

# Prothrombin Complex Concentrate for the Management of Bleeding in Factor X Deficiency



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## BACKGROUND

- Deficiency of factor X (FXD) is a rare inherited disorder, which affects one in one million patients annually.<sup>1</sup>
- Current strategies include utilization of fresh frozen plasma (FFP), prothrombin complex concentrates (4-PCC), or a new human plasma-derived FX, Coagadex®.<sup>2</sup>

## PATIENT CASE

- 24-year-old female with known FXD presented to the emergency department
- Chief complaint: severe joint pain and ecchymotic patches for two weeks
- Physical exam: unremarkable, except tenderness to the right calf and left forearm, along with mild swelling
- Had not received twice-weekly human FX (Coagadex®) infusion in past month secondary to insurance issues
- Human FX was unavailable, 4-PCC was dosed based on dosing recommendations for Coagadex®, 25 IU/kg daily until hemostasis is achieved
- FX content per 4-PCC vial was reviewed by a pharmacist, for the 50kg patient two vials totaling 1348 IU of FX was administered
- Initial labs and repeat labs after 4-PCC administration are in Table 1
- No major bleeding events or adverse drug events were appreciated

Coagulation Labs	Before 4PCC Administration	After 4PCC Administration
PT (seconds)	104.5	17.6
INR	8.7	1.5
aPTT (seconds)	32	NA
Fibrinogen (mg/dL)	397	NA
Hemoglobin (g/dL)	5.8	7.6*
Hematocrit (%)	19.2	24.7*

Table 1: Coagulation studies in our patient before and 2 hours after dosing 4-PCC. PT= Prothrombin Time; INR = International Normalized Ratio; aPTT = Activated Partial Thromboplastin Time. \*Labs drawn 12 hours after dosing 4PCC

	Factor X; Coagadex®	4-PCC; Kcentra®	3-PCC; Profilnine®	FFP
Components	Factor X	Factors II, VII, IX, X Protein C, Protein S	Factors II, IX, X	Contains all factors of the soluble coagulation system
Typical FX content	250 IU/2.5mL 500 IU/5mL	~500-1020 IU/20 mL	~320 IU/5mL ~640 IU/10mL	~178-280 IU/250 mL
Dose	25 IU/kg	Based on Factor X content in vial	Based on Factor X content in vial	20mL/kg, followed by 3-6mL/kg BID
Onset	≤ 30m	≤ 10m	≤ 30m	≤ 30m
Cost	\$\$\$	\$\$	\$\$	\$

Table 2: FX, 4-PCC, 3-PCC, and FFP for FXD-related bleeding. FX = Factor X; 4PCC = 4-Factor Prothrombin Complex Concentrate, 3PCC = 3-Factor Prothrombin Complex Concentrate, FFP = Fresh Frozen Plasma, h = hours, IU = international units, BID = twice-daily

## CONCLUSION

- Without a generic available, Coagadex® costs approximately 75% more than 4-PCC per FX IU based on wholesale price.<sup>3,4</sup>
- 4-PCC use in FXD has been previously reported in both planned and emergent surgeries without adverse events.<sup>5,6</sup>
- Given the extreme rarity of FXD, it is unlikely that institutions will routinely stock a purified FX product.
- Our case highlights a cost-effective and viable option for managing FXD-related bleeding with 4-PCC in the emergency department when Coagadex® is unavailable.

## REFERENCES

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## DISCLOSURES

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: J. Adolphsen: Nothing to disclose; J. Reeder: Nothing to disclose; J.S. Dingman: Nothing to disclose; C. Cassidy: Nothing to disclose; B. Gilbert: Nothing to disclose This research was supported (in whole or in part) by HCA Healthcare and/or an HCA Healthcare affiliated entity. The views expressed in this publication represent those of the author(s) and do not necessarily represent the official views of HCA Healthcare or any of its affiliated entities."