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DONOR INFECTIOUS DISEASE TESTING

TRANSFUSION

Economic implications of FDA platelet bacterial guidance compliance options: Comparison of single-step strategies

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Abstract

BACKGROUND: Bloodborne pathogens pose a major safety risk in transfusion medicine. To mitigate the risk of bacterial contamination in platelet units, FDA issues updated guidance materials on various bacterial risk control strategies (BRCS). This analysis presents results of a budget impact model updated to include 5- and 7-day pathogen reduced (PR) and large volumed delayed sampling (LVDS) BRCS.

STUDY DESIGN AND METHODS: Model base-case parameter inputs were based on scientific literature, a survey distributed to 27 US hospitals, and transfusion experts' opinion. The outputs include hospital budget and shelf-life impacts for 5- and 7-day LVDS, and 5- and 7-day PR units under three different scenarios: (1) 100% LVDS, (2) 100% PR, and (3) mix of 50% LVDS - and 50% PR.

RESULTS: Total annual costs from the hospital perspective were highest for 100% LVDS platelets (US$2.325M) and lowest for 100% PR-7 units (US $2.170M). Net budget impact after offsetting annual costs by outpatient reimbursements was 5.5% lower for 5-day PR platelets as compared to 5-day LVDS (US$1.663 vs. US$1.760M). A mix of 7-day LVDS and 5-day PR platelets had net annual costs that were 1.3% lower than for 100% 7-day LVDS, but 1.3% higher than for 100% 5-day PR. 7-day PR platelets had the longest shelf life (4.63 days), while 5-day LVDS had the shortest (2.00 days).

DISCUSSION: The model identifies opportunities to minimize transfusion center costs for 5- and 7-day platelets. Budget impact models such as this are important for understanding the financial implications of evolving FDA guidance and new platelet technologies.

1 | INTRODUCTION

A major safety risk in transfusion medicine is the prevention and detection of bloodborne pathogens, and other

Abbreviations: CMV, cytomegalovirus; LVDS-5, 5-day LVDS units; LVDS-7, 7-day LVDS units; PR-5, 5-day PR units; PR-7, 7-day PR units.

emerging infectious diseases, in the blood components.[1,2] According to the Centers for Disease Control and Prevention (CDC), platelet units pose the greatest transfusion-related infectious risk to patients. Bacterial contamination, the leading cause for septic transfusion-related deaths, occurs in about 1 in 1000–5000 platelet units when conventional bacterial culture testing is performed.[3,4] While platelet transfusion is a lifesaving therapy, compared to other blood products, its use comes with an increased risk for sepsis, particularly with longer periods of storage.[5] To mitigate the risk of bacterial contamination in platelet units, FDA finalized a guidance in 2019 (compliance revision in 2020). This guidance provided single- and two-step bacterial risk control strategies (BRCS) to reduce the risk of transfusion of bacterially contaminated platelet units..[6] Single- and two-step strategies are presented in Table 1.

Determining the optimal FDA platelet bacterial guidance compliance strategy for hospitals and their blood center suppliers is complex. Tools to facilitate consideration of many variables in decision-making are of increasing importance as the landscape of bacterial risk mitigation techniques changes. Implementing secondary rapid bacterial testing has shown to reduce the cases where false negative bacterial cultures result in missed contamination detection, but does not eliminate the risk.[7,8] LVDS at 36 or 48 h after collection is a culture-based risk reduction strategy relying on both additional time for bacteria to multiply to the threshold of detection, and a larger sample size to reduce sampling error risk. Waiting until 48 h to sample the unit allows for potential extension of shelf life from 5 to 7 days depending on collection bag and additive solution.[9] Pathogen reduction (PR) renders susceptible pathogens incapable of replication, thus reducing risk of transfusion-transmitted infections arising from bacteria, viruses, and parasites.[10] Extending platelet shelf life is not a new concept. In the 1980s platelet storage was extended from 3 to 5 days, and it was determined at the time that increased shelf life reduces platelet wastage due to outdating.[11] In Europe, PR platelet shelf life has been 7 days for over a decade, similar to LVDS 48-h platelets.[12,13] Currently, FDA has approved the use of 5-day PR platelet units,[6] however, the application for FDA approval of 7-day PR platelet is anticipated to be submitted in 2021. Hospitals and blood center suppliers must decide which BRCS approach will best meet their needs and budget, and thus require tools that could forecast the budget impact of these technologies.

TABLE 1 Platelet BRCS included in the model per finalized FDA 2019 guidance

Platelet type[a]	Time to expiry[b]
Single-step strategies	
Large volume delayed sampling (36-h)	5 days
Large volume delayed sampling (48-h)	7 days
Pathogen-reduction	5 days[c]
Two-step strategies	
Primary culture +8 ml secondary culture	5 days
Primary culture +16 ml secondary culture	7 days
Primary culture + rapid secondary test	7 days
Large volume delayed sampling +16 ml secondary test	7 days
Large volume delayed sampling + rapid secondary test	7 days

[a]All non-PR units may additionally receive CMV serology testing and/or irradiation, plus additional NAT testing for emerging infectious diseases (e.g., Zika).
[b]Time to expiry does not reflect maximum usable shelf life of these units.
[c]FDA submission for 7-day PR units is anticipated in 2021.

Healthcare systems are under a constant financial constraint. Cost prediction, treatment efficacy, and efficient resource allocation are key in budget and resource planning, within the context of the hospital's local environment. Health economic models and direct value assessments, at the hospital level, are a useful predictor for evaluating the impact adopting a new technology.[14] Budget impact models (BIMs) are modifiable to include provider-specific scenarios, and are commonly used by healthcare purchasers to understand the likely financial impact of adopting a new health technology or intervention.[15,16] These tools allow for simultaneous evaluation of current technologies and forward-looking projections of what may be available in the near future. In an ever-changing health economic space, BIMs are increasingly utilized by both private and public healthcare providers to inform budget and resource planning.[17–20] While often reported along with cost-effectiveness analyses (CEAs), BIMs are significantly different in the type of perspective, time horizon as well as outcome measures reported.[21] Generally, the main goal of CEAs is to determine the best value for money for the decision maker. As a result, these analyses include not only costs, but also health outcome measures. BIMs on the other hand are designed to determine the financial impact of the particular technology or intervention.[21]

In 2017 authors LTP, KMP, and JHH created the "Platelet Cost and Transfusion model" (PCT), an interactive Excel-based BIM to analyze the annual budget impact of platelet BRCS for hospital compliance with the FDA platelet bacterial guidance.[22] This model has been used in the field by both hospitals and regional and national blood suppliers since 2017. In addition, in

November 2018 BC presented the model in an FDA workshop on pathogen reduction technologies for blood safety.[23] In response to final compliance options suggested in the 2019 FDA Guidance: Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion: Guidance for Industry, the PCT was updated to include all options. This model includes direct costs, outpatient reimbursements, and shelf-life considerations, and it offers provider-specific financial impact analysis. The model includes both single- and two-step strategies. The objective of PCT is to facilitate hospitals in comparing the cost and shelf-life implications of adopting these technologies for guidance compliance.

2 | METHODS

2.1 | Model development

To understand platelet management from acquisition through transfusion, a survey was distributed to 27 US hospital transfusion service directors to set criteria for inclusion and base case parameters, and finalization of model structure consistent with the FDA guidance. In-site visits were performed to observe the processes from two hospitals – one that purchases 100% and one that self-collects 100% of their platelets. In addition, a targeted search of the peer-reviewed literature was conducted to inform model assumptions which could not be directly estimated. The final aspects included in the initial model version were platelet acquisition (purchase and/or self-collection), storage, rapid bacterial testing or PR, wastage, dispensing for transfusion, transfusion itself, and septic adverse events. Full model development methods and results of example scenarios pertaining to then available and FDA-approved technologies are reported elsewhere, and the model can be requested by contacting the first author.[22]

2.2 | Model evolution

A timeline illustrating the evolution of our model in response to FDA guidances is presented in Figure 1. Upon model creation in 2017, only a draft guidance on platelet BRCS was available. Over the subsequent years, additional guidance materials added testing for

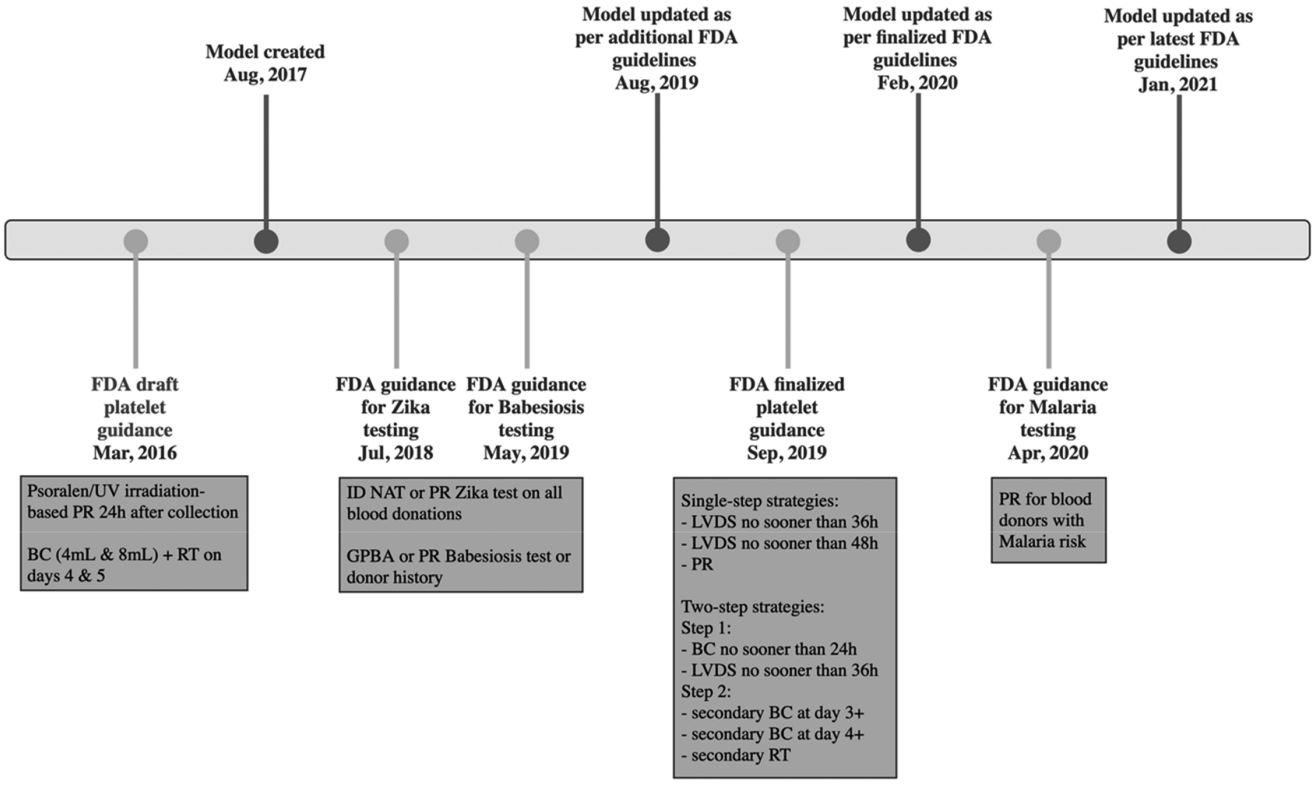

FIGURE 1 Model development and refinement timeline. BC, bacterial culture; FDA, Food and Drug Administration; GPBA, Grifols Procleix Babesia Assay; ID-NAT, infectious disease/nucleic acid testing; LVDS, large volume delayed sampling; PR, pathogen reduction; UV, ultraviolet

emerging infectious diseases, both virus and parasite, in July 2018 and May 2019.[24,25] The finalized platelet bacterial guidance published by the FDA in 2019 included single- and two-step BRCS for apheresis platelets. In addition to previously published BRCS, these guidelines included LVDS with either 36- or 48-hour hold corresponding to a shelf life of up to 5 or 7 days respectively. As the landscape of BRCS evolved, our model was reactively updated to incorporate the approved single- and two-step strategies as well as the cost for additional infectious disease testing for emerging pathogens. All platelet BRCS permitted by the recent guidances are presented in Table 1.

Seven-day PR platelets, if approved by FDA, would replace the currently approved 5-day PR units, without change in the treatment process, and are expected to be priced similarly to the current 5-day PR units. We have updated our model to include 7-day PR platelets to enhance its ability to project the potential budget impact of strategies hospitals may use to comply with FDA guidance.

2.3 | Model scenarios

Using the updated model, the budget and shelf-life impacts of 5-day PR (PR-5), 5-day LVDS (LVDS-5), 7-day PR (PR-7) and 7-day LVDS (LVDS-7) units were examined under three scenarios: (A) 100% LVDS, (B) 100% PR, and (C) a mix of 50% LVDS and 50% PR. Platelet inventory was assumed to be 100% purchased from a blood center supplier with 58 units purchased weekly (=3016 annually), representing use in a midsized hospital, since this size represent the majority of hospitals in the U.S.[26] Platelet management considerations from the hospital transfusion service perspective for purchased LVDS versus PR units are shown in Figure 2.

Model inputs are summarized in Table 2. Per-unit cost of additional NAT testing of US$ 7.50/unit for emerging diseases was applied to LVDS-5 and LVDS-7 units. Of the platelets transfused in the outpatient setting, 50% were assumed to be reimbursed

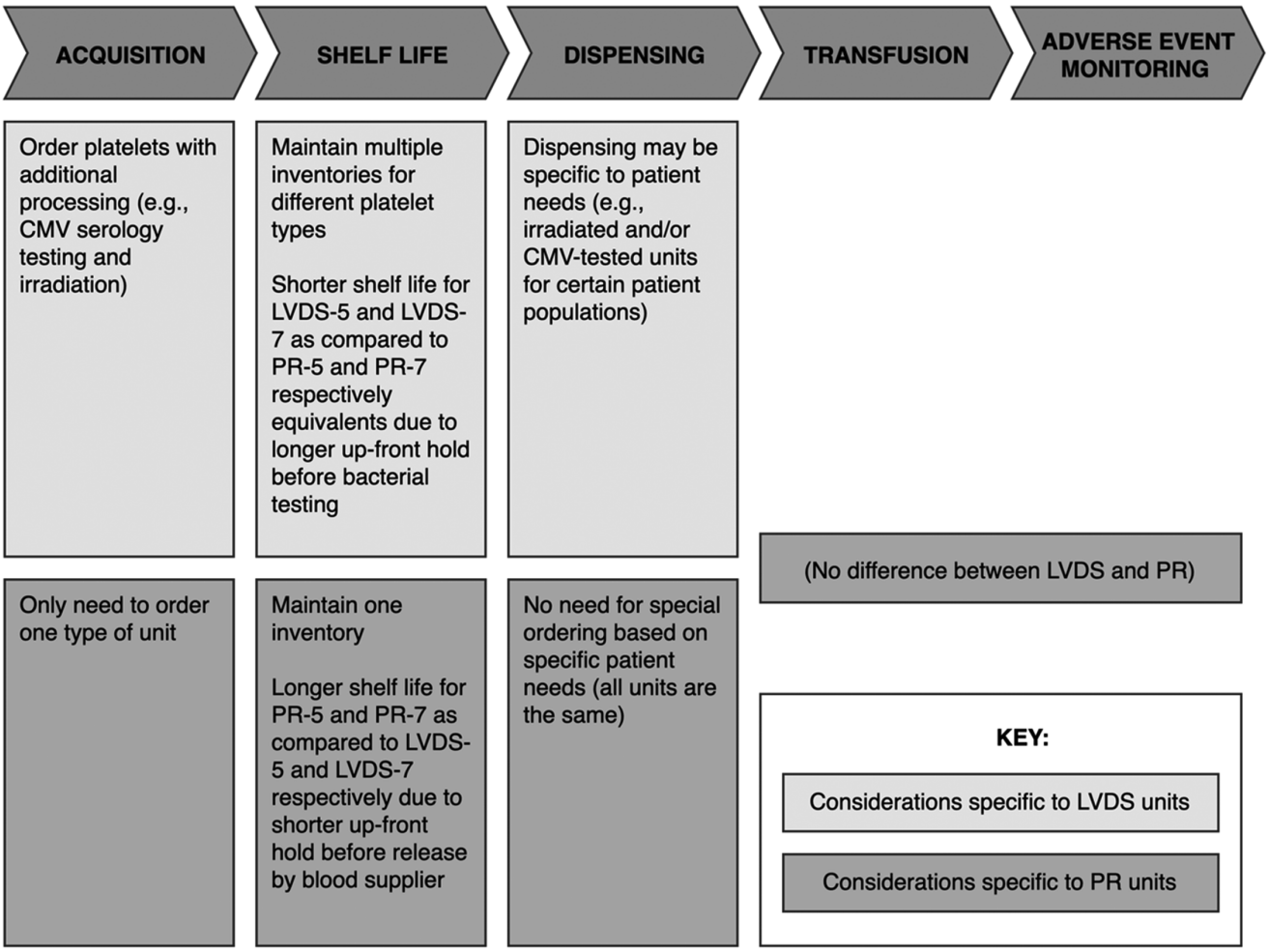

FIGURE 2 Comparison of LVDS and PR management of a 100% purchased platelet inventory. CMV, cytomegalovirus; LVDS-5, 5-day LVDS units; LVDS-7, 7-day LVDS units; PR-5, 5-day PR units; PR-7, 7-day PR units;

TABLE 2 Model inputs for LVDS and PR platelets

Parameter	Value
Acquisition	
Weekly units purchased from the blood center[a]	58
Per-unit purchase price for PR-5 & PR-7[b]	$643.00
Per-unit purchase price for LVDS-5 & LVDS-7, not irradiated[b]	$596.00
Per-unit purchase price for LVDS-5 & LVDS-7, irradiated[b]	$685.40
Percentage of LVDS-5 & LVDS-7 units which are purchased as irradiated[27]	60.7%
Per-unit cost of additional NAT testing for emerging diseases[a]	$7.50
Average LVDS-7 unit age at the time of receipt (days)[a]	4.0
Average LVDS-5 unit age at the time of receipt (days)[a]	3.0
Average PR-5 & PR-7 unit age at the time of receipt (days)[a]	2.37
Transfusion and wastage	
Mean number of platelet units transfused weekly[c]	55
Mean 5-day non-PR platelet units wasted per week[27]	6
Mean 7-day non-PR platelet units wasted per week[27]	4.8
Adverse events	
Sepsis probability for LVDS units[28]	0.0000972
Sepsis probability for PR units[29]	0
Sepsis cost per non-fatal case[d]	$80,000.00
Reimbursement	
Percentage of platelets transfused in an outpatient setting[27]	26.3%
CMS reimbursement for non-PR units, not irradiated[28]	$486.80
CMS reimbursement for non-PR units, irradiated[28]	$617.33
CMS reimbursement for PR units[36]	$583.87
Percentage of platelets reimbursed through private pay for those transfused in outpatient setting[a]	50%
Price multiplier for private pay units transfused in the outpatient setting[a]	2×
Percentage of charge which is paid by private payers[a]	75%

Abbreviations: CMS, Centers for Medicare & Medicaid Services; LVDS, large volume delayed sampling; LVDS-5, 5-day LVDS units; LVDS-7, 7-day LVDS units; NAT, nucleic acid testing; PR, pathogen reduction; PR-5, 5-day PR units; PR-7, 7-day PR units.

[a]Informed by an assumption.

[b]Aggregate costs from Jefferson internal analysis in 2020.

[c]Informed by a calculation.

[d]The average charge per payment for sepsis in 2017 per the Definitive Healthcare Medicare Database.

through private payers. Private payers were charged double the unit cost and assumed to pay 75% on these charges. For LVDS-5 and LVDS-7, 35 (60.7%) of the 58 units purchased weekly were assumed to undergo irradiation by the supplier.[22] LVDS-5 platelets were assumed to be received from the supplier on day 3 of 5 (72 h after collection) and LVDS-7 platelets were assumed to be received on day 4 of 7 (96 h post-collection).[22,27] Because less upfront processing is required for PR platelets, they were assumed to be received 56.9 h (=2.4 days) after collection. The maximum usable shelf life for each unit type was calculated based on the maximum possible platelet age minus the age at time of receipt, in hours. For example, a 7-day platelet unit has a maximum possible platelet age of 168 h (7.0 days). If received from the supplier at 4.0 days (96 h) of age, the maximum usable shelf life is 168–96 = 72 h, or 3 days. LVDS-5 and LVDS-7 units were assumed to cost US$596.00 per unit or US$685.40 for irradiated units. Per-unit purchase price for PR-5 and PR-7 platelets was assumed to be US$643.00. All acquisition costs are aggregate results from a Thomas Jefferson University internal analysis conducted in 2020. Based on results from our survey, it was assumed that 6 five-day units and 4.8 seven-day units are wasted each week yielding 55 units transfused weekly.[22] In addition, using information available in Hong et al., for non-PR platelets our model assumes a 0.0000972 probability of septic transfusion reaction.[29] For PR platelets, the probability of sepsis assumed by our model was 0 based on published data.[30] Though contamination due to error or failure in the PR process could theoretically pose a risk of sepsis, the references cited here (including French and Swiss hemovigilance data) have not demonstrated this.[31,32]

3 | RESULTS

Model results are summarized in Table 3. The annual platelet acquisition costs for each BRCS measure were US $1.983 million for 100% LVDS, US$1.939 for 100% PR and US$1.961 for 50/50 mix. Similarly, transfusion (US $113,149) and sepsis (US$22,073 for LVDS, US$0 for PR and US$11,036 for the mixed scenarios) costs were consistent across the various measures and scenarios explored.

Total annual outpatient reimbursement for 100% LVDS platelets, 100% PR, and the 50/50 mix were calculated as US$575,018, US$577,959, and US$576,488 respectively and did not differ throughout the model measures as they were calculated based on the number of acquired units rather than parameters associated with platelet shelf life. Costs associated with platelet wastage, dispensing, and transfusion varied among the different scenarios and are described below.

TABLE 3 Comparison of annual costs, outpatient reimbursements, net budget impact, and shelf-life impact for the different platelet inventory measures

	100% scenarios				50/50 mixed scenarios			
	LVDS-5	**PR-5**	**LVDS-7**	**PR-7**	**LVDS-5/ PR-5**	**LVDS-7/ PR-5**	**LVDS-5/ PR-7**	**LVDS-7/ PR-7**
Annual costs								
Acquisition: LVDS units	$1,982,864	n/a	$1,982,864	n/a	$991,432	$991,432	$991,432	$991,432
Acquisition: PR units	n/a	$1,939,288	n/a	$1,939,288	$969,644	$969,644	$969,644	$969,644
Wastage	$206,480	$188,699	$163,636	$117,548	$197,590	$176,168	$162,014	$140,592
Dispensing for transfusion and transfusion	$113,149	$113,149	$113,149	$113,149	$113,149	$113,149	$113,149	$113,149
Sepsis	$22,073	$0	$22,073	$0	$11,036	$11,036	$11,036	$11,036
Total	**$2,324,566**	**$2,241,136**	**$2,281,722**	**$2,169,985**	**$2,282,851**	**$2,261,429**	**$2,247,275**	**$2,225,853**
Annual outpatient reimbursements								
LVDS units:								
Units not further treated	$204,387	n/a	$204,387	n/a	$102,193	$102,193	$102,193	$102,193
Irradiated units	$370,631	n/a	$370,631	n/a	$185,316	$185,316	$185,316	$185,316
PR units	n/a	$577,959	n/a	$577,959	$288,980	$288,980	$288,980	$288,980
Total	**$575,018**	**$577,959**	**$575,018**	**$577,959**	**$576,488**	**$576,488**	**$576,488**	**$576,488**
Net budget impact								
Total annual costs	$2,324,566	$2,241,136	$2,281,722	$2,169,985	$2,282,851	$2,261,429	$2,247,275	$2,225,853
Total annual reimbursements	$575,018	$577,959	$575,018	$577,959	$576,488	$576,488	$576,488	$576,488
Net annual costs	**$1,759,549**	**$1,663,177**	**$1,706,704**	**$1,592,026**	**$1,706,363**	**$1,684,941**	**$1,670,787**	**$1,649,365**
Shelf-life impact								
Mean unit age when placed into inventory (days, [hours])	3.00 [72.00]	2.37 [56.80]	4.00 [96.00]	2.37 [56.80]	2.68 [64.40]	3.18 [76.40]	2.68 [64.40]	3.18 [76.40]
Maximum usable shelf life (days, [hours])	2.00 [48.00]	2.63 [63.20]	3.00 [72.00]	4.63 [111.20]	2.32 [55.60]	2.82 [67.60]	3.32 [79.60]	3.82 [91.60]

Abbreviations: LVDS, large volume delayed sampling; LVDS-5, 5-day LVDS units; LVDS-7, 7-day LVDS units; PR, pathogen reduction; PR-5, 5-day PR units; PR-7, 7-day PR units.

3.1 | 100% scenarios

Total wastage costs when purchasing a single type of platelets were US$206,480 for LVDS-5, US$188,699 for PR-5, US$163,636 for LVDS-7, and US$117,548 for PR-7 platelet units. Total annual costs to the hospital, comprising costs of acquisition, wastage, transfusion, and septic adverse events, were US$2.325 million for LVDS-5, US$2.241 for PR-5, US$2.282 for LVDS-7 and US$2.170 for 100% PR-7 platelet units.

Net budget impact, calculated as the difference between annual costs and outpatient reimbursements, was highest for LVDS-5 platelets (US$1.760 million), followed by LVDS-7 (US$1.707 million), PR-5 (US$1.663 million), and PR-7 platelets. (US$1.592 million). Under the assumptions tested, the net annual cost for PR-5 units is 5.5% below that of LVDS-5 units, and the cost of PR-7 platelets is 6.7% lower than that of LVDS-7 ones.

An important consideration in platelet acquisition decisions is shelf-life impact. The maximum usable shelf life was calculated as 2.0 days (48.0 h) for LVDS-5 platelets, 2.63 days (63.2 h) for PR-5, 3 days or 72.0 h for LVDS-7 platelets, and for the 7-day PR platelets it was calculated to be 4.63 days or 111.2 h (or 54.3% longer than LVDS-7 usable platelet shelf life).

Overall, when comparing scenarios with LVDS-5 platelets to a potential future scenario in which PR-7 platelet units are approved for transfusion by FDA, the total net budget impact for using only PR-7 platelets would be 9.5% lower than that of using only LVDS-5 units (US$1.592

vs. US$1.760 million, respectively). Finally, 7-day PR platelet unit shelf life would be 2.63 days or 63.2 h longer than LVDS-5 platelet maximum usable shelf life.

3.2 | 50% LVDS/50% PR mixed measure scenarios

For mixed BCRS measure scenarios, the highest total wastage costs were calculated for LVDS-5/PR-5 (US $197,590), followed by LVDS-7/PR-5 (US$176,168), LVDS-5/PR-7 (US$162,014), and LVDS-7/PR-7 (US $140,592) measures. Similarly, LVDS-5/PR-5 had the highest annual costs of US$2.283 million, and the lowest costs were calculated for LVDS-7/PR-7 scenario (US $2.226 million), with LVDS-7/PR-5 costing US$2.261 million and LVDS-5/PR-7 annual costs of US$2.247 million.

When comparing the net budget impact across the mixed measure scenarios, the LVDS-7/PR-5 mix had a total impact of US$1.685 million or 1.2% lower than that of LVDS-5/PR-5 (US$1.706 million). For LVDS-5/PR-7 mix, the net budget impact was calculated as US$1.671 million which is 2.1% lower than that of LVDS-5/PR-5 but 1.3% higher than the total net annual costs of LVDS-7/PR-7 measure mix (US$1.649 million).

The maximum usable shelf life was calculated as 2.32 days (or 55.60 h) for LVDS-5/PR-5, 2.82 days (or 67.60 h) for LVDS-7/PR-5, 3.32 days (or 79.60 h) for LVDS-5/PR-7, and 3.82 days or 91.60 h for LVDS-7/PR-7 measure mixed scenario.

4 | DISCUSSION

The budget impact model described here provides an informative and interactive tool for hospital transfusion services. With the ongoing evolution of FDA platelet testing regimens and guidance and newly approved platelet preparation technologies entering the BRCS market, provider decision-making becomes more intricate and complex. Economic models are a helpful tool in new technology assessment and implementation by hospital blood banks. Our model demonstrates not only its flexibility for institution-specific inputs and assumptions, it also shows the ability to be updated as new technologies and regulations emerge.

A previous analysis of financial implications for various risk reduction strategies by Kacker et al demonstrated that per-transfused unit cost is significantly higher for PR platelets as compared to other technologies.[33] However, here we demonstrate that under some scenarios, the net cost associated with PR platelets can be comparable to or less than that of LVDS platelets of the same shelf life. This is in part due to the low wastage costs and higher outpatient reimbursements, but more importantly it is due to the reduced risk of transfusion-related sepsis which has not only economic but also clinical significance. In fact, the direct cost assumption for treating sepsis may be much lower than total costs because direct costs represent only the costs of immediately treating septic transfusion reactions without accounting for other possible costs (such as legal costs).

Platelet outdating can be associated with significant costs. In Europe for more than a decade PR platelet technologies have been utilized and extending PR storage for up to 7 days has been implemented with improved platelet availability, reduced wastage without increased frequency of adverse reactions as compared to 5-day PR platelets.[12,13] In light of this, if FDA guidelines in the near future allow for PR platelet shelf-life extension up to 7 days, wastage due to expiration could be reduced even more. Our model shows that it could theoretically be reduced close to US$0 for 7-day PR units. However, we acknowledge how implausible that seems given the practical problems of inventory management faced by hospital blood banks. In addition, while 7-day LVDS platelets provide extended shelf life compared to conventional bacterial testing, pathogen reduction technology has shown efficacy against a broad spectrum of pathogens,[11,34] which is a particularly important additional layer of safety if new pathogens emerge. Shelf-life impact is an important part to consider when looking at total annual costs. While maximum usable shelf life is the highest for scenarios involving at least one type of 7-day platelet measure, it is important to notice that PR platelets can generally be accessed earlier than non-PR platelets.

As with most economic models, this BIM is limited by the scenarios we modeled, and the data available to inform the model's assumptions. For example, the model assumes that the probability of sepsis for PR platelets is zero. However, two recent case reports have explored septic transfusion reactions associated with PR platelets.[35,36] One report examined four separate septic cases thought to share the same source of contamination, but this source was unidentified at the time of publication, and only one of the four platelet units had been pathogen-reduced. Though this indicates a nonzero probability of septic transfusion reactions from the use of PR platelets, given the uncertainty in the contamination source and lack of population-level data, we are unable to estimate this probability. In addition, in our model the wastage assumption does not differentiate wastage that occurs in lab versus out the of lab, the latter of which may include orders from platelets distributed from the blood bank but are not transfused and cannot be restocked due to

improper transport of storage. Furthermore, reimbursements for inpatient transfusions are not considered in this model because they are bundled under diagnosis-related group (DRG) payments. Lack of sensitivity analysis is another model limitation. The scenarios described herein may therefore not generalize to all purchasers due to variations in hospital size and platelet inventory needs, patient population, and blood supplier pricing contracts, among other factors. However, the model is customizable, and users can test for uncertainty by modifying its inputs. Finally, models must be updated as the blood supply landscape changes; thus, there may be a lag between the issuance of a new guidance and its inclusion in the model. This model, however, brings relevant current and future interventions into discussion by incorporating anticipated or draft guidance, rather than waiting for the final guidance to be issued, thus mitigating the lag.

5 | CONCLUSIONS

Overall, economic models are a novel tool used by blood banks and hospitals to improve efficiency and minimize negative clinical and economic impact of blood-borne pathogens during transfusion. The model presented is an example of an adaptive, customizable, hospital-focused tool can help hospitals better understand the budget implications when weighing purchasing options. Our experience with this model underscores the need for such tools to be updated as clinical practice and associated guidance evolves.

CONFLICT OF INTEREST

Katherine M. Prioli: Received research support from Cerus to Rutgers University for this work. Ilze Abersone: No conflict of interest to report. Patricia M. Kopko: No conflict of interest to report. Jay H. Herman: Received consulting support from Cerus to Rutgers University for this work. Brian S. Custer: No conflict of interest to report. Laura T. Pizzi: Received research support from Cerus to Rutgers University for this work. Authors independently wrote the paper and attest that it represents their own work. The sponsor of the work was provided a courtesy copy of the draft.

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