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

The Leeds Teaching Hospitals NHS Trust

Date: 2nd and 3rd September 2019

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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 Leeds Teaching Hospitals NHS Trust, which took place on the 2nd and 3rd September 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:

- Leeds Teaching Hospitals NHS Trust
- NHS England and NHS Improvement North

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 Leeds 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, parents and carers 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.

Leeds Comprehensive Care Centre

The Leeds Comprehensive Care Centre (LCCC) was a joint adult and paediatric service. The adult haemophilia service was situated within the department of haematology at St James's University Hospital (SJUH). The paediatric haemophilia service was situated in the department of paediatric haematology and oncology at Leeds General Infirmary (LGI).

SJUH and LGI were the main acute hospitals in Leeds Teaching Hospitals NHS Trust (LTHT), and both hospitals were home to a wide range of acute specialties including several regional tertiary referral centres. The department of haematology at SJUH was managed as part of the oncology clinical service unit, and the department of paediatric haematology and oncology was managed as part of the Leeds Children's Hospital.

Referrals for investigation and diagnosis of bleeding disorders were accepted by both adult and paediatric services in the LCCC from primary care and from secondary care including surrounding district hospitals (Harrogate District Hospital, the Mid Yorkshire Hospitals, Calderdale Royal Hospital and Huddersfield Royal Infirmary). Tertiary referrals were also accepted from haemophilia colleagues in the network, as appropriate.

The LCCC provided a full range of services to patients with bleeding disorders, including open access to emergency care, specialist musculoskeletal services via specialist physiotherapists, a specialist podiatrist, orthopaedics services and paediatric rheumatology services. Radioactive synovectomy[1] was available via links with services in Bradford. Specialist care for pregnant women with bleeding disorders and those at risk of having an affected child were provided via a combined haemostasis obstetric clinic. This clinic had links with foetal medicine and reproductive medicine services. The LCCC also had established links with the Leeds Dental Institute for both adults and children. Pathways were established in the adult service for the provision of hepatology and infectious diseases specialist care.

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 inpatient admissions in last year
Haemophilia A	Adults	45 Severe 14 Moderate 60 Mild	Quality Dashboard Data for Adults and Children for Severe Haemophilia on regular prophylaxis: 75/87 patients had two documented reviews in the last year.	**Adults** 48 hospital admissions Plus 77 surgeries/procedures supported in 3 LTHT hospital sites Plus 518 day case episodes Numbers are across all bleeding disorders in adults
	Children	36 Severe 5 Moderate 16 Mild		
Haemophilia B	Adults	4 Severe 0 Moderate 6 Mild		
	Children	2 Severe 1 Moderate 0 Mild		

[1] **Radioactive synovectomy** is a very effective and gentle procedure, used for rapid and sustained pain relief of severe joint pain or arthritis, such as osteoarthritis. Through targeted sclerotisation of the synovial membrane with radioactive substances, lasting relief from pain and inflammation is achieved in most cases.

Condition		Number of patients	Number of patients who had an annual review in last year	Number of inpatient admissions in last year
Von Willebrand	Adults	391 adults (3 Type 3)		
	Children	102 children (1 Type 3)		
Other	Adults	353 adults and children		
	Children			

Emergency Care

Adults: All registered patients were encouraged to seek 24/7 advice and care, when appropriate. A telephone number for advice out of hours was provided on the bleeding disorders information card that was given to all patients. A qualified nurse triaged the call promptly and alerted the on-call haematology registrar and the senior nurse bleep holder. The patient would be asked to attend either the assessment unit on Ward 95 before 8pm or, if a bed was required and available, the patient would be admitted directly to the haematology ward. After 8pm, a patient requiring assessment would be directed to the Emergency Department (ED), and the ED staff would inform the on-call haematology registrar. The haematology on-call registrar would assess the patient on arrival and arrange treatment. If a patient self-presented to the ED or was brought by ambulance to the ED, the haematology on-call registrar would be alerted and would assess and treat the patient in collaboration with the ED staff.

Immediate advice was available for the haematology specialist registrar from the on-call consultant for the North West Yorkshire Haemophilia Network (NWYHN).

Paediatrics: All known patients were advised to contact the children's haematology and oncology day unit within working hours and, out of hours, Ward 31, 32 or 33, depending on their age. If a call was taken out of hours within the paediatric haematology and oncology facility, the on-call specialist trainee (ST1 to 3 or ST4 to 8) paediatric junior doctor would be contacted and would organise the review of the patient, as appropriate. Junior medical staff were instructed to discuss all haemophilia patients with the on-call paediatric haematologist or oncology consultant in the first instance. If further advice was required, this could be provided by a paediatric haematology consultant (if an oncologist was the primary consultant on-call) or by the on-call consultant for haemophilia for the NWYHN. Patients coming in via the ED would be referred to the paediatric haematology and oncology service. Patients who were initially referred to the children's assessment and treatment unit would be referred to the paediatric haematology and oncology service.

Ward Care

Ward care was shared with the malignant and other benign haematology service for both adults and children. Age-appropriate and adolescent facilities were available for both services.

Day Care

Dedicated haemophilia facilities were available in both children's and adult services.

Outpatient Care

Outpatient care for the adult service was shared with other haematology clinics in a dedicated haematology clinic area. Outpatient paediatric care was provided in the day care facilities.

Community Based Care

Specialist nurses in both adult and paediatric services provided home visits, as required. These included school visits in the paediatric service and care home visits in the adult service.

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The North West Yorkshire Haemophilia Network (NWYHN)

The LCCC was the hub of the NWYHN. The NWYHN was a formal clinically-led operational network amongst the Leeds, Bradford and York Haemophilia Centres. It covered a population of 2.6 million people and provided 24/7 consultant and specialist laboratory on-call services on a network-wide basis. There was a monthly network meeting, alternating between a clinical MDT meeting and a business meeting. Core clinical staff in the three centres and staff from the specialist coagulation laboratory attended both meetings. The network business meetings were co-chaired by the lead clinician for the NWYHN and a specialist commissioner from the NHS England regional specialist commissioning team. The aim of the network was to provide equitable access to comprehensive care for patients of all ages with inherited and acquired bleeding disorders across North West Yorkshire.

On the day before the full LCCC visit, the two QRS reviewers and two consultant reviewers met with a commissioner from NHS England and NHS Improvement North, representatives from the York Haemophilia Centre, and representatives from the Bradford Haemophilia Centre. A telephone conversation also took place with the consultant haematologist from Harrogate, who was the district general hospital representative on the NWYHN board.

The following section summarises the findings from the discussions with the linked centre[2] colleagues.

1. **York**

   There were fewer than five children with severe bleeding disorders being treated at York, and approximately twenty adults with severe haemophilia on prophylaxis. York Hospital and Scarborough General Hospital were both parts of York Teaching Hospital NHS Foundation Trust, and there were outreach clinics in Scarborough, but these did not usually include patients with significant bleeding disorders, who were seen in York. A small number of patients from Harrogate were also treated in York. Patients across the area requiring surgery were sometimes managed in York Hospital, but with a low threshold for referral to Leeds, for example for joint replacement surgery. Port insertion was usually carried out in Leeds.

   The Centre director had one PA dedicated to the role. The nurse specialist had no dedicated time but was usually able to make herself available to see patients when needed – including in clinic sessions – as her CNS colleagues were flexible in covering other work at these times. There was no specific haemostasis clinic, so patient reviews took place at different clinic times. The CNS was not currently undertaking any telephone clinics for the less severely affected patients, although she hoped to be able to offer this.

   Physiotherapy input for patients in York was mainly from the Leeds-based team; patients travelled to Leeds to see the physiotherapists and valued this aspect of care. There was no dedicated psychology time, although the nurse could sometimes get informal advice from the malignant haematology psychologist; otherwise, referrals were made via the GP.

   The team reported that there was no Emergency Department alert for patients with bleeding disorders. Paediatric patients had direct access to the paediatric ward at all times if they needed assessment and treatment.

   The local laboratory was able to undertake urgent factor VIII and IX levels at any time, while other investigations were usually sent to the Leeds laboratory. Factor concentrates were held in the blood bank, and some were also held in Scarborough.

   There was no dedicated data manager, but the lead nurse collected and submitted data to the National Haemophilia Database (NHD). York did not have access to the Haemophilia Computer Information System (HCIS) but were trying to get approval to enable them to use this, as data collection was more onerous without this

[2] Distances between Leeds and the linked centres: Leeds to York = 30miles; Leeds to Bradford = 13miles; Leeds to Harrogate = 17miles.

access. The team could bring their local patient data to network meetings, although formal data sharing between the sites had not been agreed.

The York team were very supportive of the network arrangements, and regularly attended meetings including joint clinical MDT meetings. They noted that the current network on-call system was working well for them when they needed out-of-hours specialist advice, and they had also found the educational events valuable. They used the network paediatric guidelines and understood that work towards shared adult clinical guidelines and audits was in progress.

2. **Bradford**

Bradford Royal Infirmary (Bradford Teaching Hospitals NHS Foundation Trust) had a large Haemophilia Centre, managing over 1000 patients in total, with just under forty adults and children with severe haemophilia, eight with type 3 von Willebrand Disease, nineteen others with very low von Willebrand activity where type is unspecified, and over seventy with factor VII deficiency. The was almost at the size at which this Centre could consider becoming a Comprehensive Care Centre, but the director indicated that there was no plan to do that, with the Bradford Centre preferring to work in the current network with Leeds.

The Centre had been visited by the NHS England (NHSE) Quality Surveillance team in April 2019, as part of a review of all non-malignant haematology services at the hospital. It had been highlighted then that there was a significant shortfall in medical and clinical nurse specialist (CNS) resources in the team. Since that time, vacant posts had been filled. There were 2 WTE adult nurse specialists covering both heritable bleeding disorders and haemoglobinopathy and 1.09 WTE paediatric nurse specialists covering both bleeding disorders and haemoglobinopathy and although the same personnel also covered the large haemoglobin disorders service, this did represent a positive improvement. There were reported to be gaps still in the administrative and clerical, and data management, staffing on the team. It was not always possible for the team to access local quality data for their patients, or to take these data to the network meetings. There was currently a locum haematology consultant in post, although long-term funding had not been agreed. The need for additional medical resource had become more pressing as the Centre director had recently taken up a clinical director role over a large group of haematology and pathology specialties. He noted that this gave him a better opportunity to direct the service in the way he and the team felt necessary, but that continued extra support was necessary to allow him to undertake both roles.

The Centre director took part in the 1:4 out-of-hours rota for the network. It was not possible for him to access the correspondence / results system at the Leeds hospitals to facilitate this.

Adult patients requiring urgent assessment or treatment during working hours called the Day Unit nurses, and out of hours they were invited to phone the ward, where the haematology registrar triaged the call, guiding the patients on whether to attend the ward or the Emergency Department, or the Day Unit the following day. Children had direct access to the paediatric assessment unit at all times.

There was a fortnightly adult haemostasis clinic, and a weekly paediatric clinic; the adult haematologist joined the lead paediatrician for this clinic service on alternate weeks. A nurse-led paediatric clinic had recently started specifically to address a backlog in reviews of more mildly affected children. Physiotherapy support had been inconsistent, and a staff member whom it was hoped would be actively engaged in the service had just left post; it was intended to re-appoint to the post and for the appointee to spend time training with the expert Leeds physiotherapy team. There was very limited access to psychology or social work services.

An identified gap was systematic genetic screening for families, following the retirement of a genetic counsellor four years previously, who had not been replaced. In the meantime, the haematologist and paediatrician discussed the need for family testing as part of the clinical discussion with patients.

No outreach clinics were in place, but patients from Airedale, Calderdale and Huddersfield hospitals were seen in the Bradford Centre.

The laboratory in Bradford was able to undertake factor VIII, IX, and XI assays and RiCof (for von Willebrand Disease) at all times for the purpose of monitoring treatment (all assays for diagnosis were sent to Leeds). Factor VII and XIII assays, and platelet function testing, were undertaken at Leeds for the Bradford patients. Earlier problems with the reliability of the Leeds laboratory in providing this support appeared to have been resolved.

Surgery and obstetrics usually took place on the Bradford site, except for paediatric surgery for which children were usually treated in Leeds. There was a good local dental service, working effectively with community dentists. Radioactive synovectomy was available in Bradford for all network patients.

There were internal incident review and governance meetings, and the Bradford team also attended the network clinical MDT meetings.

At this visit, which allowed only for brief discussion with the lead medical and nursing staff, the review team were not able to assess many aspects of the service, and it was agreed that – given the size of the Centre and previously identified issues – a formal day-long peer review visit to Bradford would be useful. There was a plan for this to take place in January 2020.

3. **Harrogate**

During a telephone conversation with the consultant haematologist at Harrogate, it was confirmed that the team there valued the support they received from the Leeds Centre, and the network arrangements.

However, it was reported that daytime phone access to the team to get advice could be problematic, and that the access was easier out of hours. It was also reported that stock rotation would be helpful, to reduce wastage of concentrate.

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Review Findings

Achievements

The team at the Leeds adult and paediatric centres were hardworking and cohesive, with strong and egalitarian leadership that drew their colleagues in to share their aspirations. They were providing excellent care. There had been some recent, new, appointments into senior posts and all members of the team in post functioned very well, with outstanding physiotherapists and an innovative podiatry service. There were clear visions of what the team hoped to achieve, and a sensitive awareness of any current limitations. The team had been successful in appointing to a new, third consultant post for the haemostasis and thrombosis team; the appointee was expected to start in six months from the date of visit. There was clear support and respect from a wide range of colleagues in the Trust, including in obstetrics, rheumatology, hepatology, oral surgery, genetics counselling and the youth worker team.

Patient feedback was overwhelmingly positive about the paediatric and adult teams, noting their dedication and hard work, and commenting that many of the team members went over and above expected levels of duty to ensure the patients received high quality care.

The NWYHN had been established three years earlier, and was an achievement stemming from co-operative working between the lead consultants in Leeds, York and Bradford, who had identified the need for strengthened collaboration if their aim of offering equitable access to comprehensive care for patients of all ages with heritable bleeding disorders across North West Yorkshire was to be achieved. These consultants had also gained support from their specialist commissioner colleagues who were now actively involved in the network's activities.

Good Practice

1. There was active patient involvement, with regular meetings of a Patient and Carer Involvement Group, and plentiful examples of changes made in response to patient and family feedback. The energetic input of the physiotherapy team in these activities was noted.
2. A Monday morning handover conference call included all the four consultants on the network-wide on-call rota, nurses, and biomedical scientists, to receive updates about any activity over the weekend and to discuss issues and planned patient procedures for the coming week.
3. Many of the written guidelines were of a very high standard; these included 'use of the coagulation screen in adults' for non-specialist colleagues, a pathway for joint surveillance in the at-risk patient, and pre-surgical and antenatal care plans. A clear 'traffic light' coloured document alerted patients and families regarding possible intravenous line infections. There were clear and concise surgery pro-forma's in place for patients with bleeding disorders.
4. A service information leaflet for the children's service was in a form that enabled the information to be translated into a wide range of languages.
5. Careful attention had been given to the needs of children of different age groups, with those under thirteen years old cared for in a separate ward area from those of thirteen or over, and a dedicated room for children was available in outpatients too.
6. There was a separate quiet non-clinical room in the Haemophilia Centre, used for private discussions with patients and families.
7. Near patient ultrasound assessment of joints for early arthropathy was undertaken in the paediatric service.
8. A template was in place to guide and record outcomes of nurse-led telephone clinics; it was noted that the name of the member of staff undertaking the consultation could usefully be included.
9. Pre-implantation genetic diagnosis (PIGD) was available in Leeds for couples who chose this approach to ensure they had an unaffected infant.

Immediate Risks: No immediate risks were identified at the time of the visit.

Concerns

1 **Staffing**

a. Psychology. There was no psychologist member of the team, although this is expected in a Comprehensive Care Centre multi-professional bleeding disorder team. It was noted that patients, families and other haemophilia team members were not therefore receiving the optimal help and support that can be offered by an integrated, familiar psychologist working as part of the centre team.

b. Consultant sessions in the adult team. One full-time and one 0.8 WTE consultant led this service; the part-time consultant worked three long days each week. When the full-time consultant was on leave, there was therefore no on-site consultant specialist in bleeding disorders for two days of the week. Advice could be sought either from the consultant on leave, or the other consultants on the network on-call rota. The situation should resolve when the newly appointed third consultant takes up post in March 2020.

c. Nursing posts in the adult team. For the two nurses in post, covering their work in the time available was a challenge. They were relatively new in post, and it had been hard to identify time for them to undertake the necessary specialist upgrade training. The situation will be eased when a third nurse joins the team; however, time for that appointee to undertake extra specialist training will also need to be identified.

d. Social work. There was a valued social worker in the adult team, but funding was only available for this social worker to provide input for eleven hours per week. Other team members (nurses and physiotherapists) were therefore having to spend time helping patients with benefits applications and offering general psychosocial support.

Further Consideration

1. Adult patients reported that they had sometimes been admitted to wards other than the haematology inpatient ward. At these times – and also when they had been admitted for surgery, or had attended the ED – they had not felt confident in the care they received from the other teams, and they had felt that staff in these other areas were not listening to them.
2. There was an inconsistent ‘alert’ on the adult ED IT system for notifying staff that a person had a bleeding disorder, and no alert on the main Trust electronic patient records system. On some, but not all, of the patients’ hard copy records, a ‘front page’ was available immediately on opening the file, listing their diagnosis. It would be helpful if, at least, this could be made available for all patients.
3. A guideline on the management of head injury could be clarified, to spell out the dose of concentrate to be used rather than indicating the need to ‘raise the level to 100’.
4. Many of the paediatric clinical guidelines, and some of the adult ones, were lengthy, and it was judged that they would be difficult to navigate when looking for specific guidance in haste. Some indexing or highlighting of key practical sections would be helpful.
5. At the time of the visit, after the departure of a genetic counsellor who had held family genetic information, there did not appear to be a robust system in place to recall potential carrier female relatives of patients for testing and counselling before they reached reproductive age.
6. The process for young people in transition from the paediatric to adult service required some improvement. Preparatory work was undertaken in the paediatric service, but the expected personal hand-over of care, with members of both adult and paediatric teams present to introduce the young person to the new team and centre, did not usually occur. A parent described the process as having felt more like a transfer than a transition.

7. The data manager post was currently vacant, with another team member 'acting up' in that role. The Haemophilia Clinical Information System (HCIS) quarterly returns were being completed, but with data pulled from a variety of sources; the reviewing team were not assured that the returns were always complete. Some tasks usually undertaken by the data manager, including managing home care deliveries, were currently falling to the nursing staff.

8. Written condition-specific information for patients was sparse and was not well displayed in the adult Haemophilia Centre.

9. Remote access to the main electronic patient record system (to access results and letters) was available to some but not all of the consultants working on the out-of-hours rota. This meant that for those who did not have remote access it was not possible to record advice remotely. In addition, consultants with remote access could only record advice for Bradford patients where their information was already on the Leeds system. None of the on-call consultants had access to the York system. The current system did not therefore allow all of the consultants to record the advice they gave while on call, though registrars were asked to document advice given.

10. The consulting rooms in the adult Haemophilia Centre had a curtain on the door to prevent passers-by from being able to see in but did not have a curtain around the examination couch in the clinic room to give privacy for patients who had brought family or friends to their consultation.

11. A good template to guide the discussion and recording of the systematic reviews for severely affected patients had recently been introduced at the adult centre. All team members need to be reminded to use this until it becomes embedded in practice.

12. Some of the hand sanitisers in the adult Haemophilia Centre were empty at the time of the visit[3].

13. Document control was incomplete, with some documents lacking authorship or review date. Some Trust documents were beyond their review date – for example, the Elective Treatment Access Policy (review date 2016), and the Lone Workers Policy (2018). A couple of guidelines had long review dates: for example, a paediatric clinical guideline written in 2013 was not due for review until 2020[4].

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[3] **Trust response** has confirmed that a decision was taken in the wider adult haematology unit that sanitisers should not be filled – in order to encourage hand washing (which is more effective against C Diff). Hand sanitisers are therefore intentionally empty. There is a notice requesting hand washing. We take on board the point that it is confusing where sanitisers are empty.

[4] **Trust response** 'this is because it had been updated regularly so that the review date is advanced after each update. The review date is within three years of each update'.

Network and Commissioning

The North West Yorkshire Haemophilia Network (NWYHN), established in 2016, had made significant improvements in services across the area. It was energetically supported by commissioners from NHS England and NHS Improvement North, who met with the teams and co-chaired the monthly network meetings. Leadership was inclusive and even-handed, and there was close collaboration between all the centre leads. There was good progress towards the goal of providing equality of access to optimal care for all affected patients and families in the area.

Notable strengths included:

- A 24/7 network out-of-hours consultant rota, so that expert clinical guidance was available for colleagues and patients across the area.
- Rigorous governance activity, including MDT clinical reviews and consideration of incidents or complaints, with shared learning.
- A multi-professional educational programme.
- Strong patient and public engagement, with evidence of changes made as a result of patient feedback.
- Network meetings were well attended, and carefully minuted.
- The network was underpinned by formal clear documentation, including an operational policy, a memorandum of understanding between the three Trusts, and a published annual report.

In addition to the work completed to date, the network had identified other work in progress and gaps to be addressed:

- Completing the set of shared network clinical guidelines: paediatric guidelines were mostly in place, and some adult guidance was written but not yet ratified for use across the network.
- Data management across the network was not optimal, because of the lack of adequate staffing at all the sites.
- Shared audits had not yet been possible. This was said to be partly because of blocks to data sharing between the sites. Information Governance was cited as a possible reason for this, although patient-level data were not required, and data sharing across less well-established networks elsewhere has not been reported to be an issue.
- The nurse appointed to the network lead post was not working to the job description to which she had been appointed, and at the time of the visit was not undertaking direct clinical work in the bleeding disorders service. It will be important for her to be able to keep up to date with her clinical skills.

Other issues discussed, for further consideration by the network, were:

- A shared database, and possibly a shared data manager working across the three sites, would be highly beneficial in improving data quality, and would allow for benchmarking and audit activities.
- Access to patient information systems across the network for all the consultants undertaking out-of-hours work would improve ease and safety of urgent discussions and enhance the quality of the advice they can offer.
- A 24/7 network nurse rota, to triage patient / family calls, has been considered and may be valuable.
- A system to prioritise which haemophilia A patients will move over to Emicizumab[5] treatment, rather than continuing with factor replacement, will be required.
- Improved recruitment to clinical trials would benefit patients and allow for cost saving. In other centres, active clinical trial activity has released funding for local and network improvements.
- In York: the team will be aided in data collection and governance if they are permitted to use HCIS. It may be possible to establish a dedicated bleeding disorder clinic for which the CNS has protected time. This would enable the more efficient use of her time in jointly seeing patients in clinic. It may also be possible for her to undertake some telephone reviews of milder patients within this session too.

[5] **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 Vlll.

- In Bradford: there have been recent improvements in staffing levels, although in most staff groups provision remains low. There are clear plans in place to continue to improve the service, and the Centre director will need support from his own organisation, and the network, to achieve this. A separate peer review visit to the Bradford centre was planned for early in 2020.

Comment

The network leadership team had great enthusiasm, and a clear understanding of how best they could progress the work that remained before the network could function optimally for its patients, families and staff. In order to achieve this, they will need additional support in terms of protected time, and personnel, and it is hoped that through continued discussion between the Trusts and Commissioners it will be possible to identify this resource.

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APPENDIX 1 Membership of Visiting Team

Visiting Team		
Linda Airey	Patient Representative	
Dr Jayanthi Alamelu	Consultant Paediatric Haematologist	Evelina London Children's Hospital, Guy's and St Thomas' NHS Foundation Trust
Sarah Bowman	Haemophilia Social Worker	Sheffield Teaching Hospitals NHS Foundation Trust
April Jones	Nurse Specialist Haemophilia	Newcastle upon Tyne Hospitals NHS Foundation Trust
Joanne Minshall	Physiotherapist	Hull University Teaching Hospitals NHS Trust
Paul Murphy	Health Care Scientist	Newcastle upon Tyne Hospitals NHS Foundation Trust
Dr Martin Scott	Consultant Haematologist	Manchester University NHS Foundation Trust
Sharon Thind	Haemophilia Specialist Nurse (Paediatrics)	Manchester University NHS Foundation Trust

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

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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.

Service	Number of applicable QS	Number of QS met	% met
Comprehensive Care	37	25	68
Network	8	3	38
Commissioning	3	3	100
Total	48	31	65

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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 saw relevant information for paediatrics but not for adult patients.

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	However, reviewers noted that this needs to be embedded and used consistently.
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.	Y	
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	See Good Practice section of the main report regarding dedicated areas for teenagers in inpatients and outpatients.
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	N	Reviewers agreed with the Centre's self-assessment.
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	N	Reviewers agreed with the Centre's self-assessment.
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	Y	

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 the 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	Reviewers did not see a training matrix as per the requirements of this standard.
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	N	Reviewers did not see evidence of completion of all mandatory training for all staff groups in the adult service. Evidence was seen for the paediatric service.
HP-299	**Administrative, Clerical and Data Collection Support** Administrative, clerical and data collection support should be available.	N	See Concerns section of the main report.
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	Y	
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	N	Reviewers agreed with the Centre's self-assessment. Guidelines are in place for paediatrics and adults. However, they have not been fully embedded, and patients reported that they did not feel the ED staff fully understood their conditions.

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	Y	
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	However, reviewers did not see evidence for (e) or (j).

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	N	Reviewers agreed with the Centre's self-assessment.
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	

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	Y	However, reviewers did not see any evidence for (d).
HP-504	**Emergency Department Guidelines** Guidelines on management of patients with inherited and acquired bleeding disorders in the Emergency Department should be in use.	N	Reviewers agreed with the Centre’s self-assessment.

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	However, reviewers heard from patients that their experience of having surgical procedures had not been positive, and that they felt that there was a lack of understanding from surgical staff regarding their bleeding conditions.
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	
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	

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	Y	
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.	Y	
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	See Further Consideration section of the main report.
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	There was some evidence of audit activity and evidence was provided by the paediatric team that they had completed relevant audits. However, it did not cover all aspects of this standard for the adult service. In addition, an audit programme (detailing dates of completed and future audit activity was not seen for either paediatrics or adults.
HP-706	**Research** The service should actively participate in research relating to the care of patients with bleeding disorders.	Y	

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	Y	
HP-799	**Document Control** All policies, procedures and guidelines should comply with Trust (or equivalent) document control procedures.	N	Reviewers saw that some documents in the adult service did not have full version control (including authorship, version numbers and review dates). However, paediatric documents were hosted in the Leeds health pathways website which had assured document control.

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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.	Y	See Good Practice section of the main report.
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	There was no named psychologist in place.
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	See Good Practice section of the main report.
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	Reviewers agreed with the Centre's self-assessment. Paediatric guidelines were shared across the network, and some adult guidelines had been developed but not yet ratified ((e) and (f)).
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	N	Reviewers agreed with the Centre's self-assessment. Achievement of this standard had not been possible because of the lack of a data sharing agreement across the network.
HY-702	**Audit** The network should have an agreed programme of audit and review covering network-wide achievement of QS HP-702.	N	Reviewers agreed with the Centre's self-assessment. Achievement of this standard had not been possible because of the lack of a data sharing agreement across the network.
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	Reviewers agreed with the Centre's self-assessment. Achievement of this standard had not been possible because of staffing issues.

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	

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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	Y	See Achievements section of the main report.
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	Y	
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.	Y	

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