

June/July 2005

The Haemostasis Registry made its public debut at the recent ANZ College of Anaesthetists Conference in Auckland. Look for us at conferences coming up around the region in the next months: ISTH (Sydney, August), HSA (Sydney, October), ANZICS (Adelaide, October), ACEM (Melbourne, November) amongst others! Please come and meet us and bring your friends and colleagues too!

Status Report

As at 30th June 2005

Registry Cases:	27
Retrospective:	43
Contemporaneous:	4

While we have had a lot of interest in the Registry, the initial stages of registration and ethics approval always seem very slow but will gather speed in the coming months.

So far we have four hospitals fully signed up and collecting data:

Victoria:

The Alfred Hospital,
The Geelong Hospital,

NSW:

Royal Prince Alfred Hospital,

ACT:

The Canberra Hospital

A number of other hospitals are in the process of obtaining ethics approval:

Victoria:

The Austin Hospital,
Royal Children's Hospital,
Royal Melbourne Hospital,

NSW:

Royal North Shore Hospital,
Prince of Wales Hospital,
Liverpool Hospital,

Queensland:

Prince Charles Hospital,

Western Australia:

Fremantle Hospital,

New Zealand:

Auckland City Hospital,
Middlemore Hospital,
Dunedin Public Hospital.

Thank you to the staff at all those hospitals who are involved in the registration and data collection processes.

Update on Clinical Trials

Two international clinical trials in the planning stages will involve local hospitals as contributors. We hope to bring you up to date with information from these trials and others as it becomes available

Trauma

At least six centres across Australia and New Zealand will be involved in the upcoming international trauma study. This study is a multi-center, randomized, double-blind, parallel group, placebo controlled trial. The objective of the trial is to evaluate the efficacy and safety of rFVIIa as an adjunct to standard treatment of trauma patients with active haemorrhage refractory to treatment.

The primary outcomes of the study will focus on the number of transfused units of red blood cells (RBC) within 24 hours after the first dose of study drug and the incidence of multi-organ failure (from hour 48 through Day 30).

Intracerebral Haemorrhage

Four centres across Australia will be involved in the international ICH study – a randomised, double-blind, placebo controlled, confirmatory efficacy and safety trial of rFVIIa in acute intracerebral haemorrhage.

The main objective being to evaluate the efficacy and safety of rFVIIa in reducing disability and improving clinical outcome by preventing early haematoma growth in patients with acute intracerebral haemorrhage as assessed by the primary endpoint of 90 day modified Rankin Scale score.



The Haemostasis Registry stand at ANZCA

Frequently Asked Questions

Do we need full Ethics Approval or can the project be considered as a Quality Assurance project?

This varies from hospital to hospital. Some ethics committees will allow it as a QA project, but others prefer to consider a full ethics submission, mostly because the information, even though de-identified, is being sent out of the hospital. A quick phone call to your ethics committee may save you the work of a full ethics submission, so it is worth checking first. Staff at the Haemostasis Registry are experienced in preparing ethics applications and are happy to prepare ethics submissions in collaboration with you.

We have been collecting data already in our hospital, can we submit old cases to the Registry?

Yes. Collection of retrospective data will be allowed subject to three strict rules;

1. You must have your own hospital ethics committee approval to submit this data,
 2. All data must be complete and submitted on our current Haemostasis Registry data forms,
 3. All cases of use of rFVIIa in your hospital within the specified period must be included – this is to avoid people submitting their ‘favourite’ or ‘special’ cases without all the others.
- To ensure the integrity of our data we need to have the good, the bad and the ugly. Hospitals will be reimbursed for the collection of retrospective data at the same rate as contemporaneous data.

I have some interesting cases that I was thinking about publishing as a case series. If I submit the data to the Registry can I still publish?

Yes. There would be no impediment to you publishing data about cases from your own hospital. We also hope that some of the contributors to the Registry will become involved in our publications too. We are planning to establish publication sub-committees in various specialty interest areas to work on publications in those fields – please let us know if you have a particular interest. In addition, if you are interested in looking at Registry data from a particular angle, and we are not

planning to tackle that area, you can apply to the Steering Committee to use Registry data.

Why are we not getting consent from patients to have their details sent to the Registry?

It has been shown in the past that by requiring consent for projects such as the Haemostasis Registry, data from a number of important patients is lost. This is either because they die or are discharged before consent is gained or because they choose not to consent. Some sub-groups of the population are less likely to give consent than others. Data on efficacy and particularly on adverse events may be skewed if these subgroups are lost. In the Canadian Stroke Network (*NEJM 2004; 350:14*) major selection bias was found through the process of requiring consent.

In the case of the Haemostasis Registry the information we are collecting is not particularly sensitive and all information is de-identified before being sent to the Registry. The impingement on patient privacy is, therefore, minimal. When weighed up against the public good that will be obtained by the results of Haemostasis Registry, we believe that it is reasonable to request ethics approval to collect data without consent.

Steering Committee

The next Steering Committee Meeting will be at the end of August. If you have any issues you would like the Steering Committee to discuss, please contact the Registry.

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haemostasis registry

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Meet the Registry Staff



Project Manager
Dr Louise Phillips

Louise is the main person involved with the day-to-day running of the Registry and the person you are most likely to have talked to or corresponded with.

Louise has a very “interesting” and unusual background for this sort of work – she obtained her PhD for research in the area of taxonomy of red seaweeds! However, for the past year she has been applying her research skills in the Emergency and Trauma Centre at the Alfred Hospital in Melbourne before moving into the Department of Epidemiology and Preventive Medicine at Monash to take on the challenge of the Haemostasis Registry.

What is the main difference between working in marine botany and in medical research? “Definitely ethics – no one cares too much about the ethics of cutting up seaweed specimens, but in the short time I’ve worked in medical research I have gained a lot of experience with the vagaries of ethics committees”

In addition to working on ethics submissions, Louise is responsible for communication with the hospitals, overseeing the data entry and validation, quality measures and reporting and will be coordinating the publications arising from the Registry data.