GUIDELINES FOR THE USE OF RECOMBINANT ACTIVATED COAGULATION FACTOR VIIA (NOVOSEVEN)
1. **Purpose**

This guideline has been formulated to assist clinicians in the appropriate use of Recombinant Activated Coagulation Factor VIIa (NovoSeven) in cases of massive haemorrhage, which has proved unresponsive to all other methods of intervention. NovoSeven used under these conditions is an off-label use outside the terms of the drug licence, for which the Trust and the prescribing clinician must carry responsibility.

2. **Personnel**

2.1. Clinicians

2.2. Laboratory staff

2.3. Nurses

3. **Area**

Trust wide

4. **Actions**

4.1. **Preconditions** – If the patient fulfils at least 2 of these conditions, there may be an indication to use Novo 7 following consultation with the hematologist.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1.1. Post partum haemorrhage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In all cases of massive obstetric haemorrhage, the use of recombinant factor VIIa MUST be considered prior to the decision to perform hysterectomy.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4.1.2. Uncontrolled bleeding Post operatively</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.3. Uncontrolled bleeding due to Road Traffic accident</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.4. Massive bleeding in a multi-transfused patient in whom all surgical cause has been excluded</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>More than 10 units of red cells should have been administered under the guidance of the Consultant Haematologist.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.5. Bleeding and coagulopathy persists despite the use of adequate blood products.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Adequate quantities of Platelets, FFP, Cryoprecipitate and other drugs should have been administered under the guidance of the Consultant Haematologist.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.6. The condition of the patient is such that, in agreement with the Managing Clinician, survival of the patient is thought to be likely if the bleeding were controlled</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4.1.7. Is the patient still for resuscitation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.8. Uncontrolled bleeding due to excessive oral anticoagulants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1.9. Uncontrolled bleeding in Jehovah Witness patients in whom all surgical causes have been excluded, and the condition of the patient is such that survival of the patient is thought to be unlikely if the bleeding is not controlled</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
4.2. Drug dose and administration

<table>
<thead>
<tr>
<th>Approx body weight (kg)</th>
<th>Dose of NovoSeven required</th>
<th>Number of 2.4mg vials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 54</td>
<td>4.8 mg</td>
<td>2</td>
</tr>
<tr>
<td>55 – 80</td>
<td>7.2 mg</td>
<td>3</td>
</tr>
<tr>
<td>81 - 110</td>
<td>9.6 mg</td>
<td>4</td>
</tr>
<tr>
<td>111 - 140</td>
<td>12 mg</td>
<td>5</td>
</tr>
<tr>
<td>141 - 160</td>
<td>14.4 mg</td>
<td>6</td>
</tr>
</tbody>
</table>

4.3. Contact key personnel

4.3.1. Inform the on-call Consultant Haematologist – bleep via switchboard

4.3.2. The drug will be issued from the blood transfusion laboratory, only following direct instructions from the On-call Haematologist.

4.3.3. The directorate to whom the patient belongs will honour payment for the drug

4.4. Additional information

4.4.1. Storage

One dose (3 X 2.4mg vials) of NovoSeven will be stored in the transfusion laboratory, subsequent doses will be stored in the emergency drug refrigerator in Pharmacy, and will be accessed by the transfusion laboratory either via pharmacy (during normal working hours) or via the hospital bleep/key holder (out of hours)

4.4.2. Administration and Monitoring

4.4.2.1. The injection vial must be kept refrigerated between 2-8°C.

4.4.2.2. Each vial of 2.4mg powder should be reconstituted with the 4.3ml diluents supplied, and should be used immediately, although it can be stored for up to 24 hours at 2-8°C.

4.4.2.3. The reconstituted product should be given as a bolus IV injection over two to five minutes.

4.4.2.4. NovoSeven should not be mixed with infusion solutions, or be given in an IV infusion.

4.4.2.5. Successful use of NovoSeven is usually seen within 60 minutes of administration, repeated, if necessary between 60 minutes and 2 hours later following further consultation with the on-call haematologist.

4.4.2.6. A coagulation screen should be performed 60 minutes after administration

4.4.2.7. Use coagulation results to guide provision of blood products to rectify any coagulopathies.

4.4.2.8. Further transfusion should not be withheld, as the product is more effective if there is an adequate circulation delivering platelets and fibrinogen to the site of bleeding.

4.4.2.9. Correct any known or expected acidosis or hypothermia. (Arterial pH should be >7 as rFV11a is critically pH-dependant)

4.4.3. Risks and Benefits

4.4.3.1. The thrombogenic potential of this drug is unknown but is thought to be small.

4.4.3.2. NovoSeven is contraindicated in patients with a known hypersensitivity to mouse, bovine or hamster proteins.

4.4.3.3. Current evidence suggests recombinant factor VIIa is more useful in blunt trauma
4.4.3.4. There is no evidence or known benefit to support the practice of repeating
administration of NovoSeven if two doses have failed to produce a response.

5. Related documents
5.1. Policy for the Administration of Blood & Blood Components & Clinical Guidelines for the
Management of Transfusion Reactions (CSP002)
5.2. Northern Lincolnshire & Goole Major haemorrhage policy
5.3. Northern Lincolnshire & Goole Trust contingency plan
5.4. Factor VIIa (NovoSeven) Audit Form (GSG003a)

6. References
6.1. G. Price, J. Kaplan & G. Skowronski. Use of recombinant factor VIIa to treat life-
threatening non-surgical bleeding in a postpartum patient. British Journal of
Anaesthesia. 2004; 93: 298 -300
6.2. F. Boehlen, M. Morales, P. Fontana et al. Prolonged treatment of massive postpartum
haemorrhage with recombinant factor VIIa: Case report and review of the literature.
BJOG 2004; 111(3): 284 -87
obstetrics and gynaecology. 2001; 13(6): 595-603
6.4. NovoSeven for massive, uncontrollable, life-threatening haemorrhage in non-
haemophiliacs. National Board of Health, Danish Centre for Evaluation and Health
Technology Assessment. 2003
6.5. D.R. Spahn,, M.A. Tucci & M. Makris. Is recombinant FVIIa the magic bullet in the
6.7. u. Martinowitz, M. Michaelson. Guidelines for the use of recombinant factor VIIa in
uncontrolled bleeding : a report by the Israeli multidisciplinary rVIIa task force. Journal of

7. Definitions
None