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Pathogen Reduced Cryoprecipitated Fibrinogen Complex

Produced from the INTERCEPT® Blood System for Cryoprecipitation

INTERCEPT® Fibrinogen Complex (IFC)

Case Study: Accelerating Treatment Delivery and Reducing Waste with Implementation of IFC[1,2]

Background

The University of California, San Francisco (UCSF) Health blood banks transfuse over 60,000 blood products annually, including ~2,300 cryoprecipitated (cryo) AHF pools across three medical centers with over 900 beds. With a large service, and varied patient populations, UCSF routinely implements processes and products that improve blood stewardship, efficiency and access, decrease waste, and enhance patient safety.

Rationale for Implementing IFC

UCSF's blood bank is able to store red blood cells, plasma, and platelets ready for immediate dispensation, but cryo AHF must be stored frozen because of its short 4-6 hour post-thaw shelf life, due in part to transfusion transmitted infection risk. Historically, cryo AHF was UCSF's highest wastage blood product. Long turnaround times and high cryo AHF waste were identified as opportunities for improvement, leading to the implementation of IFC, a cryoprecipitated product manufactured from pathogen reduced plasma that can be stored thawed, at room temperature, for up to 5 days. IFC is an immediate source of fibrinogen, factor XIII, von Willebrand factor, and other key clotting factors approved for the treatment and control of bleeding associated with fibrinogen deficiency.

UCSF Health onboarded IFC for fibrinogen supplementation in October 2022, and initially worked with a dual inventory of cryo AHF and IFC between October 2022 and July 2023. **By August 2023, ~100% of fibrinogen supplementation orders were filled using IFC** (Figure 1). As of August 2024, UCSF maintained 8 IFC units pre-thawed at all times to ensure all orders can be filled immediately.

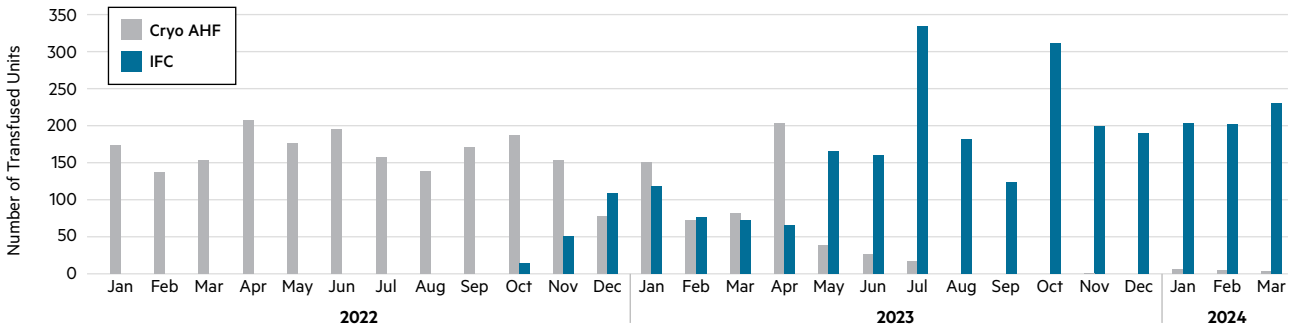

Figure 1. Transition from Cryo AHF to IFC for use in patients with hemorrhage associated with fibrinogen deficiency

IFC Impact

From October 2022 through March 2024, a total of 2,844 IFC units (FC15) were transfused. Retrospective analyses of turnaround time (TAT) from order receipt to product allocation (ready and assigned to the patient) and wastage for cryo AHF versus IFC were performed for orders prior to IFC implementation (January-October 2022) and post-implementation of IFC (July 2023-March 2024). Outliers, including all orders taking >60 minutes for issue, reflected non-urgent orders.

Significantly Improved Turnaround Times

Pre-IFC implementation, between January and October 2022, 909 cryo AHF orders were processed. During this period, 5% of orders had a 0-14 minute TAT, and 51% had a 15-39 minute TAT (Figure 2).

Post-IFC implementation, between July 2023 and March 2024, 1,638 IFC orders were processed. Of these, the majority of IFC orders were filled in less than 14 minutes, and 24% had a 15-39 minute TAT (Figure 2). In fact, 41% of IFC orders were filled in <4 minutes.

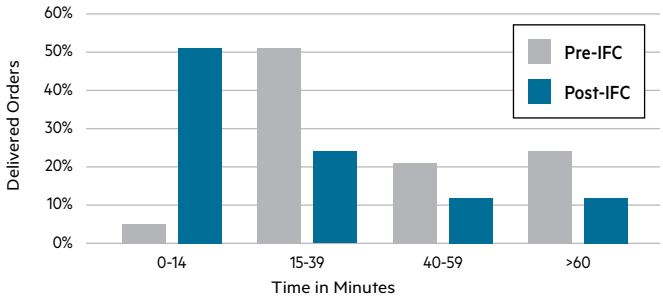

Figure 2. Comparison of Cryo AHF vs. IFC Turnaround Times

Substantially Reduced Wastage Rates

Prior to IFC implementation for fibrinogen supplementation, cryo AHF had the highest rate of blood component wastage at 15% system wide. Post-IFC implementation, wastage was nearly eliminated (<1%) as seen in Figure 3.

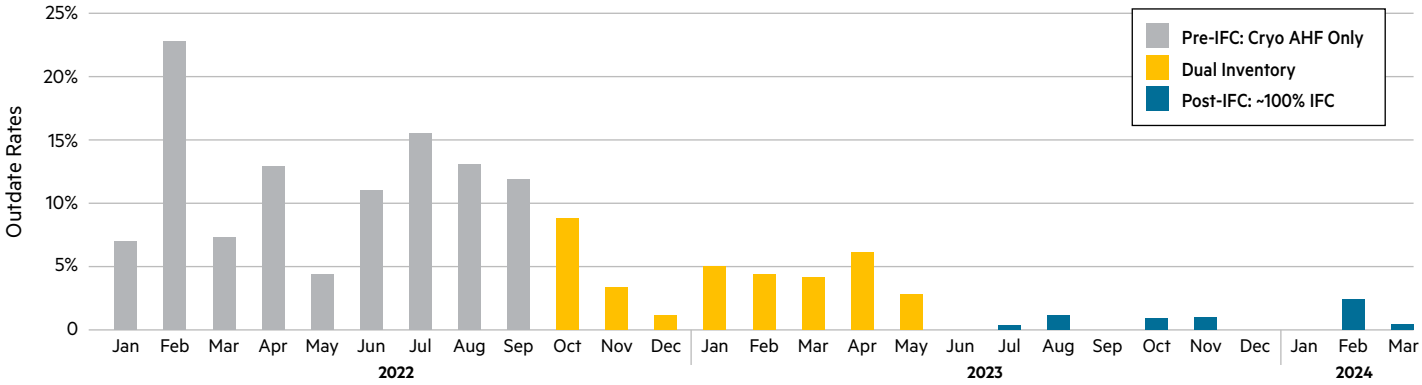

Figure 3. IFC Impact on Wastage

Conclusion

The implementation of IFC has significantly reduced turnaround times and accelerated the delivery of a critical source of fibrinogen for hemorrhaging patients. Additionally, IFC has nearly eliminated wastage, enhanced patient safety with pathogen reduced blood components, improved staff productivity and efficiency, and optimized blood product stewardship.

REFERENCES 1. Akin J, et al. (AABB 2024) P-TS-6. Transfusion, 64: 9A-334A. 2. Alvarado, A. (2025). *INTERCEPT® Fibrinogen Complex: Expanding the Use of Pathogen Reduction for Improved Blood Safety and Availability*. Cerus Corporation. https://intercept-usa.com/videos_webinars_pods/pathogen-reduced-cryoprecipitated-fibrinogen-comples-intercept-fibrinogen-complex-or-ifc-and-intercept-treated-platelets-expanding-the-use-of-pathogen-reduction-for-improved-blood-safety/. 3. INTERCEPT Blood System for Cryoprecipitation for the Manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex Package Insert.

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 PRECAUTION** 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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