

Audit: Cork Coagulation Centre

Date of Audit: 26th March 2014

Name and address of audited centre:

Cork Coagulation Centre, Cork University Hospital, Wilton, Cork, Ireland

Director(s):

Dr Susan O Shea, Consultant Haematologist (18.5hr/week, WTE 0.5)

Number of consultants

Dr Cleona Duggan, Consultant Haematologist (18.5hr/week, WTE 0.5)

Dr Clodagh Ryan, Consultant Haematologist (6hr/week)

Nursing staff (Bands/Job Title/WTEs):

WTE = 2.4

Helen Browne (31.20hr/week)

Brid Booth Fleming (18hr/week)

Annmarie Ryan Hall (18hr/week)

Norma Collins (21.01hr/week)

Physiotherapist:

No dedicated physiotherapist

Hospital physiotherapist (Nora Bradley) attends weekly adult and paediatric clinic as needed

Supporting staff [Data Manager/Secretary]:

Secretary to Dr Susan O Shea, Dr Cleona Duggan and Dr Clodagh Ryan – Mary Dinneen (35hr/week)

Data Manager – Emily Lynch (16hr/week, WTE 0.4). This is a temporary position.

Audit Team

Medical Auditor: Dr. David Perry

Nursing Auditor: Ms. Chris Harrington

Patient/Parent/Carer Auditor[s]: Mr. David Page

Scientific [Genetics Network] Auditor: Dr. Marian Hill

Date of Audit Visit: 26th March 2014

Date of Submission of Draft Audit Report to Centre: 13th June 2014

Date of Submission of Finalised Report: 1st August 2014

Audit Standards

A series of standards are provided and against which the Centre should be audited. Free text boxes are available at the end of each section for comments.

The audit document is divided into 5 sections:

- 1. Medical/Nursing/Patient-Parent**
- 2. Medical/Nursing Section**
- 3. Patient-Parent Section**
- 4. Genetics Section**
- 5. Summary**

The sections should be combined at the end of the audit to generate the final audit document

Satisfactory:	Meets minimal acceptable standards
Unsatisfactory:	Falls below minimal acceptable standards

Areas which the auditors consider to be outstanding, can be highlighted in the free text boxes. Areas of Best Practice can be summarised at the end of the audit document.

Part 1: Medical-Nursing/Patient-Parent Audit Component

1.1 The Haemophilia Centre

The audit team should note the location, layout, adjacencies etc. of the Centre and a full description of the Centre should be included in the audit report. This information may be provided in advance of the audit by the Centre.

The Cork Coagulation Centre (CCC), Cork University Hospital provides multidisciplinary comprehensive care and services to adults and children with bleeding disorders, encompassing investigation, diagnosis and management. There is close liaison with the other recognised Haemophilia centres in Ireland to promote the provision of high quality Haemophilia care nationally.

There is direct access to the centre from the outside of the hospital. There is a set down facility at the entrance to the centre, along with two disabled parking spaces. The centre is signposted from the main entrance to Cork University Hospital. If approaching from within the hospital there are also signposts from the main reception. The centre is located in the outpatient area of the hospital adjacent to the phlebotomy clinic and emergency departments. Directions to the centre are provided with new patient appointment letters. There is a patient information leaflet which is also available on the HSE website. The unit is open 8.30am to 5pm Monday to Friday.

The Coagulation Centre itself consists of:

- Dedicated waiting area with television, patient information leaflets and children's toys
- Office area for centre secretary and data manager
- Treatment area comprising: 4 outpatient rooms including a larger treatment room
- Patient and staff toilet facilities
- Clinics held include:

Adult bleeding disorder clinic (Alternate Mondays)

- Paediatric bleeding disorder clinic (Alternate Mondays)
- Nurse led clinics run Tuesday to Friday including: vaccination clinic, pre assessment clinic, investigations clinic, genetic clinic, factor clinic, education clinic, DDAVP trials clinic, DDAVP treatment clinic
- Daily drop in & emergency assessment clinic

Physiotherapy service is provided at adult and paediatric clinics, as required, by a dedicated physiotherapist. Annual joint assessment is performed on all patients with bleeding disorders at their clinic review.

A paediatric dental assessment service is in place since 2010 and runs concurrent with the paediatric clinic. This assessment service is linked to community dentistry, and dental work, if required, is mainly performed by the community dentistry team. A similar assessment service is in development for the adult service and is planned to be established by December 2014.

Orthopaedic referral is available in the CUH for both acute and semi acute issues and referral to the National Centre for Hereditary Coagulation Disorders is arranged if required (for joint replacements).

The centre also provides a diagnostic coagulation laboratory for the HSE South which is located within the main hospital haematology laboratory.

Cork University Hospital is the only Level One Trauma Hospital in the country, providing all acute services to the region. The staff of the centre liaise closely with all specialties, and manage haemostatic support for their cohort with bleeding disorders presenting to these services.

Patient Demographics

The total number of (active) registered patients with Bleeding Disorders is: **590**
The breakdown of patients attending the Cork Coagulation Centre is as follows:

Diagnosis	Number of patients	
	Adult	Paediatric
Von Willebrand Disease Type 1	86	39
Possible Von Willebrand Disease	19	1
Von Willebrand Disease Unspecified	10	2
Von Willebrand Disease type 2N	2	2
Low Von Willebrand factor	1	0
Von Willebrand Disease type 2A	2	1
Von Willebrand Disease type 2M	1	0
Von Willebrand Disease type 2B	2	0
Factor VIII deficiency mild	50	10
Factor VIII deficiency moderate	2	1
Factor VIII deficiency severe	16	16
Acquired factor VIII deficiency	1	0
Possible factor VIII deficiency carrier	10	16
Factor VIII deficiency carrier	46	15
Inherited factor VIII deficiency with inhibitor	3	2
Factor VII deficiency	5	1
Factor IX deficiency mild	8	1
Factor IX deficiency moderate	0	0
Factor IX deficiency severe	5	2
Factor IX deficiency carrier	3	0
Possible factor IX deficiency carrier	0	2
Bleeding disorder of unknown aetiology	12	0
Factor XI deficiency	7	0
Factor V deficiency	5	1
Factor X deficiency	4	0
Factor XII deficiency	5	3
Platelet function defect	12	1
Glanzmann's Thrombasthenia	1	0
Ehlers Danlos	0	1
Congenital Thrombocytopenia	3	0

These figures do not include patients with thrombotic disorders who are also cared for by the Consultants in this centre.

Departmental Haematology report was available for viewing on the day of the audit.

Additional Clinics staffed by the Centre Consultants include:

- High Risk Obstetric Haematology Clinic (Alternate Mondays)
- Complicated Thrombosis Clinic: Each Tuesday
- Anticoagulant Management Clinic (Thursday Afternoon)

The Consultants also have responsibility for management of the Anticoagulant Clinic with approximately 16,000 patient visits/year.

In 2012 there were **292** appointments in the **Adult Bleeding Disorder** clinic, comprising:

- 80 new patient appointments
- 209 follow up appointments
- 84 “did not attend” appointments (29%)
- 1 walk in follow-up appointment
- 2 walk in new appointments

In 2013 there were **294** appointments in the **Adult Bleeding disorder** clinic, comprising:

- 94 new patient appointments
- 194 follow up appointments
- 79 “did not attend” appointments (27%)
- 4 walk in follow-up appointments
- 2 walk in new appointments

In 2012 there were **136** appointments in the **Paediatric Bleeding Disorder** clinic, comprising:

- 46 new patient appointments
- 88 follow up appointments
- 12 “did not attend” appointments (9%)
- 1 walk in follow-up appointment
- 1 walk in new appointment

In 2013 there were **176** appointments in the **Paediatric Bleeding Disorder** clinic, comprising:

- 55 new patient appointments
- 113 follow up appointments
- 26 “did not attend” appointments (15%)
- 6 walk in follow-up appointments
- 2 walk in follow-up appointments

In 2012 attendances at **nurse led clinics** were as follows:

- Genetic clinic - 33 appointments
- Vaccination clinic - 37 appointments
- Pre-assessment clinic - 36 appointments

In 2013 attendances at **nurse led clinics** were as follows:

- Genetic clinic - 40 appointments
- Investigations clinic (includes emergency assessments)- 195 appointments
- Vaccination clinic - 59 appointments
- Factor clinic (includes emergency treatments)- 68 appointments
- Education clinic - 24 appointments
- Pre-assessment clinic - 66 appointments
- DDAVP trials clinic - 22 appointments
- DDAVP treatment clinic (Includes emergency treatments) - 19 appointments

1.2 Coagulation Factor Stock Control, Storage & Issue

Audit Standard: CCCs should have in place adequate procedures for factor concentrate ordering, storage, stock control, recording of issue to patients and their use by patients.

1. Procedures for the ordering of factor concentrate

Satisfactory

~~Unsatisfactory~~

2. Facilities for the storage of concentrate

Satisfactory

~~Unsatisfactory~~

3. Procedures for stock control

Satisfactory

~~Unsatisfactory~~

4. Procedures for recording of concentrate issues to patients

Satisfactory

~~Unsatisfactory~~

5. If home delivery service in place, adequate recording of concentrate issuing by company

Satisfactory

~~Unsatisfactory~~

6. Procedures for recording concentrate usage by patients on home treatment (e.g. Haemtrack, paper records) and documented evidence that this is being undertaken

Satisfactory

~~Unsatisfactory~~

Comments:

No major problems were identified.

Recording of clotting factor concentrate usage is either paper-based or using a smart phone app. 52% of patients on home treatment currently use the smart phone app.

There were concerns regarding the additional barcode labelling of concentrates and the potential for error.

1.3 Treatment

Audit Standard: Patients who are actively bleeding receive prompt and effective treatment according to established protocols throughout the 24-hour period. Appropriate arrangements are in place for routine patient review and liaison with local haemophilia centres for shared-care patients. Adequate mechanisms and protocols are in place for home treatment, prophylactic administration of concentrate and management of inhibitor patients where appropriate. General and genetic counselling is readily available for patients and their families.

1. There is an appropriate treatment area that provides privacy and comfort

Satisfactory

Unsatisfactory

2. Universal cross-infection precautions are in place

Satisfactory

Unsatisfactory

3. There is effective recording of patients' vCJD at risk status and appropriate health care measures are in place for 'at risk' patients.

Satisfactory

Unsatisfactory

4. There is evidence of regular review of patients

Satisfactory

Unsatisfactory

5. There is in place a formalised pathway protocol for out-of-hours patient review and care

Satisfactory

Unsatisfactory

6. Consultant haemophilia medical staff are available 24 hours a day for treatment advice.

Satisfactory

Unsatisfactory

7. There is evidence of effective community liaison between the unit and the patient in their home and with primary care providers

Satisfactory

Unsatisfactory

8. There is evidence of treatment in the community by nursing staff [This may be not available in some/many centres]

Satisfactory

Unsatisfactory

9. Written protocols/guidelines/procedures are available for the following:

	Satisfactory	Unsatisfactory	N/A
1. Management of bleeding episodes	Yes		
2. Commencement of home treatment/Venous access training	Yes		
3. Commencement of prophylaxis in children	Yes		
4. Management of inhibitor patients (including immune tolerance)	Yes		
5. Treatment in the Emergency Department	Yes		
6. Management of pregnancy/delivery	Yes		
7. Genetic counselling	Yes		
8. Management of surgery	Yes		
9. Transitional care	Yes		

10. Detail the mechanisms in place for orientation of medical/nursing staff for procedural training.

The haemophilia nurse specialists undertake regular orientation and training of medical and nursing staff regarding ordering, documentation and administration of factor concentrates.

This includes:

- Education of NCHD members of the haematology team which is done each time there is rotation of staff
- Educational session once every six months to the emergency department medical and nursing staff
- Coagulation Centre Clinical Nurse Specialists deliver training to ward staff, including general nursing staff and Clinical Nurse Managers

In addition the haematology specialist registrar teaching programme, which is consultant delivered every Thursday morning, includes sessions relating to bleeding disorders.

1.4 Relationship between Comprehensive Care Centre and Neighbouring Haemophilia Centres

1. List of Haemophilia Centres in locality of CCC

- University Hospital Limerick
- Waterford Regional Hospital

All other hospitals within the hospital group do not have a clinical consultant haematologist on site. The Coagulation Centre has communicated to all hospitals in the HSE South/South East Network, informing them of the services provided by the centre, including out of hours. The Centre recommends that all patients with a known bleeding disorder are reviewed in the CCC annually.

The Centre supports the proposal for all hospitals in the region, particularly the emergency departments, to have read only access to Clintech (the EPR for patients with bleeding disorders). The National Haemostasis Guidelines are available on the National Haemophilia Council website.

2. Is there a formal network arrangement between the CCC and the neighbouring Haemophilia Centres?

Yes No

3. If yes, assess the arrangements with regard to the following:

There is shared patient care

Yes No

If so, shared care arrangements are satisfactory

Yes No

There is effective liaison between the CCC and the HC for advice/patient referral over the 24-hour period

Yes No

There are shared treatment protocols/guidelines

Yes No

There are adequate arrangements for the supply of factor concentrate to the HC

Yes No

Comments including any that relate to feedback from regional Haemophilia Centres

No major problems were identified. However the feedback from patients at other centres [albeit a small number of patients] indicated some concerns – see patient feedback summary in the document.

1.5 Age Appropriate Treatment Facilities and Services – If Relevant

	Satisfactory	Unsatisfactory
Appropriate paediatric in-patient and out-patient facilities	Yes	
Child friendly waiting/play area and toys	Yes	
Child friendly treatment area	Yes	
Out-of-hours treatment facilities	Yes	
Paediatric resuscitation facilities	Yes	
Training in paediatric resuscitation	Yes	
Use of local anaesthetic creams and distraction techniques	Yes	
Appropriate transitional arrangements for the transfer of adolescents to adult services are in place	Yes	
Effective outcome monitoring of patients on prophylaxis	Yes	

COMMENTS

No major problems were identified.

The waiting area could, however be more child friendly.

1.6 Availability of Comprehensive Care Services

Audit Standard: Services required to provide a comprehensive care service are available as detailed in the Haemophilia Alliance National Service Specification. This will be replaced in 2013/2014 by the Clinical Reference Group [CRG] Specification.

A full description of these should be included in the free text audit report.

The following services/personnel are available;

	Yes	No
Centre receptionist/secretary	The centre has a secretary but her work is not confined to haemostasis services. The Secretary is shared between the three consultants. There is no dedicated administrative support for nurse led clinics	No centre receptionist
Centre data/business manager		Temporary position (2 days/ week)
Access to a social worker		No but access to hospital social work department
Dedicated Physiotherapist		On request, attends clinic
Access to a Psychologist/Counsellor		Refer to NCHCD Dublin
Dental service/Dentist (a full description of the service offered should be included)		Paediatric clinic only Adult service in development
Orthopaedic service/Orthopaedic surgeon		Referral to NCHCD
General/Specialist surgical services		Referral as needed
HIV physician	Professor Mary Horgan	

Hepatologist	Dr Orla Crosby	
Obstetric/Gynaecology service/Surgeon	On-site combined haematology/obstetric clinic	
Paediatrician (in paediatric or Paediatric/adult centre)	Dr Clodagh Ryan	
Dietician		On referral only
Genetic Counselling Services [Provide a description of the service and how this is accessed]	Regular clinic	
Antenatal diagnosis arrangements		High risk patient clinic in Cork University Maternity Hospital
Home Delivery [Comments]	National programme	
Access to Occupational Therapy		On referral
Access to Benefits Advice		Refer patients to Irish Haemophilia Society. Refer patients to hospital social work department

COMMENTS:

(Any contacts made with multidisciplinary staff during the visit should be noted.)

1. The data manager from St James's hospital attends the Centre 2-3X/annum. This should be monthly but this has been difficult to institute.

The service at present is reactive rather than proactive in terms of data management. It would seem logical to merge the data manager and quality control manager posts leading to a single post that would take on both roles. This post would also have responsibility for Haemovigilance. Currently the Haemovigilance post is a national one, based at St. James's hospital. There is no dedicated local Haemovigilance officer in Cork. This service is provided by the haemophilia nurse specialists. The CUH Haemovigilance officer does not have any input into haemophilia service.

2. Physiotherapy: There is no dedicated physiotherapist and this has to be requested when needed and in general he/she is only available for only 10% of the time required. The physiotherapist is unable to be present for all clinics and cannot see emergency 'walk-in' patients. Consideration should be given as to how this fundamentally important role can be expanded [e.g. at least 0.5 WTE] and integrated more closely with the specialist haemophilia physiotherapy services at the Crumlin Hospital and St James's Hospital. The physiotherapist should be part of the MDT and encouraged to attend these meetings but time constraints mean that this is impossible.

3. Administrative support: The numbers of patients attending the Haemophilia Service have increased significantly because they can clearly see the benefits. The service has expanded significantly without necessarily considering the impact on resources. Nurses are currently responsible for obtaining case notes in advance of clinics, making appointments, sorting out blood tests forms, capturing the Centre's activities – roles which could be undertaken by an administrative assistant.

4. Receptionist: There is no receptionist and this role is currently undertaken by the departmental secretary who works part-time to support the coagulation centre but who also has a significant commitment to the general haematology service. Consideration should be given as to how this can be addressed..

5. The consultant workload is onerous and this is of concern. The consultants have in addition to their role within the Haemophilia Centre, roles within the Haematology department including general haematology clinics, Haematology-Obstetric clinics, general laboratory commitments, blood bank governance, clinical (including both ward commitments and consultation referrals) and the management of patients with malignant disorders.

Consideration should be given as to how they workload can be reduced allowing them more time for the provision of care for patients and their families with inherited bleeding disorders.

6. There is no dedicated social worker/counselling team attached to the centre. This is a core component of comprehensive care for haemophilia and some dedicated time should be integrated into the team.

1.7 Patient Choice & Experience

1. How you been able to access information about your local CCC that allows you compare the services it offers with other CCCs?
2. Are there any Patient Satisfaction Survey/Audits/Focus Groups Reports available?

The CCC has Patient Feedback forms available at all clinics for completion by patients. These were available for viewing on day of audit.

The National Home Treatment Satisfaction Survey is currently in progress. The questionnaire was available for viewing along with completed questionnaires.

The Irish Haemophilia Society has attended the unit biannually, providing information sessions for patients attending the clinic, and also inviting the patient group, allowing a forum to raise issues that impact the care of haemophilia patients. The staff of the centre, both medical and nursing, meet with those attending the forum on the date and provide an update on the activities of the centre. This forum also allows the patient group to discuss issues relating to their care with the staff of the centre.

1.8 Clinical Governance, Audit, Teaching, CPD & Research

Audit Standard: There is evidence that CCC staff participate in clinical governance, audit and teaching activities. There is evidence that unit staff undergo regular personal performance review and participate in CPD schemes. The unit participates in clinical trials and active research.

1. CCC staff participate in clinical governance and audit activities?

YES

NO

2.1 List audits performed in the last 3 years

- Audit of adherence of documentation, prescription and traceability of coagulation factor concentrate (CFC) in Form 15.
- Audit of application of an ICD code to patients registered on the Clintech system.
- Audit of the percentage of patients who “did not attend” clinic appointments in the CCC 2012 & 2013.
- Audit of the genetic clinic service in CCC.
- Audit of the percentage of factor VIII and IX (mild, moderate) deficient patients who have had mutational analysis performed.
- Report on the number of patients attending adult bleeding disorder and paediatric bleeding disorder clinics in 2012 & 2013.
- Report on the number of patients attending nurse led clinics in 2012 & 2013.
- Audit to assess regular follow up of factor VIII and factor IX patients in the CCC.
- Audit to assess the number of patient admissions to the CCC as a day patient as opposed to being admitted as an in-patient following a joint bleed or minor trauma.
- Report on the breakdown of patient conditions in CCC.
- Audit on the method of recording of factor concentrate usage among patients on home treatment.
- Audit to assess if joint score performed annually for severe factor VIII and IX deficient patients.
- Audit of thrombophilia Testing and introduction of New Guideline
- Audit of testing for Heparin induced Thrombocytopenia with Introduction of New Guideline.

In addition there are a large number of audits carried out by the anticoagulation clinic each year (available for viewing on the day).

The Coagulation Laboratory participates in the Haematology Annual audit schedule and these audits are available for review on the day on Q pulse, as well as a supplementary folder.

2.2 Discuss the changes in practice that have arisen from these audits and how these are monitored?

[All of these audits and results with changes are available for viewing on the day of the audit visit.]

3. CCC staff participate in teaching?

YES NO

Give examples of teaching activities:

- Nurse specialist teaching to NCHDs, Emergency department staff, Paediatric and Obstetric staff
- Consultant Specialist Registrar teaching
- Weekly Consultant delivered SpR teaching each Thursday Morning.
- (Please see teaching schedule/topics in supplementary folder)
- Annual National Haematology SpR update
- Consultant Laboratory staff teaching
- Weekly Haematology Department Journal Club (schedule available for review)
- Undergraduate University College Cork Medical Students – formal lectures to MED II /III/ IV, Dental II/III
- Annual National Anticoagulation Nursing Forum Update
- Biannual Obstetric Haematology Update
- Registrar /SHO training – Formal Induction at each changeover.

4. CCC staff undergo regular performance review?

YES NO

5. CCC staff participate in continuing professional development?

YES NO

6. The unit participates in clinical trials:

YES NO

7. The unit participates in clinical research:

YES NO

The Centre is currently involved in the following Research Projects:

- Designing patient-specific factor VIII treatment regimens for haemophilia A based upon individual pharmacokinetic profiles
(Maeve Crowley, S O'Shea, James O'Donnell)
- Assessment of the effect of novel anticoagulants on routine and new laboratory coagulation assays in Cork University Hospital
(Shane Quinn & S O'Shea)

- Crowley MP, Eustace JA, O'Shea SI, Gilligan OM. Thromboprophylaxis in Myeloma: A National Survey. American Society of Hematology annual meeting in New Orleans, December 2013 (Abstract #1694)
- Crowley MP, Noone C, Higgins JR, O'Shea S. Venous Thromboembolism (VTE) prophylaxis in hospitalized obstetric patients: a multicentre cross-sectional study. European Haematology Association Meeting June 2013 (Abstract #1067P)
- Crowley MP, Kevane B, Madden M. The D Dimer test in the diagnosis of venous thrombo-embolism – an audit of its utilization in an Irish teaching hospital and a survey of junior doctor knowledge of its uses and limitations. European Haematology Association Meeting June 2012 (Abstract #1032P)
- Crowley MP, Noone C, Higgins JR, O'Shea S. Venous Thromboembolism (VTE) prophylaxis in hospitalized obstetric patients in Ireland: a multicentre cross-sectional study. XXIV Congress of the International Society on Thrombosis and Haemostasis, Amsterdam July 2013 (Abstract #2707)
- Crowley MP, Gilligan O, O'Shea S. A retrospective review of myeloma patients over a 6 year period to investigate the prevalence of venous thromboembolism (VTE) and the risk factors associated with it. XXIV Congress of the International Society on Thrombosis and Haemostasis, Amsterdam July 2013 (Abstract #1805)
- Crowley MP, Madden M. An audit of the use of the D Dimer test in the diagnosis of venous thromboembolism (VTE) in an Irish teaching hospital and a survey of NCHD knowledge of this test – Haematology Association of Ireland Annual Meeting 2011
Crowley MP, Eustace JA, O'Shea S, Gilligan O.
- Venous thromboembolism in patients with myeloma: incidence and risk factors in a 'real world' population. Clin Appl Thromb Hemost. 2014 Jan 30. [Epub ahead of print]
- Crowley MP, Kevane B. The need for an accurate understanding of the D Dimer assay by those requesting the test to improve interpretation of the result. www.bmj.com/content/344/bmj.e2985/rr/596423
- Crowley MP. Caution needed prior to large scale introduction of new oral anticoagulants. www.bmj.com/content/345/bmj.e7097/rr/613605
- National Clinical Practice Guideline on Thromboprophylaxis in Pregnancy. This guideline was developed by S O'Shea and J Higgins and has been accepted as a National Guideline by the Institute of Obstetrics and Gynaecology and The Haematology Association of Ireland. It can be viewed at: http://www.rcpi.ie/content/docs/000001/1392_5_media.pdf

In addition the CCC has recently been approved to participate in a Multicentre Study of a Dabigatran Reversal Agent.

COMMENTS:

There is evidence of an active on-going audit and research programme.

2. The Haemostasis Laboratory

Audit Standard: The haematology laboratory in which the CCC haemostasis laboratory is located should have full CPA accreditation. The haemostasis laboratory should be adequately staffed with an appropriate skill mix and have adequate space and facilities to perform an effective diagnostic and monitoring service. The laboratory should participate in a national quality assurance scheme. Clotting factor assays should be available throughout the 24-hour period.

Patients-Parents-Carers in this part of the audit may wish to explore turnaround times for samples and how urgent results are communicated to the referring doctor.

1. The Haemostasis laboratory has full CPA accreditation:

YES NO

If yes, date of last CPA inspection: **2012** [Extended to 31.12.13]

2. The staffing levels and skill mix is adequate to provide an effective service:

YES NO

3. The laboratory space and facilities are adequate:

YES NO

4. The laboratory participates in a national quality assurance scheme in coagulation:

YES NO

5. Has there been any persistent poor performance over the previous two years?

YES NO

If yes, list the problem assays

6. The following tests are available in the haemostasis laboratory:

	YES	NO
All coagulation factor assays	√	
FVIII Inhibitor screening	√	
FVIII Inhibitor quantification	√	
VWF antigen	√	
VWF activity	√	

VWF multimers		Referred to NCHCD
Platelet function testing	√	
Platelet granular constituents		Referred to NCHCD

If any of the above tests are not performed outline the alternative testing arrangements.

See table

7. List any diagnostic tests that are performed not listed above:

8. Coagulation factor assays are always available throughout the 24-hour period:

YES NO

There is no clear on-call laboratory rota but this appears to be dependent upon the goodwill of the staff.

9. A diagnostic genetic laboratory service is provided

[The Genetics Service will be audited separately during the current audit]

YES NO

COMMENTS

There is clear evidence of a high quality, patient-focused service. However, this is achieved with a relatively small number of qualified staff and which makes it very vulnerable. The number of samples processed by the lab has expanded significantly without consideration being given to the impact this has on staff and staffing levels. e.g. the service does not have a dedicated on-call rota and frequently depends upon goodwill to provide an out-of-hours service.

Staffing: There is a rather 'bizarre' – at least to the auditors – method for appointing staff to the coagulation laboratory. We did not fully understand this nor the reasons underlying it. The lab has an urgent need for a scientist with expertise in haemostasis.

The laboratory has applied for INAB accreditation and had a preliminary assessment in June 2014. A final visit is scheduled for October 2014.

3. Paediatric Care In Centres Looking After Children

Audit Standard: The care of children with haemophilia and related disorders can be complex and should only be carried out by staff who are experienced and trained in the management of children. Facilities should be adequate for the care of children.

3.1 Staff qualifications

Medical Staff	Yes	No
Consultant Haematologist has paediatric training and expertise	[√]	
Consultant Paediatric Haematologist	√	
Named Consultant Paediatrician supporting Consultant haematologist (in centres without a Consultant Paediatric Haematologist)	N/A	
Consultant Paediatric Surgeon with experience of implantable venous access devices		Referred to OLCHC
All medical staff involved in managing children should have 'Safeguarding Children Level 3'.	Staff trained in 'Child First' guidelines	
Nursing Staff/Physiotherapist		
Unit nursing staff have appropriate qualification e.g. Registered Sick Children's Nurse(s) (RSCN) RN Child Branch (Project 2000) BA Nursing (Child)	√	
All nursing staff involved in managing children should have 'Safeguarding Children Level 3'	Staff trained in "Child First" guidelines	
Physiotherapist [relevant paediatric qualification]		No dedicated paediatric physiotherapist

COMMENTS:

1. The nursing staff are very experienced and provide a first class service but are concerned re. the lack of consultant input. This is because the consultants in the Centre have other commitments in haematology such that they are not always readily available to see patients with inherited bleeding disorders.

2. The consultant staff that support the centre have many other commitments in laboratory and malignant haematology. As a consequence the time that they can devote to patients

and their families with inherited and acquired bleeding disorders is restricted. There should also be a weekly multidisciplinary meeting to review patient management in a centre of this size and complexity and it is clear that this is not happening on a regular basis apparently due to lack of consultant availability. These are major concerns that we wish to see addressed before the next audit.

3. Similarly there is no dedicated Haemophilia SpR. This is an invaluable training opportunity and in addition an SpR would support the consultant medical and nursing staff within the centre. The lack of training in Haemostasis is an area of concern and should be highlighted to the programme director for haematology.

3.2 General Paediatric Services

	Satisfactory	Unsatisfactory
Availability of trained/experienced physiotherapists		√
Growth and development assessment programme	√	
Availability of play therapist	√	
Liaison with Health Visitors/School nurses	√	
Liaison with nurseries and schools	√	

Comments:

No comments

4. Outcome Measures

Outcome measures are a fundamental part of the revised audit programme. A nationally agreed dashboard for collecting data on individuals with inherited bleeding disorders will come into operation in 2013. In addition there will also be nationally agreed CQUINS. In the current round of audits, evidence should be provided for both data collection/outcome measures and locally agreed CQUINS – if these exist.

The following is a suggestion as to the sort of data that individual centres may be collecting. Evidence of previous CQUINS or Outcomes Measures collected over previous years should be recorded if available.

Audit Standards:

1. Individuals with a severe inherited bleeding disorder should have an Annual Joint Score performed. How has this been obtained and by whom?
2. Individuals with a severe inherited bleeding disorder and on home treatment [either on-demand or prophylaxis] should record their treatments on Haemtrack or on paper. Evidence of this must be provided to the auditors.
3. Individuals with a severe inherited bleeding disorder should have their BMI calculated annually and if raised they should be counselled and if necessary referred for dietary advice and support. Evidence of this must be provided to the auditors.
4. Individuals with severe Haemophilia A or B should have a quality of life survey annually – HAL or PED-HAL [for children >4yrs].

Comments

1. Annual Joint Scores are performed and recorded by the Physiotherapist in the medical chart
2. Individuals on Home Treatment record their treatments on either their Home Scan App or Pink Treatment Sheets
3. The CCC plan to calculate and record the BMI on all patients, in both their medical chart and Clintech, on an annual basis
4. The NCHCD is in the process of applying Quality of Life Assessment tools onto a mobile device, which the CCC will also participate in. It is planned that the patient will complete the assessment at their clinic appointment. A pilot programme will be completed in each comprehensive care centre prior to roll out.
The following Quality of Life questionnaires will be applied to the mobile device:

HAL- Haemophilia Activities List – applied to a clinic IPAD

IPAQ- International Physical Activity Questionnaire – applied to a clinic IPAD

EQ5D-5L- Applied to the Home Scan App

CHO-KLAT (paediatric settings only) applied to a clinic IPAD. A demonstration of these tools will be provided on the day of the NCHCD audit visit

5. Part 2: Patient Medical Records Review [Medical/Nursing Auditors]

Audit Standard: The following should be present in the patient's medical records.
[Note - In some centres a separate genetics/pedigree file may be used.]

- Clear documentation giving the diagnosis and usual treatment
- Genetic mutation
- Family pedigree with identification of obligate carriers/confirmed carriers
- Appropriate review interval as per National Service Specification recommendation (six monthly for severe and moderate haemophilia, yearly for mild)
- Appropriate physiotherapy/orthopaedic referral with evidence of timely referrals/input/review and assessment.
- Appropriate management of HIV, hepatitis B/Hepatitis C infection as per national guidelines where applicable.
- Evidence of effective communication with primary and secondary care colleagues and affiliated regional haemophilia centres.

A random sample of 8 medical records should be reviewed.

1. There is documentation giving the patient's diagnosis

Number of records with this information: 8

2. There is documentation giving the patient's treatment

Number of records with this information: 8

3.1 vCJD status is recorded for all relevant patients

Number of records with this information: YES – where necessary

3.2 There are appropriate health care measures in place for 'at risk' patients

Number of records with this information: YES – where necessary

4. There is documentation of the patient's genetic mutation [This may not be in the C/N]

Number of records with this information: 8

5. There is documentation of the family pedigree

Number of records with this information: 8

6. There is evidence of appropriate follow up review:

Number of records showing this to be satisfactory: 8

7. There is evidence of appropriate physiotherapy/orthopaedic referral

Number of records showing this to be satisfactory: 6

8. There is evidence of regular dental review

Number of records showing this to be satisfactory: 8

9. There is evidence of appropriate management of HIV, HBV, HCV infection where applicable

Number of records showing this to be satisfactory: 8

10. There is evidence of effective communication with general practitioners and consultant colleagues

Number of records showing this to be satisfactory: 8

11. Investigation results are readily accessible in the medical records or electronically

Number of records showing this to be satisfactory: 8

COMMENTS:

The case notes that were reviewed were excellent with a very helpful 'Summary' front sheet.

No major problems were identified.

6. Part 3: Patient-Parent-Carers Audit Component

This section of the audit will be undertaken whilst the case notes review is taking place by the Medical-Nursing auditors

6.1 Patient Services At The Centre

Audit Standard: Patients, family members and carers attending the CCC should have easy access to the centre, adequate facilities whilst waiting, a private counselling area and availability of written information about all aspects of haemophilia and related disorders.

	Adequate	Inadequate
Access by car	√	
Designated Centre Car Parking		√
Access by public transport	√	
Disabled access	√	
Direct Emergency Ambulance Access		√
Signposting to centre	√	
Direct telephone line	√	
Answerphone	√	
e-mail access	Via secretary	
Waiting area	√	
Toilets	√	
Disabled toilets	√	
Age Appropriate Waiting Area)	√	
List of up-to-date educational material	√	
Could you find any information about this CCC on the Internet e.g. Google?	No	√
Seating/wheel chair waiting area	√	
Family friendly facilities available	√	

Patient Satisfaction Survey:

The auditors received 42 completed questionnaires mailed to a random selection of **Cork University Hospital** patients. Of these, 22 were completed by the patients themselves, and 20 were completed by the caregivers for paediatric patients.

Overall care was rated quite high. 79% (33/42) rated care as excellent. 19% (8/42) rated care as good. 2% (1/42) rated care as average (question 3).

Other results included:

- 98% (39/40) are satisfied with service when ringing the centre for advice (question 4);
- 96% (23/24) are satisfied with the availability of the centre team when needing to be seen for an urgent problem (question 5);
- 95% (20/21) are satisfied with the care they receive when needing to be seen for an urgent problem (question 6);
- 95% (40/42) are satisfied with the arrangements in place for regular check-ups (question 9);
- 95% (40/42) report all their questions are answered to their satisfaction at regular check-ups (question 10);
- 82% (32/39) report they know who to contact out-of-hours (question 11);
- 45% (19/42) report they have attended an A&E department in the last two years. Of these visits, 68% (13/19) were at CUH and 32% (6/19) in other hospitals (question 12);
- 89% (17/19) report they are satisfied with the care they received at A&E (question 13). Wait times and lack of knowledge about bleeding disorders at A&E are the complaints;
- 94% (16/17) are satisfied with the arrangements for home treatment (question 14);
- 100% (9/9) are satisfied with the physiotherapy and orthopaedic services (question 16);
- 52% (22/42) report that dental services are offered through the centre. 48% (20/42) report that services are not offered or they are unaware of them (question 18);
- 91% (10/11) report they are satisfied with the services for psychological and social support, the principal complaint being that the service was not offered to them (question 21);
- 88% (37/42) are satisfied with access to the centre (question 24);
- 5% (2/42) report having ever made a complaint. Neither of the two complainants reports the complaint was handled to his/her satisfaction (question 25).

Comments about patient experience in the last year

Comments were consistently positive regarding the standard of care, the professionalism and caring of the staff, the space for the new centre at CUH, quality of care at A&E and the vein training offered.

Suggestions to improve the centre

These include:

- A social worker is urgent!
- The clinics are always full. There is a need for an extra clinic.
- More professionalism regarding confidentiality of patient information.
- More availability of the dentist for adults.
- The centre needs its own day ward for children.
- Laminated cards with contact details for safe keeping in your wallet.

- When check-ups are every 1 or 2 years, a phone call from the specialist nurses every 6 months would be a good idea to ensure there are no concerns between appointments.
- Out-of-hours support: We need recorded message at centre giving name and number of doctor on call.

Other comments

This is typical of the sentiments expressed: *I cannot praise the CUH haemophilia team enough. They are knowledgeable and competent. The service has improved hugely. I feel lucky to have such a facility in my area. The back-up of the IHS is also fantastic.*

Note:

Three questionnaires were received from patients who did not identify with any of the three Irish comprehensive care centres. Limerick and Galway hospitals were mentioned. The respondents rated overall care as either average (1/3), poor (1/3) or very poor (1/3). Telephone advice was unsatisfactory (2/3). Availability of medical care personnel and quality of care for urgent situations was unsatisfactory (2/2). Questions were not satisfactorily answered at check-ups (2/2). A&E care was unsatisfactory (1/1).

(See Annex 1 for all comments.)

The visit to the Centre confirmed the comments included in the patient survey. In addition to the patients' suggestions above, a dedicated physiotherapist is critical. With sufficient time to assess acute bleeds, provide rehabilitation after bleeds and educate patients on prevention of bleeds, he/she would significantly improve patient care and potentially reduce factor concentrate utilization through reduction in target joints.

7. Part 1 continued: Medical/Nursing/Patient-Parent-Carers Auditors

7.1. Emergency Department/Out-of-Hours Setting:

Audit Standard: There should be a clear pathway for patients with inherited bleeding disorders in the ED. Staff should be aware that individuals with inherited bleeding disorders require to be seen and treated promptly to prevent a minor bleed becoming more serious. Protocols for managing patients with inherited bleeding disorders should be easily accessible. Protocols should be in place for managing 'visitors' who are not known to the CCC.

Comments:

A copy the CCC Guide for Assessment of Patients with Inherited Bleeding Disorders in the Emergency Department is included in this package.

This Guide is available on the hospital intranet and in the ED handbook.

Auditors' comments: There is a clear pathway for patients attending out-of-hours with medical input as required.

7.2 The Haemophilia Service-Genetics Service Interface

1. What proportion of the patients with haemophilia A and B registered at your Haemophilia Centre, have had their causative mutation identified?

91% of patients with severe factor VIII deficiency have had the causative mutation in their family identified

80% of patients with severe factor IX deficiency have had the causative mutation in their family identified

81% of patients with mild factor VIII deficiency have had the causative mutation in their family identified

100% of moderate factor VIII deficient patients have had the causative mutation in their family identified*

82% of mild factor IX deficiency patients have had the causative mutation identified

*No patients with moderate factor IX deficiency are registered with our centre

2. Do you record this data on the national genetic database (HCIS)?

See Comments below:

Comments:

Results available though Clintech: entered by NCHCD Genetic Service

3. Informed Consent: Please describe mechanisms that are in place within your centre to ensure that appropriate informed consent is obtained for genetic testing, and how the laboratory is made aware of any restrictions on consent.

Please indicate which format is used to document patient consent and information regarding testing

- UKHCDO consent form and information sheet
- UKHCDO consent form and information sheet with local modifications
- Alternative format consent form and information sheet (please give details)

Comments:

A genetics clinic is now in regular operation. Pedigrees are hand drawn and consideration should be given to using software to undertake this, which would allow easy updating/editing.

Part 5: Audit Feedback & Closing Meeting

1. The final meeting should include a member/representative of the Trust
2. List the issues raised at the previous audit and indicate whether or not they have been rectified.
3. Highlight areas of best practice.
4. If there are outstanding issues, what are these and what have been the barriers to resolving them?
5. Have any serious issues been identified during the current audit and how will these be addressed?
[In this situation the auditors have a professional responsibility to address these highlight these to the Trust and to the Commissioners. A formal meeting would be convened and the concerns of the auditors discussed.]
6. Issues identified during this audit meeting and mutually agreed provisional plans to address these.
7. If the auditors cannot reach consensus about any aspect of the audit this can be highlighted in the free text boxes below.

Audit Summary: This should highlight areas of best practice and areas that require improvement. The points listed above should form the basis for this summary.

In the audit report of 2008 it was recorded that the auditors had been informed by the CEO and Deputy CEO that the Hospital Board had approved a number of posts which included 0.5 WTE haemophilia physiotherapist, 0.5 WTE haemophilia secretary, 0.5 WTE social worker and 0.5 WTE data manager. This was highlighted again in the audit report of 2011. It does not appear to us that these posts are effectively in place. We would appreciate an explanation for this.

This service is very dependent on its experienced nursing staff for the day-to-day viability of the service. Urgent consideration should be given to succession planning for these posts as there will be the need for several months of training and education for any new nursing staff. A skill mix review may be helpful at this time.

There appears to be a lack of clerical and administrative support for the clinical functions of the service. The nursing staff are booking, pulling notes and discharging patients for the nurse-led clinics. It also appears that there are gaps in important functions such as checking of demographic details and activity capture. The appointment of a healthcare assistant could also be considered in order to free up specialist nursing time by supporting responsibilities such as stocking, cleaning of equipment and escorting patients to other departments.

In summary:

1. Senior medical scientist position: The post, we understand has now been filled and this development is welcomed. However, the post has not been 'backfilled' (it was an internal appointment), and there is no net gain in staff numbers to the laboratory.

Confirmation from the laboratory management team that the post has been filled is required three months from the date of issue of the final Audit report.

2. Increased Physiotherapy involvement. There is a clear requirement for a dedicated physiotherapist with at least 0.5 WTE as has previously been agreed (see previous Audit reports).
3. Increased administrative support, at least 0.5 WTE.
4. Consideration should be given to the appointment of a Data & Quality Manager.
5. Dedicated consultant time for Haemophilia services is limited by their commitments to general and malignant clinical haematology, as well as laboratory haematology and blood transfusion. Consideration should be given to an alteration in their workload to allow more time for the provision of care to patients and their families, with inherited bleeding disorders.
6. Specialist registrar input to the service is very limited. The lack of training in Haemostasis & Thrombosis is an area of concern and should be highlighted with the programme training director.
7. There are a number of IT systems in use within the centre that are not integrated, leading to duplication of work and allowing for transcription errors. This was highlighted in the previous audit. There is no evidence that this is being or has been, addressed.

Medical Auditor

Comment

There is clear evidence of a high quality, patient-focused service. There is an on-going service development [e.g. nurse-led clinics, genetic counselling] and an active audit programme. The ethos and philosophy of the staff is to provide the best possible quality care for patients and their families attending the centre.

A review of the case notes identified no major problems and the staff should be congratulated.

The service has clearly grown without necessarily considering the impact that this has on the staff.

a. The 3 consultants that provide the service have many other commitments and in addition the support from Specialist Registrars in haematology is small. Consideration should be given as to how the input from consultants can be increased. This lack of consultant input was highlighted by the nursing staff.

b. Physiotherapy – there is a requirement for a dedicated adult/paediatric physiotherapist with at least a 0.5 WTE and who can attend clinics and the MDT meetings. This is a fundamental part of the Comprehensive Haemophilia Care Service.

c. Receptionist/Data-manager/Haemovigilance office. These are again fundamental part of the Haemophilia service and are essential for the provision of a high quality, safe and effective service.

We were concerned about the IT issues and that many of the systems in use do not 'talk' to each other requiring the duplicate entry of data and the inherent risk of transcription errors. This is something that needs to be addressed.

The audit document was well prepared and the staff should be congratulated on providing a clear document which helped with the audit process.

Nursing Auditor

Comment

There is an impressive sense of commitment and motivation on the part of the whole team here alongside some frustrations with constraints on their ability to provide the level of service that should be delivered by a comprehensive care centre. The priorities are more dedicated consultant, physiotherapy, social work, data management, quality management, secretarial and administrative time.

There is evidence of high quality specialist nursing at this centre and this needs to be sustained to allow nurse-led initiatives and developments in the service to be maintained.

Patient-Parent Auditor

Comment

The opening of a dedicated space at Cork has clearly improved the patient experience. Human resources, however, remain less than adequate. An increase in physiotherapy, psycho-social and consultant resources is necessary to bring the CUH Haemophilia Centre to the standard of the other Irish centres. The great progress since 2008 does nevertheless need to be recognized and appreciated.