Implementation of Pathogen Reduced Cryoprecipitated Fibrinogen Complex in a Pediatric Level II Trauma Center

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Background

Due to the 4-6 hour shelf life to evade potential infectious transmission, the wastage rates for Cryoprecipitated Anti-Hemophilic Factor (Cryo AHF) were consistently exceeding our targets of less than 10% waste per quarter and contributing to increased costs. The FDA has approved Pathogen Reduced Cryoprecipitated Fibrinogen Complex (PRCFC) for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. The local blood center initiated the manufacture of PRCFC from amotosalen/UVA-treated plasma to mitigate transfusion transmission risk with a post thaw shelf life of 5-days (**Figure 1**). Opportunities for increasing patient safety and decreasing Cryo AHF waste were identified.

Aims

To implement Pathogen Reduced Cryoprecipitated Fibrinogen Complex to increase patient safety while decreasing wastage.

Figure 1: PRCFC vs Cryo AHF Post-Thaw Shelf Life

Results

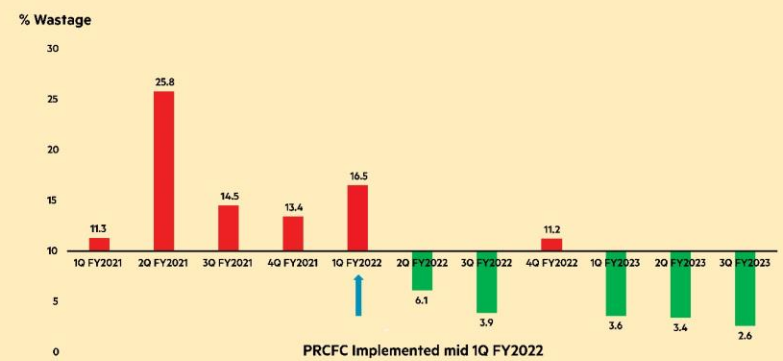
Steps identified in the project plan included product review, acceptance from physician stakeholders, blood utilization committee approval, IT, and procedure updates. The Transfusion Service determines if Cryo AHF or PRCFC is used to fill an order based on clinical diagnosis, age, weight, ABO capability, and inventory. The quarterly wastage rate for Cryo AHF ranged from 11.3% to 25.8% with an annual average wastage rate of 16.3% prior to implementing PRCFC. Following the implementation of PRCFC (dual inventory outlined in **Table 1**), the wastage rate has decreased to 2.6%, with the current fiscal year average wastage being 3.2%. (**Table 1 & Figure 2**).

Table 1: Quarterly Wastage Rate for Cryo AHF and PRCFC

	1Q FY2021	2Q FY2021	3Q FY2021	4Q FY2021
100% Cryo AHF use - % wastage	11.3%	25.8%	14.5%	13.4%
	1Q FY2022	**2Q FY2022**	**3Q FY2022**	**4Q FY2022**
75% Cryo AHF/25% PRCFC use - % wastage	16.5%			
50% Cryo AHF/50% PRCFC use - % wastage		6.1%	3.9%	11.2%*
	1Q FY2023	**2Q FY2023**	**3Q FY 2023**	
50% Cryo AHF/50% PRCFC use - % wastage	3.6%	3.4%	2.6%	

**increased number of MTPs activated, which led to an increase in wastage rates.*

Figure 2: Wastage Before/After Implementing PRCFC



Methods

Implementation of PRCFC began in November 2021 of the first fiscal quarter of FY2022 (Oct-Dec 2021). Increasing patient safety while decreasing Cryo AHF waste was managed as a process improvement project. A retrospective analysis of wastage for Cryo AHF vs. PRCFC transfusion was performed for orders placed between 1QFY2021 (October 2020) and 3QFY2023 (June 2023).

Conclusions

This process improvement project was successful as evidenced by progress and completion reports submitted to change management leadership and positive results on a six-month post implementation survey with physician stakeholders. The ability to store PRCFC thawed for the extended expiration of 5 days compared with 6 hours for Cryo AHF has contributed to a 65% decrease in wastage of this critical blood component. Implementation of PRCFC, with an FDA approved level of risk reduction of infectious transmission, has allowed our transfusion service to provide a safer source of fibrinogen and other clotting key factors and facilitate a more rapid hemostasis in bleeding patients.

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