Care of People with Inherited and Acquired Haemophilia and other Bleeding Disorders

University Hospitals of Leicester NHS Trust

Visit Date: 1st October 2019

Report Date: December 2019

8831

Contents

Introduction

This report presents the findings of the peer review of services for people with Inherited and Acquired Haemophilia and other Bleeding Disorders at University Hospitals of Leicester NHS Trust, which took place on 1st October 2019.

The purpose of the visit was to review compliance with the Quality Standards for Inherited and Acquired Haemophilia and other Bleeding Disorders (V1 July 2018) which were developed by the UK Haemophilia Centres Doctors' Organisation (UKHCDO) Peer Review Working Group working with the Quality Review Service (QRS).

The peer review visit was organised by QRS on behalf of the UKHCDO.

The aim of the standards and the review programme is to help providers and commissioners of services to improve clinical outcomes and service users' and carers' experiences by improving the quality of services. The report also gives external assurance of the care, which can be used as part of organisations' Quality Accounts and Annual Governance Statement. For commissioners, the report gives assurance of the quality of services commissioned and identifies areas where developments may be needed.

The report reflects the situation at the time of the visit. The text of this report identifies the main issues raised during the course of the visit.

Appendix 1 lists the visiting team and **Appendix 2** gives details of compliance with each of the standards and the percentage of standards met.

This report describes services provided or commissioned by the following organisations:

- University Hospitals of Leicester NHS Trust
- NHS England Specialised Commissioning East Midlands

Most of the issues identified by quality reviews can be resolved by providers' and commissioners' own governance arrangements. Individual organisations are responsible for taking action and monitoring this through their usual governance mechanisms. The lead commissioner for the service concerned is responsible for ensuring action plans are in place and for monitoring their implementation, liaising, as appropriate, with other commissioners.

About the Quality Review Service

QRS is a collaborative venture between NHS organisations to help improve the quality of health services by developing evidence-based Quality Standards, carrying out developmental and supportive quality reviews (often through peer review visits), producing comparative information on the quality of services and providing development and learning for all involved.

Expected outcomes are better quality, safety and clinical outcomes, better patient and carer experience, organisations with better information about the quality of clinical services, and organisations with more confidence and competence in reviewing the quality of clinical services. More detail about the work of QRS is available at www.qualityreviewservicewm.nhs.uk

Acknowledgments

Quality Review Service would like to thank the staff of the Leicester Comprehensive Care Centre for their hard work in preparing for the review and for their kindness and helpfulness during the course of the visit. We are grateful, too, to the patients and parents who took time to meet the review team.

Thanks are also due to the visiting team (**Appendix 1**) and their employing organisations for the time and expertise they contributed to this review.

Leicester Comprehensive Care Centre

The Haemophilia Comprehensive Care Centre was based at Leicester Royal Infirmary and cared for both adult and paediatric patients with bleeding disorders and other haemostasis issues. The unit was open between 8.30am and 4.30pm Monday to Friday, with emergency arrangements in place as outlined below. There was a children's hospital and, whilst consideration had been given to a formal separation of the services, the team felt there was value in the existing joint model, particularly when considering life-long care, care for families with inherited disorders and transitioning from children to adult services.

The unit comprised three clinic rooms, a treatment room (with clotting factor concentrate fridge), two consultant offices, a nursing office, a clinic coordinator office and a storage room. The waiting area was located in the centre of these rooms and was partitioned to allow for a small children's play area. The remaining hospital facilities were in a separate building which was nearby. Parking had been improved in recent years with the addition of a multi-storey car park, and access to the Emergency Departments was straightforward from the major roads adjacent to the hospital.

In the two years prior to the review, there had been a significant change of staffing at all levels (due to multiple retirements, maternity leave, and long-term sick leave). A full staffing complement had been achieved once again in July 2019. This had had an inevitable impact in terms of some aspects of service development, but the team felt that the overall quality of the service had been maintained well at the clinical/patient level, and that the new team were working well together.

The haemostasis team was managed via the haematology head of service, with haematology being managed within the Cancer/Haematology/General Surgery Clinical Management Group (CMG) in University Hospitals of Leicester (UHL).

The specialist haematology laboratory was situated close to the Haemophilia Centre, and good links existed between the laboratory staff and the unit. The laboratory team maintained an excellent service both in and out of hours and aimed to be responsive to the clinical changes that occurred within the field of haemostasis.

There was a weekly haemostasis Multi-disciplinary Team (MDT) meeting, with an additional board round once a week (or more frequently as required); once a month this MDT was a dedicated haemophilia / bleeding disorders MDT, which included physiotherapy input in addition to the "standard" MDT. This allowed for improved sharing with the whole team of higher-level information, such as attendance, Haemtrack performance, guideline review, national changes, UKHCDO information etc. There was a weekly haemophilia / bleeding disorders clinic for adults and a weekly clinic for children. These were MDT clinics with medical, nursing and physiotherapy input. An orthopaedic consultant held a clinic in the unit alongside the haemophilia / bleeding disorders clinic on a two-monthly basis.

At the time of the review, the following numbers of patients were registered at the Centre:

Condition		Number of patients	Number of patients who had an annual review in last year		Number of in-patient admissions in last year
Haemophilia A	Adults 93	Severe: 24 Moderate: 12 Mild: 57	Severe: 20 Moderate: 11 Mild: 20	Severe: 4 patients had appointments offered on more than 1 occasion but CNB+DNA Moderate: 1 patient appointment offered on more than 1 occasion but CNB+DNA Mild: appointment offered, pending	13
	Children 23	Severe: 11 Moderate: 4 Mild: 8	Severe: 11 Moderate: 1 Mild: 4	Moderate: 2 patients are new-borns, 1 patient appointment offered but CNB Mild: appointment offered, pending	5
Haemophilia B	Adults 26	Severe:8 Moderate:6 Mild:12	Severe: 7 Moderate: 4 Mild: 5	Severe: 1 appointment offered on more than 1 occasion but CNB+DNA Moderate: 2 patients offered appointments but CNB+DNA Mild: appointment offered, pending	3
	Children 7	Severe: 6 Moderate: 0 Mild: 1	Severe: 4 Mild: 0	Severe: 2 patients offered appointments but CNB Mild: upcoming appointment	1
Von Willebrand	Adults 222	Type 1: 13 Type 2: 11 Type 3: 1 no type: 197	46		6
	Children 27	Type 1: 4 Type 2: 5 No type: 18	11		3
Other	Adults	613	85		5
	Children	60	30		3

Emergency Care

Emergency care was identified as any care that needed to be administered outside the Centre opening hours as outlined above. The agreed process was that the patient or their carer called the on-call haematology Specialist trainee for advice. If the patient needed to attend, they would attend either the Osborne assessment unit or the Emergency Department (ED) (depending on the specific complaint) for adults. Children were requested to attend the ED.

Ward Care

The ward on which a patient was admitted depended on the specific complaint rather than their bleeding condition. For example, a person with haemophilia would be admitted to a surgical ward if attending for surgery, but to the haematology ward for a portacath infection. There was no dedicated ward for bleeding disorders.

Day Care

The haemophilia unit (described above) was dedicated to people with bleeding disorders and other thrombosis-related problems.

Outpatient Care

Each week there was a separate adult and paediatric outpatient clinic. The adult clinic was specifically for diagnosed and heritable bleeding disorders. The children's clinic was attended by patients with possible bleeding issues, haemostatic investigation of non-accidental injury, thrombosis, family history of thrombosis and complex anticoagulation issues

Community Based Care

The nursing staff within the Haemophilia Centre provided some home visits. However, this was limited because of team capacity. The paediatric nurse performed the majority of these visits, including school support visits or when a new haemophilia baby was born.

Return to Index

Review Findings

Achievements

This relatively young team, coming from a point of staffing crisis about a year before the visit, was working remarkably well together in providing a caring, patient-centred, and flexible service. Some remaining staff shortages (see Concerns below) meant that they were not able to achieve what they wanted and intended to, and to some extent the service was still evolving. The team was well led, passionate about their work, and creative in their approach. There were strong links with other clinical specialty teams. Especially noted were the contributions being made by all the nurse specialists, the data manager, and the physiotherapist, who was providing a very good service despite having very limited contracted hours. There had been recent improvement in the support the team received from clinical and non-clinical managers in the wider Trust.

Patients were overwhelmingly positive in their feedback about the care they received from all team members and were keen to express their gratitude.

The emergency pathway worked well, and patient experience of ED care was good. The clinical guideline provided by the Centre was clear, and staff in the ED were knowledgeable about immediate management for acute presentations in people with bleeding disorders. An immediate alert flashed up when patient details were entered into the 'Nervecentre' (the Trust IT system), giving the patients diagnosis and contact number for the specialist team. Patients were assessed promptly, and the specialist team were involved very early in their management.

Good Practice

1. Some of the clinical guidelines, for example, inhibitor testing and immune tolerance, were particularly good. There was a novel comprehensive integrated care pathway, 'Think, Signal, Move', for use with young people in transition from children's to adult services.
2. Detailed personalised 'Healthcare plan for pupils with medical needs' guidance was sent to the schools of all children with significant bleeding disorders.
3. Joint working with the obstetric team was exemplary. There were strong clear written guidelines, and a weekly joint clinic was very well organised by a specialist obstetric haematology nurse specialist. A named obstetrician and haematologist attended if the lead consultants were absent. Women and their partners were seen in the clinic for counselling and testing as required, and then for ongoing antenatal care where appropriate. Haematology and obstetric specialist registrars worked together in the clinic for training experience, discussing each couple with the consultants. Delivery plans were drawn up and included in the women's hand-held notes. They were also written for women who were found not to be at risk of having an affected infant, so that there was no anxiety about special precautions to be taken at the time of delivery.
4. The medical records were in hard copy, and each had a red triangle alert sticker on the front, and a yellow sticker indicating the need to avoid intra-muscular injections, non-steroidal anti-inflammatory drugs, and aspirin. A more detailed alert sheet giving the diagnosis and treatment constituted the front page within the cover.
5. The ward area available for the use of teenagers and young people was of a very high standard.

6. Haemtrack[1] compliance was close to 100%.

Immediate Risks

In the management of acute joint bleeds, the clinical guideline did not state that in patients receiving Emicizumab,[2] Feiba was contraindicated, as in combination these agents can lead to thrombotic microangiopathy and venous thrombosis, and that instead they should receive NovoSeven.

Trust response

The Centre Director has undertaken immediate remedial action and provided the following response:

The draft guideline covering the risk which surrounds co-administration of Emicizumab and FEIBA which can lead to potentially life-threatening complications, has been edited to ensure the contraindication is identified. In addition, it is worth noting that;

- Both patients on Emicizumab have an alert card with this information on it;
- The prescriptions for these patients also detail the risk;
- Before using it for the first time, the Centre Director wrote to all the haematology team detailing the risk as well.

QRS Response

We have now considered your response and can confirm that the actions, as described will address the immediate risk once fully implemented.

Concerns

1. **Staffing**

There remained significant staffing shortages, and this impacted on the team's ability to offer the multi-professional holistic care expected for children and adults with these long-term conditions.

a. Paediatric medical staff: Senior paediatric medical support for the adult haematologist leading the paediatric service was lacking, and, while the service functioned well, reviewers felt that this potentially left him vulnerable when managing specific paediatric issues.

b. Physiotherapy: A very experienced physiotherapist was working in the service but was only contracted for 0.2 WTE (one day per week). Within this time, he could see patients in the adult and paediatric specialist clinics but could not offer ongoing management of synovitis or provide long-term joint health surveillance and care. There was no cover for absence, so that in a period of sick leave earlier in the year no joint scores had been undertaken. He sometimes referred patients to the general physiotherapy service, but patients were not then having the advantage of specialist

[1] **Haemtrack** - Haemtrack is a secure recording system developed to connect patients and clinicians through the Haemtrack phone apps and website. Haemtrack enables patients to record all therapies as they occur and allows clinicians to see up-to-date therapy information to help monitor, optimise and improve patient care.

[2] **Emicizumab** (trade name Hemlibra) is a humanized bispecific antibody for the treatment of haemophilia A. It functions by bringing together other blood clotting factors to promote clotting and reduce bleeding, in the absence of factor VIII.

expertise. Patients often contacted him outside his contracted hours, but these discussions were not always fully documented. There was no guideline for long-term joint health; an audit against such guidance would be valuable in evidencing additional need.

c. Paediatric nursing staff: A 0.6 wte paediatric nurse lead was working very effectively, but there was no children specific cover for her at times of absence. Cover was provided by the haemophilia nursing team.

d. Psycho-social care: There was no psychologist working within the team, although this is an expected core team member for patients with these long-term conditions. Patients could be referred to the general hospital psychology service but could wait up to three months to be seen. Under these circumstances, only the highest-level patient and family needs were being met, and the team lacked the professional support that an integrated psychology member brings. Play therapy was usually not available at times when children were being treated; this had an impact on the work of the nurses, as two nurses were often required to manage children for cannulation etc.

e. Administrative and clerical support: This was insufficient, so the nurses and the data manager were undertaking clerical tasks such as recording and typing up minutes of meetings and answering phones. The review team learned that calls from patients and ED staff were not always answered promptly, and that this could result in delay for patients attending for urgent care.

f. Haematology medical staff: Although the PA provision was judged to be adequate, after a period of very severe under-provision, it was noted that the allocation for the Centre director to undertake this role had been reduced from 1 to 0.5 PA, and that he and his colleagues were having additional demands on their time, including a request to organise and run a regional Thrombotic Thrombocytopenic Purpura (TTP) service. If this team is to contribute, as would be expected for a Comprehensive Care Centre, to a functioning network in the East Midlands, additional resource will be required.

2. **Governance**

Audit activity appeared to be very limited: the review team were made aware of a small number of informal audits in progress, although no evidence was presented. There had been no recent audits against any of the key standards, including time for patients to receive care when they presented urgently or initiation of prophylaxis in children with severe bleeding disorders. Minutes of meetings, at which review and learning from complaints or incidents should be discussed, were not seen. It was judged that increased focus on formalising and evidencing governance activity was required.

3. **Obstetric practice at Kettering General Hospital**

In a telephone discussion with the haematologist at Kettering, it was understood that pregnant women with bleeding disorders usually delivered at Leicester Royal Infirmary, but that those carrying potentially affected babies were delivered locally. There was concern that adequate clinical expertise may not be available within the Kettering teams to manage the delivery and care of a severely affected new-born.

Further Consideration

1. The out of hours rota included some consultants who did not work regularly in the bleeding disorders service, and at these times if there was a complex acute presentation the haemostasis specialist consultants were contacted for guidance. A formal 'second on call' rota for the haemostasis consultants would be more robust.
2. Following the period of staff shortages, there remained a backlog of moderately and mildly affected patients requiring review. However, the recently appointed data manager had identified specifically who these patients were, and plans were in place to appoint them for clinic review.
3. Written diagnostic and clinical guidelines were, overall, good. However, it was felt that a clear algorithm to guide diagnosis in adults and children presenting with a probable bleeding disorder would be additionally useful, and there was very sparse guidance on genetic testing for those with inherited bleeding disorders, and on the diagnosis and management of acquired haemophilia.
4. Clinical guidelines and the service description were written mainly from an adult perspective, and could be expanded to include more focus on the paediatric service
5. It was noted that although the senior clinical staff are required to undertake Level 3 Child safeguarding training, this had recently expired.
6. Although there were 'paper' medical records, clinic letters were available electronically. However, consultants could not access this system remotely when on call from home, and it would be helpful if this could be arranged.
7. There did not appear to be a robust system for identifying, and recalling for testing and counselling, potential or obligate carrier females before they reached reproductive age. A system relying on GP's referring at the appropriate time was not considered to be fail-safe.
8. There were clear diagrammatic pathways for managing patients presenting to the ED, in and out of hours. It would be helpful if a contact extension / bleep number could be included in the section advising ED staff to call the specialist team.
9. Research activity was considered to be slight, given the number of patients being managed. It was recognised that recent staff shortages had made all but direct clinical care challenging; however, with the improved medical and nursing staff levels, it would now be possible to offer patients the opportunity of being involved in clinical trials.
10. Most of the documents and guidelines had details of authorship and the date they had been written, but few had planned review dates. The operational policy lacked any detail of authorship or dates. A few of the Trust policies offered in evidence were beyond their review date.

Return to Index

General Comment

Formal network arrangements were not in place, and the Centre team did not complete the self-assessment against the network standards HY-199 to HY-798.

The East Midlands Regional Haemophilia Committee met informally three times a year; these meetings were organised by the Nottingham CCC team and chaired by its centre director; they included members of the Leicester, Derby, Kettering and Lincoln teams. This was a useful forum at which there was some data sharing, case discussion, and educational sessions. Specialist commissioners had not attended any of the meetings. It was acknowledged that some additional aspects of network functioning, including shared guidelines, shared audits and benchmarking, and the offer of access for all patients to research studies, would be valuable and that further work towards achieving this would be appropriate. Discussion around the potential for shared staff appointments would be relevant across the East Midlands region, given the common shortfall in some key staffing areas including specialist physiotherapists and psychologists.

Return to Index

APPENDIX 1 Membership of Visiting Team

Visiting Team		
Patricia Bell	Haemophilia Nurse Specialist	University Hospital Southampton NHS Foundation Trust
Caroline Clegg	Clinical lead rheumatology / haematology therapy team	Manchester University NHS Foundation Trust
Dr John Grainger	Consultant Paediatric Haematologist	Manchester University NHS Foundation Trust
Pam Green	Haemophilia Nurse	University Hospitals Birmingham NHS Foundation Trust
Dr Kerry-Ann Holder	Consultant Clinical Psychologist in Haemophilia and Child Health	The Noah's Ark Children's Hospital for Wales
Dr Lishel Horn	Consultant Haematologist	Leeds Teaching Hospitals NHS Trust
Eileen Ross	Patient representative	

QRS Team		
Rachael Blackburn	Assistant Director	Quality Review Service
Dr Anne Yardumian	Consultant Haematologist	Programme Clinical Lead

Return to Index

APPENDIX 2 Compliance with the Quality Standards

Analyses of percentage compliance with the Quality Standards should be viewed with caution as they give the same weight to each of the Quality Standards. Also, the number of Quality Standards applicable to each service varies depending on the nature of the service provided. Percentage compliance also takes no account of 'working towards' a particular Quality Standard. Reviewers often comment that it is better to have a 'No, but', where there is real commitment to achieving a particular standard, than a 'Yes, but', where a 'box has been ticked' but the commitment to implementation is lacking. With these caveats, table 1 summarises the percentage compliance for each of the services reviewed.

Table 1 - Percentage of Quality Standards met

Details of compliance with individual Quality Standards can be found below.

	Number of applicable QS	Number of QS met	% met
Haemophilia Comprehensive Care Centre	37	22	59
Network	8	3	38
Commissioning	3	0	0
Total	48	25	52

Return to Index

Comprehensive Care Centre

Ref	Standard	Met?	Comments
HP-101	**Service Information** Written information should be offered to patients and, where appropriate, their carers covering at least: a. Brief description of the service b. Clinic times and how to change an appointment c. Ward usually admitted to and its visiting times d. Staff of the service e. Community services and their contact numbers f. Relevant national organisations and local support groups g. Where to go in an emergency h. How to: i. Contact the service for help and advice, including out of hours ii. Access social services iii. Access benefits and immigration advice iv. Interpreter and advocacy services, PALS, spiritual support and HealthWatch (or equivalent) v. Give feedback on the service, including how to make a complaint vi. Get involved in improving services (QS HP-199)	Y	

Ref	Standard	Met?	Comments
HP-102	**Condition-Specific Information** Written information should be offered to patients and, where appropriate, their carers covering at least: a. A description of their condition and how it might affect them b. How their condition is diagnosed c. Genetics of inherited bleeding disorders d. Testing for carrier status and the implications of being a carrier e. Problems, symptoms and signs for which emergency advice should be sought f. Out of hours services g. 'On demand' clotting factor treatment h. Prophylaxis i. Self infusion (or infusion by parent or carer) j. Home therapy and use of Haemtrack k. How to manage bleeding at home l. Ports, fistulae and in-dwelling access devices (if applicable) m. Possible complications, including inhibitors and long term joint damage n. Approach to elective and emergency surgery o. Women's health issues p. Health promotion, including smoking cessation, health eating, weight management, exercise, alcohol use, sexual and reproductive health, and mental and emotional health and well-being q. Dental care r. Travel advice s. Vaccination advice t. National Haemophilia Database, its purpose and benefits u. Sources of further advice and information Information should be available covering: 1. Haemophilia A 2. Haemophilia B 3. Von Willebrand Disease 4. Acquired haemophilia 5. Inherited platelet disorders 6. Other less common and rare bleeding disorders	N	Reviewers did not see any evidence of condition-specific information, and information was not visible within the clinical areas.

Ref	Standard	Met?	Comments
HP-103	**Plan of Care** Each patient and, where appropriate, their carer should discuss and agree their Plan of Care, and should be offered a written record covering at least: a. Agreed goals, including life-style goals b. Self-management c. Planned assessments, therapeutic and/or rehabilitation interventions d. Early warning signs of problems, including acute exacerbations, and what to do if these occur e. Agreed arrangements with school or other education provider and preparation for adult life (children and young people only) f. Planned review date and how to access a review more quickly, if necessary g. Who to contact with queries or for advice The Plan of Care should be communicated to the patient's GP and to relevant other services involved in their care.	Y	
HP-104	**Review of Plan of Care** A formal review of the patient's Plan of Care should take place at least six monthly for patients with severe or moderate haemophilia and at least annually for other patients. This review should involve the patient, where appropriate their carer, and appropriate members of the multi-disciplinary team. Haemtrack results should be reviewed (if applicable) and the outcome of the review should be communicated in writing to the patient and their GP.	N	Not all patients were receiving their six-monthly reviews, where appropriate.
HP-105	**Contact for Queries and Advice** Each patient and, where appropriate, their carer should have a contact point within the service for queries and advice. A clear system for triage of urgent clinical problems should be in place. If advice and support is not immediately available for non-urgent enquiries, then the timescales for a response should be clear. Response times should be no longer than the end of the next working day. All contacts for advice and a sample of actual response time should be documented.	Y	
HP-106	**Haemtrack (Patients on Home Therapy)** All patients on home treatment should be encouraged to use electronic recording of their treatment through Haemtrack.	Y	

Ref	Standard	Met?	Comments
HP-194	**Environment** The environment and facilities in out-patient clinics, wards and day units should be appropriate for the number of patients with inherited and acquired bleeding disorders and accessible by people with severe mobility problems. Services for children and young people should be provided in a child-friendly environment, including toys and books / magazines for children and young people of all ages.	Y	
HP-195	**Transition to Adult Services and Preparation for Adult Life** Young people approaching the time when their care will transfer to adult services should be offered: a. Information and support on taking responsibility for their own care b. The opportunity to discuss the transfer of care with paediatric and adult services c. A named coordinator for the transfer of care d. A preparation period prior to transfer e. Written information about the transfer of care including arrangements for monitoring during the time immediately afterwards f. Advice for young people going away from home to study, including: i. registering with a GP ii. how to access emergency and routine care iii. how to access support from their Comprehensive Care Centre iv. communication with their new GP	Y	However, evidence was not seen by reviewers for (f) – young people going away from home.
HP-198	**Carers' Needs** Carers should be offered information on: a. How to access an assessment of their own needs b. What to do in an emergency c. Services available to provide support	Y	
HP-199	**Involving Patients and Carers** The service should have: a. Mechanisms for receiving regular feedback from patients and carers about treatment and care they receive b. Mechanisms for involving patients and carers in decisions about the organisation of the service c. Examples of changes made as a result of feedback and involvement of patients and carers	N	Reviewers did not see evidence of local mechanisms for obtaining regular patient feedback.

Ref	Standard	Met?	Comments
HP-201	**Lead Consultant and Lead Nurse** A nominated lead consultant and lead nurse should have responsibility for staffing, training, guidelines and protocols, service organisation, governance and for liaison with other services. The lead consultant and lead nurse should be registered healthcare professionals with appropriate specialist competences and should undertake regular clinical work within the service and specific time allocated for their leadership role.	Y	
HP-202	**Staffing Levels and Skill Mix** Sufficient staff with appropriate competences should be available for out-patient, day unit and in-patient care and for support to urgent care services. Staffing levels should be appropriate for the number of patients cared for by the service and its role in the network. All staff should undertake regular Continuing Professional Development of relevance to their work in the inherited and acquired bleeding disorders services. Staff working with children and young people should have competences in caring for children as well as in the care of people with bleeding disorders. Cover for absences should be available. In HCCCs these staff should have sessional time allocated to their work with the IABD service. In HCs the arrangements for accessing staff who do not have sessional time allocated to the IABD service should be clearly defined. Staffing should include: a. Medical staff: i. Consultant specialising in the care of people with inherited and acquired bleeding disorders available during normal working hours ii. On-call consultant haematologist (24/7) iii. Arrangements for advice from a consultant specialising the care of people with inherited and acquired bleeding disorders (if not on call) b. Specialist nursing staff: i. Bleeding disorders specialist nurses (5/7) ii. Ward, out-patient and day unit staff with competences in the care of people with inherited and acquired bleeding disorders. c. Clinical specialist physiotherapist d. Biomedical Scientist and Clinical Scientist (further detail on the requirements are included in HP-303) e. Clinical or counselling specialist psychologist or appropriately trained psychotherapist f. Specialist senior social worker g. Data manager	N	See Concerns section of main report.

Ref	Standard	Met?	Comments
HP-203	**Service Competences and Training Plan** The competences expected for each role in the service should be identified. A training and development plan for achieving and maintaining competences should be in place.	N	Evidence was seen by reviewers for nurse members of the team but not for other members of the core team.
HP-204	**Competences – All Health and Social Care Professionals** All health and social care professionals working in the service should have competences appropriate to their role in: a. Safeguarding children and/or vulnerable adults b. Recognising and meeting the needs of vulnerable children and/or adults c. Dealing with challenging behaviour, violence and aggression d. Mental Capacity Act and Deprivation of Liberty Safeguards e. Resuscitation	Y	However, see Further Consideration section of main report relating to Level 3 safeguarding.
HP-299	**Administrative, Clerical and Data Collection Support** Administrative, clerical and data collection support should be available.	N	Although data management was strong, reviewers heard that nurses were often picking up administrative tasks.
HP-301	**Support Services** Timely access to the following support services should be available: a. Play support (children's services only) including: i. Play and distraction during any painful or invasive procedures ii. Play support to enable the child's development and well-being b. Pharmacy c. Dietetics d. Occupational Therapy e. Orthotics	N	Reviewers heard that, although there was play support available for paediatric patients, this was not timely.
HP-302	**Emergency Department – Staff Competences** Medical and nursing staff working in the Emergency Department should have competences in urgent care of people with inherited and acquired bleeding disorders including awareness of: a. Guidelines on care of patients with inherited and acquired bleeding disorders in the Emergency Department (QS HP-504) b. Who to contact for advice	Y	However, see Further Consideration section of main report regarding inclusion of a contact number on the guidelines for out of hours. In addition, there was no audit in relation to emergency waiting times.

Ref	Standard	Met?	Comments
HP-303	**Laboratory Service** a. A UKAS / CPA accredited laboratory service with satisfactory External Quality Assurance performance should be available 24/7 b. A laboratory representative (senior biomedical scientist or clinical scientist) should attend inherited and acquired bleeding disorder service multi-disciplinary team meetings (QS HP-602) regularly c. The following tests should be available: i. All coagulation factor assays (24/7) ii. Inhibitor screening iii. FVIII inhibitor quantification iv. VWF antigen v. VWF activity vi. Platelet function testing d. Molecular Genetic Laboratory service for: i. detection of causative mutations in patients with inherited bleeding disorders ii. carrier detection	N	Reviewers heard that at the time of the visit the laboratory was not UKAS accredited.
HP-304	**Specialist Services** Timely access to the following specialist staff and services should be available as part of a HCCC service. HCs should be able to access these services through network arrangements: a. Obstetrics including reproductive counselling, information about pre-implantation genetic diagnosis and antenatal diagnosis b. Foetal medicine c. Vascular access (consultant surgeon or interventional radiologist with experience of venous access devices) d. Orthopaedic surgery e. Care of older people services f. Dental services g. HIV services h. Hepatology i. Medical genetics (Genetic Counselling Services) j. Pain management services k. Rheumatology Specialist services should have an appropriate level of specialist expertise in the care of people with inherited and acquired bleeding disorders.	Y	

Ref	Standard	Met?	Comments
HP-402	**Facilities and Equipment** Facilities and equipment appropriate for the service provided should be available including: a. Fridges b. Storage c. Clinical rooms for staff of all disciplines to see patients and carers d. Room for multi-disciplinary discussion e. Room for educational work with patients and carers f. Office space for staff g. Access to Haemtrack and the Haemophilia Centre Information System (HCIS) in all clinical areas All equipment should be appropriately checked and maintained.	Y	
HP-499	**IT System** IT systems should be in use for: a. Storage, retrieval and transmission of patient information, including access to the latest vCJD status and family tree b. Patient administration, clinical records and outcome information c. Data to support service improvement, audit and revalidation d. Alerting the specialist team when patients attend the Emergency Department	Y	
HP-501	**Diagnosis Guidelines for Patients with Suspected Inherited and Acquired Bleeding Disorders** Guidelines on diagnosis should be in use covering at least a. Haemophilia A b. Haemophilia B c. Von Willebrand Disease d. Acquired haemophilia e. Inherited platelet disorders f. Other less common and rare bleeding disorders	Y	However, reviewers noted that this was a very generic document and that a diagnostic algorithm for adults and children would be helpful. There was limited content on the diagnosis and management of acquired haemophilia.

Ref	Standard	Met?	Comments
HP-502	**Guidelines: Concentrate Use and Monitoring** Guidelines should be in use covering: a. Concentrate therapy: i. Initiation and monitoring of prophylaxis ii. Home therapy b. Use of extended half life products, including inhibitor testing and PK assessment c. Management of concentrate supplies including: i. Ordering ii. Storage iii. Stock control to ensure all stock is up to date and waste is minimised iv. Prescription and delivery for patients on home treatment v. Arrangements for emergency 'out of hours' supply vi. Recording issue to patients vii. Recording use by patients, including on Haemtrack viii. Submission of data via NHD for national tenders coordinated by CMU	Y	
HP-503	**Clinical Guidelines** The following clinical guidelines should be in use: a. Management of acute bleeding episodes, including patients with inhibitors b. Inhibitor screening c. Immune tolerance therapy d. Dental care e. Care of patients with hepatitis C f. Care of patients with HIV g. Antenatal care, delivery and care of the neonate h. Management of synovitis and target joints i. Long term surveillance of musculoskeletal health j. “For public health purposes”: care of patients at risk of vCJD who are undergoing surgery	N	Evidence was not seen for (h) or (i). The generic Trust guideline did not specify that all patients who were treated with plasma-derived coagulation factor concentrates between 1990 and 2001 are at risk of vCJD for public health purposes.
HP-504	**Emergency Department Guidelines** Guidelines on management of patients with inherited and acquired bleeding disorders in the Emergency Department should be in use.	Y	See Good Practice section of main report.

Ref	Standard	Met?	Comments
HP-505	**Guidelines on Care of Patients requiring Surgery** Guidelines on the care of patients with inherited and acquired bleeding disorders who require surgery should be in use covering at least: a. Involvement of surgical and inherited and acquired bleeding disorders service in agreement of a written plan of care prior to, during and post-surgery b. Communication of the agreed plan of care to all staff involved in the patient's care prior to, during and post-surgery c. Documentation of care provided d. Arrangements for escalation in the event of unexpected problems	Y	
HP-595	**Guidelines on Transition and Preparing for Adult Life** Guidelines on transition of young people from paediatric to adult services should be in use covering at least: a. Taking responsibility for their own care b. Involvement of the young person and, where appropriate, their carer in planning the transfer of care c. Joint meeting between paediatric and adult services in order to plan the transfer d. Allocation of a named coordinator for the transfer of care e. A preparation period prior to transfer f. Arrangements for monitoring during the time immediately after transfer g. Advice for young people going away from home to study, including: i. registering with a GP ii. how to access emergency and routine care iii. how to access support from their Comprehensive Care Centre iv. communication with the young person's new GP	Y	
HP-599	**Care of Vulnerable People** Guidelines for the care of vulnerable children, young people and adults should be in use including: a. Restraint and sedation b. Missing patients c. Mental Capacity Act and the Deprivation of Liberty Safeguards d. Safeguarding e. Information sharing f. Palliative care g. End of life care	Y	

Ref	Standard	Met?	Comments
HP-601	**Service Organisation** The service should have an operational procedure covering at least: a. Ensuring all children who are in-patients have a named consultant paediatrician and a named haematologist with expertise in caring for patients with inherited and acquired bleeding disorders responsible for their care b. Ensuring all adults are under the care of a consultant haematologist with an interest in inherited and acquired bleeding disorders, either directly or through a shared care arrangement with a general haematologist c. Responsibility for giving information and education at each stage of the patient journey d. Arrangements for involving Haemophilia Centre staff in multi-disciplinary discussions relating to their patients (QS HP-602) e. Arrangements for follow up of patients who 'do not attend' f. Arrangements for transfer of patient information when patients move areas temporarily or permanently g. Ensuring patients' plans of care are reviewed at least six monthly for patients with severe haemophilia and at least annually for other patients (QS HP-104) h. Ensuring school visits for children with severe haemophilia at least at each change of school (children's services only) i. Ensuring patients are visited at home at least annually if they are unable to attend clinics, including those in nursing homes j. Lone working	Y	However, more detail is required for the paediatric elements.
HP-602	**Multi-Disciplinary Team Meetings** Multi-disciplinary team meetings to discuss patients' plans of care should take place regularly involving: a. All core members of the specialist team (HP-202) b. Senior biomedical scientist or clinical scientist with responsibility for the Coagulation Laboratory c. HC staff who are regularly involved in the patient's care as part of network arrangements	Y	However, the focus does need to be more equitable, as it is currently mainly on thrombosis. In addition, a suggestion was made that the meetings should be more frequent.

Ref	Standard	Met?	Comments
HP-603	**Multi-Disciplinary Clinics** The following multi-disciplinary clinic arrangements for patients with inherited and acquired bleeding disorders should be in place: a. Involvement of medical, specialist nursing and physiotherapy staff in clinics b. Availability of social work and psychology staff in clinics c. Combined clinics or other arrangements for multi-disciplinary discussion with: i. orthopaedics ii. rheumatology iii. obstetrics and gynaecology iv. paediatrics v. dental vi. HIV / hepatology	N	See Concerns section of main report regarding lack of paediatric haematologist / linked paediatrician.
HP-604	**Liaison with Other Services** Review meetings should be held at least annually with specialist services to consider liaison arrangements and address any problems identified.	N	Reviewers agreed with the Centre's self-assessment.
HP-701	**Data Collection** The following data should be collected: a. UK National Haemophilia Database data on all patients b. Data on concentrate use and bleeds, either through Haemtrack or an equivalent mechanism c. Data required to complete the UKHCDO National Haemophilia Dashboard or other national mechanisms	Y	
HP-702	**Audit** The services should have a rolling programme of audit covering at least: a. Clinical guidelines (QS HP-503) b. Emergency and out of hours care (QS HP-504) c. Initiation of prophylaxis in children d. Inhibitor surveillance and Immune Tolerance Induction (ITI) e. Clinical reviews including joint scores (QS HP-103 & 104) f. Concentrate use and wastage	N	Reviewers did not see evidence of audits relating to the elements of this standard, and there was no forward audit programme in place.
HP-706	**Research** The service should actively participate in research relating to the care of patients with bleeding disorders.	N	Reviewers agreed with the Centres self-assessment that this had not been achieved due to resources pressures.

Ref	Standard	Met?	Comments
HP-798	**Multi-disciplinary Review and Learning** The service should have multi-disciplinary arrangements for review of and implementing learning from: a. Positive feedback, complaints, outcomes, incidents and 'near misses' b. Morbidity and mortality c. Haemophilia Dashboard d. Review of UKHCDO Annual Report benchmarking information on concentrate use e. Ongoing reviews of service quality, safety and efficiency f. Published scientific research and guidance	N	Reviewers did not see any evidence that this was regularly taking place. See Concerns section of main report regarding governance arrangements.
HP-799	**Document Control** All policies, procedures and guidelines should comply with Trust (or equivalent) document control procedures.	N	Some Trust documents were beyond their review dates, and some local documents did not have appropriate version control.

Return to Index

Network

Ref	Standard	Met?	Comments
HY-199	**Involving Patients and Carers** The network should have mechanisms for involving patients and their carers from all services in the work of the network.	N	The Centre was part of the East Midlands network, and staff attended the meetings. However, this is an informal (and not commissioned) network arrangement led by the Nottingham CCC.
HY-203	**Inherited and Acquired Bleeding Disorders Network Leads** The network should have a nominated: a. Lead consultant and deputy b. Lead specialist nurse c. Lead physiotherapist d. Lead clinical or counselling psychologist e. Lead manager	N	See HY-199
HY-204	**Education and Training** The network should have agreed a programme of education and training to help services achieve compliance with QSs HP-203.	Y	
HY-503	**Guidelines** Network guidelines should have been agreed covering: a. Diagnosis for patients with suspected inherited and acquired bleeding disorders (QS HP-501) b. Concentrate use and monitoring (QS HP-502) c. Clinical guidelines (QS HP-503) d. Management of patients with inherited and acquired bleeding disorders in the Emergency Department (QS HP-504) e. Care of patients requiring surgery (QS HP-505) f. Transition and preparing for adult life (QS HP-595)	N	See HY-199
HY-701	**Ongoing Monitoring** The network should monitor on a regular basis: a. Submission of data on all patients to the UK National Haemophilia Database (QS HP-701) b. Network-wide data on concentrate use and bleeds	Y	
HY-702	**Audit** The network should have an agreed programme of audit and review covering network-wide achievement of QS HP-702.	N	See HY-199
HY-703	**Research** The network should have agreed: a. A policy on access to research relating to the care of patients with inherited and acquired bleeding disorders b. A list of research trials available to all patients within the network.	N	See HY-199

Ref	Standard	Met?	Comments
HY-798	**Network Review and Learning** Representatives of Comprehensive Care Centres and referring Haemophilia Centres should meet at least once a year to: a. Identify any changes needed to network-wide policies, procedures and guidelines b. Review results of audits undertaken and agree action plans c. Review and agree learning from positive feedback, complaints, critical incidents and 'near misses', including those involving liaison between teams d. Share good practice and potential service improvements	Y	

Return to Index

Commissioning

Ref	Standard	Met?	Comments
HZ-601	**Commissioning of Services** Commissioners should have agreed the configuration of clinical networks including: a. Designated Comprehensive Care Centres and Haemophilia Centres and the relationships between them b. Whether the service cares for children, adults or both c. Referral pattern to each service, taking into account the type of patients who will be treated by each team	N	Reviewers did not see any evidence of an agreed SLA outlining referral pathways and the relationships between centres.
HZ-701	**Clinical Quality Review Meetings** Commissioners should regularly review the quality of care provided by: a. Each service, including achievement of QS HP-701 b. Each network, including achievement of QS HY-701 and QS HY-798 c. Service and network achievement of relevant QSs	N	Reviewers did not see evidence that these meetings were taking place regularly, and therefore that the requirements of this standard were being met.
HZ-798	**Network Review and Learning** Commissioners should attend a Network Review and Learning meeting (HY-798) at least once a year for each network in their area.	N	Reviewers did not see evidence that these meetings were taking place regularly, and therefore that the requirements of this standard were being met.

Return to Index