Appendices

Appendix A. Search Strategies

OVID MEDLINE
1948 to February 12, 2009

Search 1: Factor VIIa Off-Label Use

> Rather than trying to represent "off-label" use with MeSH terms or keywords, this search included any article on Factor VIIa *except* case reports, editorials, animal-only studies and non-systematic reviews. This search does include systematic reviews.

1. exp factor viia/ OR ("factor viia" or "factor 7a" OR rfviia OR fviia) OR (novoseven or eptacog* OR Niastase OR proconvertin OR "novo-seven") OR ec 3 4 21 21.rn. OR ((7a or viia) adj5 (factor OR rfactor)) OR (("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated))

2. case reports or editorial or "review"

3. animals/ not humans/

1 NOT (2 OR 3 OR "*ALL RESULTS FROM THE NEXT THREE SEARCHES*")

Number of citations: 1684

Search 2: Intracranial Hemorrhages AND Factor VIIa

1. exp factor viia/ OR ("factor viia" or "factor 7a" OR rfviia OR fviia) OR (novoseven or eptacog* OR Niastase OR proconvertin OR "novo-seven") OR ec 3 4 21 21.rn. OR ((7a or viia) adj5 (factor OR rfactor)) OR (("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated))

2. exp Intracranial Hemorrhages/ OR exp brain/ OR exp skull/ OR intracranial.mp. OR intracerebral.mp. OR "basal ganglia".mp. OR brain*.mp. OR "posterior fossa".mp. OR cerebral.mp. OR parenchymal.mp. OR subdural.mp. OR subarachnoid.mp. OR pituitary.mp. OR epidural.mp

3. animals/ not humans/

(1 AND 2) NOT 3

Number of citations: 293

Search 3: Trauma AND Factor VIIa

1. exp factor viia/ OR ("factor viia" or "factor 7a" OR rfviia OR fviia) OR (novoseven or eptacog* OR Niastase OR proconvertin OR "novo-seven") OR ec 3 4 21 21.rn. OR ((7a or viia) adj5 (factor OR rfactor)) OR (("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated))

2. exp "Wounds and Injuries"/ OR (traum* or injur* or wound*).mp.

3. animals/ not humans/

(1 AND 2) NOT 3

Number of citations: 459

Search 4: Liver Transplantation/Cardiac Surgery/Prostatectomy AND Factor VIIa

1. exp factor viia/ OR ("factor viia" or "factor 7a" OR rfviia OR fviia) OR (novoseven or eptacog* OR Niastase OR proconvertin OR "novo-seven") OR ec 3 4 21 21.rn. OR ((7a or viia) adj5 (factor OR rfactor)) OR (("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated))

2. exp liver transplantation/ OR ((liver* or hepatic) adj3 (transplan* or graft*)).mp. OR exp Cardiovascular Diseases/su [Surgery] OR exp cardiovascular surgical procedures/ OR ((heart* or cardi*) and surg*).mp.OR exp Prostatectomy/ OR (Prostatectom* or (resect* and prostat*)).mp.

3. animals/ not humans/

(1 AND 2) NOT 3

Number of citations: 294

Total number of citations from OVID/MEDLINE search: 2793

EMBASE (DIALOG)
1974 to July 15, 2008

<u>Search 1: FACTOR VIIa NOT Letters, NOT Animal-only Studies</u>

S1 FACTOR VIIA! OR FACTOR()VIIA OR FACTOR()7A OR RFVIIA OR FVIIA OR NOVOSEVEN OR EPTACOG? OR NIASTASE OR PROCONVERTIN OR NOVO()SEVEN

S2 (7A OR VIIA)(5N)(FACTOR OR RFACTOR)

S3 (FACTOR()VII OR FACTOR()7 OR FVII OR RFVII OR FACTOR-

()SEVEN)(5N)(ACTIVE OR ACTIVATED)

S4 DT=LETTER

S5 (ANIMALS/DE OR NONHUMANS/DE) NOT (HUMANS/DE OR HUMAN-/DE)

S6 S1 OR S2 OR S3

S7 S6 NOT (S4 OR S5)

Number of citations: 1951 (excluding MEDLINE)

Search 2: FACTOR VIIa AND Intracranial Hemorrhage NOT Animal-only Studies

S9 BRAIN! OR SKULL! OR INTRACRANIAL OR INTRACEREBRAL OR BASAL()GANGLIA OR BRAIN? OR POSTERIOR()FOSSA OR CEREBRAL OR PARENCHYMAL OR SUBDURAL OR SUBARACHNOID OR PITUITARY - OR EPIDURAL

S10 BRAIN HEMORRHAGE! OR INTRACRANIAL HEMORRHAGES!

S11 (STROKE! OR CVA OR STROKE OR APOPLEXY OR BRAIN()VASC-ULAR()ACCIDENT? OR CEREBROVASCULAR()ACCIDENT OR CEREBROV-ASCULAR ACCIDENT/DE) AND (HEMORRHAGE! OR BLEEDING! OR H-EMORRHAG? OR BLEED?)

S12 S6 NOT S5

S13 s12 AND (S24 OR S13 OR S18)

Number of citations: 745 (excluding MEDLINE)

Search 3: FACTOR VIIa and Liver Transplantation/Heart Surgery/Prostatectomy NOT Animal-only Studies

S15 LIVER TRANSPLANTATION!

S16 (LIVER? OR HEPATIC)(5N)(TRANSPLANT? OR GRAFT?)

S17 CARDIOVASCULAR SURGICAL PROCEDURES! OR CARDIOVASCULAR SURGERY!

S18 CARDIOVASCULAR DISEASES!

S19 S32(L)SU

S20 CARDIOVASCULAR DISEASE!

S21 S20(L)SU

S22 (HEART? OR CARDI?) AND (SURG? OR PRESURG? OR POSTSURG? OR PERIOPERAT? OR OPERATION? OR OPERATIVE OR PERIOPERAT? OR PREOPERAT? OR POSTOPERAT? OR RESECT?)//TI,AB,DE

S23 PROSTATECTOMY!

S24 PROSTATECTOM? OR ((SURG? OR PRESURG? OR POSTSURG? OR PERIOPERAT? OR OPERATION? OR OPERATIVE OR PERIOPERAT? OR PREOPERAT? OR POSTOPERAT? OR RESECT?) AND PROSTAT?)

S25 (S15-S24 combined with OR) AND S12

Number of citations: 891 (excluding MEDLINE)

Search 4: FACTOR VIIa and Trauma NOT Animal-only Studies

S27 DC='C21.866.' (WOUNDS AND INJURIES)

S28 TRAUM? OR INJUR? OR WOUND?

S29 S12 AND (S27 OR S28)

Number of citations: 403 (excluding MEDLINE)

Total number of citations from EMBASE search: 3990

All OVID EBM Review Databases (Cochrane DSR, ACP Journal Club, DARE, CCTR, CMR, HTA, and NHSEED)
No date restrictions. Searched up to February 12, 2009

Factor VIIa Off-Label Use

"factor viia" or "factor 7a" OR rfviia OR fviia OR novoseven or eptacog* OR Niastase OR proconvertin OR "novo-seven" OR (7a or viia) adj5 (factor OR rfactor) OR ("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated)

Number of citations: 161

BIOSIS (ISI)
1926 to February 12, 2009

Factor VIIa Off-Label Use

Broad search aimed at retrieving all articles on Factor VIIa, but excluding letters and animal-only studies.

"factor viia" or "factor 7a" OR rfviia OR fviia OR novoseven or eptacog* OR Niastase OR proconvertin OR “novo-seven” OR (7a or viia) adj5 (factor OR rfactor) OR ("factor vii" OR "factor 7" OR fvii OR rfvii OR "factor seven") adj5 (active OR activated)

1 NOT Letters

2 NOT animals NOT humans

Number of citations: 3190

Total number of unique citations from all databases (after removing duplicate citations): 4967

Appendix B. List of Excluded Studies

Article citation	Rationale for exclusion
Abdullah F, Hunter C, Hargrove C, Arnold M, Stein J. Recombinant factor VIIa for treatment of massive liver fracture in a premature infant. J Pediatr Surg. 2006;41(10):1764-7.	Ineligible study design
Abraldes JG, Dell'Era A, Bosch J. Medical management of variceal bleeding in patients with cirrhosis. Can J Gastroenterol. 2004;18(2):109-13.	Ineligible study design
Abu-Hajir M, Hollowell J, Nagargoje G. Management of 2 patients with subdural hematoma and coagulopathy with recombinant human activated Factor VII (novoseven, rVIIa). Blood. 2001;98(11 Part 2):79b.	Small sample size
Adams GL, Manson RJ, Turner I, Sindram D, Lawson JH. The balance of thrombosis and hemorrhage in surgery. Hematol Oncol Clin North Am. 2007;21(1):13-24.	Ineligible study design
Afessa B, Peters SG. Major complications following hematopoietic stem cell transplantation. Semin Respir Crit Care Med. 2006;27(3):297-309.	Ineligible study design
Agarwal MB, Patnaik M. Recombinant activated factor VII (rFVIIa, NovoSeven). Journal of the Association of Physicians of India. 2005;53:717-20.	Ineligible study design
Agarwal N, Spahr JE, Rodgers GM. Successful management of intra-abdominal hemorrhage in the presence of severe alcoholic liver disease with activated recombinant factor VII (rFVIIa; NovoSeven): a case report and review of the literature on approved and off-label of rFVIIa. Blood Coagulation & Fibrinolysis. 2007;18(2):205-207.	Ineligible study design
Aggarwal A, Catlett J, Alcorn K. Use of recombinant activated factor VII (rFVIIa) in the management of intractable bleeding in surgical and trauma patients. Blood. 2001;98(11 Part 2):66b.	Small sample size
Aguilar C, Lucia JF. Successful control of severe postoperative bleeding with recombinant factor VIIa in a case of refractory idiopathic thrombocytopenic purpura. Am J Hematol. 2007;82(3):246-7.	Ineligible study design
Aguilar MI, Dernaerschalk BM. Intracerebral Hemorrhage. Seminars in Neurology. 2007;27(4):376-384.	Ineligible study design
Aguilar MI, Hart RG, Kase CS, et al. Treatment of warfarin-associated intracerebral hemorrhage: literature review and expert opinion.[erratum appears in Mayo Clin Proc. 2007 Mar;82(3):387]. Mayo Clinic Proceedings. 2007;82(1):82-92.	Ineligible study design
Ahonen J, Jokela R. Recombinant factor VIIa for life-threatening post-partum haemorrhage.[see comment]. British Journal of Anaesthesia. 2005;94(5):592-5.	Ineligible study design
Aitken MG. Recombinant factor VIIa. Emerg Med Australas. 2004;16(5-6):446-55.	Ineligible study design
Aiyagari V, Diringer MN. Response to discussion by Dr Philip Hebert. Use of recombinant activated factor VIIa (FVIIa) in severe head injury. J Crit Care. 2006;21(1):115-6; author reply 116.	Ineligible study design
Aiyagari V, Menendez JA, Diringer MN. Treatment of severe coagulopathy after gunshot injury to the head using recombinant activated factor VII. J Crit Care. 2005;20(2):176-9.	Small sample size
Akyildiz M, Turan I, Ozutemiz O, Batur Y, Ilter T. A cerebrovascular event after single-dose administration of recombinant factor VIIa in a patient with esophageal variceal bleeding. Digestive Diseases & Sciences. 2006;51(9):1647-9.	Ineligible study design
Al Douri M, Shafi T, Al Khudairi D, et al. Effect of the administration of recombinant activated factor VII (rFVIIa; NovoSeven) in the management of severe uncontrolled bleeding in patients undergoing heart valve replacement surgery. Blood Coagul Fibrinolysis. 2000;11 Suppl 1:S121-7.	Small sample size
Al Hammadi AM, Sallah S. Efficacy and safety of recombinant factor VIIa in the treatment of bleeding episodes in patients with aplastic anemia. Journal of Thrombosis & Haemostasis. 2007;5(2):435-6.	Ineligible study design

Al Sobhi E, Zahrani Z, Zevallos E, Zuraiki A. Imatinib-induced immune hepatitis: case report and literature review. Hematology. 2007;12(1):49-53.	Ineligible study design
Al Sobhi E. Successful outcome of using recombinant activated factor VII (rFVIIa) in liver biopsy in a patient with liver failure. J Thromb Haemost. 2006;4(9):2073-4.	Ineligible study design
Alameri A, Baker NS. Successful use of recombinant activated factor VII in the treatment of vitreous haemorrhage: a report of seven cases. Blood Coagulation & Fibrinolysis. 2005;16(8):573-8.	Small sample size
Alavi AA, Jalali SM, Rasouli MR, et al. Administration of recombinant activated factor VII in major thoracic operations.[comment]. Archives of Surgery. 2008;143(10):1021; author reply 1021.	Other: unpublished data
Alcorn K, Aggarwal A. Single Institution Experience of Recombinant Activated Factor VII (Novo-Seven) in the Management of Intractable Bleeding in Surgical and Trauma Patients. Blood. 2002;100(11):Abstract No. 3840.	Data combined for multiple conditions
Aldouri M. The use of recombinant factor VIIa in controlling surgical bleeding in non-haemophiliac patients. Pathophysiology of Haemostasis & Thrombosis. 2002;32 Suppl 1:41-6.	Small sample size
Aledort LM. Activated prothrombin complex concentrates and recombinant factor VIIa in the bleeding patient: are they appropriate and safe?[comment]. Journal of Thoracic & Cardiovascular Surgery. 2003;126(6):2112-3.	Ineligible study design
Aledort LM. Adverse reactions related to rVIIa? Am J Hematol. 2001;67(3):213.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Aledort LM. Comparative thrombotic event incidence after infusion of recombinant factor VIIa versus factor VIII inhibitor bypass activity.[see comment]. Journal of Thrombosis & Haemostasis. 2004;2(10):1700-8.	Ineligible study design
Aledort LM. MedWatch: an important instrument for postlicensing surveillance.[comment]. Journal of Thrombosis & Haemostasis. 2006;4(7):1637.	Ineligible study design
Aledort LM. Recombinant factor VIIa is a pan-hemostatic agent? Thromb Haemost. 2000;83(5):637-8.	Other populations with congenital or chronic acquired bleeding or clotting disorders (eg, Glanzmann's)
Aledort LM. rFVIIa--its thrombogenicity. Thromb Haemost. 2000;84(3):522-3.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Alexander E. Emerging role of recombinant factor VIIa in neuroscience. AACN Adv Crit Care. 2006;17(4):363-7.	Ineligible study design
Alfirevic Z, Elbourne D, Pavord S, et al. Use of recombinant activated factor VII in primary postpartum hemorrhage - The northern European registry 2000-2004. Obstetrics & Gynecology. 2007;110(6):1270-1278.	Ineligible study design
Alfirevic Z, Elbourne D, Pavord S, et al. Use of recombinant activated factor VII in	Ineligible

primary postpartum hemorrhage: the Northern European registry 2000-2004. Obstet Gynecol. 2007;110(6):1270-8.	study design
Ali ZS, Al-Shaalan H, Jorgensen J. Successful treatment of massive acute lower gastrointestinal bleeding in diverticular disease of colon, with activated recombinant factor VII (NovoSeven). Blood Coagul Fibrinolysis. 2006;17(4):327-9.	Ineligible study design
Alimoghaddam K, Ghavamzadeh A, Jahani M. Use of Novoseven for arsenic trioxide-induced bleeding in PML. American Journal of Hematology. 2006;81(9):720.	Ineligible study design
Al-Khuwaitir TS, Al-Moghairi AM, Sherbeeni SM, Al-Ghamdi AS. Rift Valley fever hepatitis complicated by disseminated intravascular coagulation and hepatorenal syndrome. Saudi Med J. 2004;25(4):528-31.	Ineligible study design
Allard S, Earley J, Davies JK, Cantwell C, Fulkes V. Hospital blood transfusion services in a mass casualty situation: lessons to be learned from July 2005 London bombings. British Journal of Haematology. 2006;133(Suppl. 1):2.	Ineligible study design
Allen GA, Hoffman M, Roberts HR, Monroe DM, 3rd. Recombinant activated factor VII: its mechanism of action and role in the control of hemorrhage. Canadian Journal of Anaesthesia. 2002;49(10):S7-14.	Ineligible study design
Allen KB, Heimansohn DA. Activated recombinant factor VII: Safety assessment in cardiovascular surgery patients at high risk for postoperative bleeding. Chest. 2006;130(4, Suppl. S):187S.	Small sample size
Al-Ruzzeh S, Mahmoud A, Shah S, O'Regan D. Caution with the use of recombinant activated factor VII in treating postoperative hemorrhage in cardiac surgery. Ann Thorac Surg. 2007;83(1):355; author reply 355-6.	Ineligible study design
Al-Said K, Anderson R, Wong A, Le D. Recombinant factor VIIa for intraoperative bleeding in a child with hepatoblastoma and review of recombinant activated factor VIIa use in children undergoing surgery. Journal of Pediatric Surgery. 2008;43(4):e15-9.	Ineligible study design
Al-Shahi R, You H. Hemostatic Drug Therapies for Acute, Nontraumatic Intracerebral Hemorrhage. Stroke. 2006.	Ineligible study design
Al-Trabolsi H, Carcao MD, Freedman J, et al. Factor VIIa overdose: Clinical and laboratory observations. Blood. 1998;92(10 SUPPL. 1 PART 1-2):104B.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Altuncu E, Berrak S, Bilgen H, Yurdakul Z, Canpolat C, Ozek E. Use of recombinant factor VIIa in a preterm infant with coagulopathy and subdural hematoma. Journal of Maternal-Fetal & Neonatal Medicine. 2007;20(8):627-9.	Small sample size
Alving BM. Platelet substitutes: The reality and the potential. Vox Sanguinis. 2002;83(Supplement 1):287-288.	Ineligible study design
Anantharaju A, Mehta K, Mindikoglu AL, Van Thiel DH. Use of activated recombinant human factor VII (rhFVIIa) for colonic polypectomies in patients with cirrhosis and coagulopathy. Digestive Diseases and Sciences. 2003;48(7):1414-1424.	Ineligible study design
Anderson JAM, Cook MK, Ludlam CA. Can factor VIIa alone secure haemostasis in patients with liver cirrhosis? Haemostasis. 2000;30(Suppl. 1):197-198.	Ineligible study design
Andonova R, Gavrilova N, Bogdanova R, Kotzeva S, Brankov O. Initial experience with recombinant activated factor VII (NovoSeven(R)) in trauma and surgery paediatric cases of uncontrolled bleeding. Anaesthesiology and Intensive Care. 2006;33(2):7-12.	Unable to obtain publication
Andrews TR, Dwyer JP, Rivera CE. Use of NovoSeven (Recombinant human coagulation factor VIIa) as treatment for bleeding in multiple myeloma with a factor VII clearing antibody. Blood. 2003;102(11):108b.	Ineligible study design
Anonymous. 21st Annual Meeting of the European-Association-of-Cardiothoracic-Anaesthesiologists, Venice, ITALY, May 24 -27, 2006. European Journal of Anaesthesiology. 2006;23(Suppl. 38):1-47.	Other: conference proceedings
Anonymous. 40th Annual Meeting of the German-Society-for-Transfusion-Medicine-and-Immunohematology, Friedrichshaften, GERMANY, September 18 -21, 2007.	Other: conference

Transfusion Medicine and Hemotherapy. 2007;34(Suppl. 1):1-74.	proceedings
Anonymous. Annual Scientific Meeting of the Trauma-Association-of-Canada, Whistler, CANADA, April 03 -05, 2008. Journal of Trauma Injury Infection and Critical Care. 2008;64(2):544-559.	Duplicate
Anonymous. Controlled off-label use of recombinant activated factor VII (NovoSeven) can build evidence base. Cardiovascular Journal of Africa. 2008;19(1):52-4.	Ineligible study design
Anonymous. Meeting on Haemostasis and Transfusion: Perioperative Management in Elderly Patients, Graz, Austria, October 27-28, 2000. Infusion Therapy and Transfusion Medicine. 2001;28(2):97-118.	Duplicate
Anonymous. Proceedings of the 4th Symposium on Hemostasis with Special Focus on Factor VIIa and Tissue Factor-Understanding the Molecular Mechanism. April 3-5, 2008. Chapel Hill, North Carolina. Thrombosis Research. 2008;122 Suppl 1:S1-81.	Animal or in-vitro study
Anonymous. Proceedings of the 9th Novo Nordisk Symposium on Haemostasis Management, November 15-16, 2007, Barcelona, Spain. Seminars in Hematology. 2008;45(2 Suppl 1):S1-74.	Ineligible study design
Ansari S, Salehi S. Coagulopathy after spider bites to a 6-year-old boy. Pediatr Hematol Oncol. 2007;24(3):233-5.	Ineligible study design
Ansell J, Hirsh J, Hylek E, Jacobson A, Crowther M, Palareti G. Pharmacology and management of the vitamin K antagonists. Chest. 2008;133(6, Suppl. S):160S-198S.	Ineligible study design
Apostolidou I, Sweeney MF, Missov E, Joyce LD, John R, Prielipp RC. Acute left atrial thrombus after recombinant factor VIIa administration during left ventricular assist device implantation in a patient with heparin-induced thrombocytopenia. Anesth Analg. 2008;106(2):404-8, table of contents.	Small sample size
Arai M. Factor VIIa in acute intracerebral haemorrhage. ClinicalTrials.gov. 2005.	No usable data
Argall J, Teece S, Mackway-Jones K. Factor VIIa for intractable blood loss in trauma. Emerg Med J. 2002;19:556-7.	Ineligible study design
Argall J, Teece S. Towards evidence based emergency medicine: best BETs from Manchester Royal Infirmary. Factor VIIa for intractable blood loss in trauma. Emerg Med J. 2002;19(6):556-7.	Ineligible study design
Arthurs Z, Cuadrado D, Beekley A, et al. The impact of hypothermia on trauma care at the 31st combat support hospital. American Journal of Surgery. 2006;191(5):610-4.	No usable data
Ashrani AA, Gabriel DA, Gajewski JL, Jacobs DR, Jr., Weisdorf DJ, Key NS. Pilot study to test the efficacy and safety of activated recombinant factor VII (NovoSeven) in the treatment of refractory hemorrhagic cystitis following high-dose chemotherapy. Bone Marrow Transplantation. 2006;38(12):825-8.	Ineligible study design
Ashrani AA, Gabriel DA, Gajewski JL, Key NS. Pilot study to test the efficacy and safety of recombinant factor VIIa (rFVIIa, NovoSeven (TM)) in the treatment of refractory hemorrhagic cystitis following high dose chemotherapy. Blood. 2004;104(11, Part 1):322A.	Ineligible study design
Athale UH, Chan AK. Hemorrhagic complications in pediatric hematologic malignancies. Semin Thromb Hemost. 2007;33(4):408-15.	Ineligible study design
Atkison PR, Jardine L, Williams S, Barr RM, Quan D, Wall W. Use of recombinant factor VIIa in pediatric patients with liver failure and severe coagulopathy. Transplant Proc. 2005;37(2):1091-3.	Ineligible study design
Auer RN, Sutherland GR. Primary intracerebral hemorrhage: pathophysiology. Canadian Journal of Neurological Sciences. 2005;32 Suppl 2:S3-12.	Ineligible study design
Auriel E, Bornstein NM. Treatment of acute intracerebral hemorrhage. Israel Medical Association Journal: Imaj. 2006;8(11):812-4.	Ineligible study design
Bacigalupo A. Haemopoietic stem cell transplants: The impact of haemorrhagic complications. Blood Reviews. 2003;17(Suppl 1):S6-S10.	Ineligible study design
Badjatia N, Rosand J. Intracerebral hemorrhage. Neurologist. 2005;11(6):311-24.	Ineligible study design
Badra G, El-Abassy M, Lotfy M, Alenzi FQ, Waked I. A life-sustaining single dose of recombinant activated factor VII for an Egyptian patient with hemorrhagic crisis. Saudi	Ineligible study design

Med J. 2007;28(6):979-81.	
Baker DS, Shenoy S. Treatment of non-hemophiliac disorders in children with recombinant FVIIa - A review of dosing, safety, and efficacy. Blood. 2005;106(11, Part 2):122B.	Ineligible study design
Baldi G, Altomonte F, Altomonte M, et al. Intracranial haemorrhage in patients on antithrombotics: clinical presentation and determinants of outcome in a prospective multicentric study in Italian emergency departments. Cerebrovasc Dis. 2006;22(4):286-93.	Small sample size
Balen S, Roganovic I, Vukelic-Damiani N. Recombinant factor VIIa in treatment of severe thrombocytopenic patients: case report. Vox Sanguinis. 2005;89(Suppl. 1):195.	Ineligible study design
Ballen J, Raabe M, Muirhead B. Aortic dissection and hypothermic arrest in a Jehovah's Witness patient: a case for recombinant factor VIIa?[see comment]. Canadian Journal of Anaesthesia. 2006;53(4):353-6.	Small sample size
Barbui T, Caruso V, Tognoni G, Marchioli R. Prognosis of veno-occlusive disease after stem cell transplantation in the DF-VOD trial. On behalf of the DF-VOD investigators. Blood. 2004;104(11, Part 1):322A.	Not on rFVIIa
Barcelona SL, Thompson AA, Cote CJ. Intraoperative pediatric blood transfusion therapy: a review of common issues. Part II: transfusion therapy, special considerations, and reduction of allogenic blood transfusions. Paediatric Anaesthesia. 2005;15(10):814-30.	Ineligible study design
Barkagan ZS. Pathogenesis and therapy of hemostatic disorders in cancer patients. Terapevticheskii Arkhiv. 1997;69(7):65-67.	Foreign language
Barkagan ZS. The role of hemostasis system components in therapy of DIC-syndrome and thrombophilias. Gematologiya i Transfuziologiya. 2005;50(6):9-12.	Foreign language
Barnes C, Blanchette V, Canning P, Carcao M. Recombinant FVIIa in the management of intracerebral haemorrhage in severe thrombocytopenia unresponsive to platelet-enhancing treatment. Transfusion Medicine. 2005;15(2):145-50.	Small sample size
Barro C, Wrobleski I, Piolat C, et al. Successful use of recombinant factor VIIa for severe surgical liver bleeding in a 5 month-old baby. Haemophilia. 2004;10(2):183-5.	Ineligible study design
Basile VS, Silver FL. Recombinant activated factor VII given within 4 hours of intracerebral hemorrhage reduced hematoma growth.[comment]. ACP Journal Club. 2005;143(2):34.	Duplicate
Baudo F, Caimi TM, Mostarda G, de Cataldo F, Morra E. Critical bleeding in pregnancy: a novel therapeutic approach to bleeding. Minerva Anestesiologica. 2006;72(6):389-93.	Ineligible study design
Bauza G, Hirsch E, Burke P, Quillen K. Low-dose recombinant activated factor VII in massively transfused trauma patients with coagulopathy. Transfusion. 2007;47(4):749-51.	Small sample size
Baxter MS, Schroeder WS, Cheng Y, Bernstein ZP. Diminished response to recombinant factor VIIa in a patient with idiopathic thrombocytopenic purpura. Annals of Pharmacotherapy. 2006;40(11):2053-2058.	Ineligible study design
Becton D, Saylors R, Morris J, Saccente S, Stine K. Treatment of bleeding with rFVIIa (NovoSeven(R)) in four diverse cases. Blood. 2001;98(11 Part 1):263a.	Small sample size
Beldowicz BC, McDonald JM, Needham CS. Confirmed graft flow following use of recombinant factor VIIa in coronary artery bypass grafting: a case report and literature review. Journal of Cardiac Surgery. 2006;21(5):483-6.	Small sample size
Bendtsen F, Krag A, Moller S. Treatment of acute variceal bleeding. Dig Liver Dis. 2008;40(5):328-36.	Ineligible study design
Benharash P, Bongard F, Putnam B. Use of recombinant factor VIIa for adjunctive hemorrhage control in trauma and surgical patients. American Surgeon. 2005;71(9):776-80.	Small sample size
Ben-Tal O, Misgav M, Kluger Y, et al. Recombinant activated factor VII (NovoSevenTM), an adjunct to replacement therapy in acute, uncontrolled, life threatening bleeding. Blood. 2003;102(11):132b.	Ineligible study design
Bernstein D. Effectiveness of the recombinant factor VIIa in patients with the coagulopathy of advanced child's B and C cirrhosis. Seminars in Thrombosis and	Ineligible study design

Hemostasis. 2000;26(4):437-438.	
Bernstein DE, Glazer S, Jeffers LJ, et al. Recombinant VIIa (rFVIIa) in the treatment of prolonged prothrombin times (PT) in cirrhotics. Hepatology. 1995;22(4 PART 2):289A.	Ineligible study design
Bernstein DE, Jeffers L, Erhardtsen E, et al. Recombinant factor VIIa corrects prothrombin time in cirrhotic patients: a preliminary study. Gastroenterology. 1997;113(6):1930-7.	Ineligible study design
Berntorp E, Stigendal L, Lethagen S, Olofsson L, Hedner U. NovoSeven in warfarin-treated patients. Blood Coagul Fibrinolysis. 2000;11 Suppl 1:S113-5.	Ineligible study design
Berntorp E. Recombinant FVIIa in the treatment of warfarin bleeding. Seminars in Thrombosis and Hemostasis. 2000;26(4):433-435.	Ineligible study design
Berthier AM, Guillygomarc'h A, Messner M, Pommereuil M, Bader G, De Mello G. Use of recombinant factor VIIa to treat persistent bleeding following dental extractions in two cirrhotic patients. Vox Sang. 2002;82(3):119-21.	Ineligible study design
Betensley AD, Yankaskas JR. Factor viia for alveolar hemorrhage in microscopic polyangiitis. Am J Respir Crit Care Med. 2002;166(9):1291-2.	Ineligible study design
Bhalla A, Hargroves D. Does early medical intervention have a role in the management of intracerebral haemorrhage? Int J Clin Pract. 2008;62(4):633-41.	Ineligible study design
Bhullar IS, Braman R, Block EF. Recombinant factor VII as an adjunct to control of hemorrhage from chest trauma in a Jehovah's Witness. Am Surg. 2007;73(8):818-9.	Small sample size
Bhuskute N, Kritzinger S, Dakin M. Recombinant factor VIIa in massive obstetric haemorrhage. Eur J Anaesthesiol. 2008;25(3):250-1.	Ineligible study design
Bianchi A, Jackson D, Maitz P, Thanakrishnan G. Treatment of bleeding with recombinant factor VIIa in a patient with extensive burns. Thromb Haemost. 2004;91(1):203-4.	Ineligible study design
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Dao A, Tuan B, Carlson N. Reversal of a potent investigational anticoagulant: idraparinux with recombinant factor VIIa. Am J Med. 2005;118(10):1172-3.	Ineligible study design
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Geoghegan J, Tasker L. A response to 'the use of recombinant activated factor VII in the control of haemorrhage following blunt pelvic trauma.[comment]. Anaesthesia. 2005;60(11):1156-7; author reply 1157.	Ineligible study design
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Hoffman M, Monroe DM, Roberts HR. Platelet-dependent action of high-dose factor VIIa. Blood. 2002;100(1):364-5; author reply 365.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)

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Horton JD, DeZee KJ, Wagner M. Use of rFVIIa in the trauma setting--practice patterns in United States trauma centers. American Surgeon. 2008;74(5):413-7.	No usable data
Hossain NH, Farzana TF, Shamsi TS, Soomro NS. Use of activated recombinant factor VII for the control of post partum hemorrhage (PTH). Blood. 2006;108(11, Part 2):84B-85B.	Ineligible study design
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Huang WY, Kruskall MS, Bauer KA, Uhl L, Shaz BH. The use of recombinant activated factor VII in three patients with central nervous system hemorrhages associated with factor VII deficiency. Transfusion. 2004;44(11):1562-6.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
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Imberti R. Efficacy and safety of Factor VIIa on rebleeding after surgery for spontaneous intracerebral hemorrhage (ICH). ClinicalTrials.gov. 2005.	No usable data
Inagaki M, Mori T, Tsunematsu Y, Ambo H, Kawai Y. Use of recombinant activated factor VII to control bleeding in a young child with qualitative platelet disorder: a case report. Blood Coagul Fibrinolysis. 2006;17(4):317-22.	Other populations with congenital or chronic acquired bleeding or clotting disorders (eg, Glanzmann's)
Ingerslev J, Sneppen O, Hvid I, Fredberg U, Kristensen HL, Sindet-Petersen S. Treatment of acute bleeding episodes with rFVIIa. Vox Sang. 1999;77 Suppl 1:42-6.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
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Isbister J, Phillips L, Dunkley S, Jankelowitz G, McNeil J, Cameron P. Recombinant activated factor VII in critical bleeding: experience from the Australian and New Zealand Haemostasis Register. Intern Med J. 2008;38(3):156-65.	Data combined for multiple conditions
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Jaschinski U, Ried M, Lichtwarck-Aschoff M, Forst H. Bleeding diathesis due to failed antagonism of heparin: successful treatment with recombinant factor VIIa. Anesth Analg. 2004;99(6):1872.	Small sample size
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Jureczko L, Kolacz M, Trzebicki J, et al. Perioperative use of recombinant activated factor VII in liver transplantation. Ann Transplant. 2003;8(4):40-2.	Small sample size
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Key N. Current insights on the risk of thrombogenicity with off-label use of rFVIIa. Clinical Advances in Hematology & Oncology. 2006;4(1):34-5.	Ineligible study design
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Khan AZ, Parry JM, Crowley WF, et al. Recombinant factor VIIa for the treatment of severe postoperative and traumatic hemorrhage. American Journal of Surgery. 2005;189(3):331-4.	Small sample size
Khan ZH, Soltani AE, Rahmani P. Postoperative pulmonary thromboembolism possibly associated with recombinant activated factor VII infusion for the treatment of uncontrolled hemorrhage during vertebral instrumentation. J Anesth. 2007;21(2):258-60.	Small sample size
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Kissela BM, Eckman MH. Cost effectiveness of recombinant factor VIIa for treatment of intracerebral hemorrhage. BMC Neurology. 2008;8:17.	Ineligible study design
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Klitgaard T, Tabanera y Palacios R, Boffard KD, et al. Pharmacokinetics of recombinant activated factor VII in trauma patients with severe bleeding. Critical Care (London, England). 2006;10(4):R104.	In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
Klitgaard T. Application of trial simulation in the design of a clinical study of recombinant factor (rFVIIa) in cirrhotic patients with active varicose bleeding. Clinical Pharmacology & Therapeutics. 2004;75(2):P40.	In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
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Kogan A, Berman M, Kassif Y, et al. Use of recombinant factor VII to control bleeding in a patient supported by right ventricular assist device after heart transplantation. Journal of Heart & Lung Transplantation. 2005;24(3):347-9.	Small sample size
Kogan A, Berman M, Stein M, Vidne BA, Raanani E. Recombinant factor VIIa use in cardiac surgery--expanding the arsenal therapy for intractable bleeding? Journal of Cardiovascular Surgery. 2004;45(6):569-71.	Small sample size
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Korte WC, Moor S. Near fatal hemorrhage in traumatic bilateral leg amputation with coagulopathy, acidosis, and hypothermia and salvage therapy with recombinant factor VIIa. Journal of Trauma-Injury Infection & Critical Care. 2007;63(1):E1-4.	Small sample size
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Kotze A. Recombinant Activated Factor VII in Trauma: Case Report and Review of Published Guidelines. British Journal of Intensive Care. 2007;17(2):66-9.	Small sample size
Kovesi T, Royston D. Pharmacological approaches to reducing allogeneic blood exposure. Vox Sanguinis. 2003;84(1):2-10.	Ineligible study design
Kozek-Langenecker S. Management of massive operative blood loss. Minerva Anestesiol. 2007;73(7-8):401-15.	Ineligible study design
Krafft A, Asmis LM, Zimmermann R. Treatment of midgestational placental haemorrhage with recombinant factorVIIa. Thrombosis and Haemostasis. 2008;100(1):154-155.	Ineligible study design
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Kristensen J, Killander A, Hippe E, Ellegaard J, Hedner U. Recombinant factor VIIa (rFVIIa) reduces the bleeding time in patients with thrombocytopenia. Blood. 1993;82(10 Suppl 1).	Ineligible study design
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Leblebisatan G, Sasmaz I, Antmen B, et al. Management of refractory hemorrhage in a kala-azar patient with thrombocytopenia and coagulopathy by using recombinant factor VIIa (rFVIIa). Blood. 2005;106(11, Part 2):103B.	Ineligible study design
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Levi M, Bijsterveld NR, Keller TT. Recombinant factor VIIa as an antidote for anticoagulant treatment. Seminars in Hematology. 2004;41(1 Suppl 1):65-69.	Ineligible study design
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McMorrow RC, Ryan SM, Blunnie WP, et al. Use of recombinant factor VIIa in massive post-partum haemorrhage. European Journal of Anaesthesiology. 2008;25(4):293-8.	Duplicate
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Miall FM, Barton LM, Ayyash R, Tadd SE, Pavord SR. Recombinant activated factor VII (rVIIa): Predicting response in intractable bleeding. British Journal of Haematology. 2005;129(Suppl. 1):20.	No eligible outcomes
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Riazi S, Karkouti K, Heggie J. Case report: management of life-threatening oropharyngeal bleeding with recombinant factor VIIa. Canadian Journal of Anaesthesia. 2006;53(9):881-4.	Small sample size
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Soghier LM, Brion LP, Weinberg G, Levin TL, Rosen O, Boctor FN. Use of recombinant activated factor VII for refractory hemorrhage in a neonate. Blood. 2003;102(11):100b.	Ineligible study design
Sokolic V, Bukovic D, Fures R, et al. Recombinant factor VIIa (rFVIIa) is effective at massive bleeding after caesarean section--a case report. Coll Antropol. 2002;26 Suppl:155-7.	Ineligible study design
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Streif W, Borum Andreasen R, Paes B, et al. Influence of activated factor VII concentrates on thrombin generation in full-term and preterm neonates. Blood Coagul Fibrinolysis. 2000;11 Suppl 1:S133-4.	Animal or in-vitro study
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Sutherland GR, Auer RN. Primary intracerebral hemorrhage. Journal of Clinical Neuroscience. 2006;13(5):511-7.	Ineligible study design
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Sykora M, Diedler J, Steiner T. Repetitive asystole in right insular haemorrhage. J Neurol Neurosurg Psychiatry. 2007;78(11):1282-3.	Small sample size
Szabo T, Ali S, Camporesi EM. Intraoperative recombinant activated factor VII for emergent epidural hematoma evacuation. Anesthesia & Analgesia;99(2):595-7.	Small sample size
Takabe K, Holman PR, Herbst KD, Glass CA, Bouvet M. Successful perioperative management of factor X deficiency associated with primary amyloidosis. J Gastrointest Surg. 2004;8(3):358-62.	Other populations with congenital or chronic acquired bleeding or clotting disorders (eg, Glanzmann's)
Taketomi T, Szlam F, Levy JH, et al. Warfarin reversal with prothrombin complex concentrate confers better antifibrinolytic activity compared with recombinant activated factor VII. Blood Coagulation & Fibrinolysis. 2008;19(1):106-8.	Animal or in-vitro study
Taketomi T, Szlam F, Levy JH, Tanaka KA. Warfarin reversal with prothrombin complex concentrate confers better antifibrinolytic activity compared with recombinant activated factor VII. Blood Coagulation & Fibrinolysis. 2008;19(1):106-8.	Animal or in-vitro study
Talkad A, Mathews M, Honings D, Jahnel J, Wang D. Reversal of warfarin-induced anticoagulation with factor VIIa prior to rt-PA in acute stroke. Neurology. 2005;64(8):1480-1.	Ineligible study design
Tanaka KA, Waly AA, Cooper WA, Levy JH. Treatment of excessive bleeding in Jehovah's Witness patients after cardiac surgery with recombinant factor VIIa (NovoSeven). Anesthesiology. 2003;98(6):1513-5.	Small sample size
Tancabelic J, Haun SE. Management of coagulopathy with recombinant factor VIIa in a neonate with echovirus type 7. Pediatr Blood Cancer. 2004;43(2):170-6.	Ineligible study design
Tanchev S, Platikanov V, Karadimov D. Administration of recombinant factor VIIa for the management of massive bleeding due to uterine atonia in the post-placental period. Acta Obstet Gynecol Scand. 2005;84(4):402-3.	Ineligible study design
Tanos M, Dunning J. Is recombinant activated factor VII useful for intractable bleeding after cardiac surgery? Interactive Cardiovascular & Thoracic Surgery. 2006;5(4):493-8.	Ineligible study design
Tawfick WA, Tawfik S, Hynes N, Mahendran B, Sultan S. Critical bleeding in vascular surgery: expanding the indication of recombinant activated factor VII. Vascular. 2006;14(1):32-7.	Ineligible study design
Teitel J, Poon MC. The safety of recombinant factor VIIa: a rebuttal.[comment]. Journal of Thrombosis & Haemostasis. 2004;2(11):2078; author reply 2079.	Ineligible study design
Teitel JM. Unexpected bleeding disorders: Algorithm for approach to therapy. Clinical & Laboratory Haematology. 2000;22 Suppl 1:26-9; discussion 30-2.	Ineligible study design
Thabut D, de Franchis R, Bendtsen F, et al. Efficacy of activated recombinant factor VII (RFVIIA; NOVOSEVEN) in cirrhotic patients with upper gastrointestinal bleeding: A randomised placebo-controlled double-blind multicenter trial [abstract]. Journal of Hepatology. 2003;38(Suppl 2).	Duplicate
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Tien H, Nascimento B, Jr., Callum J, Rizoli S. An approach to transfusion and hemorrhage in trauma: current perspectives on restrictive transfusion strategies. Canadian Journal of Surgery. 2007;50(3):202-9.	Ineligible study design
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Tieu BH, Holcomb JB, Schreiber MA. Coagulopathy: its pathophysiology and treatment in the injured patient. World Journal of Surgery. 2007;31(5):1055-64.	Ineligible study design
Tinmouth AT, McIntyre LA, Fowler RA, Tinmouth AT, McIntyre LA, Fowler RA. Blood conservation strategies to reduce the need for red blood cell transfusion in critically ill patients. CMAJ Canadian Medical Association Journal. 2008;178(1):49-57.	Ineligible study design
Tinmouth AT, McIntyre LA, Fowler RA. Blood conservation strategies to reduce the need for red blood cell transfusion in critically ill patients. CMAJ Canadian Medical Association Journal. 2008;178(1):49-57.	Ineligible study design
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Tobias JD, Groeper K, Berkenbosch JW. Preliminary experience with the use of recombinant factor VIIa to treat coagulation disturbances in pediatric patients. South Med J. 2003;96(1):12-6.	Small sample size
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Tofil NM, Winkler MK, Watts RG, Noonan J. The use of recombinant factor VIIa in a patient with Noonan syndrome and life-threatening bleeding.[see comment]. Pediatric Critical Care Medicine. 2005;6(3):352-4.	Other populations with congenital or chronic acquired bleeding or clotting disorders (eg, Glanzmann's)
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Traynor K. Budget-busting drug gets institutional oversight. American Journal of Health-System Pharmacy;61(9):866.	Ineligible study design
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Tsochatzis E, Papatheodoridis GV, Elefsiniotis I, et al. Prophylactic and therapeutic use of recombinant activated factor VII in patients with cirrhosis and coagulation impairment. Dig Liver Dis. 2007;39(5):490-4.	Ineligible study design
Tuhrim S. Intracerebral hemorrhage--improving outcome by reducing volume?[comment]. New England Journal of Medicine. 2008;358(20):2174-6.	Ineligible study design
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Udy A, Vaghela M, Lawton G, Sigston P. The use of recombinant activated factor VII in the control of haemorrhage following blunt pelvic trauma.[see comment]. Anaesthesia. 2005;60(6):613-6.	Small sample size
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Uhrig L, Blanot S, Baugnon T, Orliaguet G, Carli PA, Meyer PG. Use of recombinant activated factor VII in intractable bleeding during pediatric neurosurgical procedures. Pediatr Crit Care Med. 2007;8(6):576-9.	Small sample size
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Van Thiel DH, Anantharaju A, Mindikoglu AL, et al. Modulation of endothelial cell	In vivo in

inflammatory integrins and stress markers with rh-factor VIIa in patients with advanced chronic hepatitis C. J Viral Hepat. 2003;10(4):310-7.	humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
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Vanek T, Straka Z, Hrabak J, Jares M, Brucek PJ, Votava J. Use of recombinant activated factor VII in cardiac surgery for an effective treatment of severe intractable bleeding. Jpn Heart J. 2004;45(5):855-60.	Small sample size
Vater Y, Levy A, Martay K, Hunter C, Weinbroum AA. Adjuvant drugs for end-stage liver failure and transplantation. Medical Science Monitor. 2004;10(4):RA77-88.	Ineligible study design
Veldman A, Hoffman M, Ehrenforth S. New insights into the coagulation system and implications for new therapeutic options with recombinant factor VIIa. Curr Med Chem. 2003;10(10):797-811.	Ineligible study design
Veldman A, Josef J, Fischer D, Volk WR. A prospective pilot study of prophylactic treatment of preterm neonates with recombinant activated factor VII during the first 72 hours of life. Pediatr Crit Care Med. 2006;7(1):34-9.	Small sample size
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Velik-Salchner C, Sergi C, Fries D, Moser P, Streif W, Kolbitsch C. Use of recombinant factor VIIa (Novoseven) in combination with other coagulation products led to a thrombotic occlusion of the truncus brachiocephalicus in a neonate supported by extracorporal membrane oxygenation. Anesth Analg. 2005;101(3):924.	Small sample size
Verre M, Bossio F, Mammone A, Piccirillo M, Tancioni F, Varano M. Use of recombinant activated factor VII in a case of severe postpartum haemorrhage. Minerva Ginecol. 2006;58(1):81-4.	Ineligible study design
Verrijckt A, Proulx F, Morneau S, Vobecky S. Activated recombinant factor VII for refractory bleeding during extracorporeal membrane oxygenation. J Thorac Cardiovasc Surg. 2004;127(6):1812-3.	Small sample size
Veshchev I, Elran H, Salame K. Recombinant coagulation factor VIIa for rapid preoperative correction of warfarin-related coagulopathy in patients with acute subdural hematoma. Med Sci Monit. 2002;8(12):CS98-100.	Small sample size
Vick LR, Islam S. Recombinant factor VIIa as an adjunct in nonoperative management of solid organ injuries in children. J Pediatr Surg. 2008;43(1):195-8; discussion 198-9.	Small sample size
Vidarsson B, Onundarson PT. Recombinant factor VIIa for bleeding in refractory thrombocytopenia. Thromb Haemost. 2000;83(4):634-5.	Ineligible study design
Vidarsson B, Onundarson PT. Successful use of recombinant factor VIIa in a bleeding patient with refractory thrombocytopenia undergoing chemotherapy for acute leukemia. Blood. 1999;94(10 SUPPL. 1 PART 2):239b.	Ineligible study design
Viles-Gonzalez JF, Gaztanaga J, Zafar UM, Fuster V, Badimon JJ. Clinical and experimental experience with factor Xa inhibitors. American Journal of Cardiovascular Drugs. 2004;4(6):379-84.	Not on rFVIIa
Vilstrup H, Markiewicz M, Biesma D, et al. Recombinant activated factor VII in an	Ineligible

unselected series of cases with upper gastrointestinal bleeding. Thrombosis Research. 2006;118(5):595-601.	study design
Vincent JL, Rossaint R, Riou B, Ozier Y, Zideman D, Spahn DR. Recommendations on the use of recombinant activated factor VII as an adjunctive treatment for massive bleeding. A European perspective. Annales Francaises d'Anesthesie et de Reanimation. 2007;26(2):145-156.	Ineligible study design
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Virchis A, Hughes C, Berney S. Severe gastrointestinal haemorrhage responding to recombinant factor VIIa in a Jehovah's Witness with refractory immune thrombocytopenia. Hematol J. 2004;5(3):281-2.	Ineligible study design
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Voils S. Pharmacologic interventions for the management of critical bleeding. Pharmacotherapy. 2007;27(9 Pt 2):69S-84S.	Ineligible study design
Volk T, von Heymann C, Kox WJ. Recombinant activated factor VII and perioperative blood loss.[comment]. Lancet. 2003;361(9370):1745; author reply 1745-6.	Ineligible study design
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von Heymann C, Ziemer S, Kox WJ, Spies C. Caveat against the use of feiba in combination with recombinant factor viia.[comment]. Journal of Thoracic & Cardiovascular Surgery. 2003;126(5):1667-8.	Ineligible study design
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Vyas H, Kulkarni R, Guertin S, John F. Recombinant activated FVII (rFVIIa) for the treatment of severe bleeding episodes in pediatric patients in a community hospital. Blood. 2003;102(11):100b.	Small sample size
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Wahlgren CM, Swedenborg J. The use of recombinant activated factor VII to control bleeding during repair of a suprarenal abdominal aortic aneurysm. Eur J Vasc Endovasc Surg. 2003;26(2):221-2.	Ineligible study design
Walsham J, Fraser JF, Mullany D, et al. The use of recombinant activated factor VII for refractory bleeding post complex cardiothoracic surgery. Anaesth Intensive Care. 2006;34(1):13-20.	Small sample size
Waner M. Novel hemostatic alternatives in reconstructive surgery. Seminars in Hematology. 2004;41(1 Suppl 1):163-7.	Ineligible study design
Warkentin TE, Crowther MA. Reversing anticoagulants both old and new. Canadian Journal of Anesthesia. 2002;49(6 Supplement):S11-S25.	Ineligible study design

Warkentin TE, Jay RM, Makris M, Kelton JG. Platelet-activating anti-platelet factor 4/polyanion antibodies without preceding heparin therapy: A transient autoimmune disorder resembling heparin-induced thrombocytopenia ("spontaneous HIT"). Blood. 2006;108(11, Part 1):311A-312A.	Not on rFVIIa
Warren O, Mandal K, Hadjianastassiou V, et al. Recombinant activated factor VII in cardiac surgery: a systematic review. Annals of Thoracic Surgery. 2007;83(2):707-14.	Ineligible study design
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Warren OJ, Darzi AW, Athanasiou T. Recombinant activated factor VII in cardiac surgery - first, do no harm. Journal Of Cardiothoracic Surgery. 2007;2:50.	Ineligible study design
Wartenberg KE, Mayer SA. Reducing the risk of ICH enlargement. Journal of the Neurological Sciences. 2007;261(1-2):99-107.	Ineligible study design
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Weant KA, Flynn JF, Akers WS. Management of antiplatelet therapy for minimization of bleeding risk before cardiac surgery. Pharmacotherapy. 2006;26(11):1616-25.	Ineligible study design
Webert KE, Arnold DM, Carruthers J, et al. Utilization of recombinant activated factor VII in southern Ontario in 85 patients with and without haemophilia. Haemophilia. 2007;13(5):518-26.	Data combined for multiple conditions
Webert KE, Blajchman MA. Randomized trials in patients with blunt and penetrating trauma.[comment]. Journal of Trauma-Injury Infection & Critical Care. 2006;60(1):242-3; author reply 243-4.	Ineligible study design
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Weinberger J. Recombinant activated factor VII for acute intracerebral hemorrhage. Current Cardiology Reports. 2006;8(1):8.	Ineligible study design
Weiskopf RB. Intraoperative use of recombinant activated coagulation factor vII. Anesthesiology. 2002;96(6):1287-9.	Ineligible study design
Weiskopf RB. Recombinant-activated coagulation factor VIIa (NovoSeven): current development. Vox Sanguinis. 2007;92(4):281-8.	Ineligible study design
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Welsby IJ, Monroe DM, Lawson JH, Hoffmann M. Recombinant activated factor VII and the anaesthetist. Anaesthesia. 2005;60(12):1203-12.	Ineligible study design
Welsby IJ, Ortel TL. Invited commentary. Ann Thorac Surg. 2007;84(1):168-9.	Ineligible study design
Welsh A, McLintock C, Gatt S, et al. Guidelines for the use of recombinant activated factor VII in massive obstetric haemorrhage.[see comment]. Australian & New Zealand Journal of Obstetrics & Gynaecology. 2008;48(1):12-6.	Ineligible study design
Welsh A, McLintock C, Gatt S, Somerset D, Popham P, Ogle R. Guidelines for the use of recombinant activated factor VII in massive obstetric haemorrhage. Australian & New Zealand Journal of Obstetrics & Gynaecology. 2008;48(1):12-6.	Ineligible study design
Wheater MJ, Mead GM, Bhandari S, Fennell J. Recombinant factor VIIa in the management of pulmonary hemorrhage associated with metastatic choriocarcinoma. J Clin Oncol. 2008;26(6):1008-10.	Ineligible study design

White B, Martin M, Kelleher S, Browne P, McCann SR, Smith OP. Successful use of recombinant FVIIa (Novoseven) in the management of pulmonary haemorrhage secondary to Aspergillus infection in a patient with leukaemia and acquired FVII deficiency. Br J Haematol. 1999;106(1):254-5.	Other populations with congenital or chronic acquired bleeding or clotting disorders (eg, Glanzmann's)
White B, McHale J, Ravi N, et al. Successful use of recombinant FVIIa (Novoseven) in the management of intractable post-surgical intra-abdominal haemorrhage. Br J Haematol. 1999;107(3):677-8.	Ineligible study design
White CE, Schrank AE, Baskin TW, Holcomb JB. Effects of recombinant activated factor VII in traumatic nonsurgical intracranial hemorrhage. Curr Surg. 2006;63(5):310-7.	Small sample size
White GC, II. Congenital and acquired platelet disorders: Current dilemmas and treatment strategies. Seminars in Hematology. 2006;43(1, Suppl. 1):S37-S41.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
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Williams D, McCarthy R. Recombinant activated factor VII and perioperative blood loss.[comment]. Lancet. 2003;361(9370):1745; author reply 1745-6.	Ineligible study design
Williams DJ, Thomas GO, Pambakian S, Parker PJ. First military use of activated Factor VII in an APC-III pelvic fracture. Injury. 2005;36(3):395-9.	Small sample size
Wilson SJ, Bellamy MC, Giannoudis PV. The safety and efficacy of the administration of recombinant activated factor VII in major surgery and trauma patients. Expert Opin Drug Saf. 2005;4(3):557-70.	Ineligible study design
Wittenstein B, Ng C, Ravn H, Goldman A. Recombinant factor VII for severe bleeding during extracorporeal membrane oxygenation following open heart surgery. Pediatr Crit Care Med. 2005;6(4):473-6.	Small sample size
Wojcicki M, Lubikowski J, Wrzesinski M, et al. Outcome of emergency liver transplantation including mortality on the waiting list: a single-center experience. Transplantation Proceedings. 2007;39(9):2781-4.	Small sample size
Wong WY, Huang WC, Miller R, McGinty K, Whisnant JK. Clinical efficacy and recovery levels of recombinant FVIIa (NovoSeven) in the treatment of intracranial haemorrhage in severe neonatal FVII deficiency. Haemophilia. 2000;6(1):50-4.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Woo YJ. Cardiac surgery in patients on antiplatelet and antithrombotic agents. Semin	Ineligible

Thorac Cardiovasc Surg. 2005;17(1):66-72.	study design
Wordliczek J, Serednicki W, Grabowska I, Szczepanik AM, Nowak W, Popiela T. A 43-year-old man was admitted to the hospital with the diagnosis of acute pancreatitis of 4 days' duration. Pancreas. 2003;26(1):101-2.	Ineligible study design
Wrobel G, Dobaczewski G, Patkowski D, Sokol A, Grotthus E. Experiences with recombinant activated factor VII in the treatment of severe refractory thrombocytopenia. Pediatr Blood Cancer. 2006;47(5 Suppl):729-30.	Ineligible study design
Wu JK, Keith RH, George SG. Use of Recombinant Activated Factor VII (rFVIIa) for Acute Reversal of Warfarin in a Child. Blood. 2002;100(11):Abstract No. 3964.	Ineligible study design
Xi G, Keep RF, Hoff JT. Mechanisms of brain injury after intracerebral haemorrhage. Lancet Neurology. 2006;5(1):53-63.	Ineligible study design
Yadav SP, Chugh K, Gupta D, Sharma SD, Sachdev A, Sachdeva A. Use of recombinant factor VIIa in children with uncontrolled bleeding - A single centre experience. Blood. 2006;108(11, Part 2):94B-95B.	Ineligible study design
Yadav SP, Sharma SD, Kharya G, Gupta D, Sachdeva A. Control of massive bleeding in dengue hemorrhagic fever with severe thrombocytopenia by use of KhamRho-IV Anti D (R). Blood. 2007;110(11, Part 1):621A.	Ineligible study design
Yan Q, Chang AC. Pharmacologic therapy for postoperative bleeding in children after cardiac surgery: when will the bleeding stop?[comment]. Pediatric Critical Care Medicine. 2004;5(3):297-8.	Ineligible study design
Yang L, Jankovic Z. Orthotopic liver transplantation in Jehovah's Witnesses. Current Anaesthesia & Critical Care. 2008;19:31-41.	Ineligible study design
Yildirim H, Ucgun I, Yalcin AU, et al. Recombinant factor VIIa treatment for life-threatening haemoptysis. Respirology. 2006;11(5):652-4.	Ineligible study design
Yildirim Z, Branda RF. Use of Recombinant Activated Factor VII (rFVIIa) To Correct Coagulopathy Due to Congestive Liver Failure in Preparation for Surgery. Blood. 2002;100(11):Abstract No. 3888.	Ineligible study design
Yilmaz D, Karapinar B, Balkan C, Akisu M, Kavakli K. Single-center experience: use of recombinant factor VIIa for acute life-threatening bleeding in children without congenital hemorrhagic disorder. Pediatric Hematology & Oncology. 2008;25(4):301-11.	Small sample size
Yilmaz D, Karapinar B, Balkan C, Akisue M, Kavakli K. Single-center experience: Use of recombinant factor VIIa for acute life-threatening bleeding in children without congenital hemorrhagic disorder. Pediatr Hematol Oncol. 2008;25(4):301-311.	Unable to obtain publication
You H, Al-Shahi R. Haemostatic drug therapies for acute primary intracerebral haemorrhage [Systematic Review]. Cochrane Database of Systematic Reviews. 2008(2).	Ineligible study design
You H, Al-Shahi R. Haemostatic drug therapies for acute primary intracerebral haemorrhage. Cochrane Database of Systematic Reviews. 2006;3:CD005951.	Ineligible study design
Young G, Lloyd S, Nugent DJ. Recombinant factor VIIa in patients with liver failure undergoing surgery. Blood. 2000;96(11 Part 1):267a.	Ineligible study design
Young G, Nugent DJ. Prevention of bleeding complications in neonates with liver failure undergoing surgery using recombinant factor VIIa. Hematology. 2001;6(5):341-346.	Ineligible study design
Yovtchev V, Gancheva S. The use of recombinant activated factor VII (rFVIIa) for patients with massive hemorrhage provoked by different cases. Anaesthesiology and Intensive Care. 2006;33(2):13-16.	Unable to obtain publication
Yusim Y, Perel A, Berkenstadt H, Attia M, Knoller N, Sidi A. The use of recombinant factor VIIa (NovoSeven) for treatment of active or impending bleeding in brain injury: broadening the indications. Journal of Clinical Anesthesia. 2006;18(7):545-51.	Small sample size
Zaaroor M, Soustiel JF, Brenner B, Bar-Lavie Y, Martinowitz U, Levi L. Administration off label of recombinant factor-VIIa (rFVIIa) to patients with blunt or penetrating brain injury without coagulopathy. Acta Neurochirurgica. 2008;150(7):663-668.	Small sample size
Zahuranec DB. The 2005 International Stroke Conference, New Orleans, Louisiana, February 2-4, 2005. Journal of Neuro-Ophthalmology. 2005;25(2):150-1.	Ineligible study design
Zakhary RG, Seremetis S. Recombinant activated Factor VII in major surgery and trauma patients: a response.[comment]. Expert Opinion on Drug Safety. 2005;4(5):813-	Ineligible study design

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Zibaitis A, Schumann R. Abdominal compartment syndrome following complete abruption of the placenta, fetal demise and consumptive coagulopathy. Anesthesiology (Hagerstown). 2004;100(5):B67.	Ineligible study design
Zietkiewicz M, Garlicki M, Domagala J, et al. Successful use of activated recombinant factor VII to control bleeding abnormalities in a patient with a left ventricular assist device. J Thorac Cardiovasc Surg. 2002;123(2):384-5.	Small sample size
Zimmerman RD, Maldjian JA, Brun NC, Horvath B, Skolnick BE. Radiologic estimation of hematoma volume in intracerebral hemorrhage trial by CT scan. Ajnr: American Journal of Neuroradiology. 2006;27(3):666-70.	Duplicate
Zimring JC. Appropriate use of recombinant factor VIIa: an expanding and unanswered question. Transfusion. 2004;44(11):1544-6.	Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Zirphile X, Debien B, Perez JP, Lenoir B. Is Novoseven (R) useful in war traumatology? Medecine et Armees. 2008;36(1):3-9.	Ineligible study design
Zulfikar B, Kayiran SM. Successful treatment of massive gastrointestinal hemorrhage in acute biphenotypic leukemia with recombinant factor VIIa (NovoSeven). Blood Coagulation & Fibrinolysis. 2004;15(3):261-263.	Ineligible study design
Zupancic Salek S, Sokolic V, Viskovic T, Sanjug J, Simic M, Kastelan M. Successful use of recombinant factor VIIa for massive bleeding after caesarean section due to HELLP syndrome. Acta Haematol. 2002;108(3):162-3.	Ineligible study design
Zupancic-Salek S, Kovacevic-Metelko J, Radman I. Successful reversal of anticoagulant effect of superwarfarin poisoning with recombinant activated factor VII. Blood Coagulation & Fibrinolysis. 2005;16(4):239-244.	Ineligible study design
Zuppa AF, Nadkarni VM. Recent developments in the pharmacologic approach to pediatric critical care. Current Opinion in Anaesthesiology. 2004;17(3):223-8.	Ineligible study design

Appendix C. Additional Analyses, Tables, and Figures

Appendix Table 1. Diagnostic hiearchy and ICD-9-CM diagnsosis and procedure codes

Rank in Hierarchy	Description	ICD-9-CM Codes (PR for procedure codes) Coding based on the presence of any eligible code within a hospitalization
1	Hemophilia A and B	286.0, 286.1
2	Hemophilia-related off-label	286.2, 286.3, 286.4, 286.5, 287.1, 287.3, 287.9
3	Trauma at the brain	852, 853
4	Trauma at the body	All E-codes except E85, E87, E92, E93, E94; PR 81-90, 92-95, 98
5	Intracranial hemorrhage	430, 431, 432
6	Brain surgery	PR 1
7	Pediatric cardiac surgery	PR 35, 36, 37 (except 37.2) and age <18
8	Adult cardica surgery	PR 35, 36, 37 (except 37.2) and age ≥18
9	Obstetrics	72, 73, 74, 75; PR 63, 64, 65, 66, 67 (except 67.8)
10	Neonatal conditions	V3, 76, 77 (except for 76.0, 76.1, 76.2, 76.3) and age < 1 year
11	Aortic aneurysm	441
12	Prostatectomy	PR 60
13	Other vascular	PR 39 (except 39.94, 39.95, 39.96)
14	Liver transplantation	PR 50.5
15	Liver biopsy	PR 50.1, 50.2
16	Esophageal varices	456.0, 456.1, 456.2
17	Other liver disease	571, 572
18	Other gastrointestinal bleed	530.4, 531-535, 537, 557, 562, 569, 578
19	Other secondary hematological conditions	287 (except 287.1, 287.3, 287.9), 446.6, 283.1, 286.6, 286.7, 286.9, 964.2, V58.61, V58.63, E585.2, E934.2
20	Pulmonary	786.3, 770.3; PR 32, 33, 34
21	Cancer	140-230
22	Other surgical procedures	PR ≤ 87 (except 39.8)
23	Other, without procedures	All remaining codes

Appendix Table 2. Characteristics of included studies: sample sizes, patient age, rFVIIa dose and outcomes

Study Design	Number of Studies	Total Number of rFVIIa Patients	rFVIIa Sample Size Range	rFVIIa Mean Age Range	rFVIIa Mean Dose Range, ug/kg	Important Outcomes Evaluated	
						Direct	**Indirect**
KQ2-4 Indications							
Intracranial hemorrhage							
RCT	4	944	36 - 573	51 - 72	5 - 160	Mortality, TE events, Functional outcome	Change in hematoma volume
Comparative observational	3	64	5 - 46	60 - 71	40 - 80	Mortality, TE events, Functional outcome	Change in hematoma volume
Non-comparative	1	15	15	68	60	Mortality, TE events, Functional outcome	Change in hematoma volume
Trauma at the body							
RCT	1	139	139	29 - 33	400	Mortality, TE events, ARDS	Transfusion requirements, Hospital/ICU length of stay
Comparative observational	4	223	29 - 81	37 - 41	50 - 120	Mortality, TE events, ARDS	Transfusion requirements, Hospital/ICU length of stay
Non-comparative	3	189	36 - 108	20 - 38	74 - 140	Mortality, TE events	Transfusion requirements
Trauma at the brain							
RCT	1	61	61	52	40 - 200	Mortality, TE events	Change in hematoma volume
Comparative observational	2	60	29 - 31	40	NR	Mortality, TE events	Time to neurosurgery, Hospital/ICU length of stay
Non-comparative	1	15	15	61	59	-	-
Liver transplantation							
RCT	3	195	10 - 121	49 - 53	20 - 360	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay, Operating time
Comparative observational	4	51	6 - 28	13 - 48	20 - 80	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay, Operating time
Non-comparative	0	-	-	-	-	-	-
Adult cardiac surgery							
RCT	1	10	10	70	90	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay
Comparative observational	6	189	15 - 51	56 - 70	17 - 100	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay, Need for surgical re-exploration

Non-comparative	8	947	16 - 503	53 - 68	62 - 103	Mortality, TE events	Transfusion requirements, Blood loss, Need for surgical re-exploration
Pediatric cardiac surgery							
RCT	1	40	40	0.33	63	TE events	Transfusion requirements, Blood loss, Time to chest closure
Comparative observational	2	33	9 - 24	0.03 - 9	43 - 90	TE events	Transfusion requirements, Blood loss, Need for surgical re-exploration
Non-comparative	0	-	-	-	-	-	-
Prostatectomy							
RCT	1	24	24	61 - 64	20 - 40	Mortality, TE events	Transfusion requirements, Blood loss, Hospital/ICU length of stay, Operating time
Comparative observational	0	-	-	-	-	-	-
Non-comparative	0	-	-	-	-	-	-
KQ1 Indications:							
Other liver disease							
RCT	4*	517	71 - 170	46 - 55	5 - 800	Mortality, TE events	Transfusion requirements, Blood loss, Efficacy of bleeding control
Comparative observational	1	7	7	34	40 - 80	Mortality	Transfusion requirements, Efficacy of bleeding control, Ability to place ICP transducer
Obstetrics/gynecology							
RCT	0	-	-	-	-	-	-
Comparative observational	3	50	6 - 26	29 - 34	70 - 100	Mortality, TE events	Transfusion requirements, Blood loss
Hematology/oncology							
RCT	2	93	16 - 77	9 - 23	100 - 1120	Mortality, TE events	Transfusion requirements, Efficacy of bleeding control
Comparative observational	1	24	24	NR	NR	Mortality, TE events	Requirement for positive pressure ventilation, Hospital/ICU length of stay
Other surgery							
RCT	4	191	9 - 122	44 - 56	20 - 360	Mortality, TE events	Transfusion requirements, Blood loss, Operating time, Hospital/ICU length of stay
Comparative observational	2	55	26 -29	17 - 60	23	Mortality, TE events, Functional outcome	Transfusion requirements, Blood loss
Total							

RCT	22	2310	9 - 573	0.33 - 72	5 - 1120		
Comparative observational	28	756	5 - 81	0.03 - 71	17 - 120		
Non-comparative	13	1166	15 - 503	20 - 68	59 - 140		

RCT=randomized controlled trial; TE=thromboembolic; ICU=intensive care unit

Appendix Table 3. Mortality and Thromboembolic Events in Studies Included in Harms Analyses

Article	Study Design	Sample Size	Mean Age (SD) [Range]	Mean Dose (ug/kg) (SD) [Range]	Mortality	TE Rate
ICH						
Mayer 2005a[21] (3 arms)	RCT	108	67 (12)	40	0.18	0.06
		92	65 (12)	80	0.18	0.04
		103	64 (13)	160	0.19	0.10
Mayer 2005b[73] (6 arms)	RCT	6	51 (9)	10	0	0
		6	68 (22)	20	0	0.33
		6	68 (16)	40	0.17	0.33
		6	58 (11)	80	0	0
		6	64 (14)	120	0.17	0
		6	53 (12)	160	0.17	0
Mayer 2008[75] (2 arms)	RCT	276	65 (14)	20	0.18	0.09
		297	65 (13)	80	0.21	0.12
Mayer 2006[74] (4 arms)	RCT	8	72 (10)	5	0.25	0
		8	60 (15)	20	0.25	0.25
		8	64 (13)	40	0.38	0.13
		8	62 (12)	80	0	0
Hallevi 2008[78]	Comparative Observational	46	59.6 [38-87]	80[U] [40-80]	0.13	0.15
Brody 2005[77]	Comparative Observational	12	71 (13.1)	NR	0.42	0.17
Pickard 2000[76]	Comparative Observational	5	NR	80	NR	0.20
Sutherland 2008[79]	Non-Comparative Observational	15	68.0[U] [25 -81]	60[U] [40-92]	0.13	0
Trauma at the Body						
Boffard 2005[80] (blunt arm)	RCT	69	33 (13)	400	0.25	0.03
Boffard 2005[80] (penetrating arm)	RCT	70	29 (10)	400	0.24	0.06
Rizoli 2006[81a]	Comparative Observational	38	36.8 [30.6-43.1]	NR	0.50	NR

Article	Study Design	Sample Size	Mean Age (SD) [Range]	Mean Dose (ug/kg) (SD) [Range]	Mortality	TE Rate
Nascimento 2008[150a]	Comparative Observational	72	NR	NR	NR	0.10
Harrison 2005[84]	Comparative Observational	29	40.9 (20.8)	60 [40-80]	0.41	0.07
Dutton 2004[83b]	Comparative Observational	81	40.8 (21)	97.8	0.58	NR
Cameron 2007[85]	Non-Comparative Observational	108	38.0[U] [11-91]	90[U] [78-105][I]	0.42	0.03
Felfernig 2007[86]	Non-Comparative Observational	45	30.5 [5-81]	73.6 (27)	0.24	NR
Thomas 2007[192b]	Non-Comparative Observational	242	44.0 (21)	68[&] (45)	NR	0.11
Martinowitz 2005[87]	Non-Comparative Observational	36	19.5 [14-65]	140[U] [70-540]	0.39	NR
Perkins 2007[151c]	Non-Comparative Observational	53	23.1	109[&]	0.34	0.02
Trauma at the Brain						
Narayan 2008[88] (5 arms)	RCT	12	51.5 (21.5)^	40	0	0.17
		11	29.9 (25.3)	80	0	0.18
		14		120	0.07	0.21
		12		160	0.17	0
		12		200	0.33	0.17
Stein 2008[89b]	Comparative Observational	29		[8-140]	0.35	0.21
Bartal 2007[91]	Non-Comparative Observationl	15	61.0 (11)	59[&] [40-90]	0.07	0
Liver Transplantation						
Pugliese 2007[94]	RCT	10	NR	40	NR	0
Lodge 2005[92] (2 arms)	RCT	63	53.3 (11.2)	180	0.02[#]	0.19
		58	52.6 (9.2)	360	0.03[#]	0.12
Planinsic 2006[93] (3 arms)	RCT	18	49.4 (13.4)	20	0.06[#]	0.11*
		24	49.7 (10.1)	40	0.08[#]	0.04*
		22	51.9 (8.8)	80	0.05[#]	0.09*
Hendriks 2001[95]	Comparative Observational	6	43[U] [37-61]	80	0	0.17
Kalicinski 2005[97]	Comparative Observational	28	13.2 (4.2)	51.5 [30-100]	0.07	0
Niemann 2006[98]	Comparative Observational	11	48 (15)	58 (18)	0	0

Article	Study Design	Sample Size	Mean Age (SD) [Range]	Mean Dose (ug/kg) (SD) [Range]	Mortality	TE Rate
De Gasperi 2005[96]	Comparative Observational	6	45 (4)	30[&] [20-40]	0	NR
Adult Cardiac Surgery						
Diprose 2005[99]	RCT	9	63[U] [59-66][I]	90	0	0.22
Unpublished RCT[178] (2 arms)	RCT	35	63.6^	40	0.11	0.09
		68	63.6^	80	0.09	0.06
Romagnoli 2006[103]	Comparative Observational	15	66.3 (12.7)	17[U] [15-18.4][I]	0	0.13
Gelsomino 2008[101]	Comparative Observational	40	70.1 (9.2)	18[U] [9-16][I]	0.05	0.05
von Heymann 2005[104]	Comparative Observational	26	63.5 (12.87)	89.3[&]	0.38	0
Bowman 2008[105]	Comparative Observational	36	58	100[&]	0.08	0.11
Tritapepe 2007[102]	Non-Comparative Observational	23	62.4 (9.4)	82[&]	0.13	0.09
Karkouti 2006[179d]	Non-Comparative Observational	114	59.0 (17)	56 (25)	0.16	0.20
Dunkley 2008[113]	Non-Comparative Observational	293	63.0 (15)	92.3[U] [82-103][I]	0.17	0.14
Filsoufi 2006[106]	Non-Comparative Observational	17	65.0 (18)	103.1 (30.2)	0.29	NR
Gandhi 2007[107]	Non-Comparative Observational	17	53.0 [38-64]	78.3 [24-189]	0.29	0.24
Hyllner 2005[108]	Non-Comparative Observational	24	60.0 [34-82]	72.2[&] [19.2-104]	0.29	NR
McCall 2006[109]	Non-Comparative Observational	53	68.0 [55- 75][I]	90 (15)	0.19	NR
Raivio 2005[110]	Non-Comparative Observational	16	60 (14.9)	65 [24-192]	0.25	0.25
Aggarwal 2004[111]	Non-Comparative Observational	24	65.0[U] [26-85]	90	0.75	NR
Karkouti 2008[112]	Non-Comparative Observational	503	62.0 (15)	62[U] [40-89][I]	0.32	0.24
Pediatric Cardiac Surgery						
Ekert 2006[114]	RCT	40	0.33	63 [40-80]	NR	0
Agarwal 2007[115]	Comparative Observational	24	0.0[U] [0.01-6.53]	59.8[&]	NR	0.08
Tobias[116]	Comparative Observational	9	9 (4)	90	NR	0
Prostatectomy						
Friederich 2003[117] (2 arms)	RCT	8	61 (8.9)	20	0	0.13
		16	64 (8.5)	40	0	0

Fair+ Comparative Observational, fair or good quality comparative observational studies also included in the effectiveness review in Key Questions 2-4; Variance (e.g. standard deviation, range, or IQR) left blank if not reported.
[U]Median
[I]Interquartile Range
^Mean age (and standard deviation) for all study arms combined.
[#]Mortality is underestimated because 2 deaths each in Lodge et. al[92] and Planinsic et. al[93] were not reported by treatment arm.
*Thromboembolic events are underestimated because only arterial thromboembolic events were counted in Planinsic et. al[93].
[&]Mean dose estimated from mean or median size of individual doses, or converted from mg to ug/kg by assuming an average patient weight.
[a]Nascimento et. al[150] was used instead Rizoli et. al[81] for the analysis of thromboembolic events. Nascimento et. al is a continuation of Rizoli et. al with more patients.
[b]Dutton et. al[83] and Thomas et. al[192] have overlapping patient populations. Dutton et. al was used for the mortality analysis and Thomas et. al was used in the analysis of thromboembolic events for trauma at the body. Thomas et. al included traumatic brain injury patients, some of which were included in Stein et. al[89]. Thus, some patients are double counted between the trauma at the brain and the trauma at the body analyses of thromboembolic events.
[c]Data from Perkins et. al[151] was used instead of Spinella et. al[82]. Perkins et. al is an overlapping non-comparative study with more patients.
[d]Data from the 2006 study by Karkouti et. al[179] was used instead of the 2005 study by Karkouti et. al[100]. The 2006 study is an overlapping non-comparative study with more patients.

Appendix Figure 1. Forest plot of all thromboembolic events for ICH

Appendix D. Peer Reviewers

XXX

Appendix E: Study Abstraction Forms

Level One (Screening Title and Abstract) Abstraction Form

1. Does this article discuss the use of recombinant factor VIIa in vivo in humans who do not have hemophilia? (choose one)
No, is NOT on recombinant factor VIIa
No, is on recombinant factor VIIa but is ...: ***(do not check this circle, choose from an option below)***
...in patients who have hemophilia (congenital or acquired)
...in other populations with congenital or chronic acquired bleeding or clotting disorders (eg, Glanzmann's)
...is used in humans in vivo, but is NOT used as a therapy or for clinically relevant outcomes
...in animals or in vitro (in culture, molecular, or laboratory studies only)
Yes
Can't tell
Exclude for other reason(s), specify

2. Is in a foreign language
Yes
No

3. For an article that will NOT proceed to full review, is the article still possibly of interest to the research?
Yes
No

Level 2 (Full text article screening) Abstraction Form

1. Is the focus/study population any of the following?
Is NOT on rFVIIa
Patients who have hemophilia A or B or factor VII deficiency (congenital or acquired)
Other populations with congenital or chronic acquired bleeding or clotting disorders (eg, Glanzmann's)
In vivo in humans, but rFVIIa is NOT used as a therapy or for clinically relevant outcomes
Animals or in vitro (in culture, molecular, or laboratory studies)

2. What is/are the indication(s) for giving rFVIIa? (Check all that apply.)
Intracranial bleeding
Bleeding secondary to trauma
Liver transplant, operative bleeding (whether to prevent or treat)
Cardiac surgery, operative bleeding (whether to prevent or treat)
Prostatectomy, operative bleeding (whether to prevent or treat)
Other indication(s), specify:
Can't tell

3. Is this a secondary report of an already published article (eg, is on the same study, but with longer follow-up or on a different outcome variable)?
Yes, and specify ref ID# here, if found:

4. What type of article is this?
RCT/ Quasi-RCT (If quasi-RCT, specify why)
Observational study: includes cohort, cross-sectional, case-control and other study types (but NOT case series or report)
Case series or case report
All other (For an article that addresses a KQ1 INDICATION ONLY and is a type of article not mentioned above, check this box only and then skip to question 5. For an article that addresses a KQ2-4 INDICATION ONLY and is a type of article not mentioned above, do NOT check this box; instead check the relevant box immediately below. For an articles that addresses BOTH KQ1 AND KQ2-4 INDICATIONS and is a type of article not mentioned above, check the box here AND the relevant box immediately below.)
...Meta-analysis or systematic review
...Other type of research, specify type:
...In-progress research without results (eg, RCT methodology paper)
...Guideline or consensus statement
...Can't tell
... All other not covered above (ie, non-research, such as letter, editorial or unsystematic review)

5. Do you think this article will need to be cloned for the next level of extraction?
Yes, it reports on two or more separate RCTS, quasi-RCTs, or observational studies (but is NOT a meta-analysis or review)
Yes, it has more than one intervention arm
Yes, for other reasons, specify:

6. For an article that will NOT otherwise proceed to full review (ie, those above that are NOT RCTs, observational studies, or case series/reports), is there any special reason why it should undergo further review (eg, there is a study embedded in a letter to editor)?
Yes, specify why:

7. For an article that will not otherwise proceed to full review, does this article contain important information not otherwise captured on this form?
Yes, specify:

8. Do you have any other comments?
Yes

Level 3. Full text data abstraction form (study information and quality assessment)

1. Should this article undergo full text review at Level 3?
Yes
No
2. Where did the study take place? (check all that apply)
U.S., specify city, state
U.S. military warzone
Outside of the U.S., specify country or region
Not reported or unclear

3. What was the source of funding for the entire study (check all that apply)
Novo Nordisk®
Other Industry
Government
Foundation
Other
None
Not applicable (e.g. case report or registry)
Not reported or unclear

4. Did Novo Nordisk support any other aspect of this study (such as registry, persnnel)? For personnel, specify the nature of the relationship/support with Novo Nordisk in the appropriate text box(es)
Statistician
Other Author(s)
Member of the "study group," "research team," or similar designation (and NOT an author on the byline of the paper)
Registry
Other, specify

5. Was the number of enrolling centers reported?
1 center
>1 center
Not reported or unclear
Not applicable (e.g. case report or registry)

6. When did the study take place? Specify as a range in months and years, if given. Leave blank, if unclear.

7. Is this a registry study?
Yes

If this is CASE REPORT/SERIES or REGISTRY study (e.g. any non-comparative study), STOP HERE.

8. What was the maximum length of consistent follow-up (ie, follow-up performed/attempted to be performed for all patients)?
Number of days (or specify other unit (eg, hours), if different than days)
Not reported or Unclear
Not applicable (e.g. a retrospective study)

9. Was informed consent obtained? (check all that apply)
Obtained from patient or legal representative (eg, parents for minors)
Determined to not be required by relevant IRB, Ethics Committee, or equivalent
Not obtained for other reason, specify
Not reported or Unclear
Not applicable (e.g. most retrospective studies)

10. Was Institutional Review Board approval (or equivalent) obtained?
Yes
Was determined to not be required, give brief explanation
Not reported or unclear

If this is NOT a RCT/QUASI-RCT, SKIP to Q#13.

11. Were **providers** blinded to intervention/treatment allocation (as best you can tell from the description in the article)?
Yes (e.g., article describes placebo injections of identical volume and appearance to treatment injection being given at the same time during treatment)
Partially (e.g., article describes "blinded" treatment and placebo injections but does not provide any other information)
No
Not reported or unclear

12. Were **patients** blinded to intervention/treatment allocation (as best you can tell from the description in the article)?
Yes (e.g., article describes placebo injections of identical volume and appearance to treatment injection being given at the same time during treatment)
Partially (e.g., article describes "blinded" treatment and placebo injections but does not provide any other information)
No
Not reported or unclear

13. Were **outcomes assessors** blinded to intervention/treatment allocation (as best you can tell from the description in the article)?
Yes
Partially (e.g., article states that assessors had no access to patient names or identifying information)
No
Not reported or unclear

14. Did the study assess the success of blinding in any way?
Yes, specify

15. Were any of the following explicitly defined a priori? NOTE: Must be EXPLICITLY defined in the methods section as chosen/performed at the outset of the study to qualify as being defined as a priori. Refer to L3 GUIDELINES for term codes.
Primary outcome(s), specify:
Secondary outcome(s)
Thromboembolic harms and/or mortality outcome(s), specify:
Other harms outcome(s), specify:
Sample size calculation
Statistical analyses

16. Were the data collected prospectively for this study?
Yes, all data were collected prospectively
Partially, data were collected both prospectively and retrospectively
No
Not reported or unclear
Not applicable (e.g. retrospective case control study)

17. Were any of the following built into the study design? (check all that apply)
Interim analyses
Stopping rules

18. Are you concerned that statistical tests were applied or reported inappropriately? If so, explain why.
Yes, runs multiple analyses without correction (e.g. Bonferroni correction)
Other, explain

19. Were multivariate analyses performed to control for confounding factors?
Yes

20. **FOR COMPARATIVE OBSERVATIONAL STUDIES ONLY (RCTs skip to 21).** Did the study make any attempt to match the control group with the intervention group?
Yes, describe
No
Not Necessary, explain

21. Are you concerned about the potential introduction of bias or lack of generalizability of the study? If so, select all potential problem areas that apply and specify reason. REFER to L3 GUIDELINES for instructions and codes.
Control and intervention groups were not appropriately matched at baseline (e.g. significantly different demographic or comorbidities between the two groups at baseline, REFER to L3 GUIDELINES), specify
Control and intervention groups received differential treatment(s), besides rFVIIa
Differential follow-up time between the control and intervention group, specify
Problem with withdrawals, loss to follow-up, or other missing data, specify
Other reason, specify

For RCTs/QUASI-RCTs, skip to Q24

COMPARATIVE OBSERVATIONAL STUDIES
22. Was the control group contemporaneous or historical?
Contemporaneous
Historical

23. **FOR COMPARATIVE OBSERVATIONAL STUDIES, THIS IS THE LAST QUESTION ON THIS FORM.** Do you have any other comments?
Yes

RCTs/QUASI-RCTs

24. If the unit of randomization was not the patient, specify the unit here.
Other, specify

25. Was the method of sequence generation for randomization specified? If so, do you have any concerns (explain concerns in text box)?
Yes, was specified, and I have NO CONCERNS
Yes, was specified, but I HAVE CONCERNS, describe
No, was not specified

26. Was the method of allocation concealment described and appropriate?
Yes, it was both described and appropriate (e.g. opaque, sealed envelope)
It was described but was NOT appropriate (e.g., patient name but no other identifying information removed from chart)
No, it was not described
Not applicable

27. If unit of analysis differed from unit of treatment allocation (e.g., providers were randomized, but analyses were of patient outcomes), did authors acknowledge this issue and make appropriate adjustments or conduct sensitivity analyses?
Yes
No
Not applicable (unit of analysis did not differ from unit of treatment allocation)

28. Were analyses performed according to intention-to-treat?
Yes, explicitly stated
Yes, can be inferred (e.g., article states all patients received assigned treatment and follow-up data are available for all patients)
No
Not reported or unclear

29. Skip this question if analyses **were** performed according to intention-to-treat. But, if analyses were NOT performed according to intention-to-treat, give the following information (check all that apply):
Sensitivity analyses were performed
An explanation for why analyses were not performed according to intention-to-treat was given and is summarized here:

30. **FOR RCTs/quasi-RCTs, THIS IS THE LAST QUESTION ON THIS FORM.** Do you have any other comments?
Yes

Level 4. Full text article data abstraction form for intracranial hemorrhage studies

INTRACRANIAL HEMORRHAGE

1. Is this a RCT/Quasi-RCT that reports data on intracranial hemorrhage**? If no, STOP ABSTRACTION**
Yes
No

2. Is this a quasi-RCT? If yes, briefly describe details.
Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized/baseline			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check thetick box indicating that:
Brief description
Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols or care by the same cardiac surgery team)
Yes, briefly describe
No

6. **rFVIIa Dose Information**

rFVIIa Dose	Dose Units (e.g. mg or ug/kg)	Uniform, Mean, or Median Dose? (Use codes U, MN, MD)	SD (or Range or IQR), if applicable	Number of rFVIIa doses	Comments (e.g. specify if variance is range or IQR)

7. Time/Location of rVIIa administration
Before or at onset of surgery
During surgery, or after, but while still in OR
Postoperatively (e.g. in ICU), but prior to any reoperation
Return from reoperation for bleeding
All other, describe
Not reported or Unclear

Patient demographics and other information

Basic Demographic

8. If different than number of subjects randomized to each group, specify the number of patients with reported demographic data:

N Intervention	N Control	Comments

Variable	N (or Mean or Median) Intervention	SD (or Range or IQR) Intervention	N (or Mean or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
9. Age					
10. Gender					
11. Admission INR					
12. Hematoma volume on baseline head CT					
13. Time of rFVIIa administration in relation to time of *bleed onset*					
14. Time of rFVIIa administration in relation to time of baseline head CT					
15. Systolic blood pressure					
16. Other demographic 1, specify					
17. Other demographic 2, specify					
18. Other demographic 3, specify					
19. Other demographic 4, specify					
20. Other demographic 5, specify					

Baseline categorical variables

21. If different than number of subjects randomized to each group, specify the number of patients with reported baseline data:

N Intervention	N Control	Comments

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
22. Presence of intraventricular hemorrhage on baseline head CT			
23. History of thrombotic/embolic events, specify			
24. Other comorbidity 1, specify			
25. Other comorbidity 2, specify			
26. Other comorbidity 3, specify			
27. Other comorbidity 4, specify			
28. Other comorbidity 5, specify			

Results

29. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Continuous variable

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
30. Change in hematoma						

volume from baseline head CT						
31. Other result 1, specify						
32. Other result 2, specify						
33. Other result 3, specify						
34. Other result 4, specify						
35. Other result 5, specify						
36. Other result 6, specify						
37. Other result 7, specify						
38. Other result 8, specify						

Categorical variables

Event	**N Intervention**	**N Control**	**Comments (e.g. specify other variable)**
39. Mortality			
40. Functional status/disability			
41. Other result 9, specify			
42. Other result 10, specify			
43. Other result 11, specify			
44. Other result 12, specify			
45. Other result 13, specify			
46. Other result 14, specify			
47. Other result 15, specify			
48. Other result 16, specify			

Harm information

49. Were harms measured?
No. If checked here, stop abstraction

50. How were harms identified?
Prospectively, describe
Retrospectively, describe
Both prospectively and retrospectively
Not reported or Unclear

51. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?
Yes, specify how

52. If harms were adjudicated in any way, specify how.
Blinded panel
Other

53. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	**N Control**	**Comments**

Undifferentiated Thomboembolic Harms (i.e. *without further delineation*)

	Total events (n)	**N Intervention**	**N Control**	**Comments**
54. **All** thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
55. **All arterial** thromboembolic events (*without further delineation*)				
56. Myocardial Infarction				
57. Stroke				
58. Mesenteric thrombosis				
59. Renal infarct				
60. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
61. **All venous** thromboembolic events (*without further delineation*)				
62. Pulmonary embolism				
63. Deep vein thrombosis				
64. Mesenteric vein thrombosis				
65. Portal vein thrombosis				
66. Thrombosis in right-side chamber of heart				
67. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
68. **All instrument-related** thromboembolic events (*without further delineation*)				
69. ECMO-related thromboembolic events				
70. Arterial line clot				
71. Venous line clot				
72. Other instrument-related thromboembolic event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
73. Multi-organ failure				
74. Cardiogenic shock/need for balloon pump				
75. Respiratory failure/ARDS				
76. Renal failure				
77. Sepsis				
78. DIC				
79. Other event #1, specify				
80. Other event #2, specify				
81. Other event #3, specify				
82. Other event #4, specify				
83. Other event #5, specify				

84. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

Level 4. Full text article data abstraction form for traumatic bleeding studies

TRAUMA

1. Is this a RCT/Quasi-RCT that reports data on trauma? **If no, STOP ABSTRACTION**
Yes
No

2. Is this a quasi-RCT? If yes, briefly describe details.
Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check thetick box indicating that.
Brief description
Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols or care by the same cardiac surgery team)
Yes, briefly describe
No

6. **What types of trauma are included in this arm of the study?**
Blunt trauma
Penetrating trauma
Traumatic brain injury
Other, specify

7. **rFVIIa Dose Information**

rFVIIa Dose	Dose Units (e.g. mg or ug/kg)	Uniform, Mean, or Median Dose? (use codes U, MN, MD)	SD (or Rangeor IQR), if applicable	Number of rFVIIa doses	Comments (e.g. specify if variance is range or IQR)

8. Describe the timing and location of rVIIa administration below:

Patient demographics and other information
Basic demographic information

9. If different than number of subjects randomized to each group, specify the number of patients with reported demographic data:

N Intervention	N Control	Comments

Variable	N (or Mean or Median) Intervention	SD (or Range or IQR Intervention	N (or Mean or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
10. Age					
11. Male sex (n)					
12. Weight (or BMI or body surface area, specify units)					
13. Injury Severity Score (ISS)					
14. Other demographic 1, specify					
15. Other demographic 2, specify					
16. Other demographic 3, specify					

Baseline categorical variables

17. If different than the number of subjects randomized to each group, specify the number of patients with reported baseline data:

N Intervention	N Control	Comments

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
18. Acidosis			
19. Abnormal INR			
20. Other comorbidity 1, specify			
21. Other comorbidity 2, specify			
22. Other comorbidity 3, specify			

Results

23. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Continuous variable

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
24. RBCs transfused in 24h (packed units)						
25. FFP transfused						
26. ICU time (days)						
27. Change in intracranial hematoma volume (mL)						
28. Other result 1, specify						
29. Other result 2, specify						

Categorical variable

Event	N Intervention	N Control	Comments (e.g. specify

			other variable)
30. Mortality within 24h			
31. Mortality within 30d			
32. Number of patients requiring transfusions, specify			
33. Need for return to OR/surgical re-exploration			
34. Other result 3, specify			
35. Other result 4, specify			

Harm information

36. Were harms measured?
No. If checked here, STOP abstraction

37. How were harms identified?
Prospectively, describe
Retrospectively, describe
Both prospectively and retrospectively
Not reported or Unclear

38. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?
Yes, specify how

39. If harms were adjudicated in any way, specify how.
Blinded panel
Other

40. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	**N Control**	**Comments**

Undifferentiated Thomboembolic Harms (i.e. *without further delineation*)

	Total events (n)	**N Intervention**	**N Control**	**Comments**
41. **All** thromboembolic events				

Arterial Thromboembolic Harms

Event	**Total Events (n)**	**N Intervention**	**N Control**	**Comments**
42. **All arterial** thromboembolic events (*without further delineation*)				
43. Myocardial Infarction				
44. Stroke				
45. Mesenteric thrombosis				
46. Renal infarct				
47. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	**Total Events (n)**	**N Intervention**	**N Control**	**Comments**
48. **All venous** thromboembolic events (*without further delineation*)				

49. Pulmonary embolism				
50. Deep vein thrombosis				
51. Mesenteric vein thrombosis				
52. Portal vein thrombosis				
53. Thrombosis in right-side chamber of heart				
54. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
55. **All instrument-related** thromboembolic events (*without further delineation*)				
56. ECMO-related thromboembolic events				
57. Arterial line clot				
58. Venous line clot				
59. Other instrument-related event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
60. Multi-organ failure				
61. Cardiogenic shock/requirement for balloon pump				
62. Respiratory failure/ARDS				
63. Renal failure				
64. Sepsis				
65. DIC				
66. Other event #1, specify				
67. Other event #2, specify				
68. Other event #3, specify				
69. Other event #4, specify				
70. Other event #5, specify				

71. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

Level 4. Full text article data abstraction form for liver transplantation studies

LIVER TRANSPLANT

1. Is this a RCT/Quasi-RCT that reports data on liver transplant? **If no, STOP ABSTRACTION**.
Yes
No

2. Is this a quasi-RCT? If yes, briefly describe details.
Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized/baseline			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check the tick box indicating that:
Brief description
Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols)
Yes, briefly describe
No

6. Special type(s) of surgery performed (check all that apply)
Multiorgan transplantation, specify
Other, specify

7. **rFVIIa Dose Information**

Be sure to indicate in the comments box whether administration of rFVIIa was for preventive or emergent reasons

rFVIIa Dose	**Dose Units (e.g. mg or ug/kg)**	**Uniform, Mean, or Median Dose? (Use codes U, MN, MD)**	**SD (or Range or IQR), if applicable**	**Number of rFVIIa doses**	**Comments (e.g. specify if variance is range or IQR)**

8. Time/Location of rVIIa administration
Before or at onset of surgery
During surgery, or after, but while still in OR
Postoperatively (e.g. in ICU), but prior to any reoperation

Return from reoperation for bleeding	
All other, describe	
Not reported or Unclear	

Patient demographics and other information

Basic Demographic

9. If different than number of subjects randomized to each group, specify the number of patients with reported demographic data:

N Intervention	N Control	Comments

Variable	N (or Mean or Median) Intervention	SD (or Range or IQR) Intervention	N (or Mean or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
10. Age					
11. Gender					
12. Weight (or BMI or body surface area; specify units)					
13. Meld score (or Child Pugh classification)					
14. INR					
15. Warm ischemia at time of donor liver					
16. Cold ischemia at time of donor liver					
17. Other demographic 1, specify					
18. Other demographic 2, specify					
19. Other demographic 3, specify					
20. Other demographic 4, specify					

Baseline categorical variables

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
21. Emergency surgery (e.g. fulminant liver failure)			
22. Prior liver transplantation of other major liver surgery			
23. Presence of multiorgan failure			
24. History of thrombotic/embolic event, specify			
25. Diabetes			
26. Renal failure			
27. CHF			
28. COPD			
29. Hypertension			
30. Other comorbidity 1, specify			
31. Other comorbidity 2, specify			
32. Other comorbidity 3, specify			

Results

33. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Continuous variable

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
34. RBCs transfused (packed units)						
35. FFP transfused						
36. Blood loss (or chest tube drainage) (mLs)						
37. OR time (hours)						
38. Other result 1, specify						
39. Other result 2, specify						

Categorical variables

Event	N Intervention	N Control	Comments (e.g. specify other variable)
40. In-hospital mortality, specify			
41. Number of patients requiring transfusion, specify			
42. Need for re-operation or re-transplantation			
43. Other result 3, specify			
44. Other result 4, specify			

Harm information

45. Were harms measured?
No. If checked here, stop abstraction

46. Was there an explicit follow up time set for determination of harms?
Yes, describe

47. How were harms identified?
Prospectively, describe
Retrospectively, describe
Both prospectively and retrospectively
Not reported or Unclear

48. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?
Yes, specify how
49. If harms were adjudicated in any way, specify how.
Blinded panel
Other

50. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	N Control	Comments

Undifferentiated Thomboembolic Harms (i.e. *without further delineation*)

	Total events (n)	N Intervention	N Control	Comments
51. **All** thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
52. **All arterial** thromboembolic events (*without further delineation*)				
53. Myocardial Infarction				
54. Stroke				
55. Mesenteric thrombosis				
56. Renal infarct				
57. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
58. **All venous** thromboembolic events (*without further delineation*)				
59. Pulmonary embolism				
60. Deep vein thrombosis				
61. Mesenteric vein thrombosis				
62. Portal vein thrombosis				
63. Thrombosis in right-side chamber of heart				
64. **Other** venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
65. **All instrument-related** thromboembolic events (*without further delineation*)				
66. ECMO-related thromboembolic events				
67. Arterial line clot				
68. Venous line clot				
69. Other instrument-related thromboembolic event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
70. Multi-organ failure				
71. Cardiogenic shock/need for balloon pump				
72. Respiratory failure/ARDS				
73. Renal failure				
74. Sepsis				

75. DIC				
76. Other event #1, specify				
77. Other event #2, specify				
78. Other event #3, specify				
79. Other event #4, specify				
80. Other event #5, specify				

81. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

Level 4. Full text article data abstraction form for cardiac surgery studies

CARDIAC SURGERY

1. Is this a RCT/Quasi-RCT that reports data on cardiac surgery? **If no, STOP ABSTRACTION**
Yes
No

2. Is this a quasi-RCT? If yes, briefly describe details.
Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check the tick box indicating that.
Brief description
Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols or care by the same cardiac surgery team)
Yes, briefly describe
No

6. **Type (s) of surgery performed (for adults) (check all that apply)**
Multiple surgeries
CABG
Cardiac transplantation
Single valve repair/replacement
Any aortic
All Other, specify
No cardiac surgery for adults

7. **Type (s) of surgery performed (for child) (check all that apply)**
Reoperation (any type)
Correction of congenital heart disease
All other, specify
No surgery perfomed in child

8. **rFVIIa Dose Information**

rFVIIa Dose	**Dose Units (e.g. mg or ug/kg)**	**Uniform, Mean, or Median Dose? (use codes U, MN, MD)**	**SD (or Range or IQR), if applicable**	**Number of rFVIIa doses**	**Comments (e.g. specify if variance is range or**

					IQR)

9. Time/Location of rVIIa administration

Before or at onset of surgery	
During surgery, or after, but while still in OR	
Postoperatively (e.g. in ICU), but prior to any reoperation	
Return from reoperation for bleeding	
All other, describe	
Not reported or Unclear	

Patient demographics and other information

Basic demographic information

10. If different than number of subjects randomized to each group, specify the number of patients with reported demographic/baseline data:

N Intervention	**N Control**	**Comments**

Variable	**Mean (or Median) Intervention**	**SD (or Range or IQR Intervention**	**Mean (or Median) Control**	**SD (or Range or IQR) Control**	**Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)**
11. Age					
12. Gender					
13. Weight (or BMI or body surface area, specify units)					
14. Other demographic 1, specify					
15. Other demographic 2, specify					
16. Other demographic 3, specify					
17. Other demographic 4, specify					

Baseline categorical variables

Variable	**N Intervention**	**N Control**	**Comments (e.g. specify other variable)**
18. Emergency surgery			
19. Previous cardiac surgery			
20. History of thrombotic/embolic events, specify			
21. Diabetes			
22. Renal failure			
23. CHF			
24. COPD			
25. Hypertension			
26. Other comorbidity 1, specify			
27. Other comorbidity 2, specify			
28. Other comorbidity 3, specify			

Results

29. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Continuous variable

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
30. RBCs transfused in 24h (packed units)						
31. FFP transfused						
32. Blood loss (or chest tube drainage) (mLs)						
33. OR time (hours)						
34. Other result 1, specify						
35. Other result 2, specify						
36. Other result 3, specify						
37. Other result 4, specify						
38. Other result 5, specify						
39. Other result 6, specify						

Results categorical variables

Event	N Intervention	N Control	Comments (e.g. specify other variable)
40. In-hospital mortality			
41. Need for return to OR/surgical re-exploration			
42. Number of patients requiring transfusions, specify further			
43. Other result 7, specify			
44. Other result 8, specify			
45. Other result 9, specify			
46. Other result 10, specify			
47. Other result 11, specify			
48. Other result 12, specify			

Harm information

49. Were harms measured?
No. If checked here, STOP abstraction

50. Was there an explicit follow up time for determination of harms?
Yes, describe

51. How were harms identified?
Prospectively, describe
Retrospectively, describe
Both prospectively and retrospectively
Not reported or Unclear

52. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?
Yes, specify how

53. If harms were adjudicated in any way, specify how.
Blinded panel
Other

54. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	N Control	Comments

Undifferentiated Thomboembolic Harms (i.e. *without further delineation*)

	Total events (n)	N Intervention	N Control	Comments
55. **All** thromboembolic events				

Arterial Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
56. **All arterial** thromboembolic events (*without further delineation*)				
57. Myocardial Infarction				
58. Stroke				
59. Mesenteric thrombosis				
60. Renal infarct				
61. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
62. **All venous** thromboembolic events (*without further delineation*)				
63. Pulmonary embolism				
64. Deep vein thrombosis				
65. Mesenteric vein thrombosis				
66. Portal vein thrombosis				
67. Thrombosis in right-side chamber of heart				
68. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
69. **All instrument-related** thromboembolic events (*without further delineation*)				
70. ECMO-related thromboembolic events				

71. Arterial line clot				
72. Venous line clot				
73. Other instrument-related event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
74. Multi-organ failure				
75. Cardiogenic shock/requirement for balloon pump				
76. Respiratory failure/ARDS				
77. Renal failure				
78. Sepsis				
79. DIC				
80. Other event #1, specify				
81. Other event #2, specify				
82. Other event #3, specify				
83. Other event #4, specify				
84. Other event #5, specify				

85. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

Level 4. Full text article data abstraction form for prostatectomy studies

PROSTATECTOMY

1. Is this a RCT/Quasi-RCT that reports data on prostatectomy? **If no, STOP ABSTRACTION**.
Yes
No

Study characteristics

2. Is this a quasi-RCT? If yes, briefly describe details.
Yes, describe

3. List the number of subjects in each group below

	N Intervention	N Control	Comments
Subjects randomized/baseline			
Subjects receiving assigned therapy			
Subjects lost to follow-up or withdrawn			

4. Briefly describe inclusion/exclusion criteria. If any of the inclusion/exclusion criteria related to recent ischemic/thrombotic/embolic events, also check the tick box indicating that:
Brief description
Yes, at least one exclusion/inclusion criterion related to ischemic/thrombotic/embolic events

5. Was a standard of care defined? (e.g., special transfusion protocols)
Yes, briefly describe
No

6. Type (s) of surgery performed (check all that apply)
Radial retropubic prostatectoy
Millin prostatectomy
All other, specify

7. **rFVIIa Dose Information**

Indicate in the comments box whether administration of rFVIIa was for preventive or emergent reasons.

rFVIIa Dose	Dose Units (e.g. mg or ug/kg)	Uniform, Mean, or Median Dose? (Use codes U, MN, MD)	SD (or Range or IQR), if applicable	Number of rFVIIa doses	Comments (e.g. specify if variance is range or IQR)

8. Time/Location of rVIIa administration
Before or at onset of surgery
During surgery, or after, but while still in OR
Postoperatively (e.g. in ICU), but prior to any reoperation
Return from reoperation for bleeding
All other, describe
Not reported or Unclear

Patient demographics and other information

Basic Demographic

9. If different than number of subjects randomized to each group, specify the number of patients with reported demographic/baseline data:

N Intervention	N Control	Comments

Variable	N (or Mean or Median) Intervention	SD (or Range or IQR) Intervention	N (or Mean or Median) Control	SD (or Range or IQR) Control	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
10. Age					
11. Gender					
12. Weight (or BMI or body surface area; specify units)					
13. Other demographic 1, specify					
14. Other demographic 2, specify					
15. Other demographic 3, specify					
16. Other demographic 4, specify					

Baseline categorical variables

Variable	N Intervention	N Control	Comments (e.g. specify other variable)
17. History of thrombotic/embolic events, specify			
18. Emergency surgery			
19. Diabetes			
20. Renal failure			
21. CHF			
22. COPD			
23. Hypertension			
24. Other comorbidity 1, specify			
25. Other comorbidity 2, specify			
26. Other comorbidity 3, specify			

Results

27. If different than the number of subjects randomized to each group, specify the number of patients with reported results data:

N Intervention	N Control	Comments

Results continuous variable

Event	Mean (or Median) Intervention	SD (or Range or IQR) Intervention	Mean (or Median) Control	SD (or Range or IQR) Control	Time Frame	Comments (e.g. specify other variable, units, mean/med, SD/range/IQR)
28. RBCs transfused (packed units)						
29. FFP transfused						
30. Blood loss (or chest tube drainage) (mLs)						
31. OR time (hours)						

32. Length of hospital stay (days)						
33. Other result 1, specify						
34. Other result 2, specify						

Results categorical variables

Event	**N Intervention**	**N Control**	**Comments (e.g. specify other variable)**
35. In-hospital mortality			
36. Number of patients requiring transfusions, specify			
37. Need for re-operation or re-transplantation			
38. Other result 3, specify			
39. Other result 4, specify			

Harm information

40. Were harms measured?
No. If checked here, stop abstraction

41. Was there an explicit follow up time set for determination of harms
Yes, describe

42. How were harms identified?
Prospectively, describe
Retrospectively, describe
Both prospectively and retrospectively
Not reported or Unclear

43. Did the study specifically attempt to make the determination that harms were secondary to rFVIIa administration?
Yes, specify how

44. If harms were adjudicated in any way, specify how.
Blinded panel
Other

45. If different than the number of subjects randomized to each group, specify the number of patients with reported harms data:

N Intervention	**N Control**	**Comments**

Undifferentiated Thomboembolic Harms (i.e. *without further delineation*)

	Total events (n)	**N Intervention**	**N Control**	**Comments**
46. **All** thromboembolic events				

Arterial Thromboembolic Harms

Event	**Total Events (n)**	**N Intervention**	**N Control**	**Comments**
47. **All arterial** thromboembolic events (*without further delineation*)				
48. Myocardial Infarction				
49. Stroke				

50. Mesenteric thrombosis				
51. Renal infarct				
52. Other arterial thromboembolic event, specify type in comments box				

Venous Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
53. **All venous** thromboembolic events (*without further delineation*)				
54. Pulmonary embolism				
55. Deep vein thrombosis				
56. Mesenteric vein thrombosis				
57. Portal vein thrombosis				
58. Thrombosis in right-side chamber of heart				
59. Other venous thromboembolic event, specify type in comments box				

Instrument-related Thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
60. **All instrument-related** thromboembolic events (*without further delineation*)				
61. ECMO-related thromboembolic events				
62. Arterial line clot				
63. Venous line clot				
64. Other instrument-related thromboembolic event, specify type in comments box				

Other NON-thromboembolic Harms

Event	Total Events (n)	N Intervention	N Control	Comments
65. Multi-organ failure				
66. Cardiogenic shock/need for balloon pump				
67. Respiratory failure/ARDS				
68. Renal failure				
69. Sepsis				
70. DIC				
71. Other event #1, specify				
72. Other event #2, specify				
73. Other event #3, specify				
74. Other event #4, specify				
75. Other event #5, specify				

76. Do you have any other comments? Please use this space to describe any relevant information that could not be collected on this form.

Appendix F: Strength of Evidence and Applicability Assessment Forms

Strength of Evidence **Assessment form for:** *** Clinical Domain of:** **[_____]**

*** Outcome(s) of:** **[_____]**

Outcome of Interest	**Number of Studies**	**Number of Subjects**		**Domains Pertaining to Strength of Evidence**						**Estimated Magnitude of Effect**	**Effect of rFVIIa Dosage**	**Overall Strength of Evidence Grade**
		RFVIIa	**Usual Care**	**Risk of Bias Domains**			**Consistency**	**Directness**	**Precision**			
				Design	**Quality**	**Summary Risk of Bias***						
1.				RCTs								
				Comp Obs								
2.				RCTs								
				Comp Obs								
3.				RCTs								
				Comp Obs								
4.				RCTs								
				Comp Obs								
5.				RCTs								
				Comp Obs								

RCT, randomized controlled trial; Comp Obs, comparative observational study; SOE, strength of evidence.

*For further details on assigning a summary risk score, see guidance document.