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Pathogen Reduced Cryoprecipitated Fibrinogen Complex

Produced from the INTERCEPT® Blood System for Cryoprecipitation

INTERCEPT® Fibrinogen Complex

Case Study: Assessing Impact of INTERCEPT Fibrinogen Complex (IFC) on Wastage and Massive Transfusion Protocols (MTPs)

University of Florida Health Shands Hospital (UF Health), in Gainesville, Florida, is an 1,100 bed academic medical center and a level 1 trauma center. UF Health performs over 400 solid organ transplants per year, runs a complex cardiovascular surgery program and transfuses ~ 50,000 blood products per year.

As of September 2021, UF Health was transfusing on average 262 cryoprecipitated AHF (cryo AHF) 5-pools per month and was experiencing ~10% wastage which accounted for over 50% of their overall blood component wastage, adversely impacting the transfusion budget.

UF Health implemented IFC in October 2021. Once thawed, IFC has a 5 day shelf life, allowing for the pre-thaw of IFC for immediate response to bleeding emergencies. It was anticipated that IFC's longer post-thaw shelf life would reduce cryo AHF wastage, while improving care with faster intervention in response to life-threatening hemorrhages.

Rationale for Implementing INTERCEPT Fibrinogen Complex

Challenges with Cryoprecipitated AHF

Once thawed, cryo AHF has a 4 to 6 hour shelf life due, in part, to infectious disease risk. At UF Health, more than half of all blood component wastage was from expired cryo AHF, primarily from cardiothoracic surgery cases, where many thawed cryo AHF units were never transfused. If thawed and not used, cryo AHF does not have a long enough shelf life to be reallocated to other patients, thus it is often wasted.

Rationale for Implementing IFC

IFC is an immediate* source of fibrinogen, factor XIII, von Willebrand Factor (vWF) and other vital clotting constituents, indicated for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency.

UF Health needed a solution to address their cryo AHF wastage, and felt confident that IFC's longer post-thaw shelf-life would ameliorate their wastage issue, as well as improve outcomes with faster intervention of fibrinogen for hemorrhaging patients.

In addition, IFC reduces transfusion transmission infectious risk with broad spectrum inactivation of viruses, bacteria and parasites,** and the plasma used to produce IFC is an approved alternative to irradiation for the mitigation of TA-GvHD. UF Health was already utilizing pathogen reduced INTERCEPT Platelets, and adopting IFC allowed them to expand their use of pathogen reduced blood products.

Utilization as of July 2022

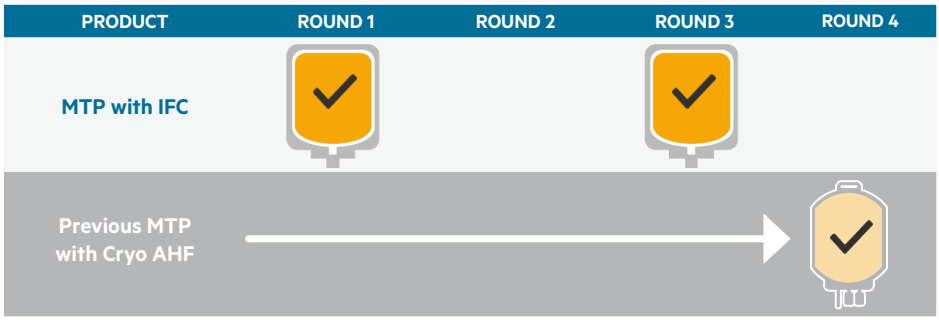
Since implementing IFC in October 2021, over 1,100 IFC units were transfused.

UF Health utilized a phased approach to implement IFC. In October 2021, IFC accounted for 10% of their fibrinogen supplementation transfusions, and by February 2022 IFC was over 50% of transfusions (Figure 1). UF Health anticipates 100% of fibrinogen supplementation transfusions will be with IFC by December 2022.

Impact on Patient Care and MTPs

UF Health maintains pre-thawed IFC to allow rapid response to bleeding emergencies. IFC is available within 15 minutes of order, instead of 1-1.5 hours, the cryo AHF wait time for preparation, thaw and delivery.

UF Health has updated its MTPs to provide earlier and more frequent use of IFC, with IFC administered to patients with every other MTP round. Previously, cryo AHF was in every 4th round of their MTP. IFC is now included in the first MTP cooler leaving the blood bank.



Impact on Availability and Wastage Rates

Having thawed IFC stored on the shelf allows UF Health to have the product available immediately at the time of order with no lengthy preparation time.

Five-day thawed IFC enables unused product to be returned to inventory and reallocated for transfusion to another patient, thus decreasing wastage (Figure 1). Usage and wastage rates were sustained for 6 months and beyond.

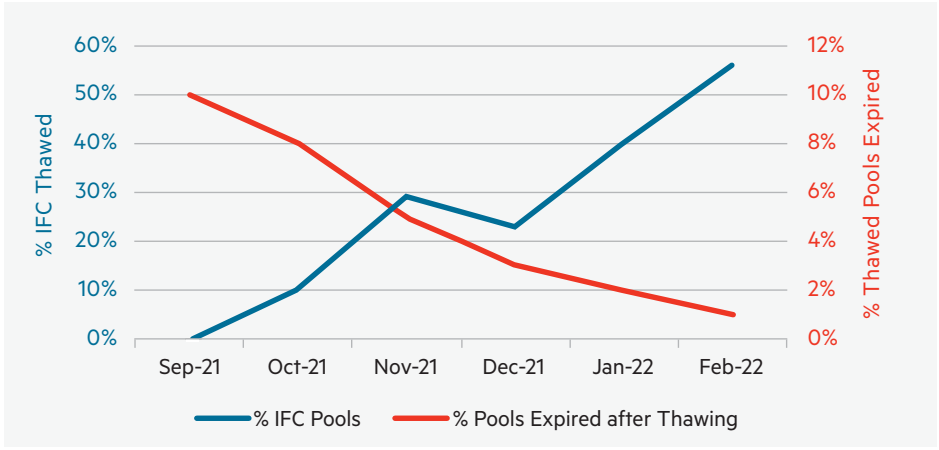


Figure 1

Blood product wastage after thawing decreased as the proportion of IFC thawed increased.

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

REFERENCES 1. 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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