**Title:** UTILIZATION AND SAFETY OF OFF-LABEL 4F-PCC IN NON-ANTICOAGULATED PATIENTS

**Abstract**

**Introduction:**

Prothrombin complex concentrate (PCC), including four-factor concentrate (4F-PCC) which contains inactivated factors II, VII, IX, X, is used to reverse the anticoagulation effects of vitamin K antagonists (e.g. warfarin), and oral Factor Xa inhibitors (e.g. apixaban, rivaroxaban), in patients with acute major bleeding or in need of urgent surgery or invasive procedure.

Non-anticoagulant associated hemorrhage in liver disease, post-operative hemorrhage, intracranial hemorrhage, gastrointestinal hemorrhage, cardiothoracic surgery, and trauma are among the off-label indications for 4F-PCC use that have been evaluated in previous studies. Robust guidance to support 4F-PCC use in non-anticoagulated populations is lacking. Additionally, 4F-PCC has been associated with an increased risk of thromboembolic events when used for off-label indications.

Given the potential risks and limited guidance of 4F-PCC use in non-anticoagulated patients, this study aims to evaluate and describe the utilization and safety of 4F-PCC in non-anticoagulated patients at the University of New Mexico Hospital.

**Methods:**

This retrospective, single-center study chart review at the University of New Mexico Hospital evaluated non-anticoagulated patients ≥18 years of age who had at least one dose of 4F-PCC administered between January 1, 2017 and September 30, 2022.  Each medical record encounter was reviewed for demographic and clinical variables, as well as the indication for 4F-PCC. Primary efficacy outcomes included the number of patients without administration of subsequent blood product transfusions or hemostatic agents, in addition to an assessment of coagulopathy parameters, such as clotting time using rotational thromboelastography. Sub-analysis of each 4F-PCC indication also occurred. The primary safety objective assessed thrombotic events within 30 days post-4F-PCC administration, and secondary safety objectives included the length of hospital stay and mortality. Outcomes were analyzed using descriptive statistics. Data is reported as percentages and means with standard deviation (or median and IQR for non-normal distribution).

**Results:** In progress.