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Pathogen Reduced Cryoprecipitated Fibrinogen Complex

Produced from the INTERCEPT® Blood System for Cryoprecipitation

INTERCEPT® Fibrinogen Complex

Case Study: Implementing the Use of INTERCEPT® Fibrinogen Complex (IFC) in the Pediatric Setting

Valley Children's Hospital in Modesto, California is a 356 bed, "not-for-profit," independent, children's hospital serving central California averaging ~ 6,000 transfusions per year. Valley Children's is the second largest children's hospital in California averaging 1 or 2 MTPs per month and managing busy cardiac surgery and ECMO programs. Valley Children's also has a 38 bed Level II Pediatric Trauma Center that cares for ~ 100,000 patients per year.

Through fiscal year 2021, Valley Children's wasted up to 26% of their thawed cryoprecipitated (cryo) AHF 5-pools per quarter, adversely impacting their transfusion budget.

Valley Children's implemented IFC in Q1 fiscal year 2022. IFC is a high dose fibrinogen replacement product that contains fibrinogen, factor XIII, von Willebrand Factor (vWF) and other key clotting factors, indicated for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency, with a 5-day post-thaw shelf life. It was anticipated that IFC's longer post-thaw shelf life would reduce cryo AHF wastage because thawed IFC could be returned to inventory and reallocated.

Rationale for Implementing IFC

Challenges with Cryo AHF

Valley Children's experienced high cryo AHF 5-pool wastage, with the greatest wastage attributed to cardiac surgery, who would request thawed cryo AHF mid-surgery and often returned it to the blood bank unused. With a 6-hour post-thaw expiration, the returned cryo AHF units always ended up wasted.

In addition, at least one cryo AHF 5-pool was wasted with almost every MTP as they attempted to stay ahead by preparing the next MTP pack to be issued.

Valley Children's target threshold for cryo AHF wastage was <10% of all thawed cryo AHF. For fiscal year 2021, they never achieved this target goal in any quarter, and averaged a 16.3% wastage rate for the year.

Rationale for Implementing IFC

First and foremost, Valley Children's believed that IFC's extended 5-day post-thaw expiration, as compared to cryo AHF's 4-6 hours, would provide the opportunity to use returned thawed IFC on another patient before expiration, improving their wastage rates, and ultimately providing cost savings to the hospital.

Second, IFC is pathogen reduced. Valley Children's has used pathogen reduced INTERCEPT Platelets since 2017, and was very comfortable with the INTERCEPT Technology. Bringing in a fibrinogen replacement alternative with similar trusted infectious risk reduction, as with platelets, would provide a safer product for their patients.

Executing IFC Implementation

Product Selection

IFC is available in five product offerings, varying in unit size and clotting factor content. Product characterization demonstrates factor content is maintained over its 5-day shelf life.

Valley Children's did a side-by-side comparison of the IFC products to their cryo AHF 5-pools, and determined that FC15 was the closest in volume, fibrinogen and factor content.

System Updates

IFC products have the new "EA" ISBT codes. Transfusion Services partnered with IT Tech to ensure their computers and printers could accommodate the new product codes, and build their Compatibility Truth Tables and Modification Rules (which would assign a new 5-day expiration at thaw). The new codes, for both frozen and thawed IFC units, were tested with their ISBT label printers and everything was fully validated and documented.

Transfusion Services partnered with their billing department to ensure proper billing and reimbursement for the administration of IFC in both the inpatient and outpatient settings. Cerus provided the correct HCPCS, procedure, diagnosis, and revenue codes and modifiers.

In order to keep the ordering process streamlined for their ordering clinicians, all related procedures and order screens were slightly modified to include IFC as an alternative fibrinogen source to cryo AHF. Transfusion Services determines when it is appropriate to fill an order with IFC based on relevant criteria, such as IFC product availability, clinical situation and patient blood type.

Training

Only minimal training was determined necessary for the blood bankers, since the product is very similar to cryo AHF in how it is handled, with the exception of the 5-day post-thaw expiration.

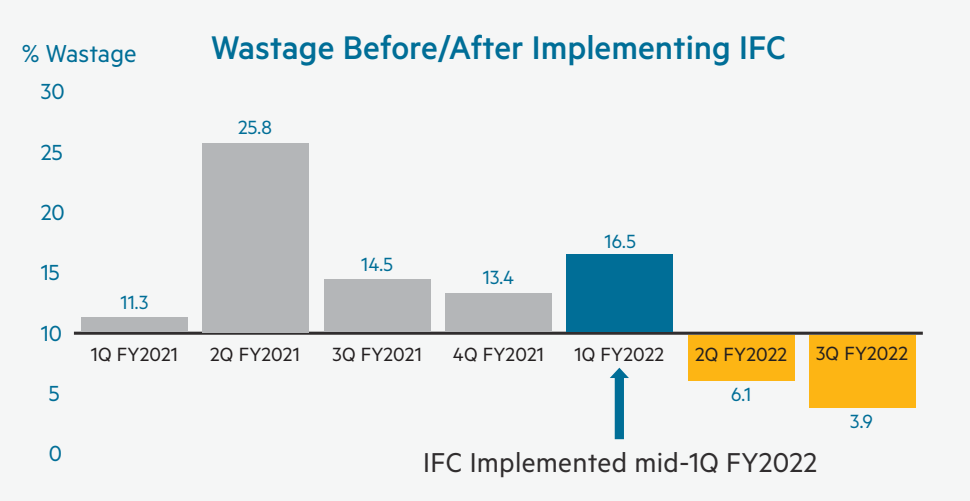
No training was determined necessary for the ED, surgery or nursery staff since the appearance and administration of IFC is exactly the same as cryo AHF, so bedside processes are indistinguishable.

Impact on Wastage Rates

Valley Children's experienced reduced wastage rates after implementing IFC due to the extended post-thaw expiration date.

The quarterly wastage rate for cryo AHF, before use of IFC, was 11.3% to 25.8% of all thawed cryo AHF.

After going live with IFC on November 1, 2021, wastage dropped significantly from a 2021 average of 16.3% to a current average of just 5.0%. In the 3rd quarter of 2022, it was down to 3.9%. For the first time (in a very long time), Valley Children's was able to meet their target of < 10% wastage in both quarters since implementing IFC.



REFERENCES 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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