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INTERCEPT® Blood System for Platelets Implementation

Case Study: Banco de Sangre de Servicios Mutuos (BSSM), Puerto Rico's largest blood bank, supports 10 hospitals in metropolitan San Juan, Puerto Rico, and distributes blood and blood products to another 30 hospitals throughout the island.

The Challenge

The Zika virus, spread primarily by the *Aedes aegypti* mosquito, arose as an emerging threat to the Americas in 2015. The US Food and Drug Administration (FDA) released a guidance to reduce the risk of the transfusion-transmission of the Zika virus (ZIKV) in February 2016, with a revised version released in August 2016.[1] Puerto Rico, an area with active ZIKV transmission, was the first US area that needed to comply with the guidance. With only 4 weeks to implement the initial guidance, Puerto Rico had the option to either suspend collections and import blood components from areas in which ZIKV is considered non-active, or obtain components locally but perform either testing or pathogen reduction.

> "Rapid implementation of the INTERCEPT Blood System helped us maintain platelet availability during a Zika outbreak."
>
> ***— Jose Alsina,***
> *Vice President & Chief Operating Officer,*
> *Banco de Sangre de Servicios Mutuos*

Importing components from the US mainland presented significant challenges:

- Disruption of self-sufficiency in donor recruitment and blood component availability on the island.
- Shortened platelet shelf-life and associated waste due to shipping times.
- Costs and logistical burden.

The Solution

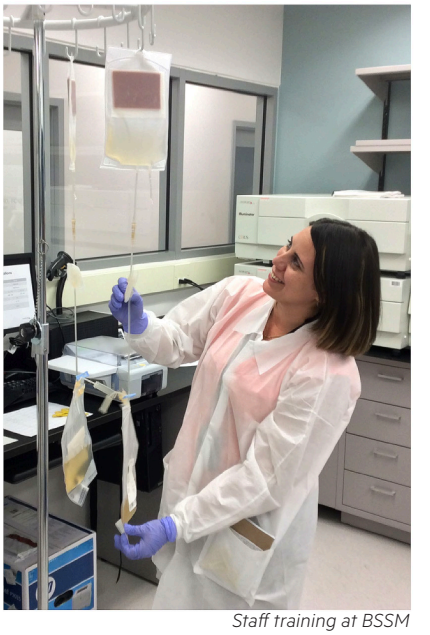
BSSM, with Cerus' experienced deployment team, implemented the INTERCEPT Blood System in just over one week, enabling it to source and supply hospitals locally, and to comply with the FDA guidance.

The availability of INTERCEPT Platelets enabled BSSM to:

- Help sustain self-sufficiency by enabling local donor recruitment and collections.
- Maximize platelet shelf-life through early platelet release, and through local collections.
- Replace bacterial culture detection and gamma irradiation for platelet components.

8 Day Implementation

FEB 29	• Agreement to use the INTERCEPT Blood System for Platelets
MAR 03	• Illuminators (INT100) and materials received
MAR 06	• Illuminators (INT100) installed • Validation plan written and approved • BECS integration initiated • Hospitals trained on ICCBBA codes
MAR 07	• Operators trained • SOPs validated • IQ/OQ
MAR 08	• PQ • Routine use of the INTERCEPT Blood System for platelets initiated - treating 100% of apheresis platelet components.



Staff training at BSSM

The Benefits

- INTERCEPT pathogen reduction is **proactive** – it can inactivate a broad spectrum of viruses, bacteria, parasites, even before a new pathogen is recognized as a blood supply threat.[2]
- Pathogen reduction may be used as an alternative to certain tests and procedures, such as bacterial testing[3,4] and gamma irradiation.[4,2]
- Cerus' deployment team offers over fifteen years of **experience** in blood center operations to help centers optimize product quality and maximize efficiency throughout the production process.

References

REFERENCES 1. FDA Zika Guidance for Industry July 2018. (Withdrawn May 13, 2021). 2.INTERCEPT Blood System for Platelets [Package Insert]. Concord, CA: Cerus Corporation; May 28, 2019. 3. "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. 4."Standards for Blood Banks and Transfusion Services," 32nd Edition. Bethesda, MD: AABB; 2020. **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 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 for 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.

RX ONLY. SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.

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