

Royal Free Hospital
Pond Street
London NW3 2QG

Tel 020 7794 0500
Fax 020 7830 2468

HAEMOPHILIA CENTRE & HAEMOSTASIS UNIT

Director: Professor Edward Tuddenham MBBS MD FRCP FRCPath
Locum Consultant: Dr Thynn Thynn Yee MBBS MSc MD MRCP
Consultant: Dr Pratima Chowdary MBBS, MRCP, MRCPath

Dr Barry White
Director
National Centre for hereditary Coagulation Disorders
St James Hospital
Dublin 8
Ireland

23rd January 2007

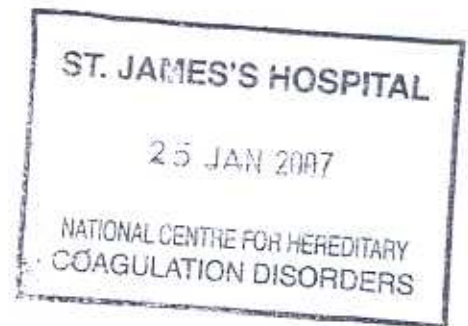
Dear Barry

I enclose a copy of the final Haemophilia Audit report signed by Mike and myself. It was a great pleasure to see you again. With my very best wishes to you and the family - and your very impressive haemophilia team.

Kind regards



Chris Harrington
Nurse Consultant in Haemophilia



**Report of Haemophilia Audit
National Centre for Hereditary Coagulation Disorders (NCHCD)
St. James's Hospital, Dublin**

Date of Audit: 13th November 2006

Auditors:

a) Dr Mike Makris,
Haemophilia Director
Sheffield Haemophilia and Thrombosis Centre, Sheffield, UK

b) Christine Harrington,
Nurse Consultant,
Katharine Dormandy Haemophilia Centre & Haemostasis Unit
Royal Free Hospital, London, UK

Summary:

This is a high quality haemophilia centre providing all the services expected from a Comprehensive Care Centre. In addition it is taking on the role of the national centre. Some of the developments such as the Advent factor tracking system and the Clintech data system are innovations of major importance to the haemophilia community internationally.

Two problems that were identified in the last audit 3 years ago continue and potentially compromise the otherwise excellent service. These are the poor inpatient facilities for patients with haemophilia and related inherited bleeding disorders and the lack of a formalized 24hour on-call rota for specialized coagulation tests.

Recommendations:

Major

a) Improved and preferably centralized and protected beds for inpatients with haemophilia should be identified. The nurses covering these beds will need to be trained in haemophilia care.

b) There should be a formalized 24 hour coagulation laboratory on call rota for the performance of specialized tests such as factor VIII assays.

Other recommendations

a) An audit of the hepatitis C RNA positive patients should be conducted to determine the reasons for reported poor uptake of recommended PEG interferon and ribavirin treatment.

b) Better signs are required within the hospital grounds to direct patients to the NCHCD. It would also be helpful for the receptionist in the main hospital to have maps of the hospital grounds to give to patients when directing them to the NCHCD.

c) A nurse representative should sit on the Product Selection Advisory Group

d) As a national centre for specialized coagulation tests it should offer VWF multimer, platelet nucleotide, and FVIII binding in-house rather than sending these to the UK. The coagulation laboratory should be encouraged to develop an R & D program with a clinical emphasis

e) The molecular genetics laboratory should be distinct from the research department and consideration should be given to integrating it with other molecular diagnostic testing in the hospital.

Background

This is the second triennial audit of the NCHCD. In the absence of a local Irish audit tool, the audit was performed according to the UK Haemophilia Centre Doctors Organisation (UKHCDO) audit tool using the format of the UK Haemophilia Centre audits.

The intention was to have a patient representative on the audit panel. However, there are as yet unresolved issues in the UK including the selection, recruitment and training of patient auditors, revision of the audit tool and clarification of the role of the patient auditor. It is the view of the auditors that future audits should incorporate an independent patient perspective.

Haemophilia Centre Staff

Consultants

Dr Barry White (Director)
Dr Beatrice Nolan
Dr James O'Donnel

Nurses

Haemophilia Nurse Manager - Jude Smith
Haemophilia Clinical Nurse Specialist – Victoria Graham
Haemophilia Clinical Nurse Specialist – Eadaoin O'Shea
HIV and Hepatitis C Clinical Nurse Specialist – Janet Cleary
Haemophilia Clinical Nurse Specialist – Ann O'Sullivan
Staff Nurse – Carmel Egan
Staff Nurse – Helen Shiel
Haemovigilance Officer – Evelyn Singleton

Other staff

Quality assurance officer – Margaret Cahill
Social worker – Olwen Halvey
Psychologist – Sarah Jameson
Physiotherapist – Emma Sherlock

Number of patients registered

The total number of patients registered is 2147. Of these 167 have severe haemophilia A, 46 severe haemophilia B and 2 severe von Willebrand's disease. Eight patients have active inhibitors.

936 clotting factor infusions were administered during 2005 of which 637 were to inpatients and 299 to outpatients.

The Haemophilia Centre

The National Centre for Hereditary Coagulation Disorders is based at St James's Hospital with its own stand alone facility.

The centre employs 30 staff and is currently implementing an electronic patient record system.

The NCHCD offers:

- Diagnostic coagulation laboratory
- Shared inpatient facilities
- Day care ward
- Outpatient clinic
- Genetic counseling service
- Psychology/social work service
- Physiotherapy service
- Dental service
- Orthopedic service

All the expected facilities are available.

Car parking remains a problem. Although there are two protected spaces, other patients park in these. There are plans to expand the protected parking spaces to four, which should help, provided a way to prevent other patients and staff parking in them is identified.

The sign posting within the hospital grounds is poor. The Centre will be difficult to find if patients have not previously been to the centre. It is suggested that the receptionist in the main hospital gives visitors and patients a map of the hospital grounds when directing them to the centre.

The lift within the haemophilia centre is too small to take a trolley and this is a potential problem if very ill patients have to be transferred from the 1st floor of the haemophilia centre. This should be taken into account when any future developments to the facility are planned.

Coagulation factor stock control, storage and issue

Since the last audit, home delivery of concentrates has been introduced. This is run by a commercial company called TCP and it is working very well.

Although until now they were unable to collect used equipment and vials from patients' houses, this is likely to change in the very near future.

All clotting factors used in Ireland are traced using a computer program called Advent whose use is closely monitored by the Haemovigilance Officer. The facilities in place to trace and document every bottle of concentrate are far superior to anything either of the auditors have come across previously.

Although only 50% of patients record their home usage this is comparable with other haemophilia centres in the UK. There are plans to improve this with the introduction of an electronic keypad.

An active quality assurance programme is demonstrated. Patients views have been sought in a number of surveys including satisfaction with home delivery of clotting factor and patient experience of nurse-led clinics. New nursing staff have a structured induction and teaching programme. It is evident that there is a culture of continuous professional development and that this is supported and resourced.

A National Haemophilia Conference and two-day coagulation course are run by the Centre.

The Haemostasis laboratory facility

The laboratory is within the stand alone haemophilia centre. The laboratory space and staffing are very generous in comparison to the other haemophilia centres audited in Ireland. The laboratory has full CPA accreditation.

Two laboratory issues were identified during the audit:

a) Although most specialized coagulation assays are offered, VWF multimers, FVIII binding tests and platelet granular constituents are sent to the Royal Free Hospital in London for analysis. It is unacceptable to have a National Centre for Coagulation and send samples for these tests abroad for analysis. A structured R&D program should be introduced in the laboratory and these 3 assays should be the first to be developed and introduced into the routine care.

b) Clotting factor assays are only formally offered during working hours. At night and at weekends if a factor assay is required, members of the laboratory staff are telephoned and if they are free they come in to do the assay. This is an unacceptable risk to the hospital. It was identified in the last audit and has still not been resolved. A formalized 24 hour on call for specialized coagulation tests should be in place in the National Centre for coagulation disorders.

A haemophilia genetic testing facility is provided. The facility was not inspected by the auditors. The UKHCDO has a separate audit program of genetic testing facilities and it is recommended that the NCHCD service takes part in this. Currently the genetics laboratory is situated in a research facility at the opposite end of the hospital site from the haemophilia centre. The routine clinical molecular genetics laboratory should be distinct from the research facility. One possible solution to this would be to integrate it with other molecular diagnostic testing facilities in the hospital.

Paediatric care facilities

This is not applicable as children are now cared for at the dedicated haemophilia centre at the Crumlin site.

Treatment delivery

The haemophilia centre has four consultation rooms, a treatment room with two beds on the first floor, a dedicated phlebotomy room, two dental suites and a social work office. The treatment facility provision in the haemophilia centre is excellent. Universal cross infection procedures are in place.

There are appropriate mechanisms for the regular review of patients. Haemophilia care at St James Hospital is consultant led. There is a 1 in 3 consultant on call service. There are excellent evidence-based protocols and guidelines for all key areas of treatment and management. These guidelines are shared with other Centres in Ireland and illustrate one aspect of the National role of the Centre in leading practice. The auditors also commend the Centre on their nurse-led clinics for genetic counseling and for new-patients. These have been set up in a thorough and robust manner to enhance the service for patients and family members.

The main problem with the delivery of care at the St James site is the lack of an inpatient facility. Although patients are admitted to the haematology/oncology ward it is often difficult to find a bed and the ideal would be a new dedicated inpatient facility for haemophilia. During the visit the auditors met with the Hospital's Chief Executive who assured them that within two and a half years the inpatient facility will be in place.

Availability of comprehensive care services

All the services required to provide a comprehensive care service as detailed in standard 5.1 of the audit tool are available at the centre. The auditors had the opportunity to meet with the social worker and physiotherapist, both of whom are whole-time appointments dedicated to haemophilia. Both are able to provide an impressive and fully comprehensive range of services for patients.

Patient medical records review

Eight sets of medical charts were selected at random for review. The quality of the charts is satisfactory. Although only 1 of 8 charts included a family tree in the volume of notes examined (some patients had earlier volumes of notes), this is less likely to be an issue than in other haemophilia centres due to the good genetic counseling service, including updating of family pedigrees, offered by two Haemophilia Clinical Nurse Specialists.

Clinical governance, audit, teaching, CPD and research

There is good evidence of participation in all these activities. An impressive research program funded to the level of 2.3million Euro is about to commence. Most of this research is however in basic science. Considering the coagulation laboratory facility within the haemophilia centre, a program of R&D within this laboratory could be developed to allow the laboratory to progress at the same pace as other aspects of the haemophilia centre.

The nursing complement and expertise of the centre should allow nursing research to take place and this should be encouraged. The national role of the centre creates the opportunity for the haemophilia nurses to demonstrate clinical nursing leadership further and influence haemophilia care in Ireland.

Patient questionnaires

Thirty questionnaires were sent to patients selected by the auditors at random (from an anonymised list provided).

13 of 30 (43%) questionnaires were returned.

Patients were in general very happy with the service. The home delivery was greatly appreciated

There were some negative comments about the waiting time in clinics, but it was appreciated that this was often necessary when more than one health professional was seen.

"You don't mind waiting when you get such a high level of attention". "Always there, always ready to help".

Patients were asked to comment what was particularly good about the center and the most common comment was the staff. "The staff have remained down to earth and approachable, while still remaining top class professionals". "Staff are engaging, compassionate and thorough".

Patients were also asked what they felt was in most need for improvement and the responses were:

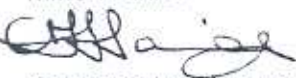
- Access to beds in the main hospital
- Waiting times at clinics and especially when attending out of hours
- Delays at night when having to go to the Accident and Emergency department, rather than being seen on a ward
- Tea/coffee machine in the waiting room
- Car parking

The final section of the questionnaire asked for any other comments. One comment here we feel reflects the comments from the questionnaires "I am very grateful to the service we receive from all the carers, who are our friends as well as medical providers".

Signed

M. Makris 12 January 2007

Mike Makris Date

 22 JAN 2007

Christine Harrington Date