

Zahra Nasrazadani, PharmD, BCPS
Emergency Medicine Clinical Pharmacist
Salina Regional Health Center
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Purpose:

This study aims to evaluate the clinical and operational outcomes that result from the implementation of a multi-faceted dose reduction strategy for the administration of four-factor prothrombin complex concentrate (4F-PCC). Implementation of this strategy occurred over the course of approximately ten months and involved multi-disciplinary education efforts, development of embedded electronic medical record support tools, continuous quality improvement and pharmacovigilance strategies, implementation of a pharmacist-driven dosing protocol, and formulary restrictions.

Methods:

Clinical data was reviewed retrospectively after the implementation of a low- and fixed-dose dosing strategy for administration of 4F-PCC. Direct oral anticoagulants (DOACs) were reversed with a 25 unit/kg dose, while vitamin K antagonists (VKAs, ie warfarin) were reversed with a maximal dose of 1500 units. Furthermore, the health-system actively excluded the novel reversal agent, andexanet alfa, from its institutional formulary. Patient data was evaluated for hemostatic efficacy, as measured by INR reduction, and total cost-savings when the low dose was compared to either the higher dose or the labeled dose with regard to DOACs and VKAs, respectively. Additionally, time to administration of these doses was evaluated to determine the potential clinical benefit of the presence of an emergency medicine pharmacist (EMP) in the efforts to achieve hemostasis.

Results:

In calendar year 2020, 30 patients required reversal of their anticoagulant therapy — seventeen DOAC and thirteen VKA reversals. Each DOAC reversal represents a potential drug cost-savings of \$59,400 per patient, which totals \$1,009,800 savings by excluding andexanet alfa from formulary. In addition, because these patients received a 25 unit/kg dose of 4F-PCC instead of 50 unit/kg, an additional 67 vials of the medication were spared, saving \$70,576, resulting in a cumulative total of \$1,080,376 saved for DOAC reversals alone. Of the eighteen warfarin reversals, 31 vials of 4F-PCC were spared, representing a cost savings of \$32,654, resulting in a cumulative cost-avoidance of \$1,113,030. Based on available data, 93% (n=28) of patients achieved adequate reversal of INR values and no patient experienced a significant thrombotic event. Lastly, when EMPs were present, the average time from physician order to administration of 4F-PCC was approximately 45 minutes, compared to 67 minutes when an EMP was not present — a 21-minute reduction in time to administration.

Conclusions:

A multi-tiered strategy for dose reduction of 4F-PCC was effective in achieving hemostasis, mitigating thrombotic risk, improving time-to-administration, and dramatically minimizing cost to the health system. When adequate reversal was not achieved, patients characteristics in this small sample (n=2) were highly discordant, generating further hypotheses regarding other measures of hemostasis. This data will be used to support an institutional initiative to implement viscoelastic testing and facilitate more targeted hemostatic interventions.