

4th Newsletter

October/November/December 2005

Status Report (as at December 1 2005)

Participating Hospitals	Ethics status	Cases submitted
The Alfred Hospital, VIC	Approved	28
The Geelong Hospital, VIC	Approved	30
The Canberra Hospital, ACT	Approved	19
Royal Prince Alfred Hospital, NSW	Approved	21
Liverpool Hospital, NSW	Approved	10
Prince of Wales Hospital, NSW	Approved	00
Royal Darwin Hospital, NT	Approved	18
The Austin Hospital, VIC	Approved	57
The Prince Charles Hospital, QLD	Approved	0
Royal Adelaide Hospital, SA	Approved	0
Nepean Hospital, NSW	Approved	2
Nambour Hospital, QLD	Approved	0
Gold Coast Hospital, QLD	Approved	0
St Vincents Hospital, NSW	Approved	10
Royal North Shore Hospital, NSW	Approved	0
Flinders Medical Centre, SA	Approved	0
Fremantle Hospital, WA	Approved	1
Modbury Hospital, SA	Approved	1
John Hunter Hospital, NSW	Approved	0
Auckland City Hospital, NZ	Approved	0
Middlemore Hospital, NZ	Approved	0
Dunedin Public Hospital, NZ	Approved	0
Royal Childrens Hospital, QLD	Approved – waiting on letter	
St Vincents Hospital, VIC	Submitted	
Royal Childrens Hospital, VIC	Submitted	
Princess Alexandra Hospital, QLD	Submitted	
King Edward Memorial Hospital for Women, WA	Submitted	
Waikato Hospital, NZ	Submitted	
North Shore Hospital, NZ	Submitted	
Christchurch Hospital, NZ	Submitted	
Wellington Hospital, NZ	Submitted	
Tauranga Hospital, NZ	Submitted	
Monash Medical Centre, VIC	Submitted	
Dandenong Hospital, VIC	Submitted	
Knox Private Hospital, VIC	Submitted	
St George Hospital, NSW	Submitted	
Royal Melbourne Hospital, VIC	Submitted	
Townsville Hospital, QLD	Submitted	
Mater Health Services Brisbane, QLD	Submitted	
Alice Springs Hospital, NT	Submitted	
Peter MacCallum Cancer Centre, VIC	Submitted	
Royal Hobart Hospital, Tas	Submitted	
Westmead Hospital, NSW	To be submitted	
Royal Perth Hospital, WA	To be submitted	
Royal Brisbane and Womens Hospital, QLD	To be submitted	
TOTAL CASES SUBMITTED		197

We have been delighted with the progress of the Haemostasis Registry as to date we have written approval from 22 hospitals with another one waiting on the final letter of confirmation Ethics applications have been submitted at nineteen other hospitals and we are waiting for the ethics review process.

More hospitals are in the process of preparing ethics submissions and we are continuing to sign up hospitals as more people find out about the registry and don't want to be left out of this exciting project. That makes a total of 45 Hospitals involved with the project so far!! Considering our aim was to have 5-6 hospitals signed up and collecting data by the end of 2006, I am sure you will agree that the result is outstanding! A big thank you to all the contributors who have made this amazing result possible.

The data is beginning to roll in now with almost 200 cases received at the Registry by the beginning of December. We are hoping to top 300 by the end of the year so if you are waiting for ethics approval, don't wait to prepare the data ready to send off once the ethics approval comes in.

The Registry has been represented at five conferences since the last newsletter: ASA, HSNZ/ASTH/ANZSBT, ANZICS, ASCTS and ACEM. Many people were excited to see the first basic information from the data and pleased to see their Hospitals up there on the posters.

To a certain extent this early data reflects the uses of the hospitals that have contributed so far and we will be interested to see how the demographics change as more hospitals send in their data. On the following page is a copy of the poster presented at ACEM which includes data received up to 15 November 2005.

The Haemostasis Registry – Evidence and Practice

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Introduction:

Recombinant activated factor VII (rFVIIa, marketed under the brand name NovoSeven®) is approved for the treatment of spontaneous and surgical bleeding in patients with haemophilia A or B and with antibodies to either factor VIII or factor IX. Recently rFVIIa has increasingly been used for indications outside the approved areas, particularly in cardiac surgery, trauma and other critical bleeding episodes. Use in these areas remains controversial.

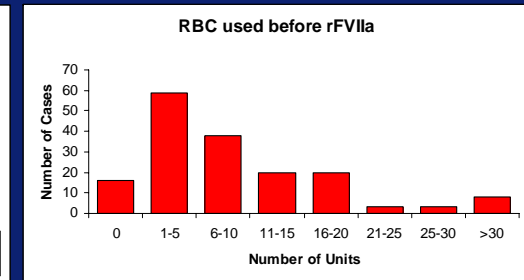
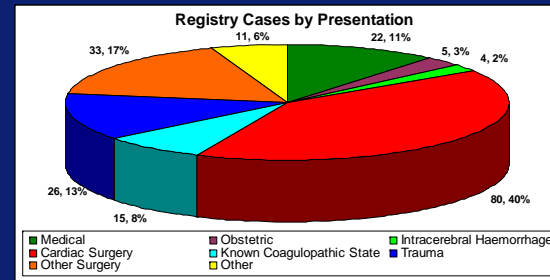
Methods:

Monash University Department of Epidemiology and Preventive Medicine has established the Haemostasis Registry (with an unrestricted educational grant from NovoNordisk Pharmaceuticals) to collect data on the use of rFVIIa, in patients with critical bleeding throughout Australia and New Zealand.

Nineteen Hospitals have completed the process of joining the Haemostasis Registry, obtaining ethics approval and are now able to submit data to the Registry. A further 23 hospitals have agreed to participate in the Registry project and are awaiting ethics approval. It is anticipated that all the major users of rFVIIa will contribute to the registry. As at 15 November, we had received 168 cases. We hope to receive in excess of 300 cases by the end of 2005.

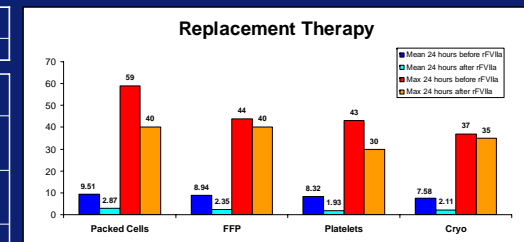
Results:

Preliminary data from the 168 cases received to date by the Haemostasis Registry are presented below. Cardiac Surgery is the main area of use in the hospitals reporting thus far. Refractory bleeding following other types of surgery, medical uses (such as for GI bleeding in patients with various forms of cancer) and trauma are also large areas of use. Most patients received a single dose of rFVIIa and, in the majority of cases, rFVIIa was administered relatively early in the course of patient bleeding (ie when 5 or fewer units of RBC had been used). Seventy percent of patients were male and approximately 70% of patients were 45 years of age or older. In 76% of cases the use of rFVIIa was considered to have had a positive effect on the control of bleeding. Six adverse events (3.57% of cases) were reported to be 'probably' or 'possibly' linked to the administration of rFVIIa. No adverse events were reported as being 'definitely' linked.



Outcome at 28 days post rFVIIa	Living	Deceased
	110 (66%)	57 (34%)

Type of Adverse Event	Linked to rFVIIa?*	Number	Details of Adverse Event
Thrombotic	Probably	2	1. small clot around aortic graft, 2. clots formed in chest drain following cardiac surgery
	Possibly	3	1. CVA, 2. CVA, 3. intracardiac thrombus
Allergic	Possibly	1	1. rash on trunk

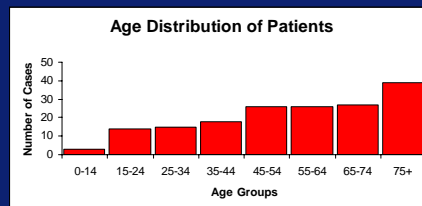


* Other reported adverse events were considered by treating physicians to be 'not linked' or 'unlikely to be linked' to rFVIIa administration

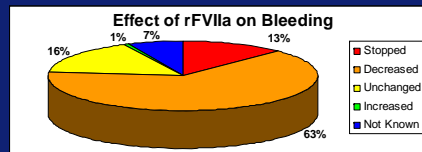
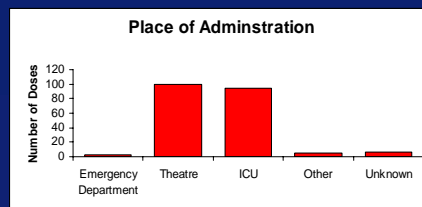
Conclusions:

Although randomized controlled trials are important in establishing the safety and efficacy of new treatments, they do not replace the need for registries, especially for treatments where clinicians believe that withholding treatment may be unethical because of potential life threatening consequences. This problem is made more difficult where there are a wide range of applications. As more data becomes available, the Haemostasis Registry data will help to elucidate the safety and efficacy of rFVIIa and provide important feedback to doctors and hospitals.

Participating Hospitals	State	Status	Cases
The Canberra Hospital	ACT	Approved	16
Nepean Hospital	NSW	Approved	2
Liverpool Hospital	NSW	Approved	10
Royal Prince Alfred Hospital	NSW	Approved	21
Prince of Wales Hospital	NSW	Approved	0
St Vincent's Hospital	NSW	Approved	0
Royal North Shore Hospital	NSW	Approved	0
John Hunter Hospital	NSW	Approved	0
St George Hospital	NSW	ethics pending	0
Royal Darwin Hospital	NT	Approved	16
The Prince Charles Hospital	QLD	Approved	0
Nambour Hospital	QLD	Approved	0
Gold Coast Hospital	QLD	Approved	0
Princess Alexandra Hospital	QLD	ethics pending	0
Royal Children's Hospital	QLD	ethics pending	0
Townsville Hospital	QLD	ethics pending	0
Mater Health Brisbane	QLD	ethics pending	0
Royal Brisbane & Womens Hospital	QLD	ethics pending	0
Modbury Public Hospital	SA	Approved	1
Royal Adelaide Hospital	SA	Approved	0
Flinders Medical Centre	SA	Approved	0
Royal Hobart Hospital	TAS	ethics pending	0
Barwon Health (Geelong Hospital)	VIC	Approved	29
Austin Hospital	VIC	Approved	42
Alfred Hospital	VIC	Approved	28
St Vincent's Hospital	VIC	ethics pending	0
Royal Children's Hospital	VIC	ethics pending	0
Monash Medical Centre	VIC	ethics pending	0
Dandenong Hospital	VIC	ethics pending	0
Knox Private Hospital	VIC	ethics pending	0
Peter MacCallum Cancer Centre	VIC	ethics pending	0
Royal Melbourne Hospital	VIC	ethics pending	0
Fremantle Hospital	WA	Approved	1
King Edward MH for Women	WA	ethics pending	0
Royal Perth Hospital	WA	ethics pending	0
Auckland City Hospital	NZ	ethics pending	0
Middlemore Hospital	NZ	ethics pending	0
Dunedin Public Hospital	NZ	ethics pending	0
Waikato Hospital	NZ	ethics pending	0
North Shore Hospital	NZ	ethics pending	0
Christchurch Hospital	NZ	ethics pending	0
Wellington Hospital	NZ	ethics pending	0
Tauranga Hospital	NZ	ethics pending	0
TOTAL CASES SUBMITTED			168



Number of Doses Per Patient	Male		Female	
	No. of Cases	No. of Doses	Mean Dose (mg)	Mean Dose (µg/kg)
1	168	207	6.52	84
2	70	30		
3 or more				



haemostasis registry