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INTERCEPT® Blood System for Platelets Pathogen Reduction System

Case Study:
INTERCEPT Platelets Demonstrate Safety in Pediatric Population[1]

Phoenix Children's Hospital conducted a retrospective evaluation of amotosalen/UVA pathogen reduced platelets (platelets treated with the INTERCEPT Blood System or INTERCEPT Platelets) in a pediatric population. This evaluation spanned 60 months, 30 months pre- and 30 months post-implementation of INTERCEPT Platelets. The results demonstrated the safety of INTERCEPT Platelets for pediatric patients, with no increase in transfusion reactions, and no cases of transfusion-transmitted infection (TTI) or transfusion-related acute lung injury (TRALI).

Background

Phoenix Children's Hospital is one of the nation's largest pediatric health systems, providing comprehensive care across more than 75 specialties through its 533-bed campus in Phoenix, Arizona, and an extensive network of hospitals and clinics. Phoenix Children's Hospital delivers state-of-the art clinical care for its high-risk pediatric patients, where transfusion safety and the effective mitigation of TTI risk are essential.[2]

To enhance transfusion safety, Phoenix Children's Hospital implemented the the use of INTERCEPT Platelets. INTERCEPT Platelets are treated with amotosalen and ultraviolet A light (A/UVA) to inactivate a broad spectrum of pathogens and leukocytes,* reducing the risk of TTIs and transfusion-associated graft-versus-host disease (TA-GVHD).[3] In addition, unlike reactive bacterial culture safety measures based on conventional or large-volume delayed sampling (LVDS), the use of INTERCEPT Platelets is proactive, with the added ability to reduce the risks from certain emerging pathogens[3] in addition to bacterial risks.

Approach

A retrospective, observational, single-institution analysis was designed to compare transfusion reaction rates before and after the implementation of INTERCEPT Platelets. Transfusion reactions were categorized according to National Healthcare Safety Network guidelines provided by the Centers for Disease Control and Prevention[4] and included allergic reactions, acute hypotensive reactions, febrile non-hemolytic transfusion reactions (FHNTR), transfusion-associated circulatory overload (TACO), transfusion-associated dyspnea (TAD), TRALI, and TTIs.

The study encompassed 30 months pre-implementation of INTERCEPT Platelets (August 2018 to February 2021) and 30 months post-implementation (February 2021 to August 2023), with a total 18,460 platelet components administered to 2,627 pediatric patients.

The Results

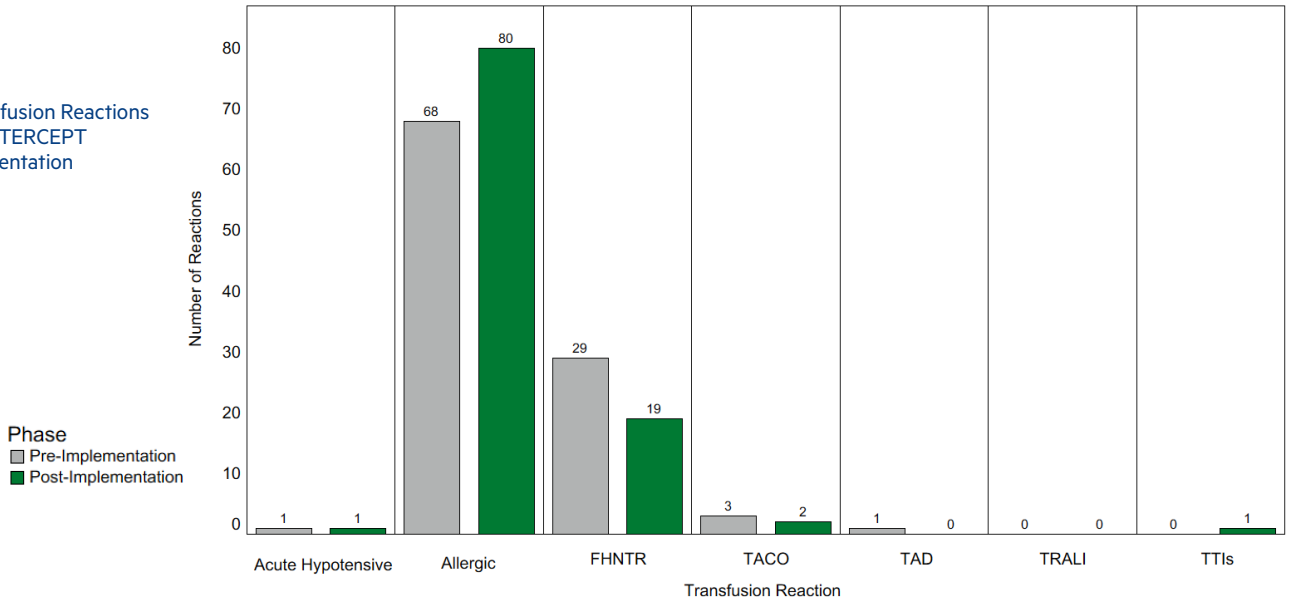
During the post-implementation period, 8,789 platelet components were transfused, including 5,116 INTERCEPT Platelets, accounting for 58% of all transfusions. The overall number of transfusion reactions remained stable at 103 (1.17%), compared to 102 reactions (1.05%) pre-implementation. This highlights the safety profile of INTERCEPT Platelets in pediatric transfusion.

Table 1.
Transfusion Summary Pre- and Post-INTERCEPT Platelets Implementation

	Pre-Implementation	Post-Implementation
Patients Transfused	1,277	1,350
Total Transfusions	9,671	8,789
INTERCEPT Platelet Transfusions	3	5,116
Non-INTERCEPT Platelet Transfusions	9,668	3,673
Total Reactions	102	103
Reaction %	**1.05**	**1.17**

In addition to no statistically significant differences observed in overall transfusion reaction rates, there was no significant difference in the distribution or reactions between the pre- and post-implementation periods (chi-squared = 10.5, p-value = 0.10). Importantly, no cases of TRALI or TTIs occurred with INTERCEPT Platelets. One post-implementation TTI was observed with LVDS tested platelets.

Figure 1.
Number of Transfusion Reactions Pre- and Post-INTERCEPT Platelets Implementation



Conclusion

The data from this observational study reaffirm published observations[5-8] that INTERCEPT Platelets are safe and effective for pediatric transfusions, demonstrating no increase in adverse events or overall transfusion reactions. In addition, the study resulted in no statistically significant difference in the incidence of any reaction type, underscoring the reliable safety profile of INTERCEPT Platelets, particularly in the prevention of TTIs within the pediatric population. The implementation of INTERCEPT Platelets can improve transfusion safety through broad-spectrum TTI risk reduction* and TA-GVHD risk mitigation without increasing the incidence of adverse transfusion reactions.[3]

*There is no pathogen inactivation process that has been shown to eliminate all pathogens. Certain non-enveloped viruses (e.g., HAV, HEV, B19 and poliovirus) and *Bacillus cereus* spores have demonstrated resistance to the INTERCEPT process. For a full list of pathogens, please refer to package inserts.

REFERENCES **1.** Pasko B, et al. "Evaluating the Safety of Pathogen-Reduced Platelets in Pediatric Patients: A Comparative Study." AABB2024. Poster P-TS-46 **2.** "Phoenix Children's." Phoenix Children's, https://www.phoenixchildrens.org. **3.** The INTERCEPT Blood System for Platelets Package Insert, Cerus Corporation; November 28, 2025. **4.** U.S. Centers for Disease Control and Prevention. (2026). The National Healthcare Safety Network (NHSN) manual: Biovigilance component hemovigilance module protocol (Version 3.0). Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases. https://www.cdc.gov/nhsn/pdfs/biovigilance/bv-hv-protocol-current.pdf. **5.** Schulz, W.L., et al., Blood Utilization and Transfusion Reactions in Pediatric Patients Transfused with Conventional or Pathogen Reduced Platelets. J Pediatr, 2019. 209: p. 220-225. **6.** Lasky, B., et al., Pathogen-reduced platelets in pediatric and neonatal patients: Demographics, transfusion rates, and transfusion reactions. Transfusion, 2021. 61(10): p. 2869-2876. **7.** Delaney, M., et al., Multinational Analysis of Children Transfused With Pathogen Inactivated Platelets. Hosp Pediatr, 2022. 12(3): p. 311-316. **8.** Hsien, S., et al., Assessing the Efficacy of Pathogen-Reduced Platelet Transfusions for Hemostasis in Children Undergoing Cardiopulmonary Bypass Surgery. Ann Thorac Surg, 2025. 120(5): p. 890-897.

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INTENDED USE The INTERCEPT Blood System for Platelets is intended to be used for ex vivo preparation of pathogen-reduced Amicus apheresis platelet components suspended in 65% PAS-3/35% plasma, and Trima apheresis platelet components suspended in 100% plasma in order to reduce the risk of transfusion-transmitted infection (TTI), including sepsis, and as an alternative to gamma irradiation for prevention of transfusion-associated graft versus host disease (TA-GVHD). **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 in 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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