Cost implications of implementation of pathogen-inactivated platelets

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BACKGROUND: Pathogen inactivation (PI) is a new approach to blood safety that may introduce additional costs. This study identifies costs that could be eliminated, thereby mitigating the financial impact.

STUDY DESIGN AND METHODS: Cost information was obtained from five institutions on tests and procedures (e.g., irradiation) currently performed, that could be eliminated. The impact of increased platelet (PLT) availability due to fewer testing losses, earlier entry into inventory, and fewer outdates with a 7-day shelf life were also estimated. Additional estimates include costs associated with managing 1) special requests and 2) test results, 3) quality control and proficiency testing, 4) equipment acquisition and maintenance, 5) replacement of units lost to positive tests, 6) seasonal or geographic testing, and 7) health department interactions.

RESULTS: All costs are mean values per apheresis PLT unit in USD ($/unit). The estimated test costs that could be eliminated are $71.76/unit and a decrease in transfusion reactions corresponds to $2.70/unit. Avoiding new tests (e.g., *Babesia* and dengue) amounts to $41.80/unit. Elimination of irradiation saves $8.50/unit, while decreased outdating with 7-day storage can be amortized to $16.89/unit. Total potential costs saved with PI is $141.65/unit. Costs are influenced by a variety of factors specific to institutions such as testing practices and the location in which such costs are incurred and careful analysis should be performed. Additional benefits, not quantified, include retention of some currently deferred donors and scheduling flexibility due to 7-day storage.

CONCLUSIONS: While PI implementation will result in additional costs, there are also potential offsetting cost reductions, especially after 7-day storage licensing.

Pathogen inactivation (PI) is an alternative approach to blood safety that is gaining widespread use.[1] PI for platelets (PLTs) has been in use in Europe for more than 10 years and one of these systems, the INTERCEPT Blood System, was recently approved by the Food and Drug Administration (FDA).[2] There are costs for implementing PI, but it is also likely

ABBREVIATIONS: DFV = dengue fever virus; PC(s) = platelet concentrate(s); PI = pathogen inactivation; PoR = point of release; WNV = West Nile virus.

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TABLE 1. PLTs collected, purchased, and transfused at participating institutions

Institutions	Number of units transfused	Number of units collected	Number of units purchased
A	None	14,000 collections, 22,000 products	None
B	5,631	1,534	4,097
C	8,707	8,707	None
D	11,162	10,046	1,116
E	13,630	None	13,630
Total	53,130	34,287	18,843

TABLE 2. Minimum, maximum, and mean costs of reagents and technologist time for tests potentially eliminated by implementation of PI (in $/unit)

Test or activity	Minimum	Maximum	Mean
Bacterial culture	8	27	17.5
PoR for bacteria			27.91
West Nile virus	4	12	8
T. cruzi	8.50	20	14.25
Syphilis	2.5	11	6.75
CMV	2.25	4.30	3.28

that there will be offsetting savings. The availability of PI PLTs may have substantial economic impact both in terms of operating costs for the facilities which collect and prepare them and in the acquisition costs to hospitals. The purpose of this study was to carry out a detailed cost analysis of the operational activities that may be affected by the adoption of PI PLTs and to project those that will apply to either blood centers or hospitals. The costs will affect hospitals in different ways depending on whether they purchase all their PLTs from an outside supplier or if they produce some fraction of the PLTs. While PI PLTs may reduce the costs associated with transfusion-transmitted disease treatment those costs were not considered in this project.

This study focuses on PLTs collected by apheresis because in the most recent survey in the United States, 91% of the total of 2,516,000 PLT units was collected by apheresis.[3] In the United States, blood centers collected approximately 89% of the apheresis PLT supply while hospitals collected 11%.[3] Collection can be done with different devices and the PLTs can be stored for up to 5 days in either donor plasma or PLT additive solution and plasma mix at room temperature. When PLTs are collected at a blood center, testing is done along with standardized whole blood testing; however, when PLTs are collected at a hospital, samples are often sent to a different facility for testing. Bacterial screening of each unit of PLTs is performed at the place of collection but when performed, point-of-release (PoR) testing is usually done at the hospital.

MATERIALS AND METHODS

Institutions participating

The participants in this study were Memorial Blood Centers division of Innovative Blood Resources, Massachusetts General Hospital, Stanford University Medical Center, University of California Los Angeles Medical Center, and University of Minnesota Medical Center, Fairview (Table 1). The methods of data acquisition and analysis are described in the Supporting Information available in the online version of this paper.

RESULTS

The impact of savings was allocated in the following groups: 1) current tests that could be eliminated; 2) test-related costs; 3) potential new tests that could be avoided; 4) elimination of irradiation; 5) decreased transfusion reactions; 6) additional PLTs available for transfusion, if 7-day storage were to be allowed; and 7) additional units available from elimination of certain tests.

Elimination of current tests and related procedures

The mean costs for tests, including the technologist time, ranged from a minimum of $3.28 for cytomegalovirus (CMV) to $29.31 for PoR testing (Table 2). As shown in Table 3, the mean cost for these activities that comprised all activities but the actual testing, ranged from $0.13/unit for proficiency testing of bacterial culture to $1.95/unit for special requests.

Eliminating testing for bacterial culture, PoR testing, West Nile virus (WNV), CMV, and syphilis totals $86.34 (Table 4). The costs described here would apply differently to each center, depending on the percentage of PLT concentrates (PCs) tested for CMV and the potential adoption of PoR testing as may be influenced by the recent FDA guidance on bacterial detection. The cost of each test and related activities is outlined in the following section and described in detail in the Supporting Information.

Bacterial culture

The costs for bacterial culture including reagents and technical time to carry out the test and record results range from $8 to $27 (mean, $17.5; Table 2). When taking into account additional activities necessary (Table 4) the total estimated additional cost of bacterial testing is $19.90/unit.

PoR testing

We estimated the cost of PoR testing from direct experience and from the literature.[4,5] We used a cost of $25 for the reagents. Additional costs associated with the use of the assay, repeat testing and the loss of positive units (Table 3) make the total cost of PoR $30.32/unit (Table 4).

TABLE 3. Other test-related costs per PLT unit obtained from participating institutions (in $/unit)

Institutions	Number of units transfused*	$ Manage results	$ Special requests	Bact Equip Maint	Culture Prof	PoR Prof & Equip	Season health department test
A	14,000 (22)	0.30	0.04	1.52	0.19	1.41	0.39
B	5,631	0.58	0.14	None	0.10	3.51	0.96
C	8,707	0.36	2.80*	2.19	0.10	2.27	0.62
D	11,162	0.28	6.75*	1.99	None	1.77	0.48
E	13,630	0.14	0.02	None	None	1.45	0.40
Mean		0.33	1.95	1.90	0.13	2.08	0.57

* Due to requests for CMV tested units.

TABLE 4. Summary of costs of current tests potentially eliminated by PI PLTs (in $/unit)

	Bact Culture	PoR	WNV	*T. cruzi*	Syphilis	CMV
Reag/tech	17.54	27.91	8	14.25	6.75	3.28
Manage results	0.33	0.33	0.33	0.33	0.33	0.33
Special request	None	None	None	None	None	1.95
Equip/Maint	1.90		None	None	None	None
QC/prof test	0.13	2.08	None	None	None	None
Seasonal	None	None	0.57	None	None	None
Other	0.04*	None	None	None	None	None
Total	19.90	30.32	8.90	14.58†	7.08	5.56
Grand total† = $71.76						

* Culture of test-positive units.
† *T. cruzi* is not included in the grand total.

WNV

The cost of reagents and associated technician time were estimated to be $4 to $12 (mean, $8/unit; Table 2). Costs associated with managing test results and the issues associated with seasonal testing (Table 4) bring the total cost of WNV to $8.90/unit.

Trypanosoma cruzi

We estimated costs related to *T. cruzi* testing of $8.50 to $20 (mean, $14.25; Table 2) with $0.33 for managing test results for a total of $14.58/unit (Table 4). We have included the *T. cruzi* cost in this report but not in the total cost savings due to PI because it is only performed on first-time donors and PLT donors are rarely first-time donors.

Syphilis

As with *T. cruzi* and WNV, syphilis testing is done along with others in a complex system and thus these costs are difficult to identify individually. We estimate the cost of testing to be $2.50 to $11.00 (mean, $6.25/unit; Table 2). Test-related costs (Table 4) add $0.33 for a total cost of $7.08/unit.

CMV

When CMV-seronegative PLTs are requested, testing may be done at the hospital or the blood center. Testing cost ranged from $2.25 to $4.30 for a mean of $3.28/unit (Table 2). Additional management costs bring the total to $5.56/unit. Charges usually added for seronegative units averaging $20.5/unit were not included.

Avoidance of potential new tests

Babesia

This testing has been done under investigational new drugs and involves testing donors in New England and the upper Midwest. Some of the studies have been completed,[6] and the operational and practical implementation issues are under discussion, while the selective use of test negative blood for specific patient groups is considered. It is likely that the test will first be considered for the currently defined *Babesia*-endemic areas; however, the travel practices have resulted in detection of infected donations in nonendemic areas. Additionally, the definition of which states are nonendemic may change upon additional surveillance testing. Open questions are whether seasonal testing of all blood should be considered for high-risk periods and how to determine these periods. However, transmission has occurred throughout the year, including one in January from an asymptomatic donor.[7,8] We have used the best estimate available of $20, based on the cost-recovery charges. This expense is expected to increase after approval. Costs associated with result management brought the total cost for *Babesia* testing to $20.90/unit. The impact of the test's 0.5% false-positive rate to donor availability was not taken into consideration in our estimates.

Dengue

In addition to the epidemic that happened in the American region of Puerto Rico, there have been autochthonous outbreaks of dengue in South Florida, Texas, and Hawaii,[9,10] and cases of transfusion-

TABLE 5. Value of units of PLTs useable if storage period increased to 7 days

Institution	Number of units	Current outdate	Projected outdate	Number of units salvaged	$ Value units*	$/unit
A	14,000 (22)	8	4	560	299,600	21.40
B	5,631	2.3	<1	73	39,055	6.94
C	8,707	14	7	609	326,077	37.42
D	11,162	3	1.5	167	89,575	8.00
E	13,630	4	2	272	145,841	10.68
Total	53,130			1,681	899,335	16.89

* Value of unit of PLTs = $535.

transmitted dengue have been reported elsewhere in the world.[11,12] Testing for dengue in the United States has been done to date only under investigational new drugs and in limited areas. Dengue and other arboviridae may be more prevalent in some parts of the country, and the costs would apply only for centers that adopt the test due to that need. Today the type of vectors for this and Chikungunya virus seem to be localized in tropical areas; however, the WNV experience has demonstrated that a new pathogen can be quickly spread in the United States. Additionally, viruses many times mutate in ways that modify their virulence and their vectors. The cost of reagents and labor to carry out the test and their incidence of positive tests needing confirmation are not known and thus we estimated the costs using the same cost per test as for *Babesia*. Since seasonal or geographic factors may be part of dengue fever virus (DFV) testing, we have used the same cost estimates for these issues as used for *Babesia* and WNV giving a total cost for DFV testing of $20.90/unit. The total savings from avoidance of introducing testing for *Babesia* and DFV is estimated as $41.80/unit.

Irradiation

The INTERCEPT process, an example of a PI technology, prevents white blood cell activation that causes graft-versus-host disease (GVHD).[13-16] This has been corroborated by extensive clinical experience in which INTERCEPT PLTs have been transfused to immunodeficient patients without resulting GVHD.[17-19]

Some institutions find it more convenient and less risky to irradiate all PLT products. The additional procedures are felt to be less costly than staff time to distinguish units for patients needing irradiated products.[17] Universal PLT irradiation also avoids the risk of failure to irradiate units for patients needing irradiated products. Thus, for this study we have presumed that all PLT products would be irradiated. Irradiation is so common and standard in most institutions that no additional costs are included here for decision taking or record keeping.

The costs for irradiation were $7.00 to $10.00 for a mean of $8.50/unit. As individual centers consider these savings, the costs for irradiation will be applicable to the extent that centers irradiate their PLTs. The range of the charges at the participating institutions is $16 to $52 (mean of $34/unit), although this cost is not included in any of our totals.

Decreased transfusion reactions with PI PLTs

The incidence of an adverse reaction to transfusion is approximately 1.7%.[19] We assumed a conservative adverse reaction rate of 1%. Patient care and transfusion physicians, nurses, and blood bank laboratory staff are involved in addressing a transfusion reaction and so costs of all of these were included. We estimated that each reaction consumed a total of 1 hour of physician time. This involved the patient care physician evaluating the patient for a possible reaction and the transfusion medicine physician evaluation and interpretation. We also estimated 1 hour of blood bank technologist time and two-thirds of an hour of the patient care nurse's time. In a previous study,[18] we carried out a detailed analysis of costs associated with transfusion reactions. The analysis results were incorporated here and total $2.70/unit.

Additional PLT unit availability

Several changes resulting from the implementation of PI could make more units of PLTs available for use. These are: 1) decreased outdating, if and when 7-day storage becomes possible; 2) units no longer removed from inventory due to eliminated positive screening tests; and 3) donors not deferred or lost, due to changes in donor deferral criteria.

1. Increased PLT unit availability might be expected due to decreased discards of units that would have tested positive if that testing had been done. These lost units represented $2675 to $26,215 to the institutions participating or a mean of $1.27/unit of PLTs currently used.
2. Prolonging storage of PLTs should provide more opportunity to use the units and thus decrease outdating. The participating institutions collected and purchased between 5631 and 14,000 units of PLTs during the past year (Table 1). Their outdating rates ranged from 2.3% to 14% (Table 5). The participants estimated that the outdating rates would decrease to the range of less than 1% to 4%. Thus, we estimate that a 7-day storage period would recover 73 to 609 units of PLTs otherwise lost

TABLE 6. Summary of potential monetary impact of INTERCEPT PLTs

Test or procedure	Procedure mean amount $	
Eliminated		
Bacterial testing	19.90	
PoR	30.32	
WNV	8.90	
CMV	5.56	
*T. cruzi**	14.58	
Syphilis	7.08	
Subtotal*		71.76
Procedures eliminated		
Irradiation	8.50	
Transfusion reactions work-up	2.70	
Subtotal		11.20
Test avoided		
Dengue	20.90	
Babesia	20.90	
Subtotal		41.80
Additional from 7-day storage		16.89
Additional savings from products not discarded due to false-positive tests		1.27
Total*		$142.92

* *T. cruzi* is not included in the total.

due to expiration at the different institutions (Table 5). At $535/unit replacement cost, this total of 1681 units has a value of $899,335 varying from $39,055 to $326,077 per institution. When allocated over all the PLTs transfused, this amounts to a mean of $16.89/unit of PLTs ($6.94-$37.42/unit; Table 5).

3. It is expected that some donor selection criteria could be revised, possibly enabling some previously deferred donors to become eligible. Examples are travel to malaria areas and tattoos or piercings. However, a dollar amount is not provided for this donor impact.

Another benefit of 7-day storage would be greater flexibility of scheduling donors; however, we did not project a cost savings for this, or cost gain for increased donor availability or increased staff efficiency.

The total potential savings per unit includes the cost of current tests that could be eliminated ($71.76/unit), potential new tests avoided ($41.80/unit), elimination of irradiation ($8.50), decrease in transfusion reactions ($2.70/unit), and additional PLTs available from 7-day storage ($16.89/unit), and additional PLTs available from current tests not done ($1.27/unit) for a total of $142.92/unit (Table 6). Of these cost savings, approximately 70% could accrue to blood centers and the remainder to hospitals, depending on where procedures take place.

DISCUSSION

The potential cost saving from implementation of PI is substantial and needs to be evaluated on an individual blood center and hospital basis. We have used specific cost information from five institutions with large consumption of PLTs. Where specific cost data were not available, estimates were made based on literature review. In addition to the cost of reagents and technologists, we determined the cost of test-related activities (Tables S1 and S2, available as Supporting Information in the online version of this paper, and Table 3). The value of additional PLTs potentially available if 7-day storage were implemented was based on existing outdate data and estimates of the reduced outdate rate from knowledgeable line staff.

Many physicians believe that leukoreduction provides adequate safety from CMV transmission and thus CMV testing is irrelevant in those facilities. However, leukoreduction does not reduce CMV DNA in plasma[20] and serology and nucleic acid testing (NAT) do not address CMV window or early-phase infection.[20] The combination of leukoreduction, serology, and NAT is also not feasible since this likely would eliminate a very large proportion of donors. Thus, many physicians believe that testing is still necessary and we have included those costs. Though costs are included for CMV testing of all the units, the percentage of CMV units tested will vary in a given facility.

PoR testing for bacterial contamination is currently not widely used[21,22] but the recent FDA guidance and future FDA requirements or AABB recommendations could stimulate widespread adoption. This would be especially true if use of PoR assays allows the extension of shelf life for PLTs to 6 or 7 days. Pathogen reduction methods have been shown to be superior to detection in ensuring no bacterial growth at later stages, especially when there is a very small initial bacterial load. Since there is a limited time from test completion until PLTs must be released, it is presumed that PoR testing will be done mostly in hospitals and hence, most of the value of eliminating or not having to adopt PoR will accrue to hospitals.

Syphilis is a federally mandated test. However, sound scientific data do not support the infectivity of blood components[23] and leaders in transfusion medicine have urged its elimination.[24,25] This could be accomplished with implementation of PI.

Elimination of bacterial culture would not only save money but would have logistic benefits as well. The recent approval of the INTERCEPT pathogen reduction system with the intended use of ex vivo preparation of pathogen-reduced apheresis PLT components to reduce the risk of transfusion-transmitted infection, including sepsis, makes it a viable replacement of bacterial detection with a shelf life of 5 days. The current guidance by the FDA predated the approval and an updated guidance document is pending. Eliminating bacterial culture would allow release of PLTs into useable inventory 1 day earlier than at present. This extra day of use could have considerable value[22,26-28] and will be analyzed further in a future study.

The recent FDA guidance proposes methodology for the extension of the shelf life of PCs to 6 and 7 days upon retesting. Six- and 7-day-old PLT components treated with a pathogen reduction system were found to be equivalent to the control for the support of patients with thrombocytopenia in a noninferiority clinical study in Europe (the TESSI trial). It is conceivable therefore that 7-day storage may be approved for pathogen-reduced PLT components in the United States, as has been in parts of Europe for more than 5 years. If the storage time for PLTs could be increased to 7 days, in addition to extra inventory days, it will also decrease outdating of PCs. The decrease in outdating would provide 73 to 609 additional units of PLTs amounting to a mean of $16.89/unit (Table 5). Three other studies provide a broader perspective. In Spain, 7-day storage resulted in a 14% decrease in outdating which represented $270,000 savings based on their PLT use.[27] In the Passport study[22] outdating decreased from an initial 6% to 20% to approximately 2%. Su and colleagues[29] reported a 10% increase in PLT distribution using a 7-day storage model compared with 5-day storage due to a reduction of outdating from 13% to 3%. Thus, the data projected in this project are consistent with other reports. Nationally, in 2011, 12.8% or 371,000 PLT units outdated.[3] At a value of $535/unit, this represents a loss of $198,485,000. Thus, even a modest decrease in outdating would have a large financial impact. There are some other benefits of PI PLTs for which costs were not determined:

Revised donor selection criteria

Plateletpheresis takes longer than whole blood donation and thus donor availability and retention are important issues. Most PLT donors are previous whole blood donors but hospital programs in particular may also attract first-time donors. Use of PI could lead to revision of PLT donor criteria, such as receipt of tattoo or piercing or travel to malaria-endemic areas applicable both to first-time and repeat donors. The number of donors that could be recovered due to such changes was estimated to 11 to 94 donors per center; we predict that the actual numbers are higher because PLT donors are experienced and some might self-defer.

The cost of acquiring new whole blood donors has been estimated by blood centers as approximately $20 to $36.[30] Thus, modification of criteria to avoid unnecessary deferrals could have a substantial monetary impact.[31,32] Because we presume that current collection activity provides an adequate PLT supply these additional donors might not provide more total PLT units and thus no monetary value was allocated to this PI-related change because the value was difficult to quantify. We nonetheless expect that the additional donors would increase the efficiency of recruitment by providing an expanded donor pool from which to draw.

Ease of donor scheduling

Storage of PLTs for 7 days would allow greater flexibility for days of PLT collection and there will be less need to schedule donors over weekends when labor is more expensive. Overall, the aggregate financial impact of PI PLTs could be substantial. Since some benefits accrue to blood centers and other benefits accrue to hospitals, the total impact will be shared within the blood supply system. Most testing-related benefits accrue to the blood collection organization, although hospitals benefit by eliminating irradiation; this is particularly important in those hospitals that irradiate all PLTs regardless of patient indication. In addition, hospitals benefit from avoiding surcharges for CMV-negative units, and PoR testing, reducing the workload of transfusion reactions and outdating fewer units due to a longer storage period.

Financial impact from health care perspective

The application of PI technology reflects both the opportunities and the challenges of introducing a disruptive innovation into the health care delivery system. Disruptive technology refers to an innovation that disrupts an existing market, thereby displacing an earlier technology.[33,34] By this definition, PI can be defined as disruptive technology: in addition to being able to replace or thwart the adoption of additional tests against potential pathogen threats, it may also affect PLT availability and/or improve logistics.

A disruptive technology like PI should be evaluated as a function of two components: quality and cost. Quality is defined as comparative effectiveness of a treatment approach, while cost is a function of the net cost increase and decrease of the new technology. A focus on cost alone is counterproductive[35] because it obscures the benefits that will come from addressing the needs of patients with particular medical conditions[36] and over time a disruptive technology will become the norm.[37]

Quality

PI PCs have demonstrated comparable hemostatic function as conventional PLTs, while offering several advantages including decreased transfusion reactions,[38] decreased bacterial infections,[39-45] increased PLT availability due to 7-day storage,[27] improved donor scheduling and donor recruitment to staffing due to 7-day storage, and increased donor availability due to revised donor selection criteria.[27]

In the SPRINT trial, a total of 645 patients with thrombocytopenia were evaluated for the incidence of Grade 2 bleeding upon receiving either PI-treated PCs or conventional. The test arm was found to be noninferior to the control arm for bleeding of Grade 2, meeting the primary endpoint, as well as Grade 3 and 4 bleeding. Some significant differences were found on the 1-hour

TABLE 7. Frequency of transfusion transmitted bacterial infections of conventional PCs and of INTERCEPT PCs based on national French and Swiss hemovigilance data*

	Conventional PLTs		INTERCEPT PLTs	
Year	Number of units transfused	Transfusion-transmitted infections (fatalities)	Number of units transfused	Transfusion-transmitted infections
French data†				
2006	231,853	4 (0)	6,420	0
2007	232,708	9 (2)	15,393	0
2008	239,349	6 (1)	15,544	0
2009	241,634	9 (0)	21,767	0
2010	253,149	2 (1)	22,632	0
2011	267,785	3 (1)	22,392	0
2012	275,834	7 (2)	24,849	0
2013	278,234	4 (1)	25,089	0
Swiss data‡				
2010	29,900	1 (0)	0	0
2011	6,600	0	26,500	0
2012	0	0	34,265	0
2013	0	0	34,750	0
Total	2,057,046	45 (8)	249,601	0

* One-sided Fisher's exact test analysis provided the following values for the assessment of statistical significance: p value French data = 0.039; p value Swiss data = 0.277; p value combined = 0.006.
† French hemovigilance data.[39,41]
‡ Swiss hemovigilance data.[42-45]

CCIs, the number of PLT transfusions (8.4 vs 6.2) utilized, and the transfusion intervals between the two arms (1.9 vs 2.4), implying that additional PLTs may be required for the support of thrombocytopenia. A different picture emerged from a retrospective study of PLT utilization during routine use of the system over a 3-year period in France, where neither the mean dose per PLT, the PLT unit number nor the total PLT dose were statistically different between arms. Similarly, data from the latest hemovigilance report from Switzerland indicate that over a 3-year period of INTERCEPT PC use, no increased production of PLTs attributable to the adoption of PI were required. In addition, the consumption of red blood cells, which is an indirect measure of bleeding, did not appreciably increase either in France or in Switzerland over a multiyear period of pathogen-reduced PLT use.

Data related to the reduction of transfusion transmitted infection and adverse events are demonstrated by French and Swiss hemovigilance data[39-45] (Table 7), where use of INTERCEPT PLTs resulted in measurable decreases of transfusion-transmitted bacterial infections and associated deaths.[2,32] Additionally, Swiss hemovigilance data show a significant decrease in the high imputability, high severity adverse events, from 1:3000 to 1:7000 reports when comparing the 3 years before and after the introduction of PI in Switzerland (Table 7).[42-45] When combined, the data above signify that PI PCs have comparable quality and practical application in routine use as control PLTs, while offering advantages in the areas of disease transfusion transmission, reduction of adverse events, and replacement of gamma and CMV testing.

PI also has the potential to improve the blood collection process and blood availability of a nation with a 7-day shelf life approval. Less restricted blood collections and improved blood availability, as well as a reduction of outdates, have been reported after adoption of INTERCEPT PLTs for the Balearics region of Spain.[27]

Cost

The cost of PI introduction may be offset should certain tests and procedures be replaced as described in this study. Cost may be decreased by as much as $142.92/unit as a result of PI implementation should the relevant claims be applicable to the center considered. Other costs to consider include those saved via the improved PLT availability, earlier release, and the ease of donor scheduling. Additionally, the potential reduction of donor deferrals, for example, due to travel, is expected to provide a reduction of costs associated with the recruitment and retention of donors in the long term.

Although not considered in this study, dual storage kit configurations such as those used in Europe for INTERCEPT PLTs enables blood centers to produce two therapeutic doses from a single kit from a double-apheresis donation.[46] In these cases costs per kit would be reduced by up to 50%. Given the high percentage of double donations[47] in many of the US centers, this is an important and unexplored cost-saving approach, in wide use in Europe.

Despite the potential savings estimated above, case-by-case analyses should be performed to determine which apply, as institutional practices differ. The specific tests performed in each center and the arrangements for

services such as gamma will have a significant influence on the savings applicable. Furthermore, certain procedures and/or tests will be incurred in blood centers while others in hospitals. It is important to note that the analysis and data provided above are specific for the system approved by the FDA in the United States and the relevant European data and that separate analysis of such data, if available, should be used to evaluate the value proposition of each PI and pathogen reduction technology.

In the broader picture of health care management, we are long past the point where it is possible or acceptable to be complacent about aggressively reengineering processes for greater efficiency and productivity. Whenever tasks are identified for elimination, there is an opportunity to combine with other task reductions through better process analysis. The reduced tasks required for ensuring blood safety identified in this analysis are part of a much broader imperative to improve quality and reduce health care costs.

CONFLICT OF INTEREST

For JG, our blood center performed an in vitro clinical trial for Cerus and is under contract to perform pathogen inactivation for an in vitro clinical trial for a different supplier. VC and AS are employees of Cerus Corporation, the manufacturer of a system for pathogen inactivation. JM receives research funding from Terumo, LLC. All other authors have disclosed no conflict of interest.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Table S1. Test-related activities that were identified for cost impact.

Table S2. Test-related activities attributed to specific tests.