

Date: November 1, 2011

To: Rural, Emergency and Critical Care Physicians, STARS, Emergency Medical Services, Nursing and Laboratory Directors and Managers

From: Transfusion Medicine Laboratory Integration Network

Re: Prothrombin Complex Concentrate Availability

PLEASE POST OR DISTRIBUTE AS WIDELY AS APPROPRIATE

Key Messages:

- Beginning in November 2011 Prothrombin Complex Concentrate will start to be distributed to rural hospital facilities with a laboratory performing INR and with an onsite emergency department. Distribution will be complete by mid December 2011.

Background:

- Prothrombin Complex Concentrates, or PCC, are human plasma protein concentrates that contain vitamin K dependent clotting factors and anticoagulant proteins. These concentrates are licensed for use as an antidote in patients who are anticoagulated with warfarin, and who are bleeding, or require an urgent surgical or invasive/interventional procedure.
- PCC made by two different manufacturers, octaplex (Octapharma) and Beriplex (CSL Behring) are licensed in Canada. These agents have been available in some Alberta hospitals located in larger urban centers for some time. This product will be more widely distributed in order to ensure that reversal of anticoagulation can begin urgently when patients present with major bleeding at a rural hospital.

Indication:

- The National Advisory Committee on Blood and Blood products have prepared a guideline related to these products that can be found at www.nacblood.ca.

PCC are recommended for:

- reversal of warfarin therapy or vitamin K deficiency in patients exhibiting major bleeding or
- reversal of warfarin therapy or vitamin K deficiency in patients requiring urgent (< 6 hours) surgery

Contraindications:

- PCC are NOT indicated for reversal of elevated INR without evidence of bleeding or need for urgent interventional procedures.**
- PCC are contraindicated in patients with a history of Heparin Induced Thrombocytopenia.
- PCC are not generally indicated for patients with elevated INR who are not warfarin anticoagulated. Use in this setting should be only on the advice of a consultant.

Recommended Dosing:

Dosing should be based on the INR. If major bleeding is present and the INR is unknown, a dose of 80 ml should be administered..

	INR 1.5 - 2.9	INR 3.0 - 5.0	INR greater than 5.0
Dose of PCC	40 mL (1000 IU)	80 mL (2000 IU)	120 mL (3000 IU)
Vitamin K1	10 (mg IV) co-administration strongly recommended if reversal is required for longer than 6 hours.		

If time permits reassessment of INR at 10 - 30 minutes post dose is recommended, with additional PCC provided if the INR remains greater than 1.5 and bleeding continues. In the event sufficient product is not available to meet the above recommendations, the maximum dose available should be given with consideration for transferring the patient to another facility for additional treatment.
Maximum total dose = 120 mL

Administration:

- PCC must be administered by direct IV push, or intravenously by syringe pump or minibag.
- The manufacturer's recommended maximal rates of infusion are:
 - Octaplex® = 3mL/min
 - Beriplex® P/N = 8 mL/min
- Vitamin K1 (10 mg IV) co-administration is strongly recommended if a reversal is required for longer than 6 hours (the half life of PCC).

Monitoring:

- If time permits re-assessment of INR 10 – 30 minutes post dose is recommended, with additional PCC provided if the INR remains >1.5 and bleeding continues.

Additional Information:

- Please refer to the NAC Guideline at www.nacblood.ca and/or the product monographs and the AHS Blood Component & Products Information at <http://www.albertahealthservices.ca/3319.asp>.
- Questions regarding PCC use may be directed to Critical Care Line Physicians, Transfusion Medicine Network Physicians, Transfusion Medicine or Hematology Consultants for your hospital.

Transfusion Medicine Network Physicians:

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This bulletin has been reviewed and approved by Dr. James Wesenberg, AHS Medical/Scientific Director, Laboratory Services - Regional Centres and Rural