Implementation & Quality Analysis of Pathogen Reduced Cryoprecipitated Fibrinogen Complex

Rakesh Sethapati, Thinh Quach, AnhThu Nguyen, Wei Cai, Jimmy Le, Tho Pham, Mrigender Singh Virk

Transfusion Medicine, Stanford Health Care, Stanford, CA

Introduction

Cryoprecipitated anti-hemophilic factor (Cryo AHF) has been used for fibrinogen replacement in actively bleeding patients, dysfibrinogenemia and hypofibrinogenemia (1). There is also evidence that suggests low fibrinogen levels are associated with higher rates of mortality in traumatic bleeding and there may be a potential benefit to rapid replacement in these settings along with a standard massive transfusion protocol (MTP). Cryo AHF has a shelf life of 4-6 hours after thawing, posing a major limitation of its use. Therefore, Cryo AHF is thawed as needed to prevent waste, but this can increase the turnaround time (TAT) in treatment of coagulopathic patients (2). Regardless of this practice, significant volumes of Cryo AHF are returned to the blood bank unused and results in high waste rates relative to other blood products.

In November 2020, the FDA approved Pathogen Reduced Cryoprecipitated Fibrinogen Complex (known as INTERCEPT® Fibrinogen Complex, IFC) for the treatment of bleeding associated with fibrinogen deficiency (3). IFC can be stored at room temperature and has a shelf life of 5 days after thawing (Figure 1).

Study design

We identified locations and specific end-users with high Cryo AHF utilization and waste. We partnered with our blood supplier to replace Cryo AHF with IFC in these locations. We aimed to analyze waste rate and turnaround time over a period of 1 year divided equally between pre- and post- implementation of IFC.

Results

The adult operating rooms (ORs) had a waste rate that exceeded non-operative locations with adult cardiac surgeries and liver transplants having the highest Cryo AHF utilization. Pre-IFC implementation, operative locations had a 17% Cryo AHF waste rate compared to 3% waste in non-operative locations.

IFC was added to our inventory to replace all Cryo AHF orders from adult ORs, and the waste rate decreased significantly. Post-implementation, IFC waste was 2.2% in ORs, Cryo AHF waste in non-operative locations was 2.5%. The overall waste of cryoprecipitated products across all locations at the adult hospital was reduced from 8.8% to 2.3% (Table 1).

The TAT for cryoprecipitated products was reduced from 30.4 minutes to 14.6 minutes (52% reduction) from the time when the transfusion request was received to the time of product issue. Cost analysis of IFC implementation is complex due to the fact that it is a more costly product, but it significantly reduces waste and is associated with a temporary reimbursement from Medicare as a new technology add-on payment (NTAP).

	Cyro AHF	IFC
TAT	30.4 min	14.6 min
Shelf-life	6h	5d
Wastage	8.8%	2.3%
Cost	$600 per pack	$825 per pack
TTI Risk	Low	Minimal

Table 1. Comparing characteristics of Cryo AHF and IFC

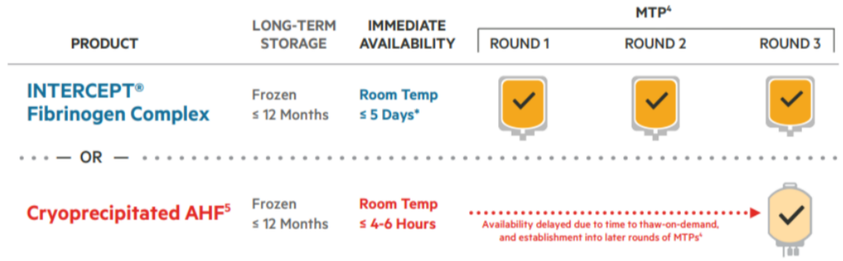

Figure 1. Adapted from AABB. Circular of Information for the Use of Human Blood and Blood Components. Bethesda, MD: AABB; 2017

Conclusion

IFC has enabled us to maintain an inventory of a thawed cryoprecipitated product, which has improved utilization efficiency and turnaround time. There has been a substantial decrease in waste since IFC can be returned to the inventory when unused. An improved TAT may allow for IFC to be considered as a source of fibrinogen replacement in massive bleeding and to be included in pre-defined massive transfusion protocols (4). Further multi-institutional studies are needed to show similar evidence and demonstrate clinical efficacy of IFC in these settings.

Each institution will need to evaluate the cost effectiveness of this product based on their current waste rates and volumes in operative versus non-operative locations. This analysis will likely need to be reevaluated upon expiry of the NTAP.

References

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Disclosures

No conflict of interest to disclose.