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Routine results of an algorithm for managing the production of blood components

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Abstract

Background and Objectives: The variability in the number of donations together with a growing demand for platelet concentrates and plasma-derived medicines make us seek solutions aimed at optimizing the processing of blood. Some mathematical models to improve efficiencies in blood banking have been published. The goal of this work is to validate and evaluate an algorithm's impact in the production of blood components in the Blood and Tissues Bank of Aragon (BTBA).

Materials and Methods: A mathematical algorithm was designed, implemented and validated through simulations with real data. It was incorporated into the fractionation area, which uses the Reveos® fractionation system (Terumo BCT) to split blood into its components. After 9 months of daily routine validation, retrospective activity data from the Blood Bank and Transfusion Services before and during the use of the algorithm were compared.

Results: Using the algorithm, the outdating rate of platelet concentrates (PC) decreased by 87.8% in the blood bank. The average shelf life remaining of PC supplied to Transfusion Services increased by almost 1 day. As a consequence, the outdating rate in the Aragon Transfusion Network decreased by 33%. In addition, extra 100 litres of plasma were obtained in 9 months.

Conclusions: The algorithm improves the blood establishment's workflow and facilitates the decision-making process in whole blood processing. It resulted in a decrease in PC outdating rate, increase in PC shelf life and finally an increase in the volume of recovered plasma, leading to significant cost savings.

Keywords

algorithm, optimization, platelet concentrate stocks, whole blood management

Highlights

- In recent years, there has been an increasing demand for platelet concentrates and a shortage of plasma for the production of plasma-derived medicines in some countries.
- Automation contributes to improving the productivity, efficiency and quality of blood components.
- The incorporation of mathematical algorithms can help address the challenging task of managing blood components production.

INTRODUCTION

The mission of blood establishments is to provide timely supply of the products required by Transfusion Services. Moreover, whole blood (WB) fractionation must be optimized to minimize waste and obtain blood components with the highest quality and safety possible. To achieve this goal, blood establishments face two problems: the rising demand for platelet concentrates (PC) [1, 2] and the insufficient collected volume of plasma to satisfy the current need for plasma-derived medicines [3].

PC is a blood component with short shelf life (a maximum of 5 days, extendable to 7 if a bacterial detection method is used or it is treated with a pathogen reduction technology [PRT] [4–6]). This, coupled with a growing and variable demand [7], makes it difficult to achieve a balance between sufficient supply and minimum outdating.

Many methodologies have been reviewed [8] and can be used by PC inventory managers to reduce the level of outdating. Some publications discussed the use of mathematical models to reduce the expiry of PC [9–12], showing that if the PC are subjected to PRT, its shelf life can be extended by 2 days and almost entirely eliminate the outdating rate [13].

Furthermore, increasing the total volume of plasma recovered from WB fractionation may be an important step in helping countries achieve self-sufficiency in the production of plasma-derived medicinal products [14]. Spain has a low level of self-sufficiency in plasma for haemoderivatives, leading to a continuous increase of the import of these medicines. In recent years, self-sufficiency has dropped, due to a fall in WB donations arising from the decrease in use of red blood cell concentrates (RBC) in transfusion and the increased use of haemoderivatives (IVIG and albumin) [15].

Reveos® Automated Blood Processing System (Terumo BCT) can process up to four units of WB within 20 min, into two (plasma and RBC; 2C-protocol) or three components (plasma, RBC and interim platelet unit; 3C-protocol) [16, 17]. This decision may be adopted at the time of processing the unit, as the set of bags is the same for all protocols. Both protocols allow for the WB unit to be separated within 2 and 12 h of collection, so called fresh blood, or after overnight hold, for the units collected between 12 and 24 h before the processing [17]. In this way, it is possible to obtain the platelet units needed with the 3C-protocol maximizing the plasma collection with the 2C-protocol [18]. Moreover, this system provides a platelet yield index (PYI) which estimates the platelet count in the interim platelet unit (IPU) containing approximately 30 mL of plasma. In order to make the final PC it is necessary to add additive solution or more plasma [19].

A software called T-Pool IPU select tool selects the units according to ABO/Rhesus blood groups and PYI. It produces PC with a minimum yield [20] in accordance with internal procedures (3.0×10^{11} platelets per unit), national procedures (Committee of Transfusion Accreditation—more than 2.4×10^{11} platelets per unit) [21] and international procedures (European Directorate for the Quality of Medicines & HealthCare—more than 2.0×10^{11} platelets per unit) specifications [22]. Besides, it proposes the number of units (four or five depending on IPUs availability) in each pool.

The Blood and Tissues Bank of Aragon (BTBA) is a public service that collected and processed 41,183 WB units and 2349 apheresis donations (plasmapheresis and plateletpheresis), suppling 6255 PC, 38,515 RBCs and 2083 plasma units in 2023 to 19 Transfusion Services (public and private hospitals) in the region of Aragon (Spain), with more than 1.3 million of inhabitants [23]. The Transfusion Services together with the BTBA compose the Transfusion Network of Aragon.

The BTBA implemented the Reveos system in 2013 and started using the Mirasol PRT (Terumo BCT) [5] in 2015 for improving the safety of platelet transfusions, and since March 2020, all produced PC are treated with PRT, extending their shelf life from 5 to 7 days.

In this scenario, this study presents the results of applying a mathematical algorithm in a blood establishment using Reveos and treating all PC with PRT.

Our objective is to show that a mathematical algorithm for blood processing:

1. Achieves minimum outdating rates of PC while avoiding stock-outs.
2. Gets the highest plasma recovery.
3. Reduces wastage during the process of WB fractionation.
4. Improves the planning of WB collections to avoid blood shortages for PC.
5. Facilitates the delivery of fresher PC to Transfusion Services.

MATERIALS AND METHODS

Mathematical algorithm and data used

To design the mathematical algorithm, the BTBA provided historical data on estimated donations and number of units collected, production of PC, supply of PC to Transfusion Services per day and per hour and PC units transfused and discarded from 1 January 2018 to 30 November 2020. The data were divided into two sets. All data from 2018 were used to design and develop the algorithm, whereas data from 1 January 2019 to 30 November 2020 were used to validate the algorithm through mathematical simulations.

Statistical analyses were carried out on the first dataset to calculate key parameters and identify trends in the data. Then a mathematical algorithm was proposed. The algorithm uses a mathematical model with nonstationary stochastic demand. To design it, the characteristics of the Reveos automatic fractioning system, the collection days, the production days and the expired PC discarded at the end of the day were taken into account. In addition, extraordinary holidays were also considered to avoid the problem of overproduction or insufficient stocks. It automatically adapts to periods of uneven demand and production such as holidays by changing the input parameters. The algorithm was implemented in the programming language Python.

To facilitate its routine use, the algorithm has been integrated into a user-friendly software application. The software consists of an Excel sheet (Figure 1), linked to a Python script. In order to prevent unintended changes, the Excel sheet has protected cells allowing users to modify only those designated for input data. Except for the data to be entered manually, the software code is compiled into an executable so that users cannot access or modify its contents.

To use the software, eight data fields must be completed daily. Once all the WB donations for a given day have been collected by the blood establishment, the staff introduces into the software: the total number of WB donations received (column 3 [REAL] in Figure 1), the number of platelet apheresis received and pending analysis (column 4 [APHERESIS]) and the stock of PC categorized by their expiry at the time of decision-making (column 5 [S1] to column 10 [S6], from the number of PC expiring tomorrow to the number of PC expiring in 6 days). In addition, the estimated number of donations for each day must be completed at the beginning of each month (column 2 [ESTIMATED]) at least 1 week before using the software. Finally, by clicking on the executable, the software generates the production recommendations based on the algorithm's calculations. More specifically, the software indicates the number of PC to be produced (column 12 [PC]) and the number of WB units to be fractionated with the 3C-protocol (column 11 [WB INTO 3C PROTOCOL]). The remaining WB units are fractioned with the 2C-protocol. If the software detects a potential blood shortage to meet the demand for PC, it generates a warning message 1 week in advance (column 13 [WARNING]), indicating the exact number of additional WB donations needed to prevent such a shortage.

Mathematical simulations performed

Due to the importance and potential impact of the software output, we decided to perform an initial validation of the algorithm using mathematical simulations with real data, prior to its incorporation into the BTBA. The dataset from 1 January 2019 to 30 November 2020 was split into two subsets. The subset of data from 1 January 2019 to 30 June 2019 was used to validate the algorithm against the usual BTBA-specific trends prior to the onset of the coronavirus disease 2019 (COVID-19) pandemic (first simulation). The subset of data from 1 January 2020 to 30 November 2020 was used to validate the algorithm against abrupt changes in trends, both in donations and demand of PC, such as those present during the COVID-19 pandemic (second simulation).

In both simulations, the activity flow of the BTBA was modelled to determine what results would have been obtained if the recommendations of the software had been followed. Then, those results were compared with the real data of the BTBA without using the software. The parameters studied to assess the performance of the algorithm were the number and percentage of produced and expired PC in the BTBA, the number of PC stock-outs, the number of WB units fractionated with the 3C-protocol and those with the 2C-protocol.

Validation in a real environment

In May 2021, following the good results obtained in the simulations, the software was incorporated into the fractionation and distribution area of the BTBA, independently of any software or medical device present there.

DATE	DONATIONS			STOCK						PC		WARNNG
	ESTIMATED	REAL	APHERESIS	S1	S2	S3	S4	S5	S6	WB units into 3C-protocol	PC	
11 May 2022	123	156	3	0	2	10	7	10	9	95	19	NO WARNING
12 May 2022	155											
13 May 2022	143											
14 May 2022	79											
15 May 2022	98											
16 May 2022	0	0	0	*	*	*	*	*	*	0	0	Holiday
17 May 2022	78											

FIGURE 1 Excel sheet illustrating the software installed in Blood and Tissues Bank of Aragon (BTBA). PC, platelet concentrates; WB, whole blood.

TABLE 1 Data used in the development and validation of the algorithm.

	Start date	End date
Design and development of the algorithm		
	1 January 2018	31 December 2018
Validation of the algorithm via simulation		
Normal situation	1 January 2019	30 June 2019
Extraordinary situation (COVID-19)	1 January 2020	30 November 2020
Evaluation of the algorithm BTBA		
Period 1 (without software)	1 May 2020	31 January 2021
Period 2 (with software)	1 May 2021	31 January 2022

Abbreviations: BTBA, Blood and Tissues Bank of Aragon; COVID-19, coronavirus disease 2019.

To ensure proper use, BTBA professionals received 1 h of training, and a 15-day time limit was set to become proficient with the software. At the end of the trial period, the staff started using the tool on a regular basis.

After 9 months of daily routine use, retrospective activity data from the BTBA and Transfusion Services was collected. On the one hand, the BTBA provided data from 1 May 2020 to 31 January 2021 on processed PC (pools and apheresis), supplied and expired PC in the BTBA and the Transfusion Services, the number of PC stock-outs, the outdating rate of PC in the BTBA, the average shelf life of PC sent to Transfusion Services, the number of WB units processed, the percentage of these units fractionated with each of the protocols, the number of IPUs discarded and the volume of plasma obtained from WB units. During this period, no tool was used to support production decision-making. We call this period 'Period 1' (no software). On the other hand, the BTBA provided the same data from 1 May 2021 to 31 January 2022, when the software was being used. This period is referred to as "Period 2" (with software). The phases of the algorithm development and evaluation are shown in Table 1.

RESULTS

This section shows the results of the mathematical simulations (Tables 2 and 3) and the results of the algorithm validation (Table 4).

Table 2 compares the results of the mathematical simulations with real data from 1 January to 30 June 2019. Table 3 compares the results of the mathematical simulations with real data from 1 January to 30 November 2020 (in the midst of the COVID-19 pandemic). In both simulations, the mathematical algorithm improves the real data of the BTBA, reducing the outdating rate of PC, avoiding stock-outs and increasing the percentage of WB units fractionated with the 2C-protocol. The results in Table 3 show that the mathematical algorithm performs well in the presence of large trend changes such as those faced during the COVID-19 pandemic.

TABLE 2 Results of the simulation and real data from 1 January to 30 June 2019.

	BTBA (real data)	Simulation (estimate data)
PC expired	75	7
PC stock-outs	1	0
3C-protocol fractionated WB	19,350	12,400
2C-protocol fractionated WB	1207	8157

Abbreviations: BTBA, Blood and Tissues Bank of Aragon; PC, platelet concentrates; WB, whole blood.

TABLE 3 Results of the simulation and real data from 1 January to 30 November 2020.

	BTBA (real data)	Simulation (estimate data)
PC expired in BTBA	70	58
PC stock-outs	0	0
3C-protocol fractionated WB	31,527	23,670
2C-protocol fractionated WB	3124	10,981

Abbreviations: BTBA, Blood and Tissues Bank of Aragon; PC, platelet concentrates; WB, whole blood.

Table 4 shows the results of the algorithm validation in the BTBA from May 2021 to January 2022 compared with the same period a year before. The demand for PC from the Transfusion Services increased from May 2021 to January 2022, compared with the same period 1 year prior (May 2020 to January 2021), so the number of PC produced in the BTBA was 12.9% higher in Period 2. Using the algorithm, the PC outdating rate decreased significantly (87.8%) and 65 PC less were discarded due to outdating in 9 months, only 0.18% of those produced because the PC production better adjusted to demand. The outdating rate decreased not only in the BTBA but also in the Transfusion Services from 4.35% to 3.80%. The algorithm also helped to increase the remaining PC shelf life supplied by nearly 1 day. Using the algorithm, the units processed with the 2C-protocol (higher volume plasma and RBC) increased to 41.6% (1313 more units in 9 months). As a result, the algorithm led to a reduction of the percentage of discarded IPUs from 25.8% in Period 1 to 11.0% in Period 2. Furthermore, 100 L of extra plasma were recovered from WB donations. No stock-outs occurred in both periods. However, the software warned of a possible shortage of 85 donations for the supply of PC and a stock-out was avoided by improving collection planning in time.

DISCUSSION

Good Manufacturing Practices [24] requires the optimization of the processing of WB units. This requirement is in line with the resolution of two of the problems faced by the blood establishments: a balanced production of PC and the maximum collection of plasma.

TABLE 4 Results of the validation in the BTBA.

	Period 1 May 2020–January 2021 (without software)	Period 2 May 2021–January 2022 (with software)
PC produced (pools + apheresis)	4083 + 365 = 4448	4604 + 420 = 5024
Expired PC at BTBA	74	9
PC sent to Transfusion Services	4374	5015
PC stock-outs	0	0
PC outdating rates (%)		
BTBA	1.66	0.18
Transfusion Services	4.35	3.80
Aragon Transfusion Network	5.94	3.98
Average remaining shelf-life of PC sent to Transfusion Services (days)	3.02	3.73
WB units	28,941	29,315
WB units fractionated with 2C-protocol (%)	10.90	15.24
WB units fractionated with 3C-protocol (%)	89.10	84.76
Discarded IPUs	7458	3224
Volume of plasma recovered (L)	7541	7641

Abbreviations: BTBA, Blood and Tissues Bank of Aragon; IPU, interim platelet unit; PC, platelet concentrates; WB, whole blood.

The gradual increase in automation of WB processing over the last four decades has resulted in continued improvements in product quality, productivity, yield, processing time and product safety, as well as reducing costs through reduced wastage and resources [25].

Reveos System (Terumo BCT) avoids many manual steps. The possibility of several working protocols together with the PYI and the T-pool Select software for selecting and combining the IPUs in the production of PC helps to optimize the production of PC [18]. In addition, it was found that treating PC with PRT, which allows for a two-day extension in shelf life, resulted in a decreased rate of PC expiration [13]. However, the number of PC that have to be produced each day, as well as the number of units that can be processed with the 2C-protocols to obtain more plasma are ultimately determined by production managers based on demand trends, their experience and quality indicators. This is where automated decision-making tools can be useful in streamlining the process.

In this article, we present a software tool based on a mathematical algorithm that has proven to be effective for this purpose. The algorithm considers the stochastic nature of demand, as production orders for a day are established before knowing the PC demand. Moreover, it is well suited to handle periods of uneven demand and production. For instance, Christmas holidays fell within Period 2 of validation, and the algorithm performed exceptionally well throughout the period. It showed that it is possible to optimize the production of blood components, getting the highest possible yield from each WB donation and improving the production of PC, while maintaining an adequate stock without expiry or stock-outs. Thus, this software is another step in the automation of blood processing.

There have been numerous studies attempting to develop models for managing PC inventory [26]. This algorithm has been able to reduce the percentage of PC discarded due to expiration, without any stock-out (see Table 4). Although the outdating rate of PC without using the algorithm was 5.94%, which is less than the national average (10% in Spanish Transfusion Network [27]), the use of the algorithm further reduced the percentage of PC that expired. Using this tool, the outdating rate of PC in the Transfusion Network of Aragón decreased to 3.98%. Note that the increase in demand in the second period naturally led to a higher production, so the outdating rate should not have seen a significant reduction if the system operated similarly in both periods. Thus, the substantial decrease in outdates in the second period can be attributed, at least in large part, to the implement of our algorithm. This conclusion is reinforced by the findings in Tables 2 and 3, where the algorithm's impact on outdating was evaluated under identical daily demands.

The fact that during the period of use of the software PC had been supplied to Transfusion Services with longer remaining shelf-life (from 3.02 to 3.73 days) contributed to a reduction in the outdating rate of the Transfusion Services and, consequently, in the Transfusion Network of Aragon. This aspect is also important because the patient receives a fresher and therefore more effective PC [28]. Also, from an economic point of view, the cost of manufacturing an inactivated platelet pool in the BTBA was 447.58 euros [29]. Therefore, the reduction in outdated PC units resulted in significant savings. Additionally, each PC contains approximately 150 mL of plasma, contributing further to the overall savings.

With this software, it was possible to optimize the WB fractionation process. During the period of use of the software, the number of discarded IPUs decreased by 56.7%, and the software proposed to fractionate more units with the 2C-protocol (not to elaborate IPUs). The ratio 3C/2C decreased from 8.17 in 2020 (without software) to

5.56 in 2021 with the software. Hence, there was an increase of 100 L in plasma recovery in Period 2 compared with Period 1, as one IPU contains approximately 30 mL of plasma. Although this increase might appear modest, it is important to consider that it is derived from a comparable number of WB units and under a significantly higher demand for PC (14.6%). This indicates that the algorithm has successfully enhanced the efficiency of plasma extraction from each WB donation. Plasma is considered a strategic resource [30]. However, in 2017, the level of self-sufficiency for albumin and immunoglobulins was 62.4% and 42.9%, respectively [15]. From a logistical, economic and ethical point of view, it is mandatory to obtain as much plasma as possible from WB donations. In 2021, in Spain, 1,622,610 WB were collected, producing 235,677 PC from WB donations. If each PC was derived from four to five donations, approximately 1,000,000 WB units were used for their production. This means that around 600,000 platelet units (buffy coat and IPU) were discarded for several causes, mainly because of outdating (e.g. 87% in the BTBA). Assuming this percentage and since each platelet unit contains 30 mL of plasma, this means that more than 16,000 L of plasma have been lost in buffy coat and IPU—otherwise valid—that were not used in the production of PC. Furthermore, during 2021 in Spain, 26,925 PC expired [27]. Assuming an approximate volume of 150 mL of plasma per PC, this would amount to over 4000 L of plasma. In summary, we estimate that the annual plasma volume discarded due to the expiration of buffy coats, IPU and PC was around 20,000 L. Given that one apheresis donation contains approximately 600 mL of plasma, this is equivalent to more than 33,000 plasmapheresis donations. Therefore, the usefulness of an algorithm to recover part of this plasma is evident.

In conclusion, the successful results of the BTBA validation demonstrate that, despite having approximately the same number of WB units but facing a 14.6% increase in demand for PC in Period 2, the algorithm not only met the demand without experiencing any stockouts of PC but also provided PC of higher quality. Additionally, it successfully recovered more plasma.

Aside from the obvious economic savings resulting from the reduction in the outdating rates of PC (the unitary cost of manufacture is around 450 euros [29]) and the increase in the volume of recovered plasma, our algorithm is beneficial from an ethical standpoint. By minimizing waste, we ensure effective utilization of WB donations, given freely by donors, contributing positively to ethical considerations.

The software has the capability to forecast, with a one-week lead time, situations where there may not be sufficient WB donations to produce the required number of PC. For this forecasting, it is necessary to include WB collection forecasts for at least the following week. This early warning allows the blood establishment to increase the number of planned WB collections.

The tool is very intuitive and easy to use as shown by the fact that 1 hour of training is enough to learn how to use it. This, coupled with the speed of data calculation, makes its routine application very straightforward.

The tool facilitates and guides production decisions regardless of the experience of the blood establishment staff. It facilitates the incorporation of new professionals and decision-making in the absence of the head of the area in the blood establishment. If the staff are very experienced, they can still use their judgement but with the help of software, which would give even better results.

The software has been applied in a blood establishment with an automated fractionation system, but it could be implemented in blood establishments that use the buffy coat method for WB fractionation, in which case the 2C protocol would be equivalent to dry-buffy coat. It can also be applied in those centres that do not treat PC with PRT or treat only a part of them. Other particular conditions of the blood establishment may require minor modifications to the algorithm, but those such as the size of the blood establishment or the distance to hospitals are not relevant in this case. Although the current algorithm does not explicitly account for blood groups, it can be adapted for individual blood groups. Some modifications would be needed in the algorithm to take into account the groups and their compatibilities in a unified way. In this situation, it would be necessary to re-validate the new version of the algorithm in one blood establishment to ensure an optimal result.

In summary, the software meets the objectives by improving PC inventory management, optimizing WB fractionation, recovering more volume of plasma as well as providing guidance on collection planning.

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A.P. and I.A. conceived and designed the study; A.P. executed data collection; I.A. and F.L. performed the statistical analysis; I.A. and F.L. developed the mathematical algorithm; I.A. implemented the algorithm; I.A. and J.S. installed the algorithm in the BTBA; A.P. and I.A. took the lead in writing the manuscript. All authors provided feedback and helped shape the research and analysis, critically reviewed and contributed to the final version of the manuscript.

CONFLICT OF INTEREST STATEMENT

Ana Isabel Pérez-Aliaga has collaborated as guest speaker in Terumo BCT. Irene Ayerra founded, holds shares in and works for Hemotic.

DATA AVAILABILITY STATEMENT

Raw data that support the findings of this study are available from the corresponding author, upon reasonable request.

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