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Impact of Shelf-Life Extension on Platelet Availability: Results from an Inventory Management Modeling Study

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Keywords
Platelets · Shelf-life extension · Shortage · Inventory management simulation · German Red Cross

Abstract
Introduction: In Germany, demand for platelet transfusion is maintained or even increasing, despite a decrease in whole blood donations observed in the last decade. The shelf-life of platelet concentrates (PCs) in Germany is 4 days, which can be extended to 5 days if appropriate safety measures are used. This short shelf-life leads to decreased PC availability. ***Methods:*** We investigated the impact of PC shelf-life extension on PC shortage, using a mathematical simulation model based on the PC production and delivery statistics of the Frankfurt Institute of the German Red Cross Transfusion Service of Baden-Württemberg-Hessen. We used a 2.2-year dataset for PC production and delivery as input data for a Monte Carlo inventory management simulation, focusing on PC shortage. The model generated the daily stock (expressed as mean number of PC units ± standard deviation), mean PC age at release, mean number of expired PC units, and shortage rates (i.e., requiring the release of more PCs than available), overall and by PC blood group. ***Results:*** Over 2.2 years, a total of 74,322 PC units were produced and 62,178 units were released at the Frankfurt Institute; the overall overproduction rate was 19.5%. Shortage rates decrease with an increase in PC shelf-life and/or increase in overproduction rates. At an overproduction rate of 20%, shortage rates would be reduced from 2.8% for a 4-day shelf-life to 0.7%, 0.3%, and 0.2%, for shelf-life lengths of 5, 6, and 7 days, respectively. Extending the PC shelf-life to 6 or 7 days would eliminate shortages almost entirely, including for rare bloods. ***Conclusion:*** These results can inform blood services and regulatory authorities on the potential medical and economic impact of extending PC shelf-life to 6 or 7 days.

Introduction

Blood transfusion practices have undergone major changes in the last decade with the widespread implementation of patient blood management (PBM) programs aiming to improve blood utilization [1–5]. Restrictive blood transfusion practices in diverse settings have resulted in a significant improvement in red blood cell transfusion utilization without a negative impact on patient outcomes and costs [6–9].

In Germany, a continuous decrease in whole blood donations has been observed in parallel to PBM implementation. The accumulated decrease reached 16% at the end of 2020, representing 1.3 million less donations than in the peak year of 2011 [10]; however, a slight

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increase (0.9%) in the number of donations was reported for the year 2021 compared to 2020 [10]. While a reduction of red blood cell transfusions has been a clear outcome of PBM, in countries like Germany and France the demand for platelet transfusion has maintained at stable or even increased levels [10, 11].

An important risk of platelet transfusion is transfusion-transmitted bacterial infection (TTBI) due to storage at temperatures of 20–24°C, in gas-permeable bags, and under gentle agitation that favor bacteria replication [12]. Contamination rates of whole-blood-derived platelet concentrates (PCs) were reported to reach 2,111 per million PC units and to result in septic reactions and fatalities of 7.9 and 0.79 per million PC units, respectively [13]. Similar contamination rates were observed for apheresis-derived compared to whole-blood-derived platelets [13, 14]. More recently, different strategies to mitigate the risk of TTBI have led to a reduction in contamination and septic reaction reporting rates. For instance, delayed, large-volume bacterial culture, bacterial polymerase chain reaction (PCR) tests, and pathogen inactivation/reduction technologies (PRT) were shown to have significantly reduced the risk of septic transmisison in Belgium, France, Germany, and Switzerland [15, 16]. Safety measures to prevent bacterial transmisison differ in Europe with a few countries routinely using PRT [17].

Logistics inherent to safety technologies dictate the choice of one technology over the other in different countries and blood services [17]. In the case of bacterial culture, some countries adopted protocols based on a delay in platelet release that may reach up to 48 h after culture starts having a major impact on PC inventory management [13, 18]. Alternatively, in Germany a PC can be tested at a later shelf-life (i.e., on day 3 or 4) for a possible extension of shelf-life from 4 to 5 days, which may result in the provision of blood products with different safety profiles. In addition, an initial bacteria-positive result will trigger the recall of all associated components. PRT on the other hand can decrease the risk of bacterial transmission and septic reactions, while proactively reducing the risk of transmission of virus and parasites and inactivating contaminating residual white blood cells [19]. Contrarily to bacterial detection, where a delay in sampling increases the likelihood of picking up an initially weak bacterial contamination, an early use of PRT increases the chance of complete inactivation of an initial contamination and eventually avoidance of endotoxin accumulation [19] to safely extend all PC shelf-life to up to 7 days. This leads to reduced PC outdating and increased availability, therefore optimizing inventory management. Yet, some PRTs rely on the addition of photochemical reagents that need to be removed after treatment, resulting in significant platelet loss that can technically be compensated by increasing the initial platelet content of the component. Additionally, the cost of PRT implementation may also be high [20]. However, it is likely that this cost could be partially offset by a PC shelf-life of 7 days [20, 21] or the use of a double pooling protocol where up to 8 buffy coats are pooled together with platelet additive solution, treated, and then split for transfusion [22].

PC shelf-life in European countries is established by national guidelines and ranges from 4 to 7 days, depending on the adopted safety measures against TTBI. The common regional guidance developed by the European Directorate for the Quality of Medicines & HealthCare foresees extension of the shelf-life up to 7 days, contingent on the type of additive solution used for storage and the use of PRT [23]. In Germany, PCs have a mandated shelf-life of 4 days that can be extended to 5 days with the use of an approved PRT or rapid bacterial detection methods [24]. This short shelf-life results in higher expiry rates, of up to 19% for whole blood-derived pooled PCs and up to 7% for apheresis-derived PCs [10]. In contrast, in some regions in Spain, the introduction of routine PRT treatment of PCs and consequent shelf-life extension to 7 days contributed to a reduction in PC expiry rates of over 80% [25], with expiry rates of only 1.2% being reported in the region of Aragon [26]. PC expiration remains an important cause of PC discard [27], leading to shortages (i.e., higher number of demanded PCs than available in stock), and high costs due to not only the production and/or delivery of new PC supply but also the destruction of outdated PCs and the required laboratory inventory management.

In the context of decreased blood donations in Germany, a judicious management of the available PC supply is needed to avoid shortages. We investigated the potential impact of PC shelf-life extension on PC shortage, using a mathematical simulation model based on the PC production and delivery statistics of the Frankfurt Institute of the German Red Cross Transfusion Service of Baden-Württemberg-Hessen. Thus, we estimated shortage rates (calculated as the percentage of unfulfilled PC demand from the total PC production) for different scenarios including different storage periods and overproduction setups (i.e., with PC production exceeding the foreseen demand).

Methods

The Frankfurt Institute of the German Red Cross Transfusion Service of Baden-Württemberg-Hessen supplies blood components to 60 hospitals in the region with a radius of approximately 150 km. To supply the platelet demand in the region, this institute counts with the production of approximately 39,000 PC units per year, more than 95% originating from pooling of PCs derived from whole blood collections and less than 5% from apheresis collection. Platelet production planning is based on an average of 20% overproduction setup. Whole blood collections are performed from Mondays to Saturdays. Apheresis is the collection method of choice in times of low whole blood donations, as during holiday seasons and long weekends, and if human leukocyte

antigen-matched platelets are needed. Platelet shelf-life is 4 days, extended to 5 days for about 18% of PC units, through the use of selective nucleic acid testing [28].

We used a Monte Carlo inventory management simulation, focusing on shortage, in Microsoft Excel [29] to simulate the effect of different shelf-lives for PC. The model was based on a 2.2-year dataset for PC production and delivery at the Frankfurt Institute of the German Red Cross Transfusion Service of Baden-Württemberg-Hessen.

In a first step, we created a program in SAS v9.4 (SAS Institute, Cary, NC, USA) to perform a descriptive analysis of the number of PC units produced and released per day. This program was then executed on the blood bank server, on the production dataset over a period of 2.2 years (783 days). PC production and release (expressed as the mean number of PC units ± standard deviation [SD]) were stratified by weekday (Monday through Sunday) and by PC type (ABO blood group, Rhesus factor, and cytomegalovirus antibody status).

In a second step, the data obtained for PC production and release were inputted in the inventory management simulation, using a normal distribution model. We simulated 5,000 weeks, in which production figures were upscaled or downscaled across weekdays and PC types, in order to simulate different rates of overproduction ranging from 5% to 50% (with increments of 2.5%). PCs entered the inventory management simulation at production day (day 1), but could only be released starting from day 2, i.e., at a shelf-life of 2 days. The produced and released PC amounts were simulated for each day, for the different overproduction rates ranging and considering different PC shelf-life lengths (set at 4, 5, 6, and 7 days). The number of PCs to be released each day was deducted from the current stock, by PC type and taking into account restrictions due to the PC shelf-life. For example, when analyzing expiry periods of 4 days, only PC units up to the age of day 4 were used. The PCs were taken evenly from all available PC ages. PC units produced the previous day were added to the daily stock. This simulation was run for consecutive days over a 50-week period and repeated 100 times, accounting for a total analyzed period of 5,000 weeks.

The model generated the daily stock (expressed as mean number of PC units ± SD), mean PC age at release, mean number of expired PC units, loss, and shortage rates (i.e., requiring the release of more PCs than available), overall and by PC type. In the model, shortages for a certain PC type could not be compensated with other PC types.

Ethics approval was not required for this modeling study. The study was initiated and funded by Terumo Blood and Cell Technologies.

Results

The descriptive analysis performed over the period of 2.2 years showed that a total of 74,322 PC units were produced in 545 production days (as a rule, there was low or no PC production on Sundays and Mondays). In total, 62,178 units were released in the same period, over 783 days, resulting in an overall overproduction rate of 19.5%. For the purpose of this simulation, we considered 20% as the actual overproduction rate at the Institute in Frankfurt.

The mean numbers of PC units produced and released were shown to vary by weekday and by PC type (Table 1). Simulated overall daily stock, shortage rate, loss and mean age at the time of PC unit release are shown in Table 2. At the currently employed overproduction rate (20%), shortage rates would be reduced from 2.8% for a 4-day shelf-life to 0.7%, 0.3%, and 0.2%, for shelf-life lengths of 5, 6, and 7 days, respectively.

When evaluating the impact of PC shelf-life on shortage rates, with a 6-day collection rhythm (Mondays to Saturdays), a peak in shortage rates was observed on Tuesdays. Simulation showed that Tuesday shortage rates decreased in parallel with an increase in PC shelf-life; the shortage rate peaked on Tuesday at 15.5% for a PC shelf-life of 4 days, and dropped to 4.2%, 1.9%, and 1.4% for shelf-lives of 5, 6, and 7 days, respectively (Fig. 1).

Shortage rates for different PC shelf-life lengths ranging from 4 to 7 days also decreased with increased overproduction rates, ranging from 4.8% to 0.6% for an overproduction rate of 5% and from 1.2% to 0.2% for an overproduction rate of 50%. Following this simulation, overproduction could be reduced from 20% to 5%, and the observed shortages of 2.8% would further be reduced to 1% or 0.6% if the shelf-life is extended to 6 or 7 days (Table 2).

The model showed that maintaining overproduction at the current rate of 20% but extending shelf-life to 7 days would cause the modest reduction of PC loss from 25.9% to 23% (Table 2). On the other hand, the simulation showed that extending shelf-life will allow blood establishment to decrease overproduction without compromising platelet supply (Fig. 2). Extending the PC shelf-life to 6 or 7 days would result in no shortages in blood group O, Rhesus negative platelets neither nor rare PC types (e.g., AB Rhesus negative/cytomegalovirus negative) (online suppl. material; for all online suppl. material, see https://doi.org/10.1159/000537700).

The mean PC age at delivery increased with an increase in PC shelf-life length. At the current overproduction of 20%, the mean age was 2.8 days for a shelf-life of 4 days and 3.9 days for a shelf-life of 7 days (Fig. 3).

Discussion

In Germany in 2021, the rate of collected donations was 44/1,000 inhabitants for whole blood and 33–34/1,000 inhabitants for apheresis [10], yet changes in donors' demographics, most specifically aging of the donor population concomitantly with lower retention rates of younger donors, threaten a sustainable supply of PCs [30, 31]. Moreover, the restrictive measures for the collection of blood imposed during the COVID-19 pandemic may have resulted in a long-standing impact on donors' behavior [32]. During the pandemic, the World Health Organization estimated a 20–30% reduction in blood supply globally [33], while a recent meta-analysis found an average of 38% decrease in blood donations, reaching 67% in some regions [34]. Blood services continued to

Table 1. Number of PC units produced and released by the Frankfurt Institute over a period of 2.2 years, by weekday and by PC type

	Production		Release	
	number of days in the analysis	mean number of PC units ± SD	number of days in the analysis	mean number of PC units ± SD
By weekday				
Monday	0	0.00±0.00	112	100.61±18.25
Tuesday	107	148.98±14.00	112	92.46±15.82
Wednesday	109	112.40±17.12	111	93.18±17.01
Thursday	110	117.72±16.13	112	86.32±18.81
Friday	105	133.12±15.70	112	88.62±16.97
Saturday	106	173.80±18.92	112	44.98±9.10
Sunday	8	97.50±18.55	112	49.82±9.55
By PC type/day				
[O+ CMV+]	545	16.04±5.57	545	13.30±4.62
[O+ CMV −]	545	25.93±7.87	545	21.75±6.60
[O− CMV +]	545	4.75±1.78	545	3.98±1.49
[O− CMV−]	545	10.58±2.61	545	8.96±2.21
[A+ CMV+]	545	17.25±5.86	545	14.25±4.84
[A+ CMV−]	545	28.43±8.51	545	23.51±7.04
[A− CMV+]	545	4.15±1.75	545	3.48±1.47
[A− CMV−]	545	10.41±2.65	545	8.79±2.24
[B+ CMV+]	545	3.22±1.50	545	2.69±1.25
[B+ CMV−]	545	6.80±2.13	545	5.69±1.78
[B− CMV+]	545	0.91±0.72	545	0.76±0.60
[B− CMV−]	545	1.71±0.82	545	1.43±0.69
[AB+ CMV+]	545	1.41±0.74	545	1.18±0.62
[AB+ CMV−]	545	3.57±1.00	545	2.99±0.84
[AB− CMV+]	545	0.34±0.50	545	0.28±0.42
[AB− CMV−]	545	0.87±0.64	545	0.73±0.54

PC, platelet concentrate; SD, standard deviation; CMV, cytomegalovirus; +/−, positive/negative.

experience decreased whole blood donor availability even after lockdown measures were eased or lifted [33, 35, 36].

Management of PC inventory under these circumstances can be extremely complex, and in countries like the USA that relies on its PC inventory almost exclusively with apheresis collections, a discussion is under way on whether an uptake in whole-blood-derived platelets would relieve the current shortage of PC [37]. In Germany, where a shelf-life of 4 days is imposed by the Paul Ehrlich Institute on PCs that do not undergo bacterial testing nor PRT, the extension of shelf-life by 1 to up to 3 days would improve PC supply management significantly. In addition, it would also alleviate donors' recruitment schedules in the institutions which collect and produce platelets exclusively by apheresis, thus helping in the retention of these precious donors. Moreover, savings from avoiding loss of expired platelets due to overproduction may compensate, even if partially, the introduction of the safety measures (PRT or bacterial testing) [22, 38].

In many Western European countries, PC shelf-life has been extended to 7 days when PRT (e.g., in Spain and France) or bacterial screening (e.g., in the UK and The Netherlands) methods were implemented [17]. The estimation of residual risk for TTBI in European countries can inform on the impact of different implemented safety measures on PC quality: bacterial contamination of PCs was found to be 5.4/1,000,000 PC units in the UK after routine implementation of late-sampling bacterial screening (compared with 16.3/1,000,000 in the preimplementation era) and 0.0/1,000,000 PC units in Belgium, France, and Switzerland, in PRT-treated PCs, with no significant negative impact on clinical outcome [15]. In Germany, a TTBI rate of 5.3/1,000,000 PC units was reported after the implementation of PC shelf-life reduction, compared to 11.4/1,000,000 in the years prior to the implementation of this measure [39].

In this study, we used an inventory management simulation to investigate how PC shelf-life extension impacts the supply chain management of this product, based on the organization of the Frankfurt Institute of the German Red Cross Baden-Württemberg-Hessen, with more than 95% of platelets produced by pooling of 4 buffy coats as example. Our analysis showed that the extension of platelet storage from 4 to 6 or 7 days would allow a decrease in overproduction down to 5% while achieving PC shortage levels lower than those currently observed (overproduction rate of 20% and PC shelf-life of 4 days). Overproduction not only creates cost, but it also increases pressure on the donor pool; hence,

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Table 2. Simulated PC daily stock, shortage rates, loss, and mean age at the time of release, at different overproduction rates, by shelf-life length

Overproduction rate, %	Daily stock (mean number of PC units)				Shortage rate (%)				Loss (%)				Mean age at the time of selling pack (days)			
	4 days	5 days	6 days	7 days	4 days	5 days	6 days	7 days	4 days	5 days	6 days	7 days	4 days	5 days	6 days	7 days
5.0	***147.1***	***187.5***	***230.7***	***276.5***	***4.8***	***1.9***	***1.0***	***0.6***	***11.1***	***7.8***	***6.9***	***6.4***	***2.7***	***3.0***	***3.3***	***3.6***
7.5	156.6	200.2	248.4	298.8	4.3	1.6	0.8	0.5	13.5	10.4	9.5	9.1	2.7	3.0	3.4	3.7
10.0	166.0	214.4	264.9	319.3	4.0	1.4	0.7	0.4	15.9	12.9	12.2	11.8	2.7	3.1	3.4	3.7
12.5	175.1	227.4	282.7	341.5	3.6	1.2	0.6	0.3	18.3	15.5	14.9	14.6	2.8	3.1	3.4	3.8
15.0	185.3	240.3	300.5	363.8	3.3	1.0	0.5	0.3	20.8	18.2	17.6	17.4	2.8	3.1	3.5	3.8
17.5	194.3	253.8	317.8	385.7	3.0	0.8	0.4	0.3	23.4	20.9	20.4	20.2	2.8	3.1	3.5	3.9
20.0	**203.3**	**267.3**	**335.5**	**406.7**	**2.8**	**0.7**	**0.3**	**0.2**	**25.9**	**23.6**	**23.1**	**23.0**	**2.8**	**3.1**	**3.5**	**3.9**
22.5	213.1	280.2	352.2	426.2	2.5	0.6	0.3	0.2	28.5	26.3	25.9	25.9	2.8	3.2	3.5	3.9
25.0	222.3	292.3	368.5	449.2	2.3	0.6	0.3	0.2	31.1	29.1	28.8	28.7	2.8	3.2	3.6	4.0
27.5	231.4	306.8	384.3	468.9	2.2	0.5	0.3	0.2	33.8	31.9	31.6	31.5	2.8	3.2	3.6	4.0
30.0	240.7	319.2	402.7	488.2	2.0	0.5	0.2	0.2	36.5	34.7	34.4	34.4	2.8	3.2	3.6	4.0
32.5	250.5	332.6	418.4	508.2	1.9	0.4	0.2	0.2	39.1	37.4	37.2	37.2	2.8	3.2	3.6	4.0
35.0	259.4	345.2	435.9	527.3	1.7	0.4	0.2	0.2	41.8	40.2	40.1	40.1	2.8	3.2	3.6	4.1
37.5	269.1	357.8	450.3	547.2	1.6	0.4	0.2	0.2	44.5	43.1	42.9	42.9	2.8	3.2	3.6	4.1
40.0	277.9	370.1	466.3	566.8	1.5	0.3	0.2	0.2	47.3	45.9	45.7	45.7	2.8	3.2	3.6	4.1
42.5	287.3	382.4	483.1	585.3	1.5	0.3	0.2	0.2	50.0	48.7	48.6	48.6	2.8	3.2	3.7	4.1
45.0	297.2	395.0	499.5	605.1	1.3	0.3	0.2	0.2	52.7	51.5	51.4	51.4	2.8	3.2	3.7	4.1
47.5	306.6	408.5	514.6	624.2	1.3	0.3	0.2	0.2	55.5	54.3	54.3	54.3	2.9	3.3	3.7	4.1
50.0	316.0	420.6	530.5	644.2	1.2	0.2	0.2	0.2	58.2	57.2	57.1	57.1	2.9	3.3	3.7	4.2

PC, platelet concentrate. Bolded black values correspond to the overproduction rate of 20%, the current average overproduction rate for PC production at the Frankfurt Institute. Overproduction could be reduced to 5% with a considerable decrease of shortage rates for a shelf-life length of 7 days (bolded italic values).

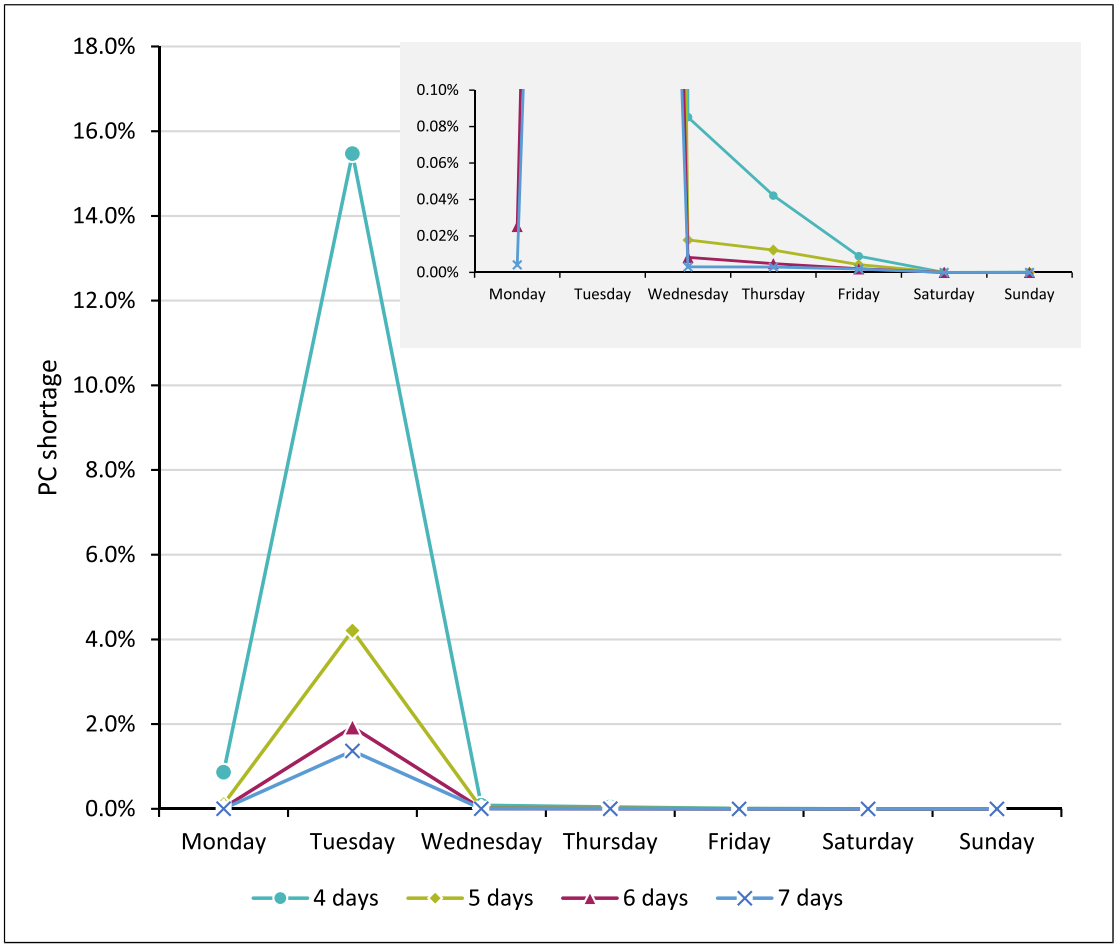

Fig. 1. Simulated daily PC shortage rates at the current overproduction level of 20.0% and different shelf-life lengths. PC, platelet concentrate. The gray box is an enlarged view of the graph for *y*-axis values up to 0.10%.

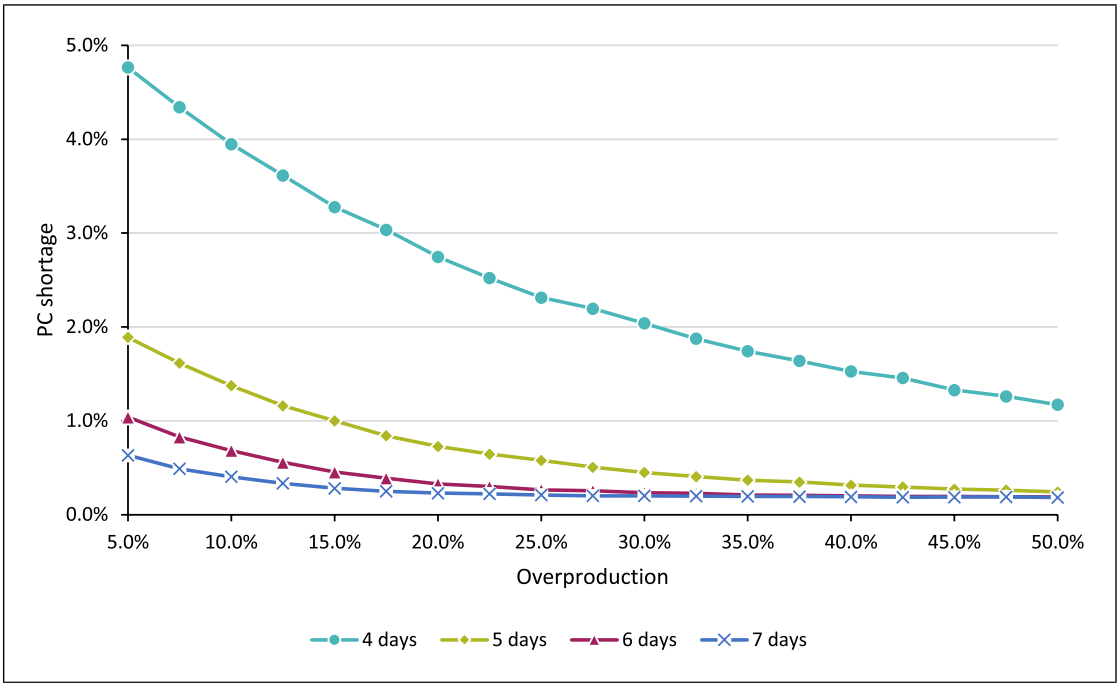

Fig. 2. Simulated PC shortage rates at different overproduction rates and different shelf-life lengths. PC, platelet concentrate.

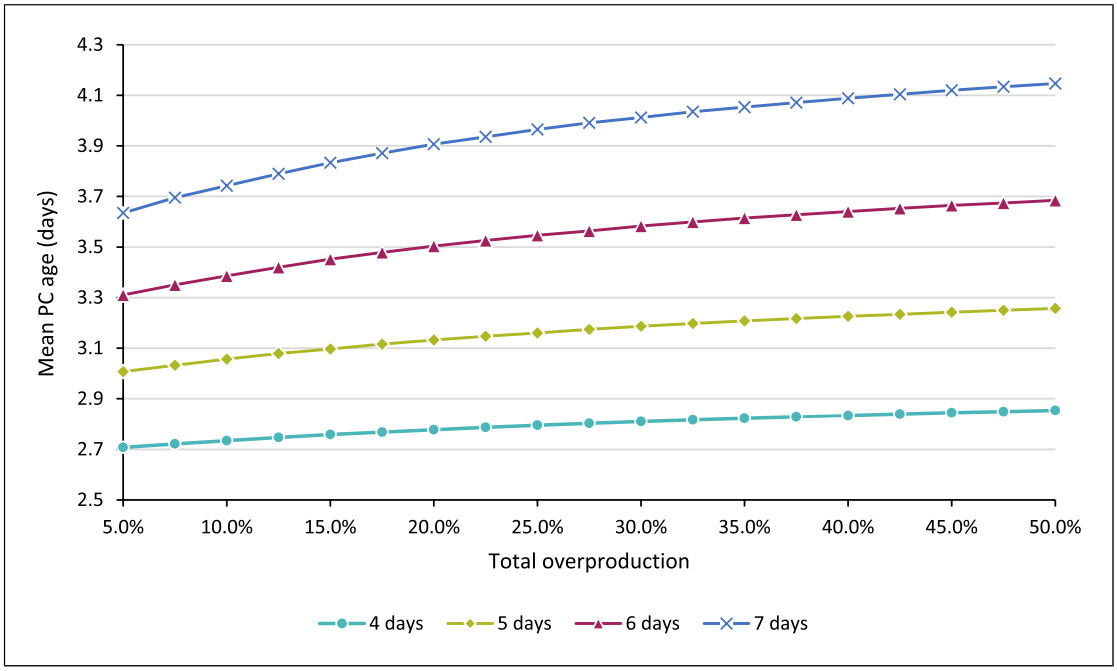

Fig. 3. Simulated mean PC age at selling time across overproduction range and different shelf-life lengths. PC, platelet concentrate.

the possibility to decrease overproduction without compromising the supply of adequate platelets seems advisable. According to our simulation, cutting overproduction by half while extending the PC shelf-life to 7 days at the Institute in Frankfurt would decrease PC loss by more than half; assuming an average price of EUR 300 per PC in Germany, this would bring savings of around EUR 2 million over a period of approximately 2 years, which could serve to finance the introduction of PRT or bacterial testing. On the other hand, extension of storage will lead to increased mean age of PC at transfusion, which might have an impact in product consumption [40]. According to our simulation, the mean age at transfusion increases by 1.1 days at the current overproduction rate of 20% when extending the shelf-life to 7 days, but decreasing overproduction may have the contrary effect, which would limit any impact on platelet consumption rates.

Other studies have used mathematical simulations based on real-world data to model PC inventory managements. Gorria et al. [38] based their model on data from two PC production centers in Spain and focused on outdate rates; they showed that an extension of PC shelf-life from 5 to 7 days can reduce outdate rates by 88–100%. In contrast, for the same 2-day extension in PC shelf-life, Blake [41] obtained a reduction of only 35.7% for the entire Canadian transfusion system, when using custom-built simulation model. Further, the Canadian authors found that pooled platelet waste and shortage rates as well as apheresis PC shortage levels increased with a decrease in pooled shelf-life, while apheresis PC waste decreased with a decrease in PC shelf-life [42]. In the current study, we did not account for production methods (apheresis or pooling of PC), but we clearly showed a marked decrease in shortage rates and a reduction of loss when PC shelf-life was extended by at least 2 days, i.e., to 6–7 days from the currently recommended 4-day length in Germany.

Our study has several limitations. First, the model simulates the mean number of PC units produced and released using descriptive data for each simulated week. However, the selection of PC age for release is difficult to model. In this model, we selected PCs evenly from all available PCs within the expiry age range. This may be handled differently in real-life situation: e.g., depending on the experience and expertise, a blood bank manager may opt to use older PCs first, to guarantee stock the next day. This aspect was not taken into account in the current model. Finally, our model did not differentiate between the PC production methods by apheresis or pooling of PCs.

In conclusion, by modeling different overproduction rates and PC shelf-life lengths, we gained a better insight on the possibilities to improve PC management in blood transfusion services and to provide an adequate and safe PC supply. The results of this study can inform blood services and regulatory authorities on the potential benefitial medical and economical impact of extending PC shelf-life from 4 to 6 or 7 days.

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Statement of Ethics

Ethical approval was not required for this research type in accordance with Local/National Guidelines.

Conflict of Interest Statement

Marcia Cardoso is an employee of Terumo Blood and Cell Technologies. All other authors have no conflicts of interest to declare.

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Author Contributions

Veronika Brixner, Marcia Cardoso, and Erhard Seifried contributed to the conceptualization, methodology, and data interpretation. Erik Spaepen developed the program for the descriptive analysis and the mathematical simulation model and performed the analysis. Marcia Cardoso wrote the first draft of the manuscript. Marcia Cardoso, Erik Spaepen, and Erhard Seifried reviewed the first and subsequent drafts of the manuscript. Marcia Cardoso, Erik Spaepen, and Erhard Seifried have read and agreed to the published version of the manuscript.

Data Availability Statement

All data generated or analyzed during this study are included in this article and its supplementary material files. Further inquiries can be directed to the corresponding author.

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