Applies to former Saskatoon Health Region area

Emergency Reversal of Warfarin Using Prothrombin Complex Concentrates (PCCs) Beriplex® or Octaplex®

SHA Physician and Nursing Protocol for PCC Usage

PCC required	Review indications for use to determine the need for Prothrombin Complex Concentrates (PCCs):	

	Indications	• **INR 1.5 or greater (caused by Warfarin therapy) AND need for immediate Warfarin reversal due to:**
		  • Major bleeding; **and/or**
		  • Need for an unplanned surgical procedure which cannot be delayed a minimum of 6 hours.

	Contraindications	• Patients with a known heparin allergy or in suspected or proven Heparin Induced Thrombocytopenia (HIT).
		• IgA deficiency with anti-IgA antibodies (applies to Octaplex® only).
		
		• Not effective for management of:
		  • Disseminated Intravascular Coagulopathy (DIC).
		  • Liver dysfunction/disease associated coagulopathy.
		  • Massive transfusion.
		  • Bleeding associated with heparin based anticoagulants, antiplatelet agents or direct thrombin inhibitors (dabigatran/Pradaxa).

	Adjunctive Therapy	• Vitamin K co-administration by intravenous (IV) or oral route is strongly recommended to complete warfarin reversal management (Do NOT administer by intramuscular or subcutaneous route). • Onset of action of Vitamin K given IV is approximately 4 hours. • Vitamin K dose and route should be tailored to the clinical circumstances, including the severity of warfarin coagulopathy. For most situations, consider oral vitamin K 1-5 mg. In the case of life-threatening bleeding, administration of 10 mg Vitamin K **slowly** by IV infusion is recommended.
Dosage		

	INR 1.5 – 2.9	INR 3.0-5.0	INR 5.1 or greater
PCC dosage	1000 units	2000 units	3000 units

- If the INR is unknown and major bleeding is present in a patient known to be taking warfarin, 2000 units (80 mL) PCC should be administered.
- **Maximum dose** not to exceed 3000 units.

Ordering	• Must be ordered by a staff physician.
	  • PCC's are a blood product and therefore **informed consent** is required.
	• Complete a Blood Product Request Form (Form #103221).
	  • Indicate the number of units required.

Preparation	• Reconstitute product as indicated on the package insert.
	  • Use the Mix2Vial® spiking device which contains a 15 um filter.
	  • Once reconstituted remove the blue portion of the Mix2Vial® device.
	  • Use a syringe to withdraw the product.
	  • Must be used immediately after reconstitution.

	• If loss of vacuum or ineffective reconstitution occurs:
	  • Grasp the outer rim of each of the Mix2Vial® components.
	  • Unscrew counter clockwise to separate.
	  • Place both vials on a clean surface.
	  • Carefully detach blue component of the Mix2Vial® from the diluent vial and discard.
	  • Swab the diluent vial with an antiseptic swab.
	  • Without touching the white luer lock tip, attach a clean syringe to this end, tightening firmly.
	  • Remove clear component of the Mix2Vial® from the product vial (with attached syringe) while maintaining aseptic technique.
	  • Wipe vial top with antiseptic swab.
	  • Aspirate estimated volume of air into syringe, equivalent to remaining diluent in vial and expel air into vial.
	  • Invert vial and draw remaining diluent into syringe.
	  • Remove clear component of Mix2Vial® with attached syringe from the diluent vial.
	  • Place the clear component with attached syringe containing the diluent into the product vial.
	  • Carefully push diluent into the product vial and proceed as usual.

Administration	• **Infusion rate** should not exceed**:**
	  • **Beriplex®** 8 mL/min.
	  • **Octaplex®** 2-3 mL/min.
	
	• Blood administration set is not required; product is considered filtered (the Mix2Vial® device contains a filter).
	• Syringe can be placed on an infusion pump or given by IV push.
	• **No other drugs/solutions can be co-administered in the same line while a PCC is being infused.**
	• Flush tubing with normal saline.
	• Must be infused within 3 hours of reconstitution.

Monitoring	• INR should be tested:
	  • 10-30 minutes post PCC dose **AND** 6 hours post PCC dose.
	  • Repeat thereafter if clinically indicated.
	
	• PCC effect is immediate and will last 6-12 hours post infusion. Expected post infusion target INR is ≤1.5 (complete warfarin reversal).
	• No additional monitoring is required.
	• Adverse reactions including immediate allergic complications are rare. Thrombosis risk is at least 1 in 100, and dependent on individual patient risk factors and PCC dose.

Approved Related Procedural Document: TML-152 Handling Requests for Prothrombin Complex Concentrates (PCC) – SOP.