Audit: National Centre for Hereditary Coagulation Disorders (NCHCD
Date of Audit: 27th March 2014

Name And Address of Audited Centre:

National Centre for Hereditary Coagulation Disorders (NCHCD)
St. James's Hospital
Dublin 8, Ireland

Director(s):

Dr Barry White

Number of Consultants:

Prof James O'Donnell
Dr Niamh O'Connell
Dr Kevin Ryan

Nursing Staff (Bands/Job Title/WTEs):

WTE= 13
CNM3 Nurse Manager – Victoria Graham
CNM3 Haemovigilence Officer – Evelyn Singleton
CNM2 Quality Assurance Officer – Ruth Hunter Nolan
CNM2 Clinical Nurse Specialist Haemophilia – Eadaoin O'Shea
CNM2 Home Treatment Nurse – Janet Cleary
CNM2 Coagulation Nurse - Ann O'Sullivan
CNM2 Haematology Nurse - Margaret Gorecki (maternity leave)
CNM2 Mono-Infection Nurse – Niamh Larkin
Staff Nurse – Helen Shiel
Staff Nurse – Mags Nolan

CNM2 Nurse Manager Noreen Boland- Warfarin clinic
Staff Nurse – Raul Diaz - Warfarin clinic
Staff Nurse – Marie Blake - Warfarin clinic
Staff Nurse – Noleen Flinter - Warfarin clinic
Staff Nurse – Finola Griffin - Warfarin clinic

Physiotherapist:

Emma Sherlock

Supporting Staff [Data Manager/Secretary]:

Grade 6 Centre manager- Carol Finn
Grade 5 Data manager- Rachel Bird
Grade 5 Office manager- Marie Hughes
Grade 4 Medical secretary- Sinead Mahon

Grade 4 Medical secretary- Valarie Magill
Grade 4 Medical secretary- Lisa O' Donohoe
Grade 4 Anticoagulation Clinic Co coordinator- Linda Leonard
Grade 3 Administrative Staff- Bernie Voakes
Grade 3 Administrative Staff- Carol Curran
Grade 3 Administrative Staff- Karen Blood

Audit Team

Medical Auditor: Dr David Perry
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Nursing Auditor: Christine Harrington
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Patient/Parent/Carer Auditor[s]: Mr. David Page
Email: dpage@hemophilia.ca

Scientific [Genetics Network] Auditor: Marian Hill
Email: Marian.Hill@nottingham.ac.uk

Date of Audit Visit: 27/03/14

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.

NCHCD Map was sent with the completed proforma as supporting evidence.

NCHCD Operational Policy was sent with the completed proforma as supporting evidence.

NCHCD Strategy 2014-2016 was sent with the completed proforma as supporting evidence.

NCHCD Annual report was provided as supporting evidence.

The NCHCD at St James' Hospital is a comprehensive care centre providing a multidisciplinary service for patients with haemophilia and related bleeding disorders and for patients with clotting disorders. The centre provides a national lead to other haemophilia centres in Ireland.

The NCHCD out-patient service is located in a purpose-built building that incorporates both clinical facilities and coagulation laboratory. The in-patient service is provided on H&H ward which is located in the main hospital building. The ward has 6 beds designated for bleeding or thrombotic conditions and a 3 bedded assessment unit which is managed by the NCHCD nursing team and used for all scheduled and unscheduled treatment.

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:

There is a robust system in place for the issuing and recording of clotting factor concentrate usage and no problems were identified.

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

All NCHCD Policies, Procedures and Guidelines were available for viewing on day of audit

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

Induction to the NCHCD Department

- All new staff must undertake the hospital corporate and department local induction programme as per the Employee Induction Policy. Policy Number: SJH: HR (P): 013. New staff members are supplied with Department Policies, Protocols Guidelines and SOPs. New staff members also receive training on Clintech from the Quality Assurance Officer.
- All Non Consultant Hospital Doctors working in the NCHCD are trained on a three monthly (Senior House Officers) and six monthly (Registrars) basis. All team members receive a one hour in-service on haemophilia and coagulation factor concentrate (CFC) management by the Haemovigilance Nurse. The in-service also includes training on the Clintech and Haemotrack systems. All SHOs must have at least one supervised practice of administering a CFC to a patient. The medical team are also required to complete a workbook relating to haemophilia and CFC usage.
- All new laboratory staff undertake the Lab Med induction programme (MF-GEN-0014) as well as hospital induction. This includes directorate structure, quality management, quality assurance, health and safety, security, reference manuals, laboratory equipment, specimen handling and housekeeping rules.
- The Nurse induction programme includes designated training programmes and competencies in all aspects of haemophilia care. All new nursing staff are supernumerary and mentored until assessed as competent across all programmes.

Nursing competencies as follows:

Ability to communicate effectively
Demonstrates ability to maintain a safe environment
Administrations of Medications
Administration of blood and blood products
Hepatitis A and B vaccinations
Management and treatment of allergic/anaphylactic reactions
Administration of Iron Infusion
Administration of low molecular weight heparin
Administration of DDAVP
Administration of coagulation factor concentrate
Assessment and management of bleeding episodes
Inheritance of haemophilia
Fitting patients for compression stockings
Education of home treatment patients
Warfarin management
Treatment and assessment for evenings and weekends
Stock management
Management of dental treatments
IV access for patients with bleeding episodes
Telephone consultations
Clintech
Nurse led carrier testing and counselling

1.4 Relationship between Comprehensive Care Centre and Neighbouring Haemophilia Centres

1. List of Haemophilia Centres in locality of CCC

There is one designated Haemophilia centre in Galway University Hospital. This centre has a Consultant Haematologist appointed with a remit to care for adult patients with bleeding disorders.

See patient feedback later in this audit re. regional centres.

2. Is there a formal network arrangement between the CCC and the neighbouring Haemophilia Centres?
Yes (managed through the formal four centre meetings)

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

There is shared patient care — Yes through Clintech

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

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

Yes

Comments including any that relate to feedback from regional Haemophilia Centres

No comments were received from the regional Centres.

1.5 Age Appropriate Treatment Facilities and Services – If Relevant

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

COMMENTS

Children and their families are seen and treated at Our Lady's Children's Hospital, Crumlin

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	√	
Centre data/business manager	√	
Access to a social worker	√	
Dedicated Physiotherapist	√	
Access to a Psychologist/Counsellor	√	
Dental service/Dentist (a full description of the service offered should be included)	√	
Orthopaedic service/Orthopaedic surgeon	√	
General/Specialist surgical services	√	
HIV physician	√	
Hepatologist	√	
Obstetric/Gynaecology service/Surgeon	√	
Paediatrician (in paediatric or paediatric/adult centre)	N/A	
Dietician	√	
Genetic Counselling Services [Provide a description of the service and how this is accessed]	√	
Antenatal diagnosis arrangements	√	
Home Delivery [Comments]	√	
Access to Occupational Therapy	√	
Access to Benefits Advice	√	

COMMENTS:

Role Descriptions for Physiotherapy, Quality Assurance, Dental Service (to follow), Data manager, Psychology and Administrative service were supplied as supporting evidence.

The Genetic Counselling SOP was provided with the proforma as supporting evidence.

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

The facilities within the centre are excellent, all the staff that we met were very enthusiastic and with a clear mission to provide the highest possible standards of care to the patients registered within the Centre.

The audit team benefitted by meeting with various members of the multidisciplinary team including:

- Chief Laboratory Scientist, Mary Byrne
- Consultant dental surgeon, Alison Dougall
- Haemophilia physiotherapist, Emma Sherlock
- Psychologist, Patricia Byrne
- Quality Assurance, Ruth Hunter Nolan
- Haemovigilance officer, Evelyn Singleton

A number of nurse-led services have been set up supported by rigorous training programmes and competency review.

- Carrier testing and genetic counselling
- Women's clinic
- Blood testing clinic
- Patient education service
- Home treatment programme

1.7 Patient Choice & Experience

1. How have you been able to access information about your local CCC that allows you to compare the services it offers with other CCCs?

2. Are there any Patient Satisfaction Survey/Audits/Focus Groups Reports available?

In 2010 a NCHCD Patient Partnership Panel was established and has been meeting three times a year in order to produce ideas for future service development and be included in initiation, design, implementation, communication and evaluation of initiatives in the NCHCD. The 2013 Patient Partnership Panel Annual Report is available for viewing on day of audit.

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

The Anticoagulation Clinic completed a patient satisfaction survey in 2013. 219 questionnaires were completed with an overall response rate 45%. The Overall Satisfaction rate is 99.5%. The complete report was available for viewing on day of audit.

The National Home Treatment Satisfaction Survey is currently in progress. The questionnaire will be available for viewing as will any completed questionnaires.

The NCHCD meets with the Irish Haemophilia Society on a quarterly basis. The purpose of these meetings is to facilitate discussion of issues that impact the care of haemophilia patients nationally and to improve haemophilia care and the patient's experience.

Comments:

Very little to add – the feedback is outstanding and there is clear evidence of a wish to improve the service, to be proactive rather than reactive. There are impressive levels of patient engagement and collaboration in service development.

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

Monitoring and evaluating Key Performance Indicators (KPIs) is part of the Quality strategy in the National Centre for Hereditary Coagulation Disorders (NCHCD). A number of clinical and operational KPIs have been identified to evaluate the NCHCD performance in relevant processes and outcomes of patient care. The 2013 NCHCD KPI report has been sent with this proforma as supporting evidence of continuous audit and quality improvement in the NCHCD.

Other audits completed since the last UKHCDO audit are as follows:

1. HIT audit presented at HAI 2011
2. Thrombophilia testing audit presented at HAI 2011
3. Inhibitors in mild FVIII deficiency M Lavin 2012 presented at WFH and HAI
4. DVT ambulatory care pathway N O'Connell 2012 presented at HAI and ICEM
5. HHT N O'Connell presented at HAI 2012
6. Anticoagulation patient self testing INR presented at HAI 2012
7. Wilate experience presented at ISTH and HAI 2013
8. Complications of NOAC in SJH presented at HAI 2013

9. PCC audit presented at HAI 2013 and National Haemovigilence meeting 2013
10. IVC filter audit presented at Grand Rounds 2014
11. Audit on the timeliness of out patient clinics, July and August 2013 presented at NCHCD RH Nolan, Management Team meeting
12. Audit on Timeliness of Treatment of "Walk In" Patients in the NCHCD, June-Sept 2013, RH Nolan presented at NCHCD Journal Club
13. Audit on vCJD Documentation on Clinical Correspondence on Clintech 2013
14. User Satisfaction Survey on the Genetic Service in the NCHCD 2013

Anticoagulation Clinic Audits

1. Incidents reported in the Anticoagulation clinic 1st + 2nd quarter 2013
2. Numbers of patients requesting a nurse consultation at the Warfarin clinic 2013
3. Review of the patient cohorts attending the anticoagulation clinic daily 2013
4. Patient satisfaction survey in the Anticoagulation clinic 2013
5. Audit on the outcome of patients on anticoagulation therapy who have received Octaplex administration in 2013

Laboratory Audits -audits for compliance with ISO 15189:2012 standard

Vertical audits = 5

1. Coagulation x 3
2. Haemostasis Molecular Biology x 2

Horizontal = 62

1. 4.12 Continual Improvement
2. 4.14 Evaluation and Audits x 2
3. 4.14.7 Quality Indicators x 8
4. 4.15 Annual Management Review for 2012
5. 4.2 Quality Management System
6. 4.3 & 4.13 Document Control and Control of Records
7. 4.4 Service Agreements
8. 4.5 Examination by Referral Laboratories
9. 4.6 External Services and Supplies
10. 4.7 Advisory Services and 5.7 Post Examination Procedures
11. 4.8 Resolution of Complaints and 4.12 Continual Improvement
12. 4.9, 4.10 & 4.11 Non-Conformances
13. 5.1 Personnel including x 3
14. 5.2 Environmental & Accommodation x 4; 5.2 Sharps Audit x 2
15. 5.3 Laboratory Equipment x 2
16. 5.4 Pre-Examination x 16
17. 5.5 Examination Procedures x 7
18. 5.6 Ensuring the Quality of Examinations x 3
19. 5.8 Reporting of Results x 4
20. 5.10 Laboratory Information System

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

The KPI report outlined all audit results and changes in practice arising from these audits. Other changes in practice secondary to audits are as follows:

The NCHCD clinic schedules were altered following the results of the audit on the timeliness of out patient clinics. This change has improved the timeliness of clinics by 30%. This audit is part of the NCHCD KPIs and will continue to be monitored on a monthly basis.

The HIT audit led to a change in a new testing algorithm in 2013.

The thrombophilia test audit led to a change in a new testing algorithm in 2012.

The IVC filter audit led to changes in the hospital wide clinical management of IVC filters in 2014. A new policy and nursing care plan were devised following the audit.

The PCC audit has led to a clinical study being designed and submitted for ethics.

The inhibitors in mild FVIII deficient patients informed us of the risk factors in this patient group although rates of inhibitor formation are low.

The HHT audit informed us of current patients and a management algorithm currently being developed.

3. CCC staff participate in teaching?

YES ~~No~~

Give examples of teaching activities:

- Undergraduate Trinity College Medical students – Formal lectures, tutorials and ongoing clinical attachments to service
- Undergraduate Trinity College Dentistry students – Formal lectures.
- Registrar/SHO Training – Formal induction at each changeover covering coagulation disorders, treatment, complications and factor administration.
- Specialist Haematology Registrar Teaching Program – Formal teaching sessions.
- Weekly Journal Club for staff of the NCHCD.
- MSc in Haematology Nursing – Formal lectures in nursing and clinical topics
- Diploma in Intensive Care Medicine – formal lecture
- Orthopaedic Team - Orthopaedic Surgery and Bleeding Disorders – formal lecture
- Irish Haemophilia Society – Formal talks covering topical issues.
- Maternal Medicine Day Coombe University Hospital 2014 – Formal lecture.
- Nursing In services on the H&H ward- lectures on Surgery and Haemophilia, Inherited Bleeding Disorders, Haemophilia management and Treatment, Idiopathic/immune Thrombocytopenia Purpura, Deep Vein Thrombosis
- Laboratory is a designated training laboratory for students of medical laboratory science

- Medical scientists and Haematology Consultants lecture at undergraduate and postgraduate courses for medical laboratory science.

Copies of lectures available for viewing on day of audit

4. CCC staff undergo regular performance review?

All nursing staff undergo performance review with their manager on an annual basis. An Annual report and Objective setting is completed for the coming year.
Consultants complete an Objective Setting Review (OSR) on an annual basis
All Grade 5 and above administrative staff complete an OSR.
All laboratory staff participates in the OSR process.
These documents are available for viewing on day of audit.

YES ~~No~~

5. CCC staff participate in continuing professional development?
Attendance lists for Nursing staff for all national and international conferences are available for viewing on the day of the audit.

Haematology Consultants participate in mandatory Professional Competence Assurance.

YES ~~No~~

6. The unit participates in clinical trials:

YES ~~No~~

7. The unit participates in clinical research:

YES ~~No~~

Research Projects 2014

[1] 'To characterise the molecular mechanism(s) underlying the bleeding risk associated with use of protamine sulphate.'
Principal Investigator – Prof. James O'Donnell
Irish Heart Foundation funded project - €84,000

[2] 'The role of factor VIII glycan structures in modulating function and clearance.'
Principal Investigator – Prof. James O'Donnell
Bayer Hemophilia Award - €170,000

[3] 'A novel role for von Willebrand factor in the pathogenesis of childhood Plasmodium Falciparum malaria.'
Principal Investigator – Prof. James O'Donnell
Children's Medical Research Foundation – €400,000

[4] 'Coagulation glycoproteins constitute novel binding partners for human galectins- characterising the molecular interactions and defining the pathophysiological significance.'
Principal Investigator – Prof. James O'Donnell
IRCSET Embark Postgraduate Fellowship Award - €72,000

[5] 'Defining the molecular mechanisms responsible for clearance of the von Willebrand factor – factor VIII complex'
Principal Investigator
Principal Investigator – Prof. James O'Donnell
Science Foundation Ireland – Principal Investigator Program Grant
€1,300,000

[6]. 'Characterising inter-individual variations in clearance of the VWF-FVIII complex in Irish patients with mild or moderate haemophilia A.'
Principal Investigators – Prof. James O'Donnell / Dr Niamh O'Connell
Baxter Investigator-Initiated PhD studentship grant - €130,000

[7] 'Designing patient-tailored treatment regimens for Irish patients with severe haemophilia A.'
Principal Investigators – Prof. James O'Donnell / Dr Niamh O'Connell
Baxter Investigator-Initiated Project Grant - €270,000

COMMENTS:

The audit and research programme is outstanding and the staff should be congratulated on their contribution to the care of individuals and their families with inherited bleeding disorders.

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~~

Inspection conducted by INAB in January 2014 and minor non-conformances are being addressed. No major non-conformances identified.

If yes, date of last CPA inspection: 2014

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

YES

3. The laboratory space and facilities are adequate:

YES

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

YES

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

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	√	
Platelet function testing	√	
Platelet granular constituents	√	

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

7. List any diagnostic tests that are performed not listed above:
VWF collagen binding assay
FVIII-VWF binding assay
FVIII chromogenic assay
VWF RIPA

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

YES

9. A diagnostic genetic laboratory service is provided
[The Genetics Service will be audited separately during the current audit]

YES ~~No~~

COMMENTS

The lab is excellent and there is evidence of a high quality, patient-focused service.

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	N/A	
Consultant Paediatric Haematologist	N/A	
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	N/A	
All medical staff involved in managing children should have ‘Safeguarding Children Level 3’.	N/A	
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)	N/A	
All nursing staff involved in managing children should have ‘Safeguarding Children Level 3’	N/A	
Physiotherapist [relevant paediatric qualification.	N/A	

COMMENTS:

Children and their families are seen and treated at Our Lady's Children's Hospital, Crumlin

3.2 General Paediatric Services

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

Comments:

Children and their families are seen and treated at Our Lady's Children's Hospital, Crumlin

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 treatment 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 obtained and documented on Clintech by the Physiotherapist.

2. Individuals on Home Treatment record their treatments on either their Home Scan App or paper Treatment Sheets (adherence).

3. BMI calculation is currently being applied to the Clintech patient record and once completed will be recorded at the patient's annual review by the clinical nurse specialists.

4. The NCHCD is in the process of applying Quality of Life Assessment tools onto a mobile device. 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 day of NCHCD audit.

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:

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

Number of records with this information:

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: 8

8. There is evidence of regular dental review

Number of records showing this to be satisfactory:

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:

No problems were identified with the case notes that were reviewed.

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	**No**	
Signposting to centre	√	
Direct telephone line	√	
Answerphone	√	
e-mail access	**Yes**	
Waiting area	√	
Toilets	√	
Disabled toilets	√	
Age Appropriate Waiting Area)	**N/A**	
List of up-to-date educational material	√	
Could you find any information about this CCC on the Internet e.g. Google?	**Yes**	
Seating/wheel chair waiting area	√	
Family friendly facilities available	**Yes**	

Comments:

No problems were identified. Patient satisfaction was very high. See below for the results of the patient satisfaction survey.

The auditors received 35 completed questionnaires mailed to a random selection of St. James's NCHCD patients. Of these, 33 were completed by the patients themselves and 2 by children's caregivers.

Overall care was rated very high. 89% rated care as excellent. 100% rated care as excellent or good (question 3).

Other results included:

- 97% (33/34) are satisfied with service when ringing the centre for advice (question 4);
- 95% (21/22) are satisfied with the availability of the centre team when needing to be seen for an urgent problem (question 5);
- 95% (19/20) are satisfied with the care they receive when needing to be seen for an urgent problem (question 6);
- 97% (33/34) are satisfied with the arrangements in place for regular check-ups (question 9);
- 97% (33/34) report all their questions are answered to their satisfaction at regular check-ups (question 10);
- 74% (26/35) report they know who to contact out-of-hours (question 11);
- 42% (15/35) report they have attended an A&E department in the last two years. Of these visits, 40% were at St. James's and 60% in other hospitals (question 12);
- 80% (12/15) report they are satisfied with the care they received at A&E (question 13);
- 100% (5/5) are satisfied with the arrangements for home treatment (question 14);
- 80% (4/5) are satisfied with the physiotherapy and orthopaedic services (question 16);
- 74% (26/35) report that dental services are offered through the centre. 26% (9/35) report that services are not offered or they are unaware of them (question 18);
- 100% (10/10) are satisfied with the services for psychological and social support (question 21);
- 74% (26/35) are satisfied with access to the centre. Parking was the principal complaint;
- 3% (1/35) report having ever made a complaint. The complaint was handled to the person's satisfaction.

Comments about patient experience in the last year
Comments were consistently positive regarding the standard of care, the professionalism of the staff and wait times.

Suggestions to improve the centre

These include:

- Text reminders for appointments
- Better "medical identity" cards
  More frequent dental appointments

Other comments

This is typical of the sentiments expressed: *The staff and doctors at St. James's Hospital are excellent and very caring.*

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 at end of report for all patient comments and suggestions.)

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:

An SOP for out-of-hours treatment was available for viewing during the audit.

There is a clear out-of-hours policy that appears to work well. There is 24-hour consultant haematologist cover for the service.

Patients with haemophilia and related conditions can directly contact the H&H ward for bleeding or other medical issues and attend for assessment and management. They are reviewed by the haematology junior doctor on-call. Direct access to the ward where staff have undertaken training and education allows for prompt and appropriate management.

This is a robust pathway that has been thoughtfully developed and implemented.

Consideration could be given to further developing training in telephone triage for ward staff who may be contacted out-of-hours.

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?
Please indicate the Haemophilia Centres served by the laboratory and the proportion of testing from local/outside sources.

Approximately 80% of families have been analysed for genetic mutations in the FVIII and FIX genes. All genetic information is available on the Progeny database and in individual patient records on Clintech.

A small number of FVIII or FIX deficient patients do not have identifiable genetic data available as shown in the table below (data as per June 2013).

	FVIII deficient	FIX deficient
NCHCD, SJH	36	22
OLCH, Crumlin	6	6
CUH, Cork	17	1

Comments: All registered patients who have attended clinics at NCHCD have had genetic analysis.
The laboratory works closely with Eadaoin O'Shea (Genetic Counselling Nurse) who runs a nurse-led carrier clinic, and has the ability to co-ordinate with Centre Directors in order to offer genetic analysis to remaining patients.

The laboratory holds and curates pedigree information from all families on Progeny, and is responsible for updating this, which requires pro-active information gathering from other Centres.

The predictable difficulties exist regarding cross-referencing family members who attend different Centres. Progeny is not utilised for pedigree documentation outside of NCHCD.

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

Yes : Genetic reports are made available via Clintech. (N/A for HCIS)

Comments:

No problems were identified.

ClinTech is used for information management, and genetic reports are fully available through this resource to all of the Haemophilia Centres.

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 with local modifications.

Comments:

No problems were identified.

8. [Part 4]: Genetic Services Audit

Laboratories must comply with the standards for Haemophilia Genetic Laboratory Services, as developed by the UKHCDO Genetics Working Party.

8.1 Haemophilia Centres Served by the Laboratory:

Please indicate the Haemophilia Centres served by the laboratory and the proportion of testing from local/outside sources.

NCHCD ~50%.
Our Lady's Children's Hospital, Crumlin [OLCH] ~15%.
Cork University Hospital (CUH) ~25%.
Galway University Hospital ~5%.

8.2. Laboratory Profile

1. Audit Standard: The genetic service should be provided by an NHS funded laboratory within a Comprehensive Care Haemophilia Centre.

Please provide a clear and concise description of the role, aims and activities of the laboratory, which should include a description of the laboratory's relationship with the Laboratory Directorate or equivalent, the Trust and other institutions.
This should include information on the range of diagnostic testing carried out by the laboratory:

Satisfactory ~~**Unsatisfactory**~~

The Haemostasis Molecular Genetics laboratory as part of the National Centre for Hereditary Coagulation Disorders (NCHCD), provides a diagnostic service for analysis of the genes that cause inherited bleeding disorders. This is part of a comprehensive service provided by the NCHCD to patients and their families with inherited bleeding disorders. The infrastructure for this service exists at St James's Hospital. The laboratory, though located in the NCHCD, is part of the LabMed (Pathology) directorate within St James's Hospital.

Services included within the scope for INAB accreditation are mutation and carrier analysis of *F8* and *F9*, mutation analysis of type 2 VWD and when requested type 1 and type 3 VWD and mutation analysis for *SERPINC1.*

Analysis of other genes such as *F10, F11, F7* is available and has been performed but the analyses are not part of the scope submitted for accreditation.

Comments:

A comprehensive genetic testing service is offered for haemophilia A, haemophilia B, and VWD.
The laboratory also offers *F10*, *F11* and *F7* sequence analysis locally, these are performed rarely and were not submitted for accreditation.
There are plans to introduce genetic testing for fibrinogen disorders, MYH9 related disorders (MYH9-RD) and hereditary haemorrhagic telangiectasia (HHT).

2. Audit Standard: The genetic service should be adequately staffed with an appropriate skill mix and have adequate space and facilities to perform an effective diagnostic service.

Staffing:
Please provide details of the staff involved with the genetics laboratory diagnostic service provision in inherited bleeding disorders (ie Clinical Scientists, BMSs, MTOs, MLAs, clerical support)
Please provide details of the staff involved with research and development in inherited bleeding disorders (i.e. Clinical Scientists, BMSs, MTOs, MLAs, clerical support).

Staff (Bands/Job Title/WTEs):

Vince Jenkins	Chief Mol. Biologist	Full time
#Catriona Keenan	Senior Mol. Biologist	Full time

Currently on maternity leave: post covered by Medical Scientist.

Satisfactory ~~**Unsatisfactory**~~

Comments:

The laboratory is staffed by two full time scientists, one of whom is currently on maternity leave. Adequate provision has been made for cover during this time.

Although staffing levels appear appropriate for workload, Dr Jenkins carries out approx. 25% of the laboratory work. The service would benefit from an additional Medical Scientist to contribute to this work. This would release Dr Jenkins to focus on his management role and the increasing demands associated with service quality and documentation (as illustrated by recent INAB inspection) and service development.

It was noted that the adjacent Coagulation laboratory carry out genotyping for Factor V Leiden and Prothrombin g.20210G>A variants. This genetic testing overlap presents an opportunity for a rotational Medical Scientist post, shared with the Coagulation laboratory, which would benefit the haemophilia genetics service and offer additional training opportunities to the Coagulation team.

3. Laboratory Facilities:

Please provide a description of the areas designated for molecular diagnostic work:

Two dedicated laboratories and an office, and use of space and grade 3 hood in coagulation laboratory

Coagulation laboratory: Sample preparation and DNA extraction using the MagnaPure.

Laboratory HCS 15: PCR set up area. Work is performed and assigned to particular areas. This room also contains the ABI3130. Samples for sequence analysis are brought in sealed for loading onto the analyser

Laboratory HCS12: Post-PCR analysis and sequence reaction prep is performed in this room. Laboratory also contains gel tanks and gel documentation equipment

Office: For use by staff working in the above labs

Satisfactory ~~**Unsatisfactory**~~

Comments:

Satisfactory facilities, adjacent to the Coagulation laboratory and the Haemophilia Unit. Sufficient office, and laboratory space, with separate areas for pre and post PCR activities. Some shared facilities with the Coagulation laboratory.

It was noted that the service is required to re-locate within the next year, as the current building is to be demolished.
It is important that considered decisions are made on the future of the haemophilia genetics laboratory. Co-location and/or stronger working links with other genetic service providers is recommended in order to optimise expertise, equipment replacement and procurement of new technologies and ensure the long term sustainability of the service

4. Laboratory Equipment:
Please provide a list of current laboratory equipment, with predicted replacement date. Please explain any mechanisms in place for replacing this equipment as required:

-80C freezer			2020
-20C freezer/ 4C fridge			2015
Refrigerated Centrifuge	Eppendorf	5810R	2018
3 Thermal Cyclers	Applied Biosystems	2720	2018
Digital gel documentation system	UVI	ProGAS7000	2018
ABI 3130 Genetic Analyser			2018
A variety of submerged gel electrophoresis tanks			

All equipment is purchased via the LabMed Directorate. A business case is made for all new and upgrades of equipment. The decision as to whether to purchase is made by the Laboratory Manager based on business case and priorities.

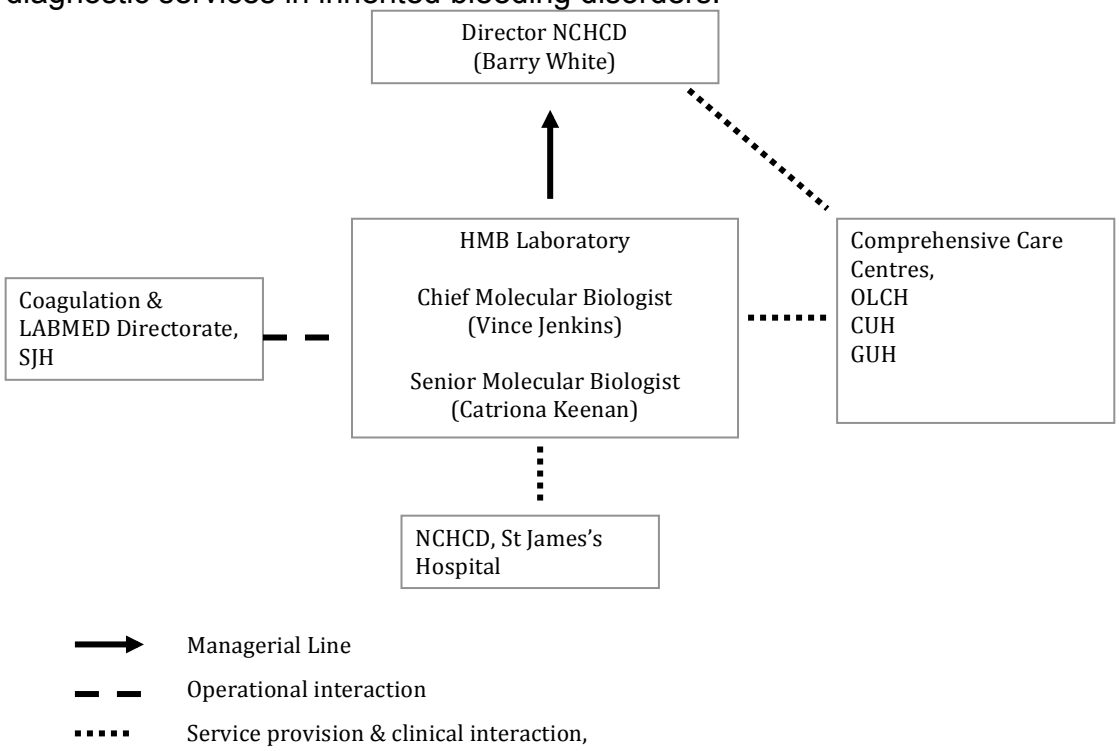
Satisfactory ~~**Unsatisfactory**~~

Comments:

Equipment is satisfactory for current workload.
There is no defined replacement program for equipment, and opportunity for new procurement is limited.

9. Service Provision

1. Management Structure/Accountability: Please provide a diagram showing lines of accountability within the laboratory and links to the Haemophilia Centre(s) for genetic diagnostic services in inherited bleeding disorders:

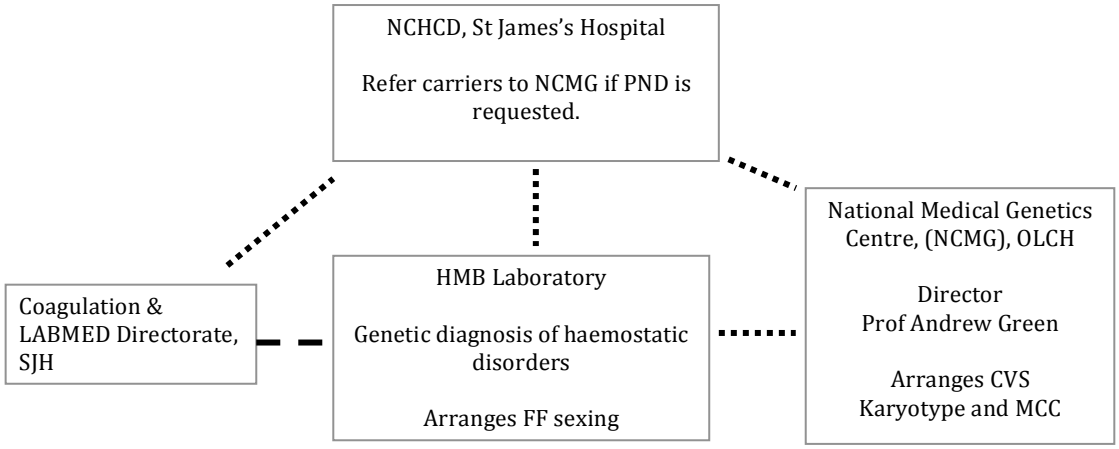


Auditor's Comments:

Satisfactory.

2. Service Provision: Please provide a clear description (preferably by means of a diagram) of the mechanisms of diagnostic service provision, particularly identifying links

with other clinical services (e.g. clinical genetics, cytogenetics), including for the provision of antenatal diagnosis.



Auditor's Comments:

Satisfactory

3. Diagnostic services provided: Please provide a summary of the genetic diagnostic services provided for inherited bleeding disorders, including the methodology utilised.

Satisfactory ~~**Unsatisfactory**~~

Haemophilia A Tests
F8 intron 22 inversion (PCR)
F8 intron 1 inversion (PCR)
Full *F8* mutation screening (PCR – sequencing)
Detection of known *F8* mutations (PCR – sequencing)
Carrier and prenatal diagnosis
MLPA

Haemophilia B Tests
Full *F9* mutation screening (PCR & direct sequencing)
Detection of unknown *F9* mutations (PCR & sequencing)
F9 linkage analysis (SNP) (PCR)
Carrier and prenatal diagnosis

von Willebrand Disease Tests
Targeted screen for common Type 2A, 2B, 2M and 2N mutations (PCR – sequencing)
Detection of common Type 1 mutations (Vicenza)
VWF mutation screening

Detection of known *VWF* mutations (PCR – sequencing)

Antithrombin deficiency
SERPINC1 (PCR and resequencing)

Other tests not included in INAB scope.
FGN mutation testing
F7 mutation screening
F10 mutation analysis
F11 mutation analysis.

Comments:

The laboratory provides testing specifically for the Haemophilia Centres within Eire. It has recently submitted three tests for accreditation under ISO15189 (genetic analysis of *F8*, *F9* and *VWF*), this has been approved pending addressing of several minor non-conformances.

The laboratory does provided a wider testing repertoire locally, including fibrinogen, *F7*, *F11* and *F10* genetic analyses, and may consider submitting these for accreditation in the future.

4. Workload: Please provide a summary of the genetic diagnostic workload in inherited bleeding disorders for the previous 12 months period. This should be provided for the various diagnostic activities (e.g. *F8* gene IVS22, Haemophilia A full mutation screen, haemophilia A carrier diagnosis etc.) undertaken internally and also for other centres.

F8

Mutation Screen	16
Carrier analysis/confirmation of mutation (2nd sample)	76

F9

Mutation screen	7
Carrier analysis/confirmation of mutation	14

VWF

Restricted mutation screen (Type 2 VWD)	16

SERPINC1

Mutation screens	6

Auditor's Comments:

Workload is addressed well for a small laboratory service. 135 samples were tested in the previous year, 67% of which were targeted analyses

10. Sample Processing

1. Specimen acceptance policy: Please identify the minimum sample identification requirements for the laboratory to accept samples for analysis.

2.3.3 The samples must be clearly labelled with the following details

Name (Surname and Forename)

Medical Record Number (MRN)

Date of Birth

Date sample taken

Satisfactory ~~**Unsatisfactory**~~

Comments:

Minimum sample acceptance criteria are available, and consistent with guidelines.

2. Specimen acceptance policy: Please identify the minimum sample identification requirements for the laboratory to accept samples for analysis.

Satisfactory ~~**Unsatisfactory**~~

Comments:

Progeny software is effectively used to manage samples and work throughput.

3. Requests for investigations:
Please outline mechanisms for receiving and recording requests for investigations
Please identify the minimum data set required for the laboratory to accept samples for analysis.

The Genetic Request Form

Samples must be accompanied by a genetic testing request form.

- The form should be a Genetic Request Form as HAEM FORM HMB 030
  This should have the following patient details:
  - i The patient's name (Forename; Surname)
  - ii Medical record number (MRN)
  - iii Date of Birth
  - iv Familial disorder and index severity
  - v Reason for request.: ie Test requested
  - vi Family names
  - vii Whether this is a first, second or confirmatory sample

- viii In the case of first or new samples, a family tree should be present highlighting the relationship between the index and extended family members may be used if present on both the sample and request form.

The Consent Form

When the request is a first sample, a copy of the genetic consent form should accompany the sample.

The form should be based on the UKHCDO form ; as per the NCHCD form:HAEM FORM 0224

Sample Details

Adult

- Unless discussed otherwise the sample consists of 2 x 9ml EDTA anti-coagulated whole blood.

Paediatric

- Due to the difficulty of obtaining samples from young children, no lower limit is given; however ideally the sample should be at least 2x 3mls of EDTA anti-coagulated blood.

The samples must be clearly labelled with the following details

- Name (Surname and Forename)
- Medical Record Number (MRN)
- Date of Birth
- Date sample taken

Cross-Reference

The details on the samples and forms should be checked and the identifiers must match.

If the sample and form details do not correspond, the sample and forms must be placed to one side and the requester/user notified as soon as possible, and a note made.

If any alteration change is made to either the form or samples by the user/requester the person must take responsibility by signing and dating accordingly on the request form.

If there is no consensus possible between the sample and form the sample must be rejected (see section 3).

Sample and request data are stored on the LIS, and on Progeny Database

Satisfactory **~~Unsatisfactory~~**

Comments:

Progeny software is effectively used to manage samples and work through-put.

4. Sample storage: A SOP is required explaining arrangements for secure storage of diagnostic samples

HAEM-QP-HMB-003 POLICY REGARDING THE STORAGE OF BUFFY COATS AND EXTRACTED DNA

Satisfactory ~~**Unsatisfactory**~~

Comments:

An SOP is available

11. Quality of the Diagnostic Service

Audit Standard: The Genetics laboratory associated with the CCC should have full CPA accreditation. The laboratory should participate in a national quality assurance scheme.

1. Does the Genetics Laboratory have full CPA accreditation?
Please delete as appropriate

CPA accreditation was in place until 31st December 2013. The laboratory was inspected (as part of a LabMed wide inspection) by the Irish National Accreditation Board (INAB) in January 2014 according to ISO15189 v.2012 standards. Accreditation is expected for the LabMed Directorate, pending close-out of minor non-conformances.

Please give date of last inspection:

Comments:

Satisfactory

F9 and *VWF* genetic analyses were submitted for accreditation under ISO15189 during recent INAB inspection

2. Documentation; A vertical audit will be carried out during the visit to evaluate the use of laboratory documentation: Full SOPs, including details and records of IQC, must be available at the audit visit for all laboratory procedures.

Satisfactory ~~**Unsatisfactory**~~

Comments:

A vertical audit was carried out successfully; this documentation and processes were reviewed for a patient sample that underwent carrier analysis. This did not raise any areas for concern.

3. Urgent Samples: There should be protocols available for handling urgent samples.

HAEM-LP-HMB-016: Receipt and Analysis of an Urgent or Priority Sample

Satisfactory ~~**Unsatisfactory**~~

Comments:

The laboratory has provision in place for dealing with these requests, and good links with other services to facilitate urgent investigations**.**

4. Turnaround time: The laboratory should comply with the agreed turnaround times. These should be stated and would normally be expected to be between 6-8 weeks for investigative tests and 2-6 weeks for confirmation of known/familial mutations. The laboratory should be able to provide a rapid turnaround (~2 weeks) for urgent requests and (3-4 working days) for PNDs.

There should be evidence that Turnaround Times are regularly audited.

What proportion of investigations meet the required turn-around time?

95% carrier samples were reported within 4 weeks in 2013 (target 85%)

- Average TAT: 3 weeks
- Median TAT: 3 weeks
- 84 carrier samples completed in 2013

85% mutation samples reported within 12 weeks (target 85%)

- Average TAT: 8 weeks
- Median TAT: 5 weeks
- 28 mutation samples reported in 2013

Satisfactory ~~**Unsatisfactory**~~

Comments:

Turnaround targets are audited and satisfactory.

5. Internal Quality Control: Give a brief description of the processes involved in ensuring the reliability and validity of generated results:

See below as from HAEM-QP-HMB-004: QUALITY ASSURANCE WITHIN THE HAEMOSTASIS MOLECULAR LABORATORY

General

- All analytical procedures have quality control criteria as described in the relevant SOPs.
- The quality control is dependent upon the procedure; guidelines are described below.
- All hard copy of results files: PCR files; Sequence logs, Sequence screens – should contain IQC failure record sheet (Haem-Form-HMB-074). This sheet should contain records of failures of IQC or poorly performing runs etc.
- The IQC failure record sheet should be reviewed regularly (bi-monthly).

***F8* Inversion Analysis**

- Refer to SOP Haem-LP-HMB-005 *F8 Int 22 inversion analysis* and Haem-LP-HMB-006 *F8 Int 1 Inversion Analysis.*
- Inversion positive samples for the intron 22 or the intron 1 inversion event must be used with each run; details of which samples can be used are found with the relevant SOP.
- In the event of a control sample giving an unexpected result, all results should be ignored and the run should be repeated.

- In the event of a failure of amplification in a single run, the control amplification should be repeated.

PCR Amplification: General Points

- Refer to the relevant SOPs Haem-LP-HMB-003 *F8 Gene Screen Amplification;* Haem-LP-HMB-004 *F9 Gene Screen Amplification.*
- Amplicons (Amplification products) should be of the expected size as shown in the appendix of each SOP.
- The only exception to 4.3.2 is the presence of an insertion or deletion; detectable on repeat analysis and sequence analysis .
- The intensity of product should be scored on a score of 0 (no amp) to 3 (strong amp).
- A non-template control is used in each screen.
- Non-template control (NTC) should be included for runs that are performed for carrier, confirmation or verification of mutations.
- Any amplification of a NTC should be logged as a non-conformance, the PCR run ignored and binned, and reagents used in the PCR run should be binned. All surfaces should be thoroughly cleaned using Virkon or similar.
- In the event a non-template control demonstrating the presence of an amplicon, the run should be ignored, and repeated with 'fresh' previously unused reagents.

Sequence Analysis: General Points

- Sequence analysis quality is monitored by examination of a signal and signal to noise ratio as described in SOP: HAEM-LP-HMB-011: *Analysis of Sequencing Data by Use of Software*.
- All carrier analyses should be co-analysed with an index sample where possible.
- All samples are checked against a 'wild-type' sequence and reference sequence.
- All laboratory results are co-signed.
- Multiple poor sequences in a given run should be recorded
- Poorly performing sequences of the same amplicon should be evaluated by examining the PCR amplification and if required redesign of the PCR should be considered

Satisfactory **~~Unsatisfactory~~**

Comments:

Appropriate IQA procedures are in place to support and ensure test quality.

6. External Quality Assurance: The laboratory must participate satisfactorily in appropriate EQA scheme(s). Please provide details of schemes participated in and any unsatisfactory performance during the last 2 years, including information on how any unsatisfactory performance has been addressed

Participant in NEQAS BC Genetics scheme
Participant in EMQN sequencing scheme

No unsatisfactory performances.

Satisfactory **~~Unsatisfactory~~**

Comments:
Satisfactory performance in EQA

7. Clinical and Laboratory Audit: The laboratory should provide evidence of participation in both Clinical and Laboratory local audit.

Audit schedule recorded on Q Pulse.

Satisfactory **~~Unsatisfactory~~**

Comments:
An audit schedule was available.

12. Reporting

1. Databases: Please identify patient/result databases and explain mechanisms for safe maintenance and confidentiality of these, in accordance with Caldicott guidelines.

1. LIMS- record of sample receipt under the patient name. Specified users and password protected. No record of result.

2. Progeny database- record of sample and family tree. Patient results are entered and kindred data recorded. Specified users only and password protected. 3 licences available.

3. Clintech (electronic patient database and record). Consent images are scanned onto 'Clintech'. All patient reports are entered under the relevant patient record. No family trees are held on Clintech.

All data is held in accordance with Caldicott guidelines

Satisfactory ~~**Unsatisfactory**~~

Comments:

It was noted that the availability of genetic reports electronically, together with consent information was advantageous.

2. Approved Reporting Format: Are report formats in accordance with CMGS Best Practice Guidelines?

Yes

Satisfactory ~~**Unsatisfactory**~~

Comments:

Satisfactory

3. Validation Procedures: Please describe mechanisms for result reporting, including validation and authorisation of reports. Individuals responsible for result validation and report authorisation must be professionally registered.

See section below from HAEM-LP-HMB-013 Preparation and Authorisation of Patient Reports.

Overview of Report

- The report **must** contain three unique identifiers of the patient. Name and DOB must be two of the identifiers. Hospital MRN should be a third identifier. If the MRN from

an external hospital is not identified, an unique laboratory number from the referring hospital may under exceptional circumstances be used.

- The report **must** contain the clinical reason for genetic analysis and the gene analysed.
- The report **must** contain unique identifiers of the sample (including date received), the source of the sample and relevant laboratory tracking and test identifiers.
- The report **must** contain the result of the investigation in an unambiguous form.
- The report **must** contain a descriptive and unambiguous interpretative comment of the results.
- The report **must** contain identification of relevant reference sequences and of nomenclature used.
- The report **should** briefly mention the method of analysis including in the absence of a result.
- The report **should** contain relevant phenotype and laboratory data that aid the understanding of the report.
- The report **may** contain a family tree that identifies the index case and patient being analysed.
- The individual patient report **should not** identify any other family member or their results with the exception of index patients analysed and individuals where knowledge of their result is required for unambiguous interpretation of the results.
- The report **must** be authorised by two staff. Those qualified to sign the report are the Chief Molecular Scientist, Senior Molecular Biologist and Consultant staff.

Satisfactory ~~**Unsatisfactory**~~

Comments:

Satisfactory

13 Providing an Integrated Service

1. Coagulation Laboratory: Please explain links with the coagulation laboratory and mechanisms for the provision of phenotypic data relevant to genetic investigations.

The coagulation lab and molecular lab are adjacent. There is ready access to all phenotype data via LIMS. Weekly report sign out meetings attended by coagulation chief, chief molecular biologist and Consultant Haematologists.

Satisfactory ~~**Unsatisfactory**~~

Comments:

Excellent links currently exist due to co-location, it is important that these links are acknowledged and maintained, as this may not be the case after re-location.

2. Clinical Service: Provide examples e.g. regular meetings between laboratory and clinical staff involved with the genetic diagnostic service provision.

MDT Genetics meetings (quarterly).
Weekly result sign off and lab management meetings with consultants.

Satisfactory ~~**Unsatisfactory**~~

Comments:

Again, co-location of services has advantages that may be lost on re-location and it is important that good two-way communication between the laboratory and clinical services is maintained.

14. Service Continuity

1. Outline plans to ensure an uninterrupted continuity of service in the event of
    - Staffing problems e.g. sickness, leave, recruitment problems etc.
    - Equipment failure – catastrophic loss of essential equipment e.g. sequencer.
    - Facilities issues e.g. fire, flood etc. rendering facilities unusable.
    - Supply failure – inability to access essential reagents or consumables.
    - Technical failure – unable to generate a result.

A service level agreement exists between the Regional Genetics Service at Sheffield Children's Hospital and NCHCD to provide genetic services in the event of continuity of service being interrupted at the NCHCD.

Specific provisions within St James's Hospital are described below.

Staffing: Long term absence staff can be recruited on approval of the vacancy.
Equipment failure: Use of equipment in CMD and LabMed (including ABI 3130).
Facilities issues: Relocation of service to Lab Med.
Supply failure or technical failure: Test request(s) will be performed at Regional Genetics Laboratory, Sheffield or accredited genetics lab within the UKHCDO Genetic laboratory network.

Satisfactory **~~Unsatisfactory~~**

Comments:
Satisfactory procedures are in place.

15. Service Development

1. Please explain the mechanisms (staffing, equipment, funding etc) within your centre to enable service developments as are required to maintain an up-to-date and high quality diagnostic service provision.

Staffing: replacement of staff due to long-term absence through illness or maternity leave etc is made by application to human resources and hospital management via a VAF (vacancy approval form).

Equipment: replacement of any equipment or funds for additional equipment are made by submitting a business case to LabMed manager, and if substantial funds to the hospital board.

Comments:

Service development is challenging for a small laboratory, and additional technical post would be beneficial in providing service continuity, and facilitating service development.

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 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.

The inpatient facilities are very impressive and it is imperative that the National Centre for Hereditary Coagulations Disorders (NCHCD) is co-located immediately adjacent to the inpatient and walk-in ward to ensure optimal continuity of safe care and a fully integrated service.

The development of the walk-in service on the H&H assessment unit provides an ideal opportunity for the development of advanced nurse practitioner roles.

The centre is well-resourced but the capacity of a highly specialised team of nurses to sustain a complex service is vulnerable to unpredictable loss of staff due to sickness or maternity leave. Whilst rotation of staff between anticoagulation and haemophilia allows flexibility, the demands of high volume anticoagulation services can lead to a risk of eroding the availability of specialist haemophilia expertise. We recommend that any potential impact is carefully monitored.

The team look for opportunities that may be relevant to this field such as the Stanford model, Living Well with Long Term Conditions, and have taken the commendable initiative to utilise this self-management programme.

Medical Auditor

Comment

It is difficult to find anything to fault with this service. It is a world class, patient-focused service and the staff within the Centre and the Hospital should be proud of this. It is proactive rather than reactive and has many novel and innovative approaches to the management of individuals and their families with inherited bleeding disorders.

There are countless examples of best practice and the auditors agreed that all the staff worked as a team to provide the highest standard of care. The centre has a fully comprehensive team that has to be the envy of many centres.

We were able to visit the new in-patient and out-patient facilities and our only concern relates to the geography of the new Centre when it is built, with the relocation of the Children's Hospital to the St James's site. It is imperative that the new centre is in close proximity to the in-patient and out-patient facilities.

We are aware that the genetics lab will decant to the main Central Pathology Laboratory (CPL) although we understand that the exact arrangement is yet to be determined. This is a logical evolution but it is important that close links with the clinical services remain.

It was a pleasure to audit this centre.

Nursing Auditor

Comment
This is an exemplar centre for the care of individuals and families affected by inherited bleeding disorders. There is a quality culture that is embedded in all aspects of the service. The commitment, enthusiasm and motivation of the staff to continuously develop the service in partnership with patients are most impressive and inspiring. There is strong leadership demonstrated here and team members clearly work together to create shared goals and are empowered and recognised for their contribution. The nursing group have developed nurse-led services and are committed to enhancing their role and advancing their practice. They consider trends such as the growing numbers of ageing patients and anticipate how the service will respond. The development of the walk-in service on the H&H assessment unit provides an opportunity for the haemophilia nurses to further exercise advanced assessment and management skills.

Patient-Parent Auditor

Comment

The Centre at St. James's is clearly of the highest calibre. Both the visit to the Centre and the patients confirm this. The final patient comments sum it up well.

I want to thank the centre for their kindness over the years.

I'm someone who has several medical conditions that require me to see several doctors. In my haemophilia centre, I'm rarely left waiting more than 15 minutes which isn't the same in other hospitals. It makes a real difference.

The staff and doctors at St. James's Hospital are excellent and very caring.

I have great praise for the centre. I am known by name, treated with total respect from the moment I enter reception. The nurses, doctors, dentist are all warm and friendly. They are never too busy to pass without saying hello.

A friendly and well-educated staff.

Genetics Auditor

Comment

The Haemophilia Centre currently benefits from a bespoke genetic laboratory service, with excellent links to the clinical service. Although the laboratory is small, they address the workload well and with a high level of expertise.

The re-location of the Haemophilia Centre is likely to separate clinical and laboratory services, and it is important that the good links between these are maintained.
This is also a good opportunity for the genetic laboratory to consider closer working with other genetics services in order to take advantage of new technologies/ procurement opportunities in the future.

The laboratory would benefit greatly from an additional member of staff to contribute to the technical work. On suggestion would be for a rotational Medical Scientist post shared with the Coagulation laboratory to be established, which would support the haemophilia genetics service and offer additional training opportunities to the Coagulation team. It would also release Dr Jenkins to focus on his management role and the increasing demands associated with maintaining service quality (as illustrated by recent INAB inspection) and service development. It was noted that similar concerns regarding staffing were raised at the previous audit, and in view of the additional pressures associated with the imminent re-location of the services this issue should be considered with high priority.