



## 7th Newsletter October-December 2006

### **2006**

An extremely busy and productive year is drawing to a close. I am not quite sure where December has disappeared to but I am looking forward to a break over Christmas and the New Year. We are ending the year with nearly 850 cases and with some of the large hospitals about to commence sending us data (RBH and Westmead) we have every expectation that the 1000<sup>th</sup> case will arrive fairly early in the year. Take a look at the status report over the page to see how your hospital is doing! Congratulations to our Northern Territory Hospitals which on a hospital coverage and per capita basis are leading the country! 2007 is shaping up to be another exciting year for the Haemostasis Registry. See details below.

### **2<sup>nd</sup> Annual Investigator Workshop**

We are very pleased to announce the 2<sup>nd</sup> Annual Investigator Workshop will take place on **May 2<sup>nd</sup> 2007** in the AMREP Seminar Room at the Alfred Hospital in Melbourne. Like this year's workshop, the programme will be designed so that clinicians can fly in and out the same day from most states. Programme details are yet to be finalised but will include updates from the three therapeutic area sub-committees as well as an overview of the registry progress. Invitations will be sent out early in 2007 but mark this date in your diary now!!

### **Web Entry Launch & Training Day**

Database Manager and Steering Committee Member Andrew Hannaford and Haemostasis Registry Database Manager "M" Pruksawongsin are hard at work on the web interface for data entry. The launch date is set for **1<sup>st</sup> May 2007** and early in the new year we will be sending invitations to Data Collectors from around Australia and New Zealand to join us for a day of updates and training.

### **New Data Collection Forms**

As mentioned in the last Newsletter, new Data Collection forms have been introduced to slightly revise some of the data items being collected and including supplementary data forms for four specialist areas (Cardiac, Trauma, ICH and Obstetric). Ethics amendments have been made to all ethics committees and most of these have been passed allowing data collection on the new forms.

We do recognise that the supplementary forms require some additional information to be collected and where supplementary forms are completed we are able to offer an additional fee of \$20 (ie a total of \$120 for cases with supplementary forms). Hospitals that have already submitted cases on the new forms will be able to sort out the charges with Louise in the New Year.



**Best Wishes  
for the  
Festive Season  
from the  
Haemostasis  
Registry**

### **Stickers**

The stickers distributed after the last newsletter have proved every popular at some hospitals. Please drop us a line to let us know if you are using them and whether they are successful. Please don't hesitate to ask for more if you need them!

### **New Registry Staff**

The success of the Registry and the hard work of our data collectors has meant that the Haemostasis Registry has had to take on some new staff to cope with the volume. As well as Andrew and "M" who look after the database construction and maintenance, and Louise who manages the project, we also rely on Rosalie and Georgina who are both working part time with us as taking care of data entry and verification, ethics and many of the other administrative details. You may speak to them on the phone (particularly if I am out of the office) and I am sure you will find them both extremely friendly and helpful.

### **Presentations**

Current Registry data was presented at several conferences in Australia and overseas this year: ACCCN, ICEM, Trauma 2006, ANZICS, HSAZ, ASA, ASCTS, ACEM and the NBA Data Workshop. It was great to catch up with many of our contributors at these conferences and to discuss the results emerging from the Registry.

### **Publications**

Three publications from the Registry will be submitted to journals by the end of 2006. The Steering Committee has been working on a General Overview of data received to date – see the abstract of the submitted paper over the page. The Trauma and Cardiac sub-committees have likewise prepared manuscripts looking at data from their area of interest.





**Status Report (as at December 15 2006)**

Participating Hospitals	Ethics Status	Cases
<b>ACT</b>		
The Canberra Hospital	Approved	22
<b>NSW</b>		
Blacktown Hospital	Approved	0
Concord Repatriation Hospital	Approved	22
John Hunter Hospital	Approved	7
Liverpool Hospital	Approved	36
Nepean Hospital	Approved	2
Prince of Wales Hospital	Approved	80
Royal North Shore Hospital	Approved	68
Royal Prince Alfred Hospital	Approved	114
St George Hospital (Private and Public)	Approved	2
St Vincents Hospital (Private and Public)	Approved	65
Westmead Hospital	Approved	0
Lismore Base Hospital	Ethics Submitted	
Tweed Heads Hospital	Ethics Submitted	
<b>NT</b>		
Alice Springs Hospital	Approved	10
Royal Darwin Hospital	Approved	29
<b>QLD</b>		
Gold Coast Hospital	Approved	12
Mater Health Services Brisbane	Approved	14
Nambour Hospital	Approved	3
Prince Charles Hospital	Approved	30
Princess Alexandra Hospital	Approved	19
Royal Brisbane and Womens Hospital	Approved	0
Royal Childrens Hospital	Approved	0
Townsville Hospital	Approved	0
John Flynn - Gold Coast Private Hospital	Ethics Submitted	
<b>SA</b>		
Flinders Medical Centre	Approved	8
Modbury Hospital	Approved	1
Queen Elizabeth Hospital	Approved	9
Repatriation General Hospital	Approved	2
Royal Adelaide Hospital	Approved	8
Womens & Childrens Hospital	Approved	0
<b>TAS</b>		
North West Regional Hospital	Approved	0
Royal Hobart Hospital	Approved	3
<b>VIC</b>		
Alfred Hospital	Approved	38
Austin Hospital	Approved	90
Box Hill Hospital	Approved	1
Cabrini Hospital	Approved	3
Dandenong Hospital	Approved	0
Epworth Hospital	Approved	1
Geelong Hospital	Approved	46
Knox Private Hospital	Approved	5
Monash Medical Centre	Approved	4
Peter MacCallum Cancer Centre	Approved	4
Royal Childrens Hospital	Approved	12
St Vincents Hospital	Approved	17
Royal Melbourne Hospital	Ethics Submitted	

Participating Hospitals	Ethics Status	Cases
<b>WA</b>		
Fremantle Hospital	Approved	4
King Edward Memorial Hospital for Women	Approved	0
Princess Margaret Hospital for Children	Approved	0
Sir Charles Gairdner Hospital	Approved	6
St John of God Hospital - Murdoch	Approved	0
St John of God Hospital - Subiaco	Approved	0
Royal Perth Hospital	Ethics Submitted	
The Mount Hospital	Ethics Submitted	
<b>NZ</b>		
Auckland City Hospital	Approved	23
Christchurch Hospital	Approved	0
Dunedin Public Hospital	Approved	0
Middlemore Hospital	Approved	11
North Shore Hospital	Approved	2
Tauranga Hospital	Approved	1
Waikato Hospital	Approved	0
Wellington Hospital	Approved	2
Grey Hospital	Ethics Submitted	
<b>TOTAL CASES SUBMITTED</b>		<b>836</b>

**RECOMBINANT ACTIVATED FACTOR VII IN CRITICAL BLEEDING: EXPERIENCES FROM THE AUSTRALIAN AND NEW ZEALAND HAEMOSTASIS REGISTER**

Isbister J, Phillips L, Dunkley S, Jankelowitz G, McNeil J, Cameron P

**Abstract**

*Background:* There has been increasing use of recombinant activated factor VII (rFVIIa/NovoSeven®, Novo Nordisk, Bagsvaerd, Denmark) for patients with critical bleeding. Given the lack of high level evidence the clinical indications, observed response and adverse events are important to capture.

*Methods:* The Haemostasis Registry collects retrospective and contemporaneous data on all use of rFVIIa at participating institutions for non-haemophilic patients with critical bleeding.

*Results:* As of October 2006, 694 cases had been reported into the register from 37 hospitals across Australia and New Zealand. These comprise an array of therapeutic categories including the salvage use in: perioperative cardiothoracic surgery (44%), trauma (16%), medical bleeding (9%), obstetric bleeding (4%) and other types of critical bleeding (28%). Patients received a median (IQR) dose of 91 µg/kg (75-103), and 83% of patients received a single dose of rFVIIa. The documented response rate to a single dose of rFVIIa was 69%. The 28 day survival was 68% but varied with clinical category. The rate of adverse events probably or possibly linked to the use of rFVIIa was 6%, with the majority of the thromboembolic adverse events occurring in the cardiac surgery group.

*Conclusions:* The Haemostasis Register cannot replace well designed prospective randomised controlled trials, but in their absence this register provides a basis for understanding the real world experience with rFVIIa. Registers continue to be vital in monitoring off-label uses of medications.