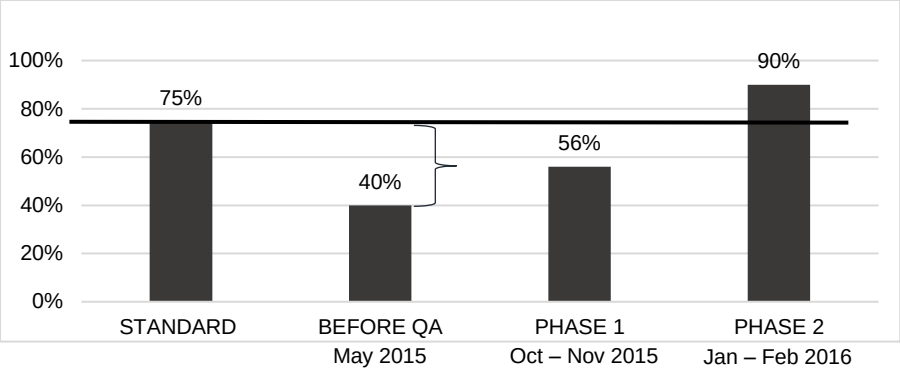


Figure 2: Pre and post-remedial achievements: Percentage of PCs that reached the platelet count standard (more than 60 x 10^9 per unit).

Table 1: Improvement results on MOGC.

Step	Process of Care	Criteria	Standard	Pre - Remedial	Post-Remedial
1.	Blood donation	1. All donors met the blood donation criteria	100%	100%	100%
		2. Blood collection time does not exceed 12 minutes	100%	100%	100%
		3. The blood box temperature at the blood donation site was 20-24°C	90%	81%	91%
2.	Transportation to the processing laboratory	The transportation temperature from the collection site to the processing laboratory was 20-24°C	90%	81%	91%
3.	Weighing the blood bags	1. Blood bags' weight falls within the normal range.	95%	89%	92%
		2. The verification of spring weighing scale was carried out every 3 months	100%	50%	100%
4.	Component processing	1. Processing done within 24 hours after donation (preferably within 12 hours)	100%	100%	100%
		2. Using refrigerated centrifuge machine that has been validated on the optimum program setting	Optimum	Not optimum	Optimum
		3. Separation of blood components: Platelets were separated into satellite bag	95%	90%	95%
5.	Weighing the platelet	Complied with specified weight/volume range (50-70ml)	95%	93%	98%
6.	Storage of platelet bags	Storage temperature at 20-24°C, agitation 70x/min, arranged on a single layer (no overlapping) and kept for 5 days only	100%	100%	100%

This notable improvement was also demonstrated in increment of patients' platelet count post PCs transfusion. The expected platelet count increment after transfusion of one unit of PC was from 5 to 10 x 10^9/ml. Analysis on the increment of platelet count in post-PCs transfusion patients before and after remedial actions were taken had increased from 5 x 10^9/ml to 9 x 10^9/ml. This illustrated that the quality of the PCs had improved hence improving therapeutic effect of PCs transfusion in reducing patient's morbidity. Repeated transfusion rate for PCs components had also decreased from 22% before the remedial actions to 18% post-remedial. The reduction of repeated PCs transfusion rate benefited the patients as it can reduce the risk for infection of infectious diseases (HIV, Hepatitis B, Hepatitis C and Syphilis) and transfusion reactions such as allergy and others. The staff workload in the blood transfusion unit could also be decreased with the reducing number of repeated request of PCs. In addition, high platelet quality would be expected to result in improved clinical efficacy, determined by count increment, improved haemostasis, and lower risk for adverse reactions in recipients.

Lessons and Limitations

It was evident from this study that proper management of blood cold chain system and standardisation of all procedures involved in preparation and processing of PCs were very crucial in ensuring quality of PCs. Besides, full commitment from the staffs and top management in achieving organisation's target was a foundation in overcoming long standing problem.

We still did not manage to ensure more than 95% of collected blood bag in mobile session within the desired weight. The mechanical spring scales that were being used to weigh the blood bag during blood donation might not accurate enough and subject to user handling variance. Delay in clamping the blood bag tubing especially in crowded and big target mobile session will also lead to overweight blood bag. A better option to prevent overweight blood bag is by using automated blood mixer. The machine will mix and weigh the blood bag continuously and will clamp the blood bag tubing automatically once the desired weight is achieved.

Conclusion and the Next Steps

From the study, it can be concluded that the implementation of appropriate and effective improvement measures could result in better output. All members of the unit need to be committed in ensuring the continuity of the improvement measures. Achievements were successfully maintained after the study which was 89% in March to April 2017 (mean 78 x 10^9 per unit).

Despite not all remedial actions achieved the pre-determined standard, the QC of PCs has been met. The use of automated blood mixer may help to overcome the remaining hurdle. Proposal to purchase additional automated blood mixers will be submitted to the hospital management.

With such good results and performance, Blood Transfusion Unit HSNZ would become more confident in providing PCs to help care for patients in need. However, in order to improve and maintain achievement, continuous monitoring would be carried out as well as updating procedural guideline with the latest technique. The improvement step of this study had the potential of being shared and implemented at other blood collection and processing centers of PCs to improve the quality of health services.

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Conflict of Interest

None

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None

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