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# Latin American experience with blood component's quality control obtained by buffy coat method

Dalia María Moreno Cardona, Ludwig Frontier, Ignacio Álvarez, Yolanda Ibarra, Yazmín Morales, Alicia Alvarado, Karin Martínez, Nohora Cristancho, Mary Rolón, Zuly Hernández

## ABSTRACT

**Aims:** To explore the compliance with European standards for the quality control (QC) parameters of blood components production in Latin American blood banks, evaluating QC data results processed with red blood cell (RBC), and platelet concentrates (PL) produced.

**Methods:** An observational retrospective cross-sectional study was conducted with data from one year's production QC data of platelet concentrate (PL) from the buffy-coat (BC) removal method. Red blood cell was collected in three blood banks from Mexico, Colombia, and Chile. Analysis of the quality limits established in each country was made using Pearson's Chi-square test. Dunnett's T3 test evaluated the comparative analysis of the mean. All the tests were performed with bilateral contrast, achieving statistical significance when  $p \leq 0.05$ .

**Results:** The mean of the total results for the RBC evaluated was volume  $277 \text{ mL} \pm 21$ ; hematocrit (HCT)

$58.7\% \pm 3.6$ ; leukocytes ( $\times 10^9/\text{mL}$ )  $0.47 \pm 0.31$ . Results for PL were volume:  $67 \pm 10$ ; platelet count ( $\times 10^9/\text{mL}$ ):  $76.8 \pm 24$ ; leukocytes ( $\times 10^9/\text{mL}$ )  $0.02 \pm 0.02$ . According to these total results, the compliance with respect to the control performed was for RBC: Volume 97.9%; hematocrit 98.8%; leukocytes 97%. For PL was 100% for volume; platelet count 82.3%; leukocytes 95.3%.

**Conclusion:** The QC results conclude that the RBC with the BC removal process produces high-quality components, with a reduced concentration of leukocytes, complying with European Union (EU) guidelines and allow to obtain single platelet from BC with high quality.

**Keywords:** Blood bank, Latin America, Platelets concentrate, Quality control, Red cell concentrates

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## INTRODUCTION

Quality control (QC) in Latin American countries' blood components has significantly impacted recent years. From the Pan American Health Organization (PAHO), quality standards were created in 1999 to contribute to Latin America's blood safety [1]. The purpose of the standards is to provide safe blood for patients requiring transfusion therapy.

The blood component's QC in blood banks has become a tool to monitor products' production and ensure compliance with local and international standards [2]. In recent years, significant advances have been observed to improve the quality of blood components, including advances in international standards for the preparation of blood products, redefining the principles for high-quality production practices, establishing new parameters and reference values to guarantee quality in blood banks [3].

Unfortunately, establishing a quality control program and implementing it in blood banks, especially in Latin America, are not easy. There is still no clarity in the regulations to carry out this objective in several regions.

Therefore, it will be interesting to share the experience of three blood banks from Latin American countries: Banco de Sangre de Córdoba (Colombia), Centro de Sangre Valparaíso (Chile), and Banco de Sangre UMAE Puebla (Mexico), which have more than two years controlling the production of blood components through its quality control programs, welcoming compliance with local regulations in each country.

The production of red blood cells (RBCs) and platelet concentrates (PLs) in the three centers evaluated is similar, since the collection and processing of whole blood are aimed at obtaining RBC BC removed in additive solution (SAGM), PL from BC and plasma. These three institutions have been using Maco Pharma systems to obtain the mentioned blood components (Top and Bottom (T&B) Quadruple Bag MQT6285LS) for more than three years.

Colombian blood banks must comply with local regulations, established in the Manual of Technical Standards, administrative, and blood banks (Decree 1571/93) [4]. In 2012, Colombia's National Institute of Health (NIH) published a technical document detailing the country's quality control values compiled by all blood production centers [5]. Mexican blood banks must comply with the standards protocol established in the Official Mexican Standard NOM-253-SSA1-2012 to dispose of

human blood and its components for therapeutic purposes [6]. Chilean institutions are supervised by the Ministry of Health, which in 1983 published the Standards for Blood Banks [7]. They establish the parameters to be followed to guarantee the adequate quality of the blood components produced in the country (Tables 1 and 2).

## MATERIALS AND METHODS

### Study design

An observational retrospective cross-sectional study was conducted with QC data of PL and RBC collected from three Latin American centers: Banco de Sangre UMAE—Puebla, Mexico, located in the city of Puebla (Calle 7 Sur 1510, Centro, 72000 Puebla, Pue., Mexico), collecting an average of 25,000 donors/year, and one of the most important IMSS (Instituto Mexicano de Seguro Social) institutions in this state; Banco de Sangre de Córdoba, Colombia, located in Montería city (Cra. 6 #26-08, Montería, Córdoba), with an average collection of 18,000 donors/year; and Centro de Sangre Valparaíso, Chile, located in the city of Valparaíso (Blas Cuevas 985 Subida, El Litre, Valparaíso, Chile), which collects approximately 48,000 donors/year.

The centers were chosen, taking into account that all three have similar processing methods, especially for obtaining platelets and the removal of the BC in the red blood cells with T&B system collection.

Red blood cell production on the three centers was carried out following the protocol for the *Red Cells Buffy-Coat removed in additive solution* [8], with initial hard spin centrifugation for the whole blood, to obtain beside the RBC, the BC removed, and plasma component. Once the BC was separated from white blood cell (WBC), platelets were obtained doing soft spin centrifugation, to comply with the steps to produce *platelet, recovered, single units* [8] (Table 3).

Table 1: Quality criteria required for RBC according to each institution

Parameter	Red blood cells without buffy-coat in additive solution			
	INVIMA (Colombia)	COFEPRIS (Mexico)	MINSAL (Chile)	EDQM (EU Standard)
Volume	250–350 mL	250–350 mL	280 ± 60 mL (220–340 mL)	To be defined for the system used
Hematocrit	50–70%	50–70%	50–70%	50–70%
Hemoglobin	N/A	>43 g/U	>43 g/U	>43 g/U
Leukocytes	<1.2 × 10 <sup>9</sup> /U	<1.2 × 10 <sup>9</sup> /U	<1.2 × 10 <sup>9</sup> /U	<1.2 × 10 <sup>9</sup> /U
Hemolysis	N/A	<0.8%	N/A	<0.8% of red cell mass
Culture	Negative	Negative	N/A	Negative
Frequency	1% or 4 U	4 U min monthly	1% monthly	1% monthly

Table 2: Quality criteria required for platelet concentrates according to each institution

Platelet concentrates				
Parameter	INVIMA (Colombia)	COFEPRIS (Mexico)	MINSAL (Chile)	EDQM (EU Standard)
Volume	50–70 mL	>40 mL	Locally define	>40 mL per $60 \times 10^9$ of platelets
Platelet count	$>5.5 \times 10^{10}/U$	$>6.0 \times 10^{10}/U$ (90%)	$>55 \times 10^9/U$ (75%)	$>60 \times 10^9/U$
pH	6.2–7.4	6.4–7.4	6.4–7.4	>6.4
Residual WBC	$<0.5 \times 10^8/U$	$<0.05 \times 10^9/U$	$<0.5 \times 10^8/U$ (75%)	$<0.5 \times 10^8/U$
Culture	Negative	Negative	Negative	Negative
Frequency	1% monthly or 4 U	1% or 10 U	1% or 10 U	1%

Table 3: Centrifugation parameters

Center	Hard spin g force	Hard spin time	Soft spin g force	Soft spin time
Mexico	4.348 g	12 min	335	7 min
Colombia	3.562 g	10 min	321	5 min
Chile	4.068 g	13 min	269	7 min

Data corresponding to one year of production was consolidated and analyzed. The study parameters seek compliance with European standards for RBC: Leukocytes count  $<1.2 \times 10^9/mL$ ; hematocrit  $>52\%$ . For platelets: cell count  $>60 \times 10^9/mL$ , leukocytes  $<0.5 \times 10^8/mL$  [8].

### Inclusion and exclusion criteria

Being a retrospective and observational study, we didn't have exclusion criteria, since all the QC data collected was included into the analysis.

### Laboratory tests

Each center performed the cellular count for QC with the following hematology analyzers:

Mexico: Swelab Alfa Standard—Boule Diagnostics (Spånga, Sweden)

Colombia: ABX Micros ES60—HORIBA Medical (Minami-ku, Kyoto, Japan)

Chile: Beckman Coulter FC500, Beckman Coulter (Brea, California)

### Statistical analysis

Pearson's Chi-square test analyzed the quality control parameters established in each country. The comparative analysis of the mean values in all centers

was performed using Dunnett's T3 test. All the tests were performed with bilateral contrast, considering the differences statistically significant when the error type was  $\leq 0.05$ .

The number of cases, the arithmetic mean, the standard deviation, the median, the 95% confidence interval, and the minimum and maximum values were obtained from all the quantitative parameters evaluated in this statistical analysis.

### RESULTS

The analyzed sample (N) was 1402 RBC, distributed by countries: Colombia 308 (22%), Chile 864 (61.6%), and Mexico 230 (16.4%). The total sample for platelet concentrates was 1245 units, distributed: Colombia 308 (24.7%), Chile 695 (55.8%), and Mexico 242 (19.4%).

The total compliance criteria of RBC for each parameter in all countries were Volume, 97.9%; HCT, 98.8%; Hb, 96.0 (only for Mexico and Chile), WBC, 97%. This means that the total compliance on RBC concentrates for all center parameters were Colombia, 98.7%; Mexico, 86.5% and Chile, 90.6%; for 91.7% (see Table 4).

Platelet concentrates compliance criteria for each parameter in all three countries were Volume, 100%; platelet

Table 4: Compliance in red cell concentrate by parameter and center

RBC Buffy Coat layer removed				
Parameter	Country			Total
	INVIMA (Colombia)	COFEPRIS (Mexico)	MINSAL (Chile)	
Volume	304 (98.7%)	204 (84.3%)	864 (100.0)	1.372 (97.9%)
Hematocrit	308 (100.0%)	228 (99.1%)	849 (98.3%)	1.385 (98.8%)
Hemoglobin	N/A	221 (96.1%)	829 (95.9%)	1.050 (96.0%)
Leucocytes	308 (100.0%)	225 (97.8%)	826 (95.6%)	1.360 (97.0%)
<b>All criteria</b>	<b>304 (98.7%)</b>	<b>199 (86.5%)</b>	<b>783 (90.6%)</b>	<b>1286 (91.7%)</b>

count, 82.3%; pH, 99.2% (only for Colombia and Chile); WBC, 95.3%. According to these results, total compliance on platelet concentrates by center were Colombia, 99.7%; Mexico, 87.2%; Chile, 93.8% (see Table 5).

**DISCUSSION**

Daily blood component production faces a critical challenge, consisting of complying with the community’s transfusion needs and providing blood products with the quality required to promote all recipients’ recovery. Over the past two decades, the quality of blood components has improved remarkably, due to technological advances looking to optimize the collection and processing steps, guides, and manuals of world-renowned institutions that seek to lay the foundations to work with the necessary standards in all the regions [9].

As a characteristic of the Latin American region, it is known that developing countries face considerable obstacles to increase transfusion security. However, there are countries where this tendency has generated its need to adapt and adhere to international standards that, over the years, have proven to be of great help and guidance for the improvement in the production of blood components.

Some Latin American countries have focused on using the T&B methodology, increasing transfusion safety without investing much in resources. Chile, Colombia, and Mexico, in particular, have been adapting their routines toward European standards. This is reflected in local regulations, which are similar to the expected values of the *European Directorate for the Quality of Medicine & Healthcare* (EDQM).

The results of this study show us that three different countries in a region as large as Latin America can implement and carry out a QC program for their production of blood components and find significant similarities in their results, despite the population difference and all that this implies. This outcome reveals that the essential part of achieving these similarities was using a T&B technique: removing the BC layer of RBCs and obtaining platelets from the BC.

An important parameter to verify the quality of the RBC is the HCT value, which for the three countries involved found average values of (%): 60.3 ± 3.1 (Colombia), 57.8 ± 3.6 (Chile), and 59.9 ± 2.9 (Mexico). Results reveal very close values with a similar standard deviation (SD), even though it is essential to highlight that the mean HCT was significantly higher in the centers of Colombia and Mexico than in the center of Chile (p <0.05) (Table 6).

Table 5: Compliance in platelet concentrate by parameter and center

Parameter	Platelet concentrate			
	Country			
	INVIMA (Colombia)	COFEPRIS (México)	MINSAL (Chile)	Total
Volume	308 (100.0%)	242 (100.0%)	Locally defined	550 (100.0%)
Platelet count	307 (99.7%)	136 (82.3%)	582 (83.7%)	1.025 (82.3%)
pH	308 (100.0%)	N/A	687 (98.8%)	995 (99.2%)
Leucocytes	308 (100.0%)	218 (90.1%)	660 (95.0%)	1.186 (95.3%)
<b>All criteria</b>	<b>307 (99.7%)</b>	<b>211 (87.2%)</b>	<b>652 (93.8%)</b>	<b>1.170 (94.0%)</b>

Table 6: Comparative analysis of parameters evaluated in RBC

Parameter	Country	N	Mean ± SD	Median	95% Confidence Interval		Minimum	Maximum	ANOVA p-value
					Lower bound	Upper bound			
					Volume	Colombia*			
Chile	864	273 ± 20	271	272		274	221	338	
Mexico	230	271 ± 17	272	269		273	198	325	
Total	1402	277 ± 21	276	276		278	198	338	
Hto	Colombia	308	60.3 ± 3.1	60	60	60.7	50.7	69.5	< 0,001
	Chile*	864	57.8 ± 3.6	57.6	57.6	58	42.4	75.6	
	Mexico	230	59.9 ± 2.9	59.9	59.5	60.2	49.3	69.4	
	Total	1402	58.7 ± 3.6	58.7	58.5	58.9	42.4	75.6	
WBC	Colombia	308	0.47 ± 0.20	0.47	0.45	0.49	0.08	1.15	< 0,001
	Chile	864	0.50 ± 0.33	0.43	0.48	0.53	0	2.19	
	Mexico*	230	0.36 ± 0.34	0.27	0.32	0.41	0	2.73	
	<b>Total</b>	<b>1402</b>	<b>0.47 ± 0.31</b>	<b>0.42</b>	<b>0.46</b>	<b>0.49</b>	<b>0</b>	<b>2.73</b>	

\* p < 0.05 in comparison with the other centers (post-hoc analysis, Dunnett's test)

On the other hand, the residual leukocytes analyzed met 97% of the expected values in all countries ( $<1.2 \times 10^9/\text{mL}$ ), which indicates a production method that favors the quality of red blood cells. Detailing each result, we found that the average leukocyte count in red blood cell concentrates was significantly lower in Mexico's institution than Colombia and Chile's blood banks ( $p < 0.05$ ) (Table 6).

The production of platelet concentrates can vary according to the preparation standards and methodology that each country establishes. However, compliance with

the platelet count of 82.3% was achieved in the three institutions, which is the expected value in the local regulations of  $>55 \times 10^9/\text{mL}$  for all three countries.

According to the results, we can conclude that the mean platelet count was significantly lower in Mexico's blood bank than in Colombia and Chile ( $p < 0.05$ ). In addition, the residual leukocytes evaluated in platelets concentrate were also complying with local standards. The mean residual leukocyte count in platelet concentrates was significantly lower in Colombia than Chile and Mexico ( $p < 0.05$ ) (Table 7).

Table 7: Comparative analysis of parameters evaluated in platelet concentrate

Parameter	Country	N	Mean ± SD	Median	95% Confidence Interval		Minimum	Maximum	ANOVA p-value
					Lower bound	Upper bound			
Volume	Colombia*	308	61 ± 5	61	61	62	50	70	p < 0.001
	Chile*	695	66 ± 9	65	65	66	44	104	
	Mexico*	242	78 ± 9	78	76	79	51	141	
	Total	1245	67 ± 10	65	66	68	44	141	
Platelet count	Colombia	308	80.31 ± 17.20	76.72	78.38	82.24	55	153.03	p < 0.001
	Chile	695	79.95 ± 26.11	79.78	78.01	81.9	20.75	251.09	
	Mexico*	242	63.22 ± 20.30	62.02	60.65	65.79	18.48	138.52	
	Total	1245	76.79 ± 24.04	75.68	75.45	78.13	18.48	251.09	
WBC	Colombia*	308	0.01 ± 0.01	0.01	0.01	0.01	0	0.04	p < 0.001
	Chile*	695	0.02 ± 0.02	0.02	0.02	0.02	0	0.33	
	Mexico*	242	0.02 ± 0.04	0.01	0.02	0.03	0	0.22	
	<b>Total</b>	<b>1245</b>	<b>0.02 ± 0.02</b>	<b>0.01</b>	<b>0.02</b>	<b>0.02</b>	<b>0</b>	<b>0.33</b>	

\* p < 0.05 in comparison with the other centers (post-hoc analysis, Dunnett's test)

## CONCLUSION

According to the QC results for three different countries included in this evaluation, we can conclude that the RBC with BC processing allows obtaining high-quality components, with a reduced concentration of leukocytes, complying with international standards (EU guidelines), which adds significant value in emergency transfusion situations, especially in countries with little experience using this type of processing.

It is also important to mention the results obtained by single platelet methodology preparation (from BC), which also complying with EDQM standards, demonstrating that this component is the right showed an excellent choice for transfusion therapy, and superior to other techniques still in used [10].

The results prove that by working with similar techniques, it is possible to obtain comparable values for blood components with quality in compliance with local and international standards, such as the data analyzed from the three countries mentioned in this article. It is also essential to highlight the importance of quality control

programs in preparing blood components throughout the region, which will favor the adequate standardization of all countries' implementation processes.

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### Author Contributions

Dalia María Moreno Cardona – Conception of the work, Design of the work, Acquisition of data, Analysis of data, Interpretation of data, Drafting the work, Revising the work critically for important intellectual content, Final approval of the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

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**Conflict of Interest**

Authors declare no conflict of interest.

**Data Availability**

All relevant data are within the paper and its Supporting Information files.

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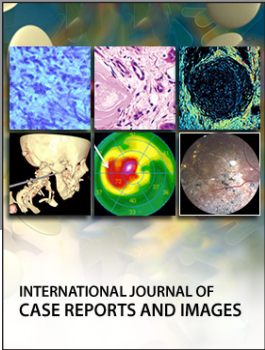
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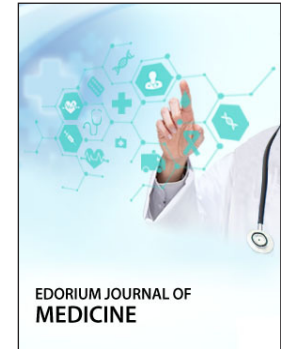
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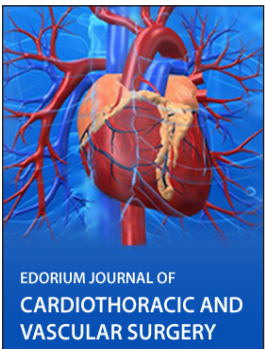
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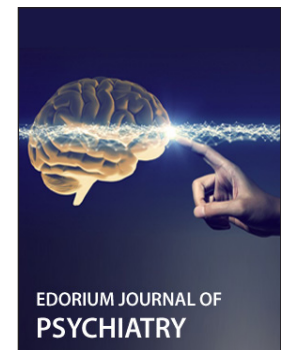
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