

Assessment of the Productivity Features and Analysis of the Quality Parameters from the Control Units Processed Using a Semi-Automated, Buffy Coat Method, in a Colombian Blood Bank Center

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Introduction

The assessment of product quality parameters and operational procedures among healthcare and blood bank centers has increased in recent years. Understanding the insights and differences among medical devices and procedures to optimize the outcomes is needed.^{[1][2][3][4]}

Objectives

The aim of this study is to analyze and review multiple product quality parameters from the control units processed in LaCardio Blood Bank Center (BBC), located in Bogotá, Colombia, using a semi-automated, buffy coat method.

In addition, this study aims to perform in LaCardio BBC a value stream mapping on the semi-automated, blood processing system (using the buffy coat method) to better understand the multiple manual steps that operators are required to perform as well as the timings from each one of them.

Methods

We performed in LaCardio BBC a value stream mapping of its semi-automated, blood processing system. The mapping included the listing and timing of all operator manual steps, as well as the assessment of productivity and management bottlenecks, and the feasibility of LaCardio BBC to increase the quantity of processing cycles using the current semi-automated, blood processing system.

The technologies used were the separator CompoMat® 5G (Fresenius Kabi) and the centrifuge Sorvall® RC 12BP X-23 T4 (ThermoFisher Scientific), as well as other minor equipment such as the sealer Hematron® (Baxter).

In addition, we performed a retrospective analysis of 9 product quality parameters from the control units processed in LaCardio BBC between 1st January 2020 and 30th September 2022. The same semi-automated, blood processing system and medical technologies were used throughout the timeframe.

Visual charts were developed to portray the outcomes.

Results

Between January 1st, 2020, to September 30th, 2022, quality parameters from 671 control units from LaCardio BBC, processed with the semi-automated, buffy coat method, were analyzed.

As shown in Table 1, the averages from whole blood units' parameters were: volume (477,4±8,8ml); leukocytes (2,8±0,7×10⁹/L).

The averages from red cell concentrates' parameters were: volume (298,6±27,7ml); hematocrit (59,5±2,8%); hemoglobin (20,4±1,1g/dl).

The average volume from plasma units was 248,3±33,8ml.

The averages from platelet units' parameters were: volume (60,8±5,9ml); leukocytes (0,019±0,013×10⁹/L); platelets (86,5±19,8×10⁹/L).

From the value stream mapping, 59 operator manual interventions were registered and timed.

Table 2 shows all the interventions as well as the time required for each one of them.

Productivity bottlenecks were found related to daily delivery schedule of whole blood units, available room space, quantity of manual interventions and required operators, current software program to register the data, operator training and experience, and type of whole blood processing system.

Conclusions

Quality parameters from control units processed in LaCardio BBC between January 1st, 2020, to September 30th, 2022, have maintained similar levels and comply with international guidelines and Colombian national regulations on whole blood products. At the same time, more automatized whole blood processing systems could optimize the standardization process, decreasing the standard deviation, and increasing the quantity for selected parameters such as hematocrit, hemoglobin, volume, platelets, etc.

In addition, considering that their current method requires multiple manual interventions that can lead to errors, limits productivity and scalability, and, due to training requirements, is operator dependent, other blood processing systems could improve these elements.

Acknowledgments

We thank all the employees from LaCardio BBC, and especially Luis Eduardo Duarte, nurse assistant and whole blood processing operator, for their support and assistance throughout the control units' data gathering and the performance of the value stream mapping.

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		Semi-automated processing system	
Product	Parameters	Average	Standard Deviation
Whole Blood unit			
	Volume (mL)	477,4	8,8
	Leukocytes (count/U)	2,8E+09	7,0E+08
Red Cell Concentrate			
	Volume (mL)	298,6	27,7
	Hematocrit (%)	59,5	2,8
	Hemoglobin (g/dL)	20,4	1,1
Plasma concentrate			
	Volume (mL)	248,3	33,8
Platelet unit			
	Volume (mL)	60,8	5,9
	Leukocytes (count/U)	1,9E+07	1,3E+07
	Platelet (count/U)	8,7E+10	2,0E+10
	pH	7,0	0,1

Table 1. Parameters' average and standard deviation from each product control unit processed using a semi-automated, buffy coat method during 1st January 2020 to 30th September 2022.

Manual operator steps	LaCardio BBC		
	Blood units	Minutes	Seconds
Measure the temperature from the bags and/or box	1	0	3
Write down the temperature measurement	1	0	2
Check that donor questionnaires match the whole blood bags delivered and that they are correctly filled	1	0	5
Prepare and remove objects from the processing table	NA	1	0
Clean and disinfect the processing table	NA	1	0
Place the whole blood bags on the processing table	4	1	0
Open the excel file to fill it with the data from the blood bags	NA	0	10
Scan the whole blood bags	1	0	2
Weigh the whole blood bags	1	0	5
Write down the weigh on the same blood bags	1	0	3
Fill in the excel file the weigh of each blood bags	1	0	3
Extract the baskets from the centrifuge	2	0	5
Put the whole blood bags in the baskets	1	0	10
Weigh the baskets	1	0	5
Balance the baskets with tiny plastic pieces	2	0	25
Switch on the centrifuge (Sorvall RC 12BP X-23 T4 from ThermoFisher Scientific)	NA	0	10
Place the baskets in the centrifuge	2	0	10
Close the centrifuge cover	NA	0	2
Select the centrifuge protocol	NA	0	7
Click start for the centrifugation process	NA	0	1
Centrifugation process* (up to 3500RPM)	NA	12	0
Centrifuge deceleration process*	NA	9	30
Switch on the separator (Compomat 5G from Fresenius)	NA	0	20
Open the calibration excel file to register the separator calibration data	NA	0	20
Calibrate the separator (once a day)	NA	1	0
Fill the calibration excel file with the calibration data	NA	0	15
Open the centrifuge cover after the centrifugation is over	NA	0	2
Place the blood bags into the separator	1	0	45
Scan the blood bag, the separator, and the operator tag	1	0	3
Select the separator procotol	1	0	6
Click start for the separator process	1	0	1
Separation process*	1	6	0
Extract the fraccionated bags from the separator	1	0	10
Place the plasma on the processing table	1	0	5
Hang the red cell concentrate (RCC) for the filtration process	1	0	5
The RCC remains hanged for the filtration process during 16 minutes*	1	16	0
Hang the buffy coat	1	0	10
The buffy coat remains hanged during 2 hours*	1	120	0
Remove the RCC from the hanger and place it on the table	1	0	5
Seal the RCC to detach it from the filter and the previous bag	1	0	5
Perform a stripper to the RCC	1	0	10
Seal the RCC tubes with Hematron from Baxter to have 4 control pilots	1	0	10
Place the two tubes from the RCC at each side of the bag for a proper storage	1	0	20
Remove the buffy coat from the hanger	1	0	5
Agitate the buffy coat	1	0	10
Place the buffy coat into the centrifuge baskets	1	0	15
Weigh the centrifuge baskets	2	0	5
Balance the weigh among centrifuge baskets with tiny plastic pieces	2	0	15
Place the centrifuge baskets into the centrifuge	2	0	5
Close the centrifuge cover	NA	0	2
Select the centrifuge protocol	NA	0	7
Click start for the centrifugation process	NA	0	1
Centrifugation process* (up to 1100RPM)	NA	10	0
Centrifuge deceleration process*	NA	8	30
Open the centrifuge cover after the centrifugation is over	NA	0	1
Place the buffy coat into the separator	1	0	40
Scan the blood bag, the separator, and the operator tag	1	0	3
Select the separator procotol	1	0	6
Click start for the separator process	1	0	1
Separation process to get platelets (part 1: buffy coat separation) *	1	0	45
The separator stops and the operator needs to manually extract the air bubbles from the platelet bag	1	0	20
Click continue for the separator process	1	0	1
Separation process to get platelets (part 2: weigh the platelet bag and seal it) *	1	0	10
Extract the buffy coat and discard it	1	0	5
Extract the fraccionated platelet bags from the separator and place them on the processing table	1	0	5
Register the platelet unit in the excel file scanning the bar	1	0	5
Place the platelet bag on a shelf	1	0	10
The platelet bag remains on a shelf during 2 hours*	1	120	0
Place the platelet bag into the platelet shaker	1	0	30
The platelet bag remains on the platelet shaker during 24 hours*	1	1440	0
Total manual steps	59		

Table 2. Value stream mapping of all operator manual interventions for the semi-automated, blood processing system. *Step where the operator needs to wait until the process is completed.