



Use of INTERCEPT Platelets at a US Tertiary Care, Academic Medical Center

Gains in Operational Efficiency, Fresher Platelets

CASE STUDY

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 draft guidance¹ represents the ongoing effort to address bacterial transfusion-transmitted infections and related sepsis risk. The draft guidance indicates that platelets must either be tested for bacteria or undergo pathogen reduction. If testing is selected as a mitigation strategy, procedures must include an early bacterial culture test at ≥ 24 hours following collection at the blood center, as well as a secondary test likely to be performed at the hospital at days four or five. If pathogen reduction is used, bacterial testing is not 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.¹

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 Platelet units were transfused across all patient care units, to all patient age groups.

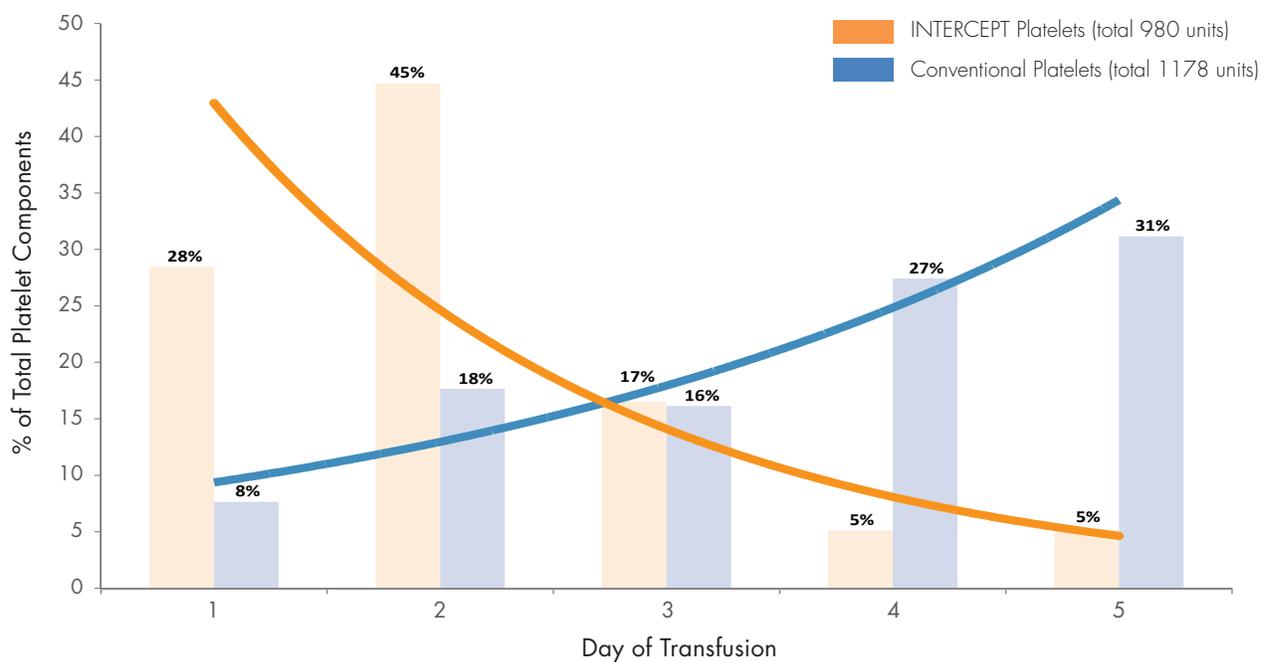
The use of INTERCEPT Platelets has:

- 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.

The Benefits

- In contrast to bacterial testing, INTERCEPT pathogen reduction offers broad spectrum protection against multiple pathogens and T-cells, including bacteria, viruses, and protozoa.
- 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 30th Edition Standard 5.19.3.1.³
- Fresher platelets can be obtained due to bacterial culture replacement and early release of platelet components.

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=2.1 days | Average age of conventional platelet products at 3.6 days

Rx only. Certain non-enveloped viruses (e.g., HAV, HEV, B19 and poliovirus) and *Bacillus cereus* spores have demonstrated resistance to the INTERCEPT process.

CONTRAINDICATIONS Contraindicated for preparation of plasma or platelet components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of plasma or platelet components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength <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 plasma or platelets are approved for use in the INTERCEPT Blood System. Use only the INT100 Illuminator for UVA illumination of amotosalen-treated plasma or platelet components. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any plasma or platelet components not exposed to the complete INT100 illumination process. Tubing components and container ports of the INTERCEPT Blood System for Plasma and Platelets 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.

PLATELETS: Pulmonary events: Acute Respiratory Distress Syndrome (ARDS). INTERCEPT processed platelets may cause the following adverse reaction: *Acute Respiratory Distress Syndrome (ARDS)*. An increased incidence of ARDS was reported in a randomized trial for recipients of INTERCEPT processed platelets, 5/318 (1.6%), compared to recipients of conventional platelet components (0/327). Monitor patients for signs and symptoms of ARDS.

PLASMA: Amotosalen-treated plasma may cause the following adverse reaction: *Cardiac Events*. In a randomized controlled trial of therapeutic plasma exchange (TPE) for TTP, five patients treated with INTERCEPT Blood System processed plasma and none with conventional plasma had adverse events in the cardiac system organ class (SOC) reported. These events included angina pectoris (n=3), cardiac arrest (n=1), bradycardia (n=1), tachycardia (n=1) and sinus arrhythmia (n=1). None of these events resulted in documented myocardial infarction or death. Monitor patients for signs and symptoms of cardiac events during TPE for TTP.

REFERENCES 1. "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion," FDA Draft Guidance for Industry, March 2016. 2. The INTERCEPT Blood System for Platelets - Dual Storage Set Package Insert, March 15, 2016. 3. "Standards for Blood Banks and Transfusion Services," AABB, 30th edition, 2015.