Aim
To provide guidelines for the indications, preparation and administration of fibrinogen concentrate at King Edward Memorial Hospital.

Background
Fibrinogen is the first coagulation factor to fall in major haemorrhage. Two main forms of replacement are currently available: cryoprecipitate and fibrinogen concentrate (RiaStap). Currently in Australia the use of fibrinogen concentrate in acquired bleeding situations is “off label” and hence not funded by the National Blood Authority. It is thus considerably more expensive to use than cryoprecipitate and hence should only be used under appropriate guidance.

KEY POINTS
1. RiaSTAP is for intravenous use only.
2. It must be reconstituted prior to use.
3. It must only be prepared and administered in a fully monitored environment by anaesthetic medical staff who have received the appropriate education.

INDICATIONS AND USAGE
At KEMH, fibrinogen concentrate is indicated for the correction of low fibrinogen states associated with major haemorrhage. See “Criteria for Use” for specific criteria to be met prior to administration.

CONTRAINDICATIONS
Patients who have manifested severe immediate hypersensitivity reactions, including anaphylaxis to RiaSTAP or its components.

CRITERIA FOR USE
1. Patients must be experiencing critical bleeding. a

2. Fibtem A5 <7mm b or there is a high clinical suspicion of coagulopathy in a life-threatening haemorrhage situation. c Patients refusing cryoprecipitate but needing fibrinogen supplementation may require a higher FIBTEM trigger. d

3. Consultant anaesthetist or haematologist approval is required prior to before use.

   a. Critical Bleeding is defined as “major haemorrhage that is life threatening and likely to result in the need for massive transfusion.”
b. Fibtem A5 <7mm is a laboratory measurement performed on the ROTEM device. It is indicative of a severe fibrinogen deficiency and is associated with a very high likelihood of progression to a massive transfusion if not corrected.

c. This would occur rarely but may be appropriate in situations where the ROTEM device is either unavailable or in very rare clinical situations such as suspected amniotic fluid embolism.

d. Some Jehovah’s Witness’ and other patients may refuse cryoprecipitate but may be willing to receive fibrinogen concentrate.

PREPARATION AND RECONSTITUTION

- Do not use RiaSTAP™ passed its expiry date.
- The preparation and reconstitution shall be performed using an aseptic technique.
- Only reconstitute with sterile water for injections. Do not mix RiaSTAP™ with other medicinal products or intravenous solutions.
- Reconstitute using the sterile water in the fibrinogen concentrate pre-prepared kits in the theatre fluid warming cabinets.

Process of reconstitution

1. Remove the cap from the product vial to expose the central portion of the rubber stopper.
2. Clean the surface of the rubber stopper with an antiseptic solution and allow it to dry.
3. Using a sterile syringe, transfer 50mL of sterile water for injections into the vial.
4. Gently swirl the vial to ensure the product is fully dissolved. **Do not shake the vial.** After reconstitution the solution should be colourless and clear to slight opalescent.
5. Visually inspect the solution for particulate matter and discolouration prior to administration. Do not use if the solution is cloudy or contains particulates. (Some froth is OK)
6. Discard partially used vials.

ADMINISTRATION

- In critical bleeding situations administer via syringe driver over 2-4 minutes per gram (50 mL).
- In less critical situations consideration may be given to slowing the rate of infusion.

WARNINGS AND PRECAUTIONS

**Allergic Reactions**

Allergic reactions may occur. If symptoms of allergic or early signs of hypersensitivity reactions (including hives, generalised urticarial, tightness of the chest, wheezing, hypotension and anaphylaxis) occur, immediately discontinue administration. The treatment required will depend on the nature and severity of the reaction.
**Thrombosis**
Thrombosis may occur spontaneously in women with fibrinogen deficiency with or without the use of fibrinogen replacement therapy. Weigh the benefits of RiaSTAP™ administration versus the risk of thrombosis. Women receiving RiaSTAP™ should be monitored for signs and symptoms of thrombosis.

**Transmissible Infectious Agents**
RiaSTAP is made from human plasma. Products from human plasma may contain infectious agents (e.g. viruses and theoretically the Creutzfeldt-Jakob disease agent) that may cause disease. Patients must be informed that the product is made from human plasma and may contain infectious agents that can cause disease.

**Adverse Reactions**
Allergic – anaphylactic reactions, thromboembolic episodes, including myocardial infarction, pulmonary embolism, deep vein thrombosis and arterial thrombosis have been reported following the use of RiaSTAP™.
The most common adverse reactions are allergic reactions and generalised reactions such as chills, fever, nausea and vomiting.

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**References**


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**Related WNHS policies, procedures and guidelines**

- Medication Safety: Procedure for the Reconstitution and Administration of Intravenous Drugs
- Medication Safety: Intravenous Medications – Checking and the Administration of by Medical and Nursing / Midwifery Staff
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