Platelet Bacterial Mitigation Strategies

Review of Current Practices: Pathogen Reduction and LVDS

Corinne Goldberg MD
Medical Director, Carolina Regions

September 13, 2022

0

Disclosure Statement

- I have no real or apparent conflict of interest or other relationships related to the content of this presentation.
- There is no off-label and/or investigational use of products discussed in this presentation.
- I have no relevant financial relationship to disclose

1

Objectives

- Describe how Pathogen Reduction (PR) and Large Volume Delayed Sampling (LVDS) can reduce risk for bacterial contamination in apheresis platelet units.
- Understand the residual risks with PR and LVDS after transfusion.
- Assess the cost and operational effectiveness associated with these platelet bacterial contamination mitigation strategies.

2

The FDA's Bacterial Risk Control Strategies

3

Blood Donation Contamination Preventive Measures Prior to FDA Guidance

- Stringent donor screening criteria
- Enhanced disinfection solutions (e.g. chlorhexidine)
- Diversion of first 30 – 40 ml of drawn whole blood
- Increased specificity and sensitivity of infectious disease testing

With these measures, reduction of platelet component contamination risk is reduced by **77%**

Cloutier M et.al. Vox Sanguinis. 2022;117:879 – 886.

4

Transfusion Transmission Infection (TTI) Risk

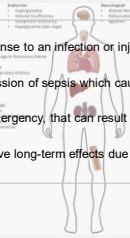
- FDA reported that for the four-year period of 2016 – 2020, 184 transfusion fatality cases were reported; of which 13% were associated with contamination.
- Bacterial contamination is the Leading transfusion transmitted infection risk with platelet units.
- Reported clinical septic reactions of ~1:5000 units transfused is likely an under-representation.

Microorganism	Risk per Unit Transfused
HIV	1:2,135,000
HBV	1:277,000
HCV	1:1,930,000
HTLV	1:2,993,000
Treponema pallidum (Syphilis)	Rare (last reported US case in 1966)
Trypanosoma cruzi (Chagas)	7 cases (US and Canada)
WNV	1:350,000
Zika Virus	2 reported cases (Brazil)
Bacteria - Platelets	1:1,000 -1:5,000

Fatalities Reported to FDA Following Blood Collections and Transfusion Annual Summary for FY2020.. https://www.fda.gov/media/160859/download. Accessed on 8/19/2022
Bihl F.et.al. Journal of Translational Medicine 2007;5:25

5

Clinical Presentation of Sepsis



- Sepsis is the body's response to an infection or injury that results in organ dysfunction
- Septic shock is the progression of sepsis which causes severe hypotension
- Classified as a medical emergency, that can result in death within hours of diagnosis
- Those who survive can have long-term effects due to chronic organ dysfunction

Image, Medical Clinics: https://www.medical.theclinics.com/article/S0025-7125%2820%2930019-5/fulltext

Mahapatra S et.al. StatPearls Publishing; 2022: https://www.ncbi.nlm.nih.gov/books/NBK430939/

6

FDA's Center for Biological Evaluation and Research (CBER) Bacterial Mitigation Strategies

Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion

Guidance for Industry

7

2020 FDA Guidance: Bacterial Mitigation Strategies for Collected Platelets

United States. FDA CBER. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion Guidance for Industry. Department of Health and Human Services. 2020.

8

2020 FDA Guidance: Bacterial Mitigation Strategies for Collected Platelets

United States. FDA CBER. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion Guidance for Industry. Department of Health and Human Services. 2020.

9

Platelets with 7 Day Storage

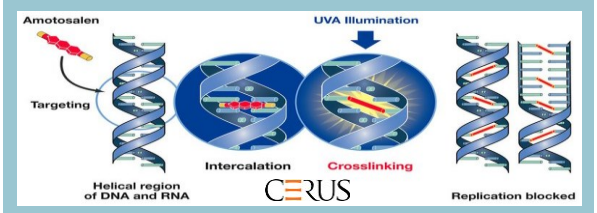
- LVDS ≥ 48 hours
- LVDS ≥ 36 hours + secondary rapid testing
- LVDS ≥ 36 hours + secondary culture testing ≥ Day 4
- Standard platelet ≥ 24 hours + secondary rapid testing (≤ 24 hrs. of transfusion) ≥ Day 4
- Standard platelet ≥ 24 hours + secondary culture testing (aerobic and anaerobic) ≥ Day 4

Note: FDA approved container for 7-day storage is required, and not all platelet products qualify.

United States. FDA CBER. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion Guidance for Industry. Department of Health and Human Services. 2020.

10

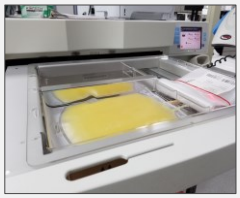
Pathogen Reduction



11

Pathogen Reduction INTERCEPT Blood Systems

- Illuminator – 6 minutes exposure to UV-A light.
- Product is transferred to another container which contains a compound adsorption device (CAD).
- Product is placed on an agitator. Plasma 12 – 24 hours; Platelet additive solution (PAS) 6 – 16 hours.
- Transfer to final product container.



American Red Cross 12

12

Benefits of Pathogen Reduction

PR can reduce risk of accepting donors with the following:

- With an asymptomatic presentation
- Non-compliance to responding to eligibility questionnaire (e.g., test seekers)
- Consideration to the limitations of current testing (1) presence of microbes below the test's detection threshold; (2) directed to a select panel of pathogens; (3) lack of universal testing for infections in endemic area or detection of emerging infections

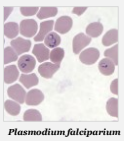
American Red Cross 13

13

[Potential] Benefits of Pathogen Reduction

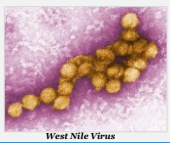
Stramer et.al Transfusion. 2022;62:1388 – 98.

- Assess donor retention for those previously deferred by donor screening and testing
- Study by Deferrals for Babesia, Plasmodium, *Trypanosoma cruzi*, West Nile Virus
- Estimate: **27,758 American Red Cross blood donors deferred / year**



Plasmodium falciparium

Tryponsoma cruzi

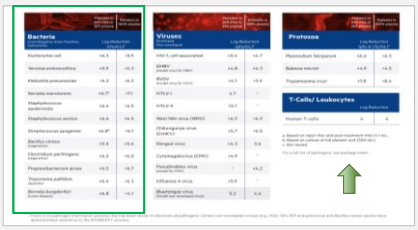


West Nile Virus

American Red Cross Image: CDC - https://www.cdc.gov/dpdx/malaria/index.html 14

14

INTERCEPT Effect on Pathogen

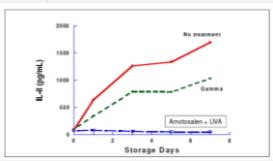


American Red Cross INTERCEPT Blood Systems for Platelets Pathogen Reduction Systems. 2019, https://intercept-usa.com/wp-content/uploads/sites/4/2021/03/INTERCEPT_Overview_MAY2019-1.pdf 15

15

Further Benefits of Pathogen Reduction

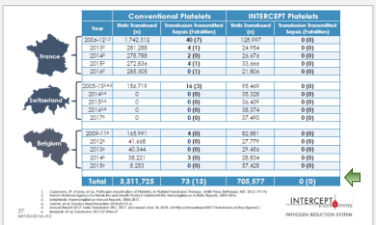
- Reduce risk of TA-GvHD + irradiation usage
- Reduce CMV transmission
- Reduce FNHTR and alloimmunization



American Red Cross Grass JA, et al. Blood 1998; 91(6):2180-2188 16

16

Clinical Performance of Pathogen Reduction



American Red Cross Benjamin R. Pathogen Reduction of Platelets and Red Cells. 2019. Cerus Corporation. Microsoft PowerPoint Presentation 17

17

Clinical Performance of Pathogen Reduction

- Knutson F et.al. Vox Sanguinis. 2015;109:343 – 352.
  11 countries (2003 – 2010) participated in the Cerus sponsored hemovigilance study
  0 transfusion transmitted infections occurred with 19,175 PR platelet units
- Kracalik I et.al. Transfusion. 2021;61:1424 – 1434.
  201 US medical facility participants (2019) of the National Healthcare Safety Network (CDC)
  18 transfusion transmitted bacterial infections with 1.2 million conventional platelet units
  0 transfusion transmitted infections with 39,533 PR platelet units

18

Residual Effects of Transfused Platelets

- Evasion of pathogen reduction by microbial agents
- Low platelet yields impact to therapeutic efficiency
- Neonatal phototoxicity

19

Evasion by Microbial Agents: No Pathogen Reduction Methodology is 100% Effective

Evasion of pathogen reduction for specific microbes
- Clostridium perfringens – spore species
- Bacillus cereus – spore species
- Klebsiella pneumoniae – fast growing

Log of reduction (cfu/ml)
FDA approval requirement ≥ 4 logs

	INTERCEPT
BACTERIA	
Ecoli	>6.2[1]
Serratia marsescens	>6.6[1]
Klebsiella pneumonia	5.8[1]
Enterobacter cloacae	5.5[1]
Staph epidermidis	>6.0[1]
Staph aureus	>5.3[1]
Bacillus cereus (spore)	3.7[1]
Priprionobacterium acnes	>6.4[1]
Yersenia enterocolitica	5.9

Image: Hartmann Science Center: https://www.hartmann-science-center.com/en/hygiene-knowledge/pathogens-a-z/pathogens-2/bacillus-cereus
Prowse CV Vox Sanguinis 2013; 104:183-199.

20

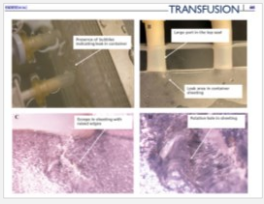
Bacterial Contamination Post Pathogen Reduced Platelets

- FDA 12/2/2022 communication: Important Information for Blood Establishments and Transfusion Services Regarding Bacterial Contamination of Platelets for Transfusion
- Seven cases reported with combination of the following bacteria: *Acinetobacter spp, Staphylococcus saprophyticus, Lecleria adecaboxylata*
- Four of the seven reported cases were associated with PR platelets. Two died of sepsis.
- CDC genetic testing of three events indicated a similar source
- Source remained to be determined

US Food and Drug Administration. Important Information for Blood Establishments and Transfusion Services Regarding Acinetobacter sp. Contamination of Platelets for Transfusion. FDA 2021. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-blood-establishments-and-transfusion-services-regarding-bacterial

21

Bacterial Contamination of Platelets <u>After</u> Pathogen Reduction



Fadeyi E et.al. Transfusion. 2021;61:641 – 648.

22

Low Platelet Yield and Its Impact on Hemostatic Control

Known factors that can impact PR platelet counts and function per unit
- Narrow range of platelets required per unit to ensure pathogen reduction processing
- Processing loss during product transfer to receiving containers
- Premature activation during processing and storage (especially if PAS is present)

Metrics of hemostatic control
- Post-transfusion platelet Corrected Count Increment, CCI-1, -24 hrs. (normal >5,000 – 7,500)
- Number of RBC and platelets used to control bleeding
- Frequency of platelets used after the initial bleeding event, to control subsequent bleeds

23

Study	Study Subjects	CCI 1-hr.	CCI 24-hr.	Bleeding Events # Patients with ≥ WHO Grade 2	PLT Transfusions Units per Patient	PLT Transfusions Interval in Days
SPRINT 2004	Apheresis PR/PAS: 318 CP: 327	PR < CP PR/PAS: 11,100 CP: 16,000	PR < CP PR/PAS: 6,700 CP: 10,100	PR = CP **Patients with 1+ event** PR/PAS: 186 (58.8%) CP: 188 (57.5%) --- **RBC units / patient** PR/PAS: 4.8 CP: 4.3	PR > CP PR/PAS: 8.4 CP: 6.2	PR < CP PR/PAS: 1.9 CP: 2.4
EFFIPAP 2018	Apheresis or WB PR/PAS: 263 CP/PAS: 265 CP: 262	Not done	PR/PAS < CP/PAS < CP PR/PAS: 5,000 CP/PAS: 8,200 CP: 10,200	PR = CP **Patients with 1+event** PR/PAS: 126 (47.9%) CP/PAS: 120 (45.3%) CP: 114 (42.5%) --- **RBC units/patient** PR/PAS: 5.1 CP/PAS: 5.1 CP: 5.3	PR > CP PR/PAS: 6 CP/PAS: 5 CP: 5	PR < CP PR/PAS: 2 CP/PAS: 2.7 CP: 3

American Red Cross

SPRINT: McCullough J et.al. Blood. 2004;104: 1534 – 1541.
EFFIPAP: Garban F et.al. JAMA Oncology. 2018;4:468 - 475.

24

24

Study	Study Subjects	CCI 1-hr.	CCI 24-hr.	Bleeding Events # Patients with ≥ WHO Grade 2	PLT Transfusions Units per Patient	PLT Transfusions Interval in Days
SPRINT 2004	Apheresis PR/PAS: 318 CP: 327	PR < CP PR/PAS: 11,100 CP: 16,000	PR < CP PR/PAS: 6,700 CP: 10,100	PR = CP **Patients with 1+ event** PR/PAS: 186 (58.8%) CP: 188 (57.5%) --- **RBC units / patient** PR/PAS: 4.8 CP: 4.3	PR > CP PR/PAS: 8.4 CP: 6.2	PR < CP PR/PAS: 1.9 CP: 2.4
EFFIPAP 2018	Apheresis or WB PR/PAS: 263 CP/PAS: 265 CP: 262	Not done	PR/PAS < CP/PAS < CP PR/PAS: 5,000 CP/PAS: 8,200 CP: 10,200	PR = CP **Patients with 1+event** PR/PAS: 126 (47.9%) CP/PAS: 120 (45.3%) CP: 114 (42.5%) --- **RBC units/patient** PR/PAS: 5.1 CP/PAS: 5.1 CP: 5.3	PR > CP PR/PAS: 6 CP/PAS: 5 CP: 5	PR < CP PR/PAS: 2 CP/PAS: 2.7 CP: 3

American Red Cross

SPRINT: McCullough J et.al. Blood. 2004;104: 1534 – 1541.
EFFIPAP: Garban F et.al. JAMA Oncology. 2018;4:468 - 475.

25

25

Study	Study Subjects	CCI 1-hr.	CCI 24-hr.	Bleeding Events # Patients with ≥ WHO Grade 2	PLT Transfusions Units per Patient	PLT Transfusions Interval in Days
SPRINT 2004	Apheresis PR/PAS: 318 CP: 327	PR < CP PR/PAS: 11,100 CP: 16,000	PR < CP PR/PAS: 6,700 CP: 10,100	PR = CP **Patients with 1+ event** PR/PAS: 186 (58.8%) CP: 188 (57.5%) --- **RBC units / patient** PR/PAS: 4.8 CP: 4.3	PR > CP PR/PAS: 8.4 CP: 6.2	PR < CP PR/PAS: 1.9 CP: 2.4
EFFIPAP 2018	Apheresis or WB PR/PAS: 263 CP/PAS: 265 CP: 262	Not done	PR/PAS < CP/PAS < CP PR/PAS: 5,000 CP/PAS: 8,200 CP: 10,200	PR = CP **Patients with 1+event** PR/PAS: 126 (47.9%) CP/PAS: 120 (45.3%) CP: 114 (42.5%) --- **RBC units/patient** PR/PAS: 5.1 CP/PAS: 5.1 CP: 5.3	PR > CP PR/PAS: 6 CP/PAS: 5 CP: 5	PR < CP PR/PAS: 2 CP/PAS: 2.7 CP: 3

American Red Cross

SPRINT: McCullough J et.al. Blood. 2004;104: 1534 – 1541.
EFFIPAP: Garban F et.al. JAMA Oncology. 2018;4:468 - 475.

26

26

Study	Study Subjects	CCI 1-hr.	CCI 24-hr.	Bleeding Events # Patients with ≥ WHO Grade 2	PLT Transfusions Units per Patient	PLT Transfusions Interval in Days
SPRINT 2004	Apheresis PR/PAS: 318 CP: 327	PR < CP PR/PAS: 11,100 CP: 16,000	PR < CP PR/PAS: 6,700 CP: 10,100	PR = CP **Patients with 1+ event** PR/PAS: 186 (58.8%) CP: 188 (57.5%) --- **RBC units / patient** PR/PAS: 4.8 CP: 4.3	PR > CP PR/PAS: 8.4 CP: 6.2	PR < CP PR/PAS: 1.9 CP: 2.4
EFFIPAP 2018	Apheresis or WB PR/PAS: 263 CP/PAS: 265 CP: 262	Not done	PR/PAS < CP/PAS < CP PR/PAS: 5,000 CP/PAS: 8,200 CP: 10,200	PR = CP **Patients with 1+event** PR/PAS: 126 (47.9%) CP/PAS: 120 (45.3%) CP: 114 (42.5%) --- **RBC units/patient** PR/PAS: 5.1 CP/PAS: 5.1 CP: 5.3	PR > CP PR/PAS: 6 CP/PAS: 5 CP: 5	PR < CP PR/PAS: 2 CP/PAS: 2.7 CP: 3

American Red Cross

SPRINT: McCullough J et.al. Blood. 2004;104: 1534 – 1541.
EFFIPAP: Garban F et.al. JAMA Oncology. 2018;4:468 - 475.

27

27

Therapeutic Efficacy of Pathogen Reduction

Transfusion outcomes between regular and low yield pathogen reduced platelets across different patient populations in a single institution

- Single institutional, Stanford University, retrospective study
- 1402 patients: PR 930 vs PR-low yield 472
- Mean platelet yield (x10 ^{11}/ unit): PR 3.2 vs PR-low yield 2.8
- **No significant difference** observed for the following:
  - # platelets [RBC] units / patient: PR 2 [2] vs PR-low yield 2 [2]
  - # days between platelet transfusions
  - CCI (<6-hr.): PR 10,200 vs PR-low yield 11,000

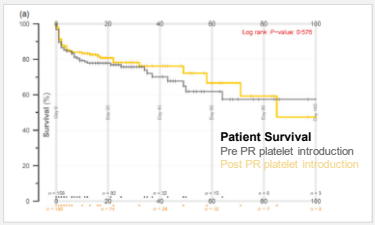
American Red Cross

Tang MS. Et.al. Transfusion. 2022; ahead of print.

28

28

Therapeutic Efficacy in the Massive Transfusion Event



American Red Cross

Nussbaumer et.al. Vox Sanguinis. 2017;112: 249 – 256.

29

29

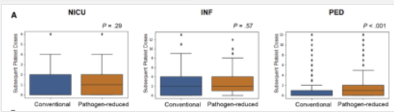
Therapeutic Efficacy in Pediatric Patients

Table 1. Total number of patients and transfusions between November 2016 and July 2018

Category	NICU	INF	PED	Total
Total patients	72	45	131	240
Total platelet transfusions	236	379	1317	1932
Conventional	91 (39%)	125 (33%)	644 (49%)	860 (45%)
Pathogen-reduced	145 (61%)	254 (67%)	673 (51%)	1072 (55%)

Groups include NICU, INF, and PED patients. Patient age was calculated at the time of transfusion, so total number of patients is less than the sum of each group, as patients may be listed in multiple age groups.

Platelet utilization within 48 hours of transfusion of a CP or PR/PAS platelet



Hemostatic efficiency of PR platelet vs CP is similar, regardless of patient age

American Red Cross

Schulz WL et.al. The Journal of Pediatrics. 2019;209:220 – 225.

30

30

Therapeutic Efficacy in Pediatric Patients

TABLE 3 Comparison of median chest tube output (ml/kg/h) at various time points in patients receiving PR versus non-PR platelets

Chest tube output (ml/kg/h) with time points, median (IQR)	Non-PR platelets (n = 104)	PR platelets (n = 36)	p-values
1 h	3.5 (2.3–5.8)	3.8 (2.7–6.3)	.286
2 h	2.2 (1.5–3.6)	2.6 (1.9–3.6)	.334
4 h	1.7 (1.1–2.4)	2.3 (1.4–2.8)	.082
8 h	1.3 (0.8–1.8)	1.9 (0.9–1.9)	.562
24 h	0.6 (0.3–0.9)	0.6 (0.4–0.9)	.770

Note: For all time points time 0 at arrival in PICU.

PR = PR/PAS products

No significant differences were seen between patients receiving either product type for the following: (1) quantity of supportive blood products received; and (2) PICU length of stay, length of mechanical ventilation, thrombotic events, nosocomial infections, and in-hospital mortality.

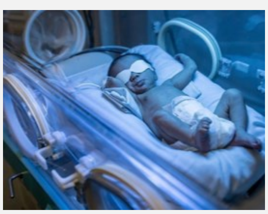
American Red Cross

Hsien S et.al. Transfusion. 2022;62:298 – 305.

31

31

Photosensitivity in Neonates



- Intercept manufacture's insert warns that neonates receiving PR platelets, while undergoing phototherapy that emits light with wavelength <425 nm or have a lower emission bandwidth of <375 nm might be at risk for erythema.
- Phototherapy devices in the US are compliant with American Academy of Pediatrics standards to emit blue/green visible light, 430 – 490 nm, for the treatment of neonatal hyperbilirubinemia.
- Neonates undergoing phototherapy, while receiving PR platelets is considered **safe.**

American Red Cross

Image: medicine. https://www.emedicinehealth.com/newborn_jaundice/article_em.htm Accessed 8/22/2022.

32

32

Photosensitivity in Neonates

Study	Product	Adverse Reaction
Schulz WL et.al. (2019)	29 - PR/PAS	none
Lasky B et.al. (2021)	6 - PR 6 - CP 7 - PR + CP	none

American Red Cross

Schulz WL et.al. The Journal of Pediatrics. 2019;209:220 – 225
Lasky B et.al. Transfusion. 2021;61:2869 – 2876.

33

33

Large Volume Delayed Sampling [LVDS]

American Red Cross

34

34

American Red Cross

Image: Cerus. https://insights.interceptbloodsystem.com/fda-guidance-bacterial-risk-control-blood-collection-and-transfusion. Accessed 8/23/2022.

35

35

Defining LVDS

Standard Platelet BacT Testing	LVDS
▪ Sampling of 'mother' bag occurs ≥ 24 hrs. after collection. ▪ Sample size ≥ 8 ml for an aerobic (16 ml to include Anaerobic) culture bottles. Total # culture bottles = 2 ▪ Product(s) stored for additional 12+ hours prior to distribution.	▪ Sampling of split products occurs ≥ 36 hrs. or ≥ 48 hrs. after collection. ▪ Sample size ≥ 16 ml is split Into aerobic and anaerobic culture bottles. Total # of culture bottles = 2 – 6 ▪ Product(s) stored for additional 12+ hours prior to distribution.

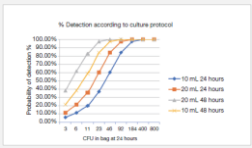
American Red Cross

United States. FDA CBER. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion Guidance for Industry. Department of Health and Human Services. 2020.

36

36

Improving Probability of Bacterial Detection with LVDS



- Gray line: highest test sensitivity - largest volume and longest wait time to sampling
- Blue line: lowest test sensitivity – smallest volume and shortest wait time to sampling

American Red Cross

Delage G and Bernier F. Annals of Blood. 2021;6:30 – 37.

37

37

Cost and Operational Effectiveness of PR Platelets and LVDS

American Red Cross

38

38

Platelet Product Unit Cost

Conventional Platelet	Rapid Testing	PR-Platelet	LVDS Platelet
$516 [491 – 543]	+$25	+$150	+$75 – 120

American Red Cross

1. Verax Biomedical. https://www.veraxbiomedical.com/take-control-of-your-platelet-supply-and-budget/
2. United States. FDA CBER. Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion Guidance for Industry. Department of Health and Human Services. 2020.

39

39

Factors that Impact Operational Efficiency

Pathogen Reduction
▪ Reduce clinical management of transfusion transmitted infections for a broad spectrum of infectious pathogens ▪ Enhance staff availability due to elimination of secondary bacterial testing and performance of irradiation ▪ Enhance early accessibility to inventory ▪ Increase demand for patients not responsive to low yield platelets, inventory volume impact

American Red Cross

40

40

Factors that Impact Operational Efficiency

LVDS
▪ Enhance staff availability due to elimination of secondary bacterial testing, for the product's shelf life: LVDS-36 hrs. (5 days); LVDS-48 (7 days) ▪ Increase dedicated staff time for further infectious disease (CMV) testing and irradiation ▪ Increase product wastage and staff time commitment to manage reactive culture tests ▪ Distribution delay by 48 – 60 hrs due to testing

American Red Cross

41

41

Hospital Usage

Year	Facility type	Percent of facilities reporting transfusion of PRT units, % (n/N)	PRT apheresis platelet units transfused (n)
2019	Hospital Transfusion of Pathogen Reduced Units, Total	13 (247/1908)	175,017 (n = 234)
	Hospital-based blood center	17 (11/64)	33,617 (n = 10)
	8000 or more inpatient surgeries annually*	29 (46/159)	104,052 (n = 42)
	Less than 8000 inpatient surgeries annually*	11 (190/1685)	37,348 (n = 162)
2017	Hospital Transfusion of Pathogen Reduced Units, Total	6 (138/2279)	52,752 (n = 119)
	Hospital-based blood center	13 (11/84)	18,796 (n = 11)
	Greater than 8000 inpatient surgeries annually*	14 (22/152)	22,380 (n = 19)
	Less than 8000 inpatient surgeries annually*	5 (105/2043)	11,576 (n = 89)

*Excluding hospital-based blood centers.

National Blood Utilization and Collection Survey
Comparison of PR platelet usage 2019 vs 2017

42

Calculated Annual Cost

	LVDS-36 hrs.	LVDS-48 hrs.	PR
Annual Costs			
Acquisition	$1,982,864	$1,982,864	$1,939,288
Wastage	$206,480	$163,636	$188,699
Transfusion	$113,149	$113,149	$113,149
Sepsis	$22,073	$22, 073	$0
Outpatient Reimbursement	$575,018	$575,018	$577,959
Net annual Costs	$1,759,549	$1,706,704	$1,663,177

- Assumption for a mid-size hospital in the US: 58 platelet units/ week = 3,016 platelet units/ year
- LVDS acquisition fees: included irradiation (~60% of ordered units), CMV testing
- Product wastage, unit loss per week: 6 (LVDS-36 hrs. and PR) and 4.8 (LVDS-48 hrs..)

43

Response by US Collection Centers to the FDA Platelet Bacterial Mitigation Strategies

New York Blood Center

- Aim is to provide mix of PR-platelets and LVDS units

American Red Cross

- Aim is to provide 100% PR-platelets
- LVDS-36 hrs. is serving as a bridge during the transition period

44

Reimbursement Considerations

In recognition of the additional costs associated with PR and LVDS platelets, CMS reimburses these products at a higher rate than for CP products. In the outpatient setting:

	Product Code(s)	Reimbursement rate for CY22
LVDS Platelet	P9035 +P9100*	$496.91 + $56.85
PR Platelet	P9073	$596.13

NOTES:
1) P9035 is a product code for apheresis platelet [P9031 – whole blood derived platelets]
2) P9100 is a testing code, applies to bacterial testing. This is the only instance where two P Codes can be combined in a claim for a single product

45

In conclusion…

- PR platelets have been demonstrated to be superior to other bacterial mitigation strategies in that they significantly reduce transfusion transmission infections with minimal adverse events.
- Use of PR platelets does come with its own set of complications to consider: (1) the potential effect of low dose platelets; (2) residual contamination; (3) and psoralen hypersensitivity among newborns.
- LVDS can serve as an alternate platelet product to reduce risk of transfusion transmitted bacteria, especially if PR platelets are not available or not financially feasible to the ordering facility.

46

47