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INTERCEPT® Blood System for Platelets Pathogen Reduction System

Case Study: Use of INTERCEPT Platelets at a US Tertiary Care, Academic Medical Center[1]

Gains in Operational Efficiency, Fresher Platelets

The following case study highlights the use of INTERCEPT pathogen reduced products at one of the country's largest health care providers which supports more than 1,100 patient beds. This US hospital system specializes in cancer care, women's health, and houses a Level I trauma center and Level III neonatal intensive care unit.

The Challenge

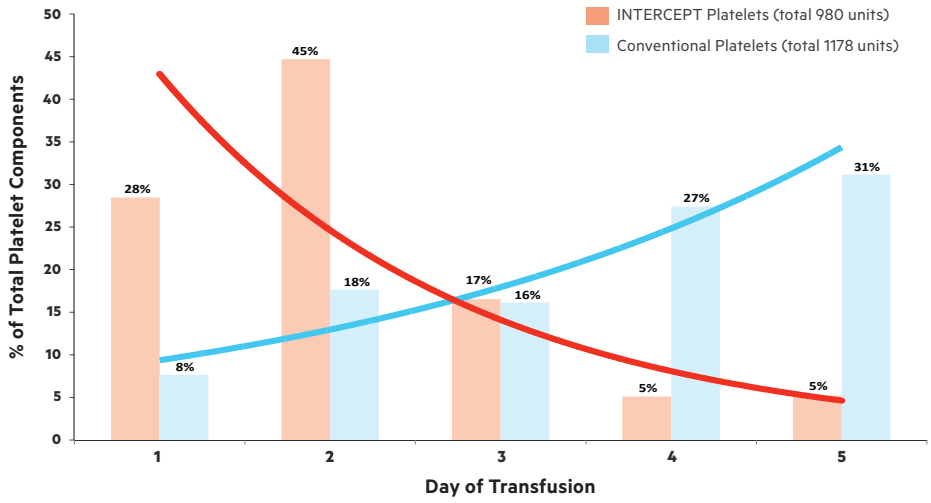
Industry concern has recently been heightened about the risk of bacterial contamination in platelet components. The release of the FDA guidance[2] represents the ongoing effort to address bacterial transfusion-transmitted infections and related sepsis risk. The guidance indicates that platelets must either be tested for bacteria or undergo pathogen reduction. If testing is selected as a bacterial mitigation strategy, shelf life is dependent on balancing primary culture delays and secondary testing options. If pathogen reduction is used, neither bacterial testing nor changes to hospital procedures are required. Additional concerns include the ability to respond to threats posed by emerging pathogens, which would not be mitigated by bacterial testing.

Specific concerns expressed about secondary testing include:

- The cost and resources required to implement a new testing platform, related procedures, and required levels of training to conduct the testing procedures.
- The complexity inherent in labeling units after testing, including re-testing and re-labeling if units are not transfused within 24 hours of testing.
- Documented high false positive rate resulting in increased costs for repeated tests and discarded platelet units.[2]

Figure 1.
Age Distribution of Transfused Platelet Components - INTERCEPT Platelets versus Conventional Platelets

Date from 3/1/2016 to 9/30/16 | Average age of INTERCEPT Platelet units at receipt=2.1days | Average age of conventional platelet products at 3.6 days



The Solution

The highlighted US tertiary care/academic center implemented the use of INTERCEPT Platelets in March 2016. From March through September 2016, approximately 980 INTERCEPT-treated platelet units were transfused across all patient care units, to all patient age groups.

The use of INTERCEPT Platelets has:

- Shifted the age distribution in platelet units delivered such that patients are able to receive fresher platelets as a result of bacterial culture elimination and early platelet release from the blood center (Figure 1).
- Allowed for the avoidance of the implementation of secondary bacterial testing and the associated costs, logistics, and labor required to perform the test.
- Replaced the need for gamma irradiation and CMV serology.[3]

The Benefits

- In contrast to bacterial testing, INTERCEPT pathogen reduction offers broad spectrum risk reduction against multiple pathogens and T-cells, including bacteria, viruses, and protozoa.[3]
- Certain tests and procedures may be replaced with pathogen reduction, including gamma irradiation to prevent transfusion-associated graft versus host disease (TA-GVHD), in accordance with the AABB 33rd Edition Standard 5.19.4.1.[4]
- Fresher platelets can be obtained due to bacterial culture replacement and early release of platelet components.

References

1) Healy MJ, et al. "Implementation of Psoalen-treated Pathogen Reduced Platelets: A US Transfusion Service Perspective." Poster AP-61, AABB 2016. 2) "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion," FDA Guidance for Industry, December 2020. 3) The INTERCEPT Blood System for Platelets Package Insert, Cerus Corporation; September 6, 2022. 4) Standards for Blood Banks and Transfusion Services," AABB, 33rd edition, 2022.

CONTRAINDICATIONS Contraindicated for preparation of platelet components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of platelet components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen. WARNINGS AND PRECAUTIONS Only INTERCEPT Processing Sets for platelets are approved for use with the INTERCEPT Blood System. Use only the INTERCEPT INT100 Illuminator for UVA illumination of amotosalen-treated platelet components. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any platelet components not exposed to the complete INT100 illumination process. Tubing components and container ports of the INTERCEPT Blood System contain polyvinyl chloride (PVC). Di(2-ethylhexyl)phthalate (DEHP) is known to be released from PVC medical devices, and increased leaching can occur with extended storage or increased surface area contact. Blood components will be in contact with PVC for a brief period of time (approx. 15 minutes) during processing. The risks associated with DEHP released into the blood components must be weighed against the benefits of therapeutic transfusion.

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