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OBJECTIVE

- Evaluate by indication the appropriateness of prothrombin complex concentrate (PCC) use in a community health system

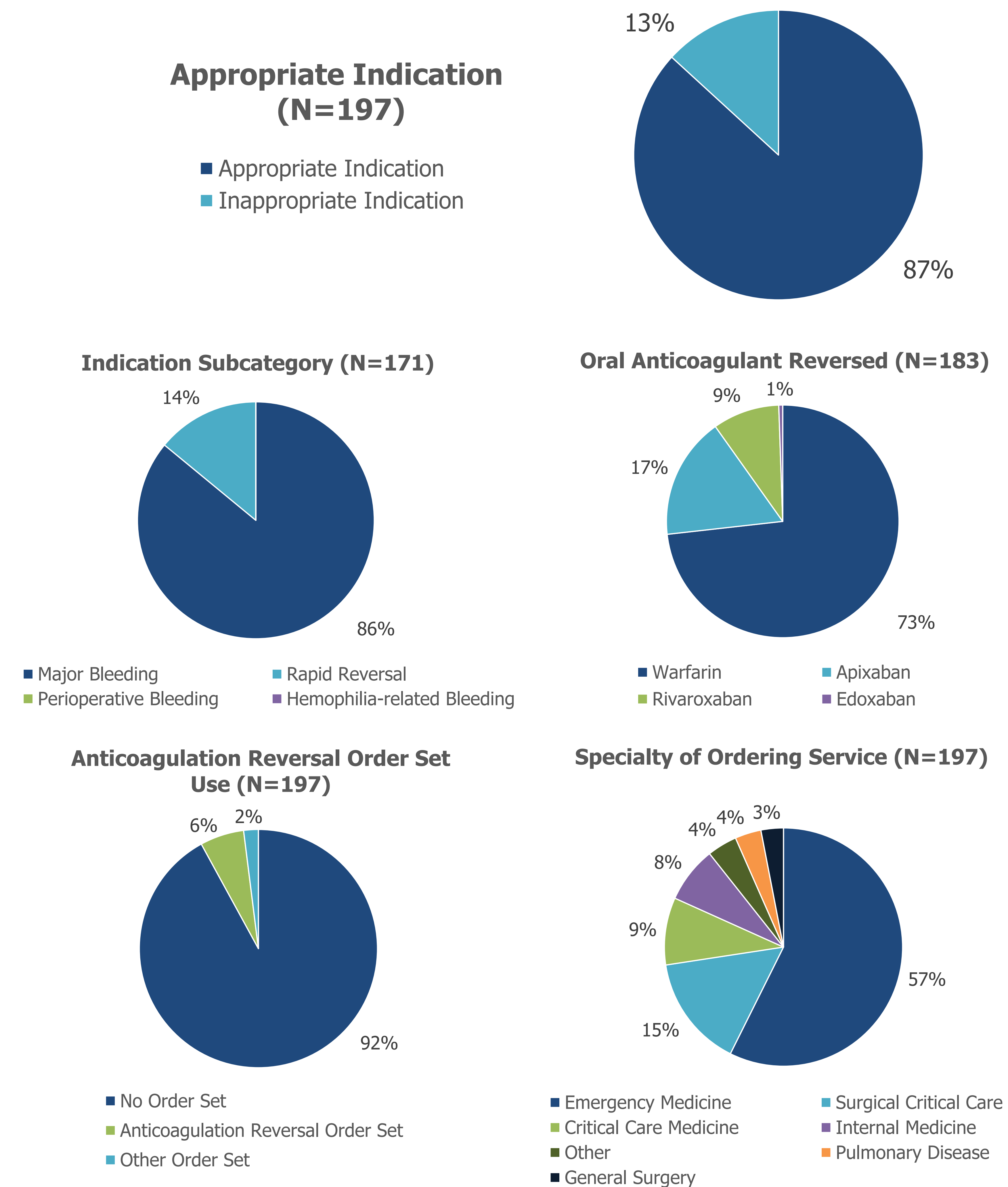
BACKGROUND

- Management of bleeding is a major clinical challenge.
- PCCs are plasma-derived agents used to promote hemostasis and rapidly reverse anticoagulation.^{1,2}
- PCCs are frequently used for off-label indications, such as direct oral anticoagulant reversal, trauma, and perioperative bleeding.³⁻⁹
- PCC safety and efficacy data for off-label indications is limited.
- Current guidelines provide some recommendations for off-label uses but often lack specificity for optimal dosing and patient populations.
- The purpose of this study is to describe PCC use within a community health system in the Midwest. This health system includes a 440-bed, level 2 trauma center and 6 affiliate hospitals.

METHODS

- Retrospective chart review of adult subjects who received four factor PCC or activated PCC
- Data collected on subjects admitted from 7/2016 through 2/2018
- Primary outcome:**
 - Proportion of patients receiving PCCs for appropriate indication
 - Appropriate indication defined as:
 - FDA-approved^{1,2}
 - Recommended by current oral anticoagulation reversal, surgery, and trauma guidelines³⁻⁸
- Secondary outcomes:**
 - Indication subcategory
 - Major bleeding
 - Rapid reversal of anticoagulation required for urgent or invasive procedure
 - Perioperative bleeding
 - Hemophilia-related bleeding
 - Oral anticoagulant reversed
 - Warfarin
 - Apixaban
 - Rivaroxaban
 - Edoxaban
 - Proportion of orders from the health system's adult anticoagulation reversal order set
 - No Order Set
 - Anticoagulation Reversal Order Set
 - Other Order Set
 - Specialty of ordering service
 - Emergency Medicine
 - Critical Care Medicine
 - Other
 - General Surgery
 - Surgical Critical Care
 - Internal Medicine
 - Pulmonary Disease
 - Concomitant vitamin K use
 - Time from order input to administration

RESULTS



Concomitant Vitamin K Use

Indications for Vitamin K	Orders for Vitamin K
134	119

Time from Order Input to Administration

Minimum	Maximum	Median (IQR)
7 minutes	427 minutes	33 minutes (23-45)

DISCUSSION & CONCLUSIONS

- PCCs were used for appropriate indications in approximately 87% of patients, most frequently for major bleeding and reversal of vitamin K antagonists.
- Twenty six patients inappropriately received PCCs. Of 14 patients who were not receiving oral anticoagulation, 7 patients received PCCs for major bleeding refractory to other blood products. Eleven patients received PCCs in the setting of oral anticoagulation but without evidence of major bleeding or need for rapid reversal. One patient intentionally overdosed on rivaroxaban and PCCs were given prophylactically. Another patient received PCCs while being worked up for disseminated intravascular coagulopathy.
- It is evident that FDA-approved and guideline-recommended indications do not address all clinical contexts for PCC use, especially for critically ill patients. This may make the reported frequency of inappropriate uses within the health system artificially high.
- Twelve PCC orders came from the anticoagulation reversal order set. This low frequency may be due to the multiple steps required to find the order set within the health system's electronic ordering system. Additionally, the order set may be cumbersome to use as it includes suggested reversal algorithms for anticoagulants that may or may not require PCCs.
- Of 134 patients for which concomitant vitamin K was indicated, only 119 patients received this therapy. Two orders without concomitant vitamin K came from the anticoagulation reversal order set. This may be due to lack of order set use or clinicians opting for transient anticoagulation reversal.

Limitations

- Retrospective chart review resulted in missing or unclear information.
- Key data components, such as PCC indication and oral anticoagulant reversed, were manually reviewed.
- Evaluation of bleeding severity or urgency of procedure can be subjective.
- Utilization within a single health system may limit generalizability.

Conclusions and Impact on Practice

- PCC administration for non-major bleeding or non-urgent reversal remains as an issue.
- An order panel may improve use of concomitant vitamin K for reversal of vitamin K antagonists.
- Additional studies for PCC use in off-label indications, especially for coagulopathies unrelated to oral anticoagulation, are needed.

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Corissa L. Piatka: Nothing to disclose Tim Johnston: Nothing to disclose Jim Roy: Nothing to disclose

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