

The Credit Valley Hospital – CLINICAL PRACTICE GUIDELINES

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Title: Warfarin Reversal - Acute Management in **Adults CPG**

PURPOSE

To provide a guideline to assist physicians in the management of patients who have elevated INRs or bleeding secondary to warfarin administration.

NOTE: The CVH guidelines are adapted from The Eighth American College of Chest Physicians (ACCP) Conference on Antithrombotic and Thrombolytic Therapy: Evidence-Based Guidelines. For additional information, refer to the complete guidelines available at <http://www.chestnet.org>

SELECTION CRITERIA

- Adult patients on warfarin therapy with an elevated INR above the therapeutic range
- Adult patients on warfarin therapy that require acute reversal of their INR for surgery/procedure within 6 hours
- Adult patients on warfarin therapy with major/life threatening bleeding requiring acute reversal of their INR

RESPONSIBILITY

The acute reversal of warfarin with Prothrombin Complex Concentrate (PCC) (Octaplex®) is restricted to Emergency Physicians, Intensivists and Haematologists.

All patients that receive PCC Octaplex® require follow up with a haematologist to monitor for thrombotic events.

ASSESSMENT AND TREATMENT AND/OR MONITORING

Acute reversal of warfarin is directed by the INR value. It should be noted that INR values greater than 4.5 are less reliable than values in or near the therapeutic range. These guidelines represent an approximate guide for high INRs.

Following PCC (Octaplex®) use – check INR at 10 to 15 min and then as per Appendix A, monitor clinical outcomes (including thrombotic events) for 24 hours and up to 30 days

See Table 1. **Drug Information** for indications and exclusions for PCC (Octaplex®) and Vitamin K₁ used to reverse warfarin therapy. For more detailed information consult the package insert for PCC and the CPS for Vitamin K₁.

See Appendix A Algorithm: **Management of Warfarin Reversal** for treatment and monitoring of patients that require acute management of anticoagulant effects of warfarin.

Table 1. Drug Information

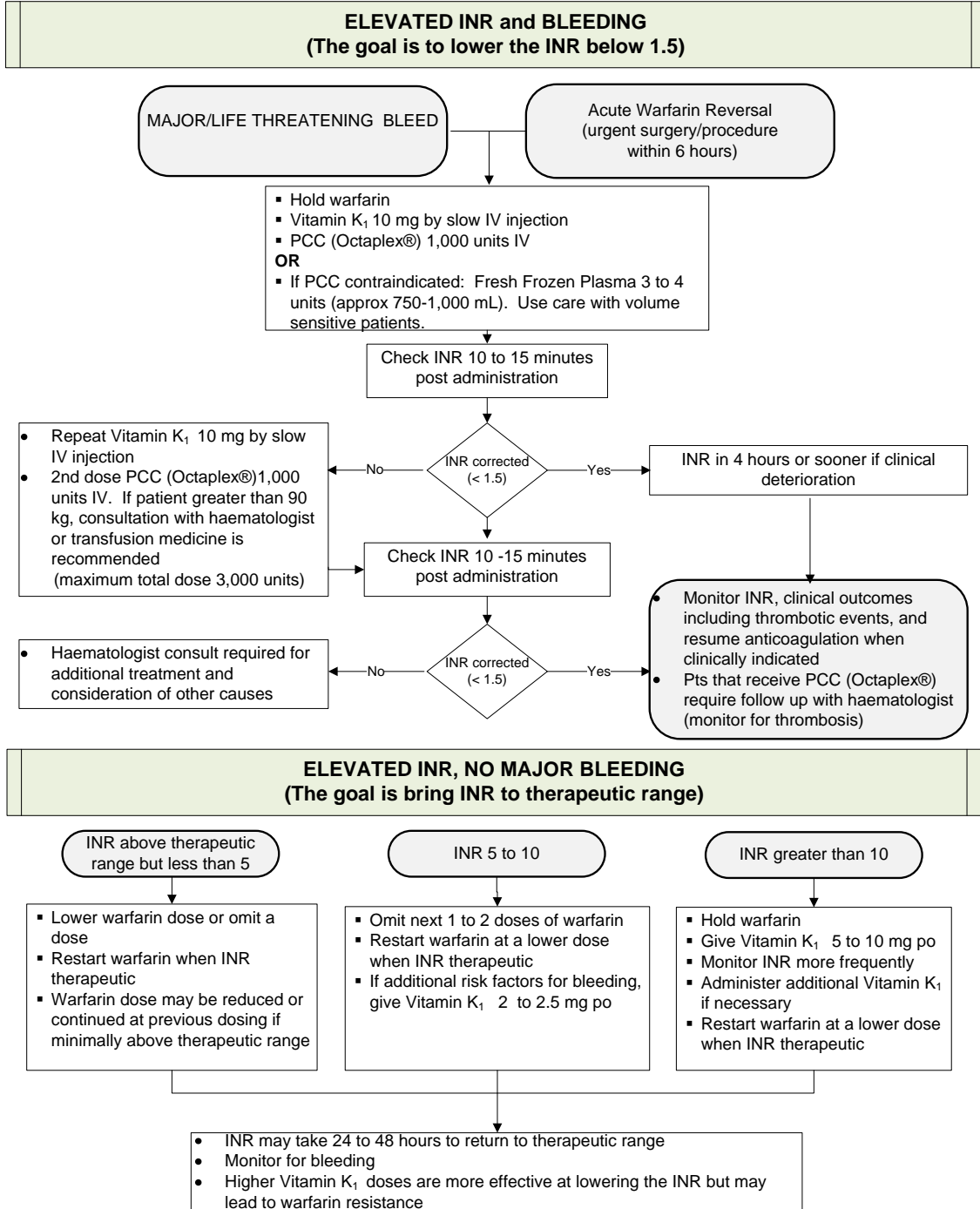
Prothrombin Complex Concentrate (Octaplex®)	
Indications	Exclusions/Warnings
<ul style="list-style-type: none"> Reversal of warfarin therapy in patients exhibiting major/life threatening bleeding manifestations Reversal of warfarin therapy in patients requiring urgent (less than 6 hour) surgical procedures <p>Notes:</p> <ul style="list-style-type: none"> PCC contains a concentrate of human coagulation factors II, VII, IX and X and protein C and S One 20 mL vial contains approximately 500 units Factor IX 	<p>Contraindications:</p> <ul style="list-style-type: none"> History of Heparin Induced Thrombocytopenia (HIT) Hypersensitivity to any ingredient in the product including heparin <p>Not Recommended for:</p> <ul style="list-style-type: none"> Reversal of oral anticoagulant therapy for <u>elective</u> invasive procedures Treatment of elevated INRs without bleeding or need for surgical intervention Massive transfusion Coagulopathy associated with liver dysfunction Recent history of thrombosis, myocardial infarction, ischemic stroke or disseminated intravascular coagulation (DIC) <p>Warnings:</p> <ul style="list-style-type: none"> High doses of PCC have been associated with instances of MI, DIC, venous thrombosis and pulmonary embolism
<ul style="list-style-type: none"> Consent for Blood and Blood Product Administration required (human blood product) See nursing Administration of Octaplex® Procedure for infusion information 	
Vitamin K₁ (Phytonadione)	
Indications	Exclusions/Warning
<ul style="list-style-type: none"> Reversal of the anticoagulant effects of warfarin in patients whose INR puts them at risk for bleeding 	<p>Contraindications:</p> <ul style="list-style-type: none"> Hypersensitivity to Vitamin K₁ <p>Warnings:</p> <ul style="list-style-type: none"> Severe reactions, including fatalities, have occurred during and immediately after IV Vitamin K₁ even when precautions have been taken to dilute the Vitamin K₁ solution and to avoid rapid infusion
<ul style="list-style-type: none"> When Vitamin K₁ must be administered IV it should be given by slow IV infusion, at a rate not exceeding 1 mg/minute, in order to reduce the chance of anaphylaxis An oral formulation of Vitamin K₁ is not available in Canada. The injectable form is used for oral use. To administer Vitamin K₁ injection orally, the required amount of Vitamin K₁ (phytonadione) should be drawn up using the 10 mg/mL ampoule and a TB syringe. The injection may be added to a small amount of juice for oral administration. 	

Warfarin Reversal - Acute Management in Adults CPG

Appendix A

Management of Warfarin Reversal

Note: PCC is a *warfarin antidote*. It will not work for other coagulation disorders.


ELEVATED INR, NO MAJOR BLEEDING
 (The goal is bring INR to therapeutic range)

REFERENCES

- Ansell J, Hirsh J, Hylek E et al. Pharmacology and management of the Vitamin K Antagonists. Chest 2008; 133:160S-198S.
- National Advisory Committee on Blood and Blood Products. Recommendations for use of Octaplex® in Canada. Sept 16, 2008. www.nacblood.ca
- Royal United Hospital Bath NHS. Guidelines for the management of warfarin reversal. Dec 2008.
- Vitamin K monograph, CPhA Monograph, eCPS accessed Aug 2009.

RELATED DOCUMENTS

Administration of Octaplex procedure – Clinical Documents, Nursing Practice/Transfusion Medicine – Nursing
Factor Concentrate Descriptions and Indications – Laboratory Medicine/Transfusion Medicine

EDUCATION

The Document Leader will be responsible for an education plan to ensure staff members directed by the information contained in the clinical practice guideline are notified. New staff will receive education through hospital and/or department orientation.

EVALUATION

PCC Octaplex® usage will be monitored by the Transfusion Medicine Committee.

DEVELOPED BY

Transfusion Medicine Manager
Quality and Risk Facilitator

APPROVED BY

Medical Advisory Committee – Oct 5, 2009