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Changing patterns of off-licence use of recombinant activated factor VII (rFVIIa; NovoSeven) in the management of major haemorrhage

J Orr¹, J Trattles², J Ryan³, K Nesbitt⁴, D Cox⁵, E King⁶, T Biss⁷

¹Department of Haematology, James Cook University Hospital, South Tees Hospitals NHS Foundation Trust, UK;

²Department of Haematology, Sunderland Royal Hospital, City Hospitals Sunderland NHS Foundation Trust, Sunderland, UK; ³Pathology Department, Darlington Memorial Hospital, County Durham and Darlington NHS Foundation Trust, Darlington, UK; ⁴Department of Haematology, Queen Elizabeth Hospital, Gateshead Health NHS Foundation Trust, Gateshead, UK; ⁵Department of Haematology, University Hospital of North Tees, North Tees and Hartlepool Hospitals NHS Foundation Trust, Stockton-on-Tees, UK; ⁶Department of Haematology, Cumberland Infirmary, North Cumbria University Hospitals NHS Trust, Carlisle, UK; ⁷Department of Haematology, Royal Victoria Infirmary, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle-upon-Tyne, UK

Recombinant activated factor VII (rFVIIa; NovoSeven) was previously used in many centres for the management of major haemorrhage. However, lack of evidence of efficacy, along with reports of arterial thrombosis, have resulted in advice against its use in this setting.

This retrospective cohort study reviewed clinical features, laboratory data and outcomes for patients in the North of England who received off-licence rFVIIa for significant bleeding over a 24-month period from January 2013. We compared current use against historical data from a published regional study of a 45-month period from August 2001.

Twenty-five patients received off-licence rFVIIa for significant bleeding from January 2013 - December 2014. Data were available for 23. Median age was 62 years (range: 2-90) and 14 were male. Indications included cardiothoracic surgery (22%), GI-tract bleeding (17%), GI surgery (13%) and trauma (9%). Bleeding was associated with direct oral anticoagulants in 4/23 (17%). At administration, 12 had documented coagulopathy, 3 were hypothermic and 7 had acidosis. The majority received an initial dose of 90 mcg/kg and two received a second dose. 7/23 (30%) died within 24 hours and only 6/23 (26%) survived for >100 days or to discharge from hospital. Thrombotic complications were seen in 6 patients (26%).

Compared to historical data, annual rFVIIa use had increased, from 9.6 patients/year to 11.5 patients/year. Use for GI-tract bleeding and DOAC-related bleeding had increased whereas use for bleeding in obstetrics had ceased. Survival rate for recent use was 26% vs. 47% for historical use.

Off-licence use of rFVIIa for major haemorrhage continues in our region despite poorer survival and thrombotic complications. This may be due to use being limited to cases of futility. These data do not support efficacy and safety of rFVIIa and with the advent of DOAC antidotes its role in major haemorrhage is likely to be limited even further.

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Pre-transfusion testing and confirmation of patient ABO group for first time transfused patients

H Frost¹, H Wood², J Cole¹, P Glinski¹, A Karlsen¹, A Andrews¹, A Arasaretnam²

¹Transfusion Department, Brighton and Sussex NHS Trust, UK; ²Department of Clinical Haematology, Brighton and Sussex NHS Trust, UK

The British Committee for Standards in Haematology guidelines for pre-transfusion compatibility procedures recommend that a second sample is requested for confirmation of a patient ABO group for a first time transfused patient. A second separate group check is a critical control point in pre transfusion testing, the aim being to negate any potential errors in patient identification, leading to patient morbidity and mortality from ABO-incompatible transfusions. Transfusion laboratories aim to practice a zero tolerance sample acceptance policies.

After a local hospital transfusion team meeting where suspected incidents of initial and confirmatory samples at one patient contact were raised, we reviewed events over a month.

There were 37 suspected incidents: 30% of the two recommended group samples were taken at the same time, 22% of samples were labelled with different times but sent with only one sample form, 14% of samples were labelled with one sample label generated by a barcode and one handwritten raising the suspicion they had been taken at one phlebotomy contact, 11% of samples had the time on one sample amended by hand to appear it was taken at a separate time, 11% where two handwritten samples with different timings and identical handwriting were received at the same time in the laboratory- again raising suspicion that there had only been one phlebotomy contact. The remaining cases (5/37) included suspicion of splitting one sample into two separate tubes.

Index of suspicion in the laboratory should prompt discussion with clinicians and a request for another confirmatory sample. Only accepting barcode generated labels which clearly document timing of patient contact and also renaming the second sample a 'confirmatory' one, to emphasize its role, or use of a different coloured confirmatory bottle available to collect from the laboratory may all reduce these incidents. Ongoing education and training remains crucial.

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A red cell dosage calculator could promote single unit red cell transfusion, prevent over-transfusion and reduce red cell usage

S Grey, P Kinsella, K Sweeney, A Steele, C Patalappa, S Roberts

Department of Haematology, Bolton NHS Foundation Trust, Bolton, UK

A computer based application was developed that calculates the volume of red cells required to achieve a target haemoglobin (Hb) increment, based upon the indication for transfusion, the patient's body weight and cardiovascular (CV) risk factors. The aim of the study was to determine the optimum target Hb value for use in the dosage calculation that results in a post-transfusion Hb level of greatest concordance with the target post-transfusion Hb range. The effect of actual and standardized body weight and CV risk was also assessed.

Each model was characterised by actual or standardised weight and CV risk with a range of target Hb's used for the dosage calculation. In the standardised weight group, body weight was standardised

for gender (males 85Kg and females 70Kg), and CV risk was standardised based on age alone (assumed risk if age >70 years). The data were analysed for number of units actually transfused compared to dosage calculator recommendation (same, more, less), target Hb outcomes (achieved, exceeded, not achieved), versus units recommended by calculator category (same, more, less), and number of units actually transfused versus number of units recommended by the dosage calculator.

The best performing models (Hb outcomes and reduction in units) were the actual weight/CV risk and standardised weight/CV risk groups, both with Hb targets for the dosage calculation of 70 g/L (for restrictive transfusion) and 80 g/L (for non-restrictive transfusion). There appeared to be no significant difference between actual and standardised weight/CV risk (as a group effect), however this is important to individual patients particularly with low body weight. Both models demonstrated a reduction in excessive Hb increments (26% to 4%, and 41% to 6% respectively). Combined data for both groups showed a potential 34% overall reduction in red cell usage, and a 48% increase in single unit transfusion.

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Optimisation of preoperative anaemia in patients undergoing elective cardiac surgery

N Blunt¹, N Balani¹, G Hallward¹, S McCorkell¹, M Ghosh-Dastidar², J Roxburgh², A Bott², K Duncombe², A O'Sullivan², D Radia³, R Kesse-Adu³, S Robinson³
¹Department of Anaesthesia, Guy's and St Thomas' NHS Foundation Trust, London, UK; ²Department of Cardiac Surgery, Guy's and St Thomas' NHS Foundation Trust, London, UK; ³Department of Haematology, Guy's and St Thomas' NHS Foundation Trust, London, UK

Audit conducted over 22 months identified that 25% of elective cardiac surgery patients (338/1360) are anaemic. Lower preoperative haemoglobin (Hb) was associated with increased transfusion and increased intensive care unit and hospital stay ($p < 0.001$). For every 10 g/L increase in Hb there is an estimated decrease in probability of transfusion by 11%, 8% and 3% for red cells, platelets and FFP ($p = 0.001$), respectively.

In January 2015, a six-month pilot cardiac surgery patient blood management (PBM) pathway, was commenced.

Statistical analysis, by means of a Sign Test, was performed using an SPSS software package. Continuous variables were described using median and interquartile ranges. A p value < 0.05 was significant.

Referral criteria for oral iron: ferritin < 30 $\mu\text{g/L}$ in the absence of anaemia (male >130 g/L, female >120 g/L) or Hb ≥ 110 g/L and ferritin $> 30 < 100$ $\mu\text{g/L}$. Criteria for intravenous (iv) iron: Hb < 110 g/L or anaemia and ferritin < 30 $\mu\text{g/L}$.

64 patients met criteria for oral (38/64 (60%)) or iv (22/64 (40%)) iron, the median Hb was 127.5 g/L (120–131.3) and 109 g/L (100–126), ferritin 51.5 (28.8–73.2) and 28.5 (10–65.3) respectively. The median increment in ferritin was 9 $\mu\text{g/L}$ (3.2–13.5) and 177.5 $\mu\text{g/L}$ (62.6–312.8) respectively. The median increment in Hb was 0 g/L (-3.5–5.5) and 12 g/L (4.8–20.8) respectively. The oral iron group did not increase Hb or ferritin significantly ($p = 1.000$ and 0.092). The iv iron group did increase Hb and ferritin significantly ($p = 0.001$ and 0.016).

With limited time to correct iron deficiency anaemia and iron depletion between preoperative assessment and surgery, the pathway was revised. Patients with Hb ≥ 110 g/L and ferritin < 100 $\mu\text{g/L}$, or ferritin < 30 $\mu\text{g/L}$ or Hb < 110 g/L now receive iv iron.

Following pilot completion, audit against original parameters is required to confirm whether or not the pathway improves outcome

alongside health economic analysis. These data are necessary to support discussions with primary care and consider tariffs for PBM.

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ABSTRACT WITHDRAWN

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Tertiary neonatal single centre experience of fresh frozen plasma transfusion - an audit of current practice

S Dillon¹, J Yong¹, C Baithun¹, Z Molnar¹, A Qureshi², N Bhatnagar²

¹Oxford Newborn Care Unit, Women's Centre, John Radcliffe Hospital, Oxford, UK; ²Department of Paediatric Haematology and Paediatrics, John Radcliffe Hospital, Oxford, UK

Neonates are at higher risk of haemorrhage and fresh frozen plasma (FFP) transfusion is often used in Neonatal Intensive Care. FFP transfusion carries risks of infection transmission, fluid overload and is expensive. FFP transfusion is inappropriate if used solely to correct clotting values; as there is little published information on normal clotting values for extremely premature (< 28 weeks gestation) infants. We conducted a retrospective audit of our current FFP transfusion practice at a large UK tertiary neonatal unit over a three month period (September to December 2015). We compared our practice to the British Committee of Standards in Haematology (BCSH) 2004 guideline which states the use of FFP should be reserved for neonates with active bleeding and associated coagulopathy. We also analysed the appropriate use of FFP in extremely premature infants and those undergoing therapeutic hypothermia as these groups are at higher risk of bleeding. 22 episodes of FFP transfusion were identified through transfusion laboratory records during the study period. 10 (45%) FFP transfusions were given for massive haemorrhage in 4 neonates (all > 28 weeks gestation). 3 (13%) FFP transfusions were given for stage 3-4 haemorrhage (modified WHO bleeding assessment score) in 2 neonates. 4 of the neonates with bleeding symptoms were undergoing therapeutic hypothermia. 8 (36%) FFP transfusions were given for abnormal clotting in the absence of bleeding, 6 (75%) of which were in extremely premature infants. In conclusion, 13 out of 22 (59%) FFP transfusions given met the BCSH guidelines. However, 9 (41%) FFP transfusions were given to preterm neonates without any bleeding symptoms. We recommend more focus and education on treating bleeding symptoms rather than clotting values. This study illustrates a need for longitudinal studies to understand the natural history of neonatal haemostasis and better identify bleeding risk factors in this vulnerable population to prevent inappropriate FFP use.