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Pathogen Reduced Cryoprecipitated Fibrinogen Complex

Produced from the INTERCEPT® Blood System for Cryoprecipitation

INTERCEPT® Fibrinogen Complex

Case Study: Implementation of INTERCEPT Fibrinogen Complex (IFC) at Stanford Hospital - Improves Wait Times and Reduces Wastage

Background

Stanford Health Care is a leading academic health system with 53 operating rooms and 101 licensed ICU beds and employs more than 3,000 medical personnel.[1]

Stanford Hospital historically used ~3,000 cryoprecipitated (cryo) AHF 5-pools and wasted 10% annually. The operating room was the main source of wastage, up to 17% annually. The typical wait time for cryo AHF was approximately 45-60 minutes.

In early 2022, Stanford implemented INTERCEPT® Fibrinogen Complex (IFC) to improve wait times and reduce wastage. IFC is a pathogen reduced blood component for fibrinogen supplementation with a 5-day post-thaw shelf life. IFC is an immediate source* of fibrinogen, factor XIII, von Willebrand factor, and other key clotting factors, which are required for clot strength and hemostasis in patients with massive hemorrhage associated with fibrinogen deficiency.[2]

Challenges with Cryo AHF - Long Wait Times, Short Shelf Life & High Wastage

Once thawed, cryo AHF has a 4-6 hour shelf life due, in part, to infectious disease risk. Therefore, cryo AHF is thawed on demand, and if not used, does not have a long enough shelf life to be reallocated to other patients, and is often wasted.

At Stanford, cryo AHF took approximately 45-60 minutes to prepare and deliver to the operating room once ordered. This delay between lab results and cryo AHF arrival could lead to lab results not accurately representing a patient's current coagulation status at the time the cryo AHF arrives in the operating room. This is of greater concern when a second round of cryo AHF is needed, requiring an additional 45-60 minutes.

Stanford chose to implement IFC for use in the operating room due to its immediate availability* and 5-day post-thaw shelf life.

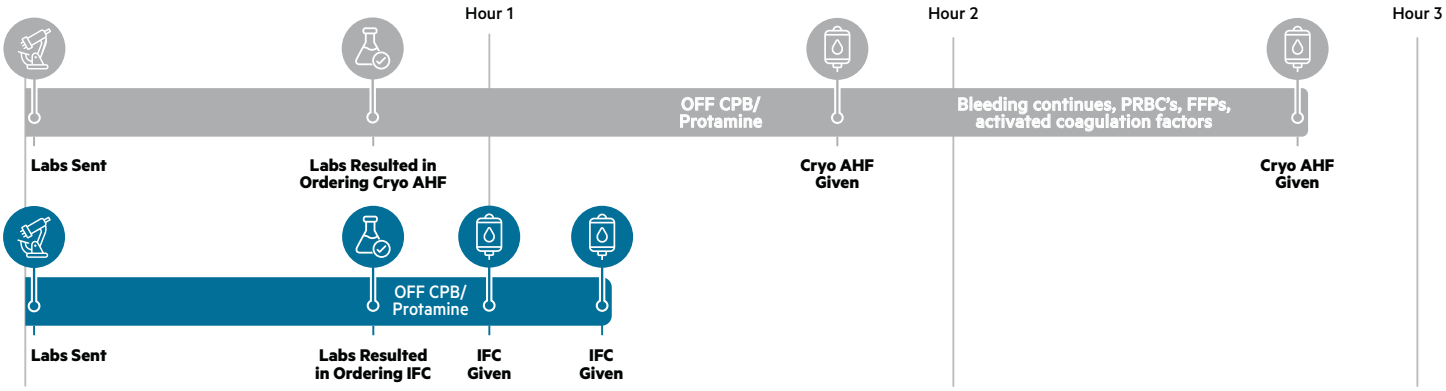
Stanford Hospital wasted about 10% of its cryo AHF annually. The operating room was the primary source of wastage with ~17% annual cryo AHF wastage. This was primarily driven by anticipatory ordering during cardiac and liver transplant cases, and the inability to reissue cryo AHF if unused.

Rationale for Implementing IFC

Stanford chose to implement IFC for use in the operating room due to its immediate availability* and 5-day post-thaw shelf life. The FC15 was selected because it contains a similar amount of fibrinogen as a cryo AHF 5-pool. The blood bank has 4 IFC units prepared in advance and available to immediately issue when needed. This eliminates the need for anticipatory ordering and enables reallocation of unused product, thereby reducing wastage.

Impact on Wait Time in the Operating Room

Cardiac Operating Room Workflow with Cryo AHF and IFC



Timeline following two orders results in up to **2 hours 45 minutes** for cryo AHF vs. **1 hour 15 minutes** for IFC.

IFC is delivered to the operating room in only 10-15 minutes following an order, compared to 45-60 minutes for cryo AHF. This ensures the lab results more accurately reflect the patient's coagulation status at the time of IFC transfusion. When needed, a second IFC can also be transfused within 15 minutes following an order, reducing the previous cryo AHF wait time by up to 1.5 hours. The time saved could lead to less blood loss, help prevent unnecessary transfusions, and reduce operating room costs.

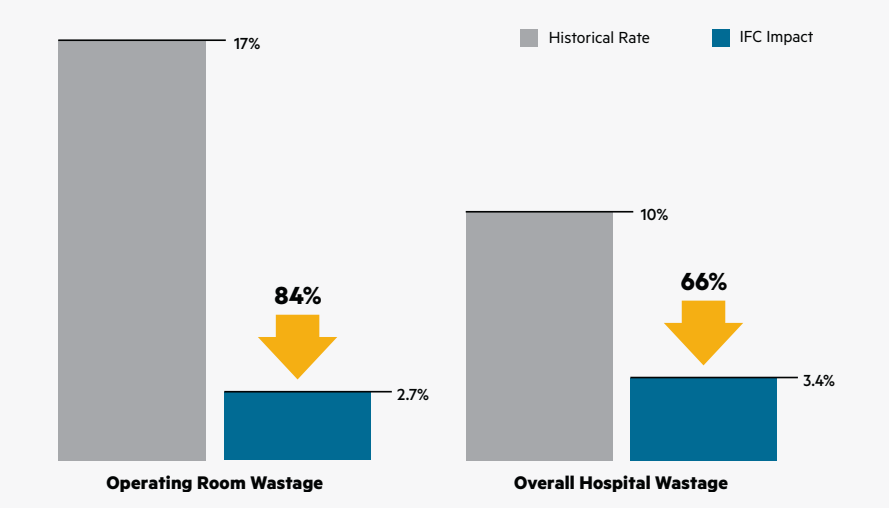
Impact on Wastage Rates

Stanford successfully reduced wastage in the operating room from 17% to 2.7%, and the overall hospital wastage decreased from 10% to approximately 3.4%.

This significant improvement can be attributed to the ability to reallocate IFC if unused due to its 5-day post-thaw shelf life.

Transition to IFC from cryo AHF for use in patients with hemorrhage associated with fibrinogen deficiency.

Reduced Wastage with IFC in Use



* INTERCEPT Fibrinogen Complex is available for immediate use for up to 5 days when stored thawed; when stored frozen, requires thawing prior to use.

REFERENCES 1. Stanford Healthcare FY20/FY21: https://stanfordhealthcare.org/content/dam/SHC/about-us/quality/docs/shc-about-us.pdf. 2. INTERCEPT Blood System for Cryoprecipitation [Package Insert] For the manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex. Concord, CA: Cerus Corporation; January 20, 2021. **INTERCEPT Blood System for Cryoprecipitation for the manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex: INDICATIONS FOR USE** • Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. • Control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available. • Second-line therapy for von Willebrand disease (vWD). • Control of uremic bleeding after other treatment modalities have failed. Limitations of Use: Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used for replacement of factor VIII. **CONTRAINDICATIONS** Contraindicated for preparation of blood components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of blood 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 the INTERCEPT Blood System for Cryoprecipitation is approved for use to produce Pathogen Reduced Cryoprecipitated Fibrinogen Complex. For management of patients with vWD or factor XIII deficiency, Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used if recombinant or specific virally-inactivated factor preparations are available. In emergent situations, if recombinant or specific virally-inactivated factor preparations are not available, Pathogen Reduced Cryoprecipitated Fibrinogen Complex may be administered.
Rx only. See package insert for full prescribing information.

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Global Headquarters | 1220 Concord Avenue | Concord, CA US 94520 | 855.835.3523

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