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EAHAD Haemophilia Centre Audit Report

Centre Information

Name of Centre: Coagulation Center Cologne-Rhine Erft, Hemostaseology and Hemotherapy, Hemophilia and von Willebrand Center

Type of Centre (EHTC/EHCCC): EHTC

Date of Audit: January 12th, 2026

Audit Chair: Fariba Baghaei (physician)

Audit Team Members:

- Wolfgang Miesbach (Physician)

Centre members present at the audit:

- Kai Severin (Director & Physician)
- Ralf Karger (Physician)
- Miriam Müller (Haemophilia Nurse and Centrum coordinator)
- Petra Cacciatore (Nurse/medical assistant therapy area)
- Fabienne Schönenborn (Physiotherapist)
- Annika Fiedler (Laboratory)
- Birgit Dänicke (graduate biologist/IT coordinator)
- Birgitt Hein-Nau (Psychologist under recruitement)

EAHAD Office-Coordinator: Noa Kabera

Executive Summary

General Observations

The Coagulation Center Cologne–Rhine Erft provides high-quality, patient-centred haemophilia care supported by strong leadership, excellent laboratory capability, and a motivated multidisciplinary team. The centre fulfills the majority of EAHAD standards and demonstrates a solid foundation in clinical governance, patient management, and quality systems. Continued development in structured outcome assessment, international engagement, and expansion of multidisciplinary protocols will further strengthen the centre's maturity and integration within the European haemophilia network.

Strengths:

- → Outstanding leadership and clear organizational structure with highly engaged team members.
- → Strong multidisciplinary collaboration, including physicians, nurse, physiotherapist, and laboratory staff.
- → Excellent laboratory expertise, providing comprehensive coagulation diagnostics with rapid turnaround.
- → Robust quality management system, aligned with ISO 9001 principles, with thorough SOPs, complaint handling, adverse event procedures, and regular internal/external audits.
- → Improving number of patients in short time which demonstrates high-quality patient care, including proactive follow-up, well-defined treatment plans, 24/7 advisory service, and close collaboration with the EHCCC in Bonn for complex cases.
- → Effective data and record management, including secure electronic medical records and national registry participation.
- → Dedicated physiotherapy services with strong engagement and readiness for further expansion in structured assessments.

Areas for Improvement:

- → Outcome data collection only partially implemented: limited documentation of days missed from work/school, structured joint health scoring (HJHS), QoL assessment, and systematic ultrasound (HEAD-US).
- → Limited international nursing engagement, with currently no collaboration with EAHAD nursing networks, and no current involvement in nursing research or GCP-based trial activities.
- → International surveillance participation incomplete, with no current involvement in EUHASS.
- → Musculoskeletal assessments not fully standardized, though basic monitoring of pain and range of motion is in place.
- → Explore closer collaboration with Köln university hospital.

Conclusion

The Coagulation Center Cologne–Rhine Erft is a well-functioning EHTC with strong clinical performance, exemplary team commitment, and a mature quality framework. The centre is highly suitable for continued accreditation, with developmental opportunities primarily in the areas of structured outcome monitoring, enhanced musculoskeletal evaluation, and stronger international engagement, especially within EAHAD networks. Targeted improvements in these domains will align the centre even more closely with best-practice standards across the European haemophilia community.

Audit Findings

1. General Requirements

1.1 Facility

Standard	Description	Yes	No	Not appl.
1.1.1	There should be dedicated disabled car parking spaces for patients/parents with bleeding disorders in the vicinity of the EHTC/EHCCC and appropriate disabled access throughout the haemophilia treatment area.	X		
Note	Designated parking spaces are available for patients in the courtyard with direct access to the elevator connecting to the centre. Access to the centre is wheelchair accessible. (Tour of the applicant centre and document provided by the director)			
1.1.2	Within the EHTC/EHCCC, clinical treatment of patients takes place in dedicated clinical areas that must be comfortable, quiet and appropriately equipped. These areas must have facilities to allow confidential discussion between staff and patients.	X		
Note	Tour of the applicant centre and documents provided by the director.			
1.1.3	Within the EHTC/EHCCC, there must be a secretariat where records of patients are kept available to the multidisciplinary team and emergency department.	X		
Note	Records are available to the MDT members at the centre. The centre is not located at a hospital and therefore any direct access to the records are not available for external bodies.			
1.1.4	EHTC/EHCCC must have the possibility of using telemedicine for communication with the patients in case when physical contact must be avoided. However, regular on-site review of patients should be encouraged whenever possible.	X		
Note	The possiblity is available through common digital communication systems like Teams, etc, mostly used for evaluation of bleeds etc. Regular visits are performed on-site.			

1.2 General policy and objectives

Standard	Description	Yes	No	Not appl.

1.2.1	The EHTC/ EHCCC Director and multidisciplinary team must formalize a work plan describing the mission, general objectives and policies of the Centre.	X		
Note	The information was provided by pre-audit documents. The audit team was provided with a comprehensive document, booklet containing the key information, policies.			
1.2.2	Consistent with general objectives and policies, and also in relation to critical issues resulting from systematic quality monitoring activities (see para. 1.9), the EHTC/EHCCC Director must develop specific quality improvement objectives to be assessed on a periodic basis.	X		
Note	Quality Management System for the centre and the laboraoty with SOP according to DIN EN ISO 9001 is in place. All MDT members have access to SOPs. The standardized SOPs are aming to achieve efficiency, quality output, and uniformity of performance, while reducing miscommunication and failure to comply with medical regulations.			

1.3 Information about the Centre

Standard	Description	Yes	No	Not appl.
1.3.1	The EHTC/EHCCC must draw up a document for patients which sets out at least the following: services offered, how to access the Centre, information about the centre staff and collaborating consultants and hospitals in the network.	X		
Note	Written information (broschyr) as well as information through the website is available.			

1.4 Organization and staffing

The cornerstone of the treatment of haemophilia and other related bleeding disorders is comprehensive care delivered by a multi-disciplinary and specialised team.

Standard	Description	Yes	No	Not appl.

1.4.1	The core team members of an EHTC/EHCCC consist of the following personnel: - medical staff, who carry out routine and emergency treatment and follow-up clinical reviews. - nursing staff, who provide treatment, education, support and advocacy for patients and may co-ordinate the supply of coagulation factor concentrates; - physiotherapist and/or physiatrist who help to maintain and restore maximum movement and functional ability; - laboratory staff, who provide a diagnostic and factor replacement monitoring service. - a data manager, ideally separate person. Not all members will be full-time employees of the EHTC/EHCCC itself; they may be members of other clinical departments who collaborate with the Centre to provide a part-time clinical commitment. In the case of an external laboratory, written agreements must be in place with the Centre (see para. 4).	X		
Note				
1.4.2	There must be in place an organizational chart of key personnel and functions within the EHTC/EHCCC. The Director is responsible for assigning roles and responsibilities within the Centre.	X		
Note	Pre-audit documents, interview and the booklet.			
1.4.3	There must be meetings between the multidisciplinary team members on a regular basis, as defined by the Centres.	X		
Note	Pre-audit documents, interview and the booklet.			

1.5 Policies and procedures

Standard	Description	Yes	No	Not appl.

1.5.1	The EHTC/EHCCC establishes and maintains policies and procedures addressing aspects of management and activities. These documents must include all elements required by these Standards and shall address at a minimum: - organization of the Centre; - patients' evaluation and treatment; - personnel appraisal and continuing education; - management and monitoring of facilities and equipment; - supply and management of therapeutic products, including home treatment, laboratory reagents and medical devices; - quality planning, evaluation and improvement; - participation in clinical research.	X		
Note				
1.5.2	The EHTC/EHCCC has evidence of a system for preparation, approval, implementation, review, revision and archival of all policies and procedures.	X		
Note	See 1.2.2			
1.5.3	All policies and procedures are regularly reviewed in order to ensure the availability of appropriate and up-to-date references for personnel of the EHTC/EHCCC, which should be aligned with the quality system of the hospital.	X		
Note	Internal and external audits. At least every 2 years.			

1.6 Record-keeping and data collection

Accurate recording of clinical information is essential for the effective delivery of haemophilia care. Data handling can be complex and EHTC/EHCCC should have in place the financial and human resources to facilitate the collection of information required.

Standard	Description	Yes	No	Not appl.
1.6.1	The EHTC/EHCCC maintains a patient register with a clear indication of those patients who are on regular treatment and those who attend for regular review.	X		
Note	Data base at the centre with detailed information about the treatments, reviews.			

1.6.2	The EHTC/EHCCC ensures proper record keeping of all medical records related to patients. In particular, the EHTC/EHCCC must prepare and update for each patient a file containing at least: - general data of the patient; - findings of each review; - treatment plans; - informed consents obtained from patient for their clinical details, according to the local regulations - copies of correspondence with patient's general practitioner and, where appropriate, other specialists; - any other relevant correspondence relating to the patient.	X		
Note	Pre-audit documents and documents available during the interview with the director.			
1.6.3	In the EHTC/EHCCC, all medical records must be kept in a confidential manner in accordance with applicable laws and regulations on data protection.	X		
Note	Electronical medical records. There are plans for updating the electronical medical records to a more modern platform in the future.			
1.6.4	Emergency procedures must be in place in the EHTC/ECCC to ensure the proper performance of its activities in the event of medical data on electronic systems being temporarily unavailable.	X		
Note	Server back-up in place. No paper back-up.			
1.6.5	Records related to quality management, training of personnel, facility and equipment maintenance or other general EHTC/EHCCC's issues must be retained in accordance with applicable laws and regulations, or defined policies and procedures.	X		
Note				
1.6.6	The EHTC/EHCCC ensures the traceability of the personnel responsible for generating all critical records (e.g. medical records).	X		
Note				
1.6.7	The EHTC/EHCCC identifies all the medical and management records to be maintained for established periods of time, also including them in specific lists, according to governmental or institutional policy, where applicable.	X		
Note	Medical records are maintained lifelong.			

1.7 Personnel appraisal and continuing education

All staff within EHTC/EHCCC must have adequate knowledge and experience to perform their assigned tasks and must comply with regulations regarding appraisal and continuing professional education which may be in place.

Standard	Description	Yes	No	Not appl.
1.7.1	The EHTC/EHCCC identifies and formalises the skills and professional qualifications required for the personnel performing activities critical to quality of patient care and implements plans in order to guarantee their adequate training before they start working.	X		
Note	Interview with physician. Documents available during the interview with the director.			
1.7.2	The EHTC/EHCCC Director must systematically identify the training needs for personnel operating within the Centre and plan training activities in order to guarantee that their skills are constantly updated and developed.	X		
Note	See 1.7.1			
1.7.3	Within the EHTC/EHCCC, records must be retained relating to personnel training and competency.	X		
Note				
1.7.4	The EHTC/EHCCC implements systems for the periodic assessment of the staff's skills in order to ensure that all members of staff can adequately perform the tasks assigned to them.	X		
Note	Detalied information about a systematic periodic assessment of all staff's skills could not be verified. However information was provided both through interviews, pre-audit documents and documents during the audit (booklet) indicating that the centre has high ambitions to provide training and further education of staff in a proper manner.			

1.8 Supply and management of therapeutic products, reagents and medical devices

Standard	Description	Yes	No	Not appl.
1.8.1	Procedures must be in place in the EHTC/EHCCC for the management of therapeutic products, laboratory reagents (if applicable), and medical devices in order to guarantee their correct selection, provision, inspection, storage under the appropriate environmental conditions and use.	X		
Note	Information provided by pre-audit documents and during the interview and inspection of the facilities and SOPs.			

1.8.2	The EHTC/EHCCC applies systems to prevent the use of expired medicinal products and, where applicable, laboratory reagents.	X		
Note				

1.9 Quality planning, evaluation and improvement

The EHTC/EHCCC management is responsible for continuously monitoring the quality of the Centre's performance by establishing a system designed to identify the need for improvement and consequently implementing adequate organizational and technical changes.

Standard	Description	Yes	No	Not appl.
1.9.1	The EHTC/EHCCC implements systems in order to guarantee a systematic monitoring of the quality of its performance for the identification of any critical situation that requires corrective actions, or for the identification of any unfavourable trends requiring preventive actions.	X		
Note	Information provided by pre-audit documents and during the interview and checking the SOPs.			
1.9.2	Procedures must be in place in the EHTC/EHCCC for detecting, evaluating, documenting and reporting any adverse events that occur in association with the administration of haemostatic drugs, including tranexamic acid, desmopressin, coagulation factor concentrates, non-replacement treatment and gene therapy, e.g. allergic reactions and inhibitor development	X		
Note	See 1.9.1.			
1.9.3	Procedures must be in place in the EHTC/EHCCC for managing complaints and for undertaking periodic surveys of patients' opinions about their care.	X		
Note	There is SOP in place for managing complaints. However question about periodic surveys of patients' opinions were not asked during the audit and cannot be verified.			
1.9.4	The EHTC/EHCCC conducts systematic clinical and quality audits to assess compliance with policies and procedures established within the Centre. The EHTC may organize audits in collaboration with the EHCCC.	X		
Note				
1.9.5	Procedures must be in place in the EHTC/EHCCC for the identification and investigation of the cause of all critical issues and for the implementation of corrective or preventive actions.	X		

Note	SOPs are in place and are implemented.			
1.9.6	The EHTC/EHCCC Director must conduct periodic analysis and global assessment of the EHTC/EHCCC's quality-related data, involving all the staff of the Centre in order to evaluate: - adequacy of the EHTC/EHCCC's general policies and objectives (see para. 1.2); - achievement of quality improvement objectives (see para. 1.2); - outcome indicators (see para. 2.6); - level of satisfaction of patients and their associations (see Standard 1.9.3); - degree of application of policies and procedures within the Centre, resulting from clinical and quality audits (see Standard 1.9.4); - adequacy of staff skills and need for training (see para. 1.7); - adequacy of facilities and equipment (see para. 1.1).	X		
Note				
1.9.7	Records of quality monitoring, evaluation and improvement must be maintained by the EHTC/EHCCC.	X		
Note				

1.10 Participation in registries related to inherited and acquired bleeding disorders

Individual countries should be encouraged to create and update patient registries related to haemophilia and other related bleeding disorders.
Standard 1.10.2 applies only when a (regional/national) registry is established.

Standard	Description	Yes	No	Not appl.
1.10.1	The EHTC/EHCCC maintains a database of patients under its care.	X		
Note				
1.10.2	The EHTC/EHCCC participates in the regular collection and transmission to pertinent authorities of data obtained from registries of haemophilia and other related bleeding disorders. The data may be used to support epidemiological surveillance, pharmacovigilance, health planning and pharmacoeconomic evaluations. Data collection and transmission must comply with regulations concerning processing of sensitive data.	X		
Note	The centre participates in the German Hemophilia Registry of the Paul Ehrlich Institute			

1.11 Participation in clinical research

Standard	Description	Yes	No	Not appl.
1.11.1	The EHCCC participating in clinical trials must record the type of products, batch number and number of units or components used in the trials.	X		
Note	Although the centre is EHTC, there is currently evidence of participation in limited clinical trials, mostly observational clinical trials. The centre director reveals plans for expanding theses activities in the near future.			
1.11.2	The management of the records related to the trials must be maintained by the EHCCC in accordance with institutional policies and applicable laws and regulations.	X		
Note				
1.11.3	The EHCCCs are encouraged to participate in clinical trials such as novel non-replacement treatments and gene therapy.	X		
Note	Currently there aren't any plans for participation in gene therapy trials according to the director.			

2. Patient care

2.1 Awareness, information and education of patients and their families

Haemophilia and other related bleeding disorders have a significant impact on the patients and their family, which may lead not only to physical disability but also to problems with schooling, employment and relationships.

Patients and their carers should be encouraged to be active participants in, and assume appropriate responsibility for, their delivery of care. Effective haemophilia care can be optimised by the establishment of a close dialogue between the EHTC/EHCCC and patients.

Standard	Description	Yes	No	Not appl.
2.1.1	The EHTC/EHCCC organizes in collaboration with patient associations events for the education and training of patients and their families, including home therapy/self-administration of the drugs, but also training about scientific knowledge and shared decision-making. Collaboration with other EHTC/EHCCC should be considered when developing training and education programs.	X		
Note	Documents are provided.			

2.1.2	Each patient must receive information about: - the nature of the disorder treatment and possible complications; - the EHTC/EHCCC and the multidisciplinary treatment team; - contact details of EHTC/EHCCC; - rights and obligations of the patient; - local and national patient support organization. The family of the patient may be involved, with the approval of the patient.	X		
Note	Documents are provided.			

2.2 Diagnosis of haemophilia and other related bleeding disorders and all forms of acquired haemophilia

Standard	Description	Yes	No	Not appl.
2.2.1	The EHTC/EHCCC prescribes the necessary tests in cases of suspected bleeding disorders, according to national and, where relevant, international professional guidelines.	X		
Note	Pre-audit documents as well as interview with the director, laboratory staff and inspection of the laboratory.			
2.2.2	The diagnosis of a coagulation disorder must include disease type, severity, presence or absence of inhibitor and mode of inheritance.	X		
Note	See 2.2.1			
2.2.3	The EHTC/EHCCC must issue a written report on diagnosis within one month from the initial review.	X		
Note	The laboratory at the centre provides analysis of all coagulation factors, tests for assessment of primary hemostasis (PFA-200, Born aggregometry) in a timely manner.			
2.2.4	After diagnosis, the patient must be registered with the EHTC/EHCCC and, if applicable, with a regional/national registry.	X		
Note	Data base at the centre and national registry.			
2.2.5	Each patient must be issued with a medical emergency card, which contains at least basic information about his/her diagnosis as well as contact details of the EHTC/EHCCC.	X		
Note				

2.3 Therapy of haemophilia and other related bleeding disorders and all forms of acquired haemophilia

2.3.1 Treatment programme

Standard	Description	Yes	No	Not appl.
2.3.1.1	A tailored treatment programme must be prescribed by the EHTC/EHCCC for each patient, detailing the therapeutic product, dosage and regimen, on the basis of patient's individual response and bleeding episodes. Patients' views must be taken into consideration.	X		
Note	Pre-audit documents as well as inspection on-site.			
2.3.1.2	All treatments offered by the EHTC/EHCC should be in line with national and, where relevant, international professional guidelines. Patients with haemophilia or other bleeding disorders must be treated with specific coagulation factor concentrates, or non-replacement and gene therapy if available, but not plasma or cryoprecipitate. Desmopressin (DDAVP) and tranexamic acid should be used when indicated.	X		
Note				
2.3.1.3	The treatment program and clinical records must comply with all legal requirements which may apply to provision of consent.	X		
Note				
2.3.1.4	The care of children with haemophilia and other inherited bleeding disorders is complex and should only be carried out in the EHTC/EHCCC by clinical staff specifically trained in the care of children with inherited bleeding disorders.			X
Note				
2.3.1.5	Transfer from paediatric to adult care is a particularly sensitive time for the teenager with a hereditary bleeding disorder, particularly if the adult Centre is at a different hospital. The EHTC/EHCCC have a protocol for transition from paediatric to adult care.			X
Note				

2.3.2 Prophylaxis

Standard	Description	Yes	No	Not appl.

2.3.2.1	Prophylactic treatment should be available in the EHTC/EHCCC to patients with severe haemophilia, as well as non-severe haemophilia with a severe bleeding phenotype as it has been shown to prevent chronic joint disease onset and progression. Bleeding episodes should be monitored and documented in order to define a tailored treatment programme. The aim of prophylaxis is to prevent bleeds at all times.	X		
Note				

2.3.3 Home treatment plan

Wherever appropriate, the care of patients with haemophilia and other inherited bleeding disorders should be delivered in the home setting which will minimise hospital attendance and absence from school and work, enabling them to live as normal a life as possible.

Standard	Description	Yes	No	Not appl.
2.3.3.1	The EHTC/EHCCC draws up and periodically updates a home treatment plan for each patient based upon the patient's individual clinical needs, bleeding phenotype and individual pharmacokinetics	X		
Note				
2.3.3.2	Patient and his family must be instructed as to the importance of recording all bleeding and treatment episodes. EHTC/EHCCC staff must assess the theoretical knowledge and practical competence of the patient before embarking upon home treatment and subsequently at regular intervals as part of the follow-up process (see para. 2.4). Patients are encouraged to use personalized digital platform for monitoring PK and recording treatment applications and bleeding episodes.	X		
Note	Patients are encouraged to use patient Apps like Florio or paper reports.			
2.3.3.3	The EHTC/EHCCC provides patients with written instructions and/or instruments for recording data on the infusion of therapeutic products at home or in the ambulatory care setting.	X		
Note				
2.3.3.4	The EHTC/EHCCC must have a system in place for the monitoring of product usage by patients on home treatment.	X		
Note	There is a system in place which could be verified during the inspection.			

2.3.4 Treatment of acute bleeds and prevention

Standard	Description	Yes	No	Not appl.
2.3.4.1	The EHTC/EHCCC must have 24/7 access to an adequate stock of supplies of all treatment products tailored to the type and number of treated patients in order to ensure continuity of care as well as the appropriate and timely treatment of haemorrhagic episodes.	X		
Note	There is stock of supplies of some treatment products at the centre which was visited during the on-site audit. There is an emergency depot of essential factor concentrates at the centre. However, the HTC is not located in connection to an ER at the hospital but 24/7 advisory service is available.			

2.3.5 Emergencies, treatment outside normal working hours

Standard	Description	Yes	No	Not appl.
2.3.5.1	The EHTC provides 24-h medical cover by formalized arrangements with other departmentsand/or designated EHCC.	X		
Note	Documents in place.			
2.3.5.2	The EHCCC provides 24-h expert haemophilia medical cover.	X		
Note				
2.3.5.3	Protocols covering emergencies and arrangements for patients presenting outside normal working hours must be in place in the EHTC/EHCCC, aimed at both patients and medical staff.	X		
Note				
2.3.5.4	Patients must be informed by the EHTC/EHCCC of whom they should contact in the event of an emergency or in case treatment is needed outside normal working hours.	X		
Note				

2.3.6 Elective surgery

Standard	Description	Yes	No	Not appl.

2.3.6.1	Elective major surgery in non-inhibitor patients and elective surgery in patients with inhibitors must only be carried out in EHTCs/EHCCCs with experience of such cases.	X		
Note	There is a close collaboration with EHCCC at Bonn.			

2.3.7 Treatment of patients with inhibitors, including immune tolerance

Standard	Description	Yes	No	Not appl.
2.3.7.1	All patients who develop inhibitors must be reviewed in a EHCCC and the level of antibody titre determined and recorded.	X		
Note	There is a close collaboration with EHCCC at Bonn.			
2.3.7.2	Notifications of new cases must be reported by the EHTC/EHCCC to the regional/national registry, if applicable, and other pharmacovigilance programmes (such as EUHASS or Eurovigilance).	X		
Note	National registry. The director is considering to join EUHASS in the future.			
2.3.7.3	An individualised treatment programme for patients with a high inhibitor titre must be drawn up by a EHCCC. The extent to which these patients are treated at a local EHTC must be determined on an individual basis through discussion between the two Centres.	X		
Note				
2.3.7.4	In the individualised treatment programme for patients with a high inhibitor titre, immune tolerance induction therapy should be available as soon as possible after inhibitor development. The option of long term prophylaxis with non-replacement therapies or bypassing agents should be considered in patients who fail to respond or are not candidates to immune tolerance.	X		
Note				

2.3.8 Gene therapy

Standard	Description	Yes	No	Not appl.
2.3.8.1	Gene therapy should be available for all patients with haemophilia and the indication for this type of treatment.			X
Note	Not currently relevant.			

2.3.8.2	Gene therapy for haemophilia should be organized through the structured collaboration between centres, such as the hub-and-spoke model. The communication protocol between hub and spoke haemophilia centres should be determined in order to facilitate patient treatment management.			X
Note	Not currently relevant.			
2.3.8.3	The criteria for the European Haemophilia Gene therapy Centre (EHGTC) have been defined. Patients should be treated in centres with the most experience in gene therapy for haemophilia and receive follow-up care in their own local centres, working in close collaboration with the EHGTC.			X
Note	Not currently relevant.			
2.3.8.4	Detailed plan for treatment and follow-up should be made upfront in agreement with the patient.			X
Note	Not currently relevant.			
2.3.8.5	If a hepatologist is not a member of the core team within the EHTC/EHCCC or where the hepatological care is provided external to the EHTC/EHCCC, a protocol for communication should be agreed.			X
Note	Not currently relevant.			

2.3.9. Management of patients with chronic viral infections, thrombosis or cardiovascular events

Standard	Description	Yes	No	Not appl.
2.3.9.1	In the EHTC/EHCCC, patients with chronic hepatitis and/or HIV infection must be reviewed at least once a year by a specialist physician and be offered appropriate therapy in accordance with accepted guidelines.	X		
Note				
2.3.9.2	In the EHTEC/EHCCC, protocols for management of patients with arterial or venous thromboses necessitating management decisions on anticoagulation and/or other therapeutic interventions should be available. Management of these patients often requires close collaboration between different disciplines.	X		
Note				

2.3.10 Treatment of patients with acquired haemophilia and acquired vWD

Acquired haemophilia and acquired von Willebrand's disease are rare conditions but often associated with serious haemorrhagic manifestations and other underlying disorders. Management of these patients is thus particularly challenging.

Standard	Description	Yes	No	Not appl.
2.3.10.1	An individualised treatment programme for patients with these rare acquired disorders must be drawn up by the EHCCC in accordance with accepted guidelines. The extent to which these patients are treated at a local EHTC must be determined on an individual basis through discussion between the two Centres.	X		
Note				

2.3.11. Treatment of paediatric population with haemophilia and other related bleeding disorders

Standard	Description	Yes	No	Not appl.
2.3.11.1	The care for children should be carried out by clinical staff with paediatric training or significant experience, such as paediatric haematologists, paediatric nurses, paediatric psychologists, paediatric physiotherapists and family/pedagogical support.		X	
Note	The centre is providing care for adult patients, however a few adolescents are currently under the care of the centre.			
2.3.11.2	The EHTC/EHCCC staff should organize process of starting prophylaxis in young children with the aim of achieving full prophylaxis in all children with severe haemophilia and non-severe with severe bleeding phenotype at the age of 2 years. Central venous access devices should be available whenever necessary to facilitate early access to bleed treatment and prophylaxis. Regular evaluation of inhibitor development should be performed up to 50ED.			X
Note	No PUPs are under the care at the centre.			

2.3.11.3	EHTC/EHCCC staff should ensure availability of home therapy, motivate family caregivers and provide comprehensive training that should include education about bleeding disorder, recognition of bleeds and treatment possibilities. Before home treatment is initiated caregivers should demonstrate understanding of how to recognize bleeds and have the ability to infuse or administer non-replacement therapy where applicable. The haemophilia nurse coordinator (or home infusion nurse) should be available to provide ongoing family support, education and skills development to enable home treatment. This should also be available for older children and adolescents, to ensure that they gain necessary haemophilia knowledge for self-management before they make the transition from pediatric to adult care.	X		
Note	The centre is providing care for adult patients, however a few adolescents are currently under the care of the centre.			
2.3.11.4	EHTC/EHCCC has procedures in place to ensure DDAVP treatment in children is given in a safe manner.			X
Note				
2.3.11.5	In children with haemophilia, a multidisciplinary review including haematologic, musculoskeletal, and quality-of-life assessments by the core comprehensive care team members should be performed at least every 2 years, and every 6 months in children with haemophilia on prophylaxis or severe VWD.		X	
Note	Not really relevant for the centre since the patients are mainly adults.			
2.3.11.6	EHTC/EHCCC has procedures and instruments in place to monitor outcome Quality of Life in children with haemophilia and other inherited bleeding disorders with appropriate instruments such as the Canadian Haemophilia Outcomes-Kids Life Assessment Tool (CHO-KLAT) and Paediatric Haemophilia Activities List (PedHAL).		X	
Note	See 2.3.11.5			
2.3.11.8	Children with haemophilia and other inherited bleeding disorders should be referred to a dentist/designated dental care centre at the time of the first tooth eruption (around 6 months of age) or by age 1 in order to reduce the complications, morbidity, costs, and health and psychosocial impacts associated with oral diseases in people with haemophilia.		X	
Note	See 2.3.11.5			

2.3.11.9	Children and adults with haemophilia should be administered the same routine vaccines as the general population; however, they should preferably receive the vaccines subcutaneously rather than intramuscularly or intradermaly, as it is as safe and effective as the latter does not require clotting factor infusion. If intramuscular injection must be the route of administration, a risk of bleeding should be assessed based on the factor levels and prophylaxis treatment and the dose of clotting factor concentrate should be given when appropriate, and the smallest gauge needle available (25-27 gauge) should be used.			X
Note	See 2.3.11.5			
2.3.11.10	For children with haemophilia and other inherited coagulation disorders, the EHTC/EHCCC care team provides family support and, if needed, additional psychosocial support and assessment.			X
Note	See 2.3.11.5			

2.3.12. Musculoskeletal services

Standard	Description	Yes	No	Not appl.
2.3.12.1	The EHTC/EHCCC should have access to a physiotherapist or physiatrist to maximize quality of life and movement potential for people with bleeding disorders.	X		
Note	Physioterapy service is provided external by Physio-Praxis. During the interview with the dedicated physiotherapist, the audit team could verify the high level of the engagement of the physiotherapist team and indications of potential improvements for the musculoskeletal services in the near future.			
2.3.12.2	If this physiotherapist or physiatrist is not a member of the core team within the EHTC/EHCCC or where the physiotherapy care is provided external to the EHTC/EHCCC, a protocol for communication should be agreed.	X		
Note				
2.3.12.3	Physiotherapy should be available to all individuals with bleeding disorders as part of comprehensive care to develop, maintain and restore maximum movement and functional ability throughout the lifespan and should encompass physical, psychological, emotional, and social wellbeing.	X		
Note				

2.3.12.4	The EHTC/EHCCC should have a protocol for the regular review of musculoskeletal health, including chronic pain. The EHTC/EHCCC should have a protocol for the monitoring and rehabilitation of severe haemarthrosis or hematomas, synovitis, haemophilic arthropathy and following orthopaedic surgery.	X		
Note	The MS health is not evaluated in a structured manner through scoring systems such as HJHS or HEAD-US at the moment. However, the chronic pain and reange of motions are evaluated regularly.			
2.3.12.5	The EHTC/EHCCC should offer persons with a bleeding disorder, timely, comprehensive, holistic assessment and treatment of their musculoskeletal condition and personal needs built on shared decision-making in order to develop a personalised physiotherapy plan and personal goals based on relevant outcome measures.	X		
Note	See 2.3.12.4			
2.3.12.6	For children with haemophilia recovering from a joint or muscle bleed, the physiotherapist and family caregiver should remain in close contact to discuss and decide on the appropriate sports and activities for the child ' s progressive rehabilitation.		X	
Note				
2.3.12.7	The EHTC/EHCCC should offer persons with a bleeding disorder, supported self-management as part of the management plan to recognise and develop their capability to manage their own health and take responsibilities on their wellbeing.	X		
Note				

2.3.13. Specificity of nurse care for the patients with haemophilia and other related bleeding disorders

Standard	Description	Yes	No	Not appl.
2.3.13.1	The EHTC/EHCCC must have one or more dedicated Haemophilia Nurse as a member of the core team, see paragraph 1.4.1 and protocols defining the nurses' role and patient access to nursing staff.	X		
Note				

2.3.13.2	the Haemophilia Nurse must have knowledge and clinical experience of bleeding disorders, treatment and any complications which may arise from either the disorder or treatment at a level reflecting the core competencies in the EAHAD Nurses Curriculum: - the Haemophilia Nurse at an EHTc must have skills at Competent level - the Haemophilia Nurse at an EHCCC must have skills at Proficient level OR must have a written plan on how to attain the above-mentioned competences within two years	X		
Note	The haemophilia nurse was encouraged to get more information about the EAHAD Nurses Curriculum and EAHAD's nursing committee during the interview.			
2.3.13.3	To enable continuous development and evidence-based nursing care of patients with bleeding disorders the EHTC/EHCCC must have a record of the Haemophilia Nurse's training and education, reviewed and updated annually, see paragraph 1.7: - attendance at training, courses, journal clubs and peer review - attendance at national and/or international congresses and meetings	X		
Note	GTH educational programme for nurses. Currently no attendance at the international congresses or meetings.			
2.3.13.4	The EHTC/EHCCC must have a record of the Haemophilia Nurse's collaboration on a national and international level, reviewed and updated annually: - the minimum being membership of the European Haemophilia Nurses Network (EAHAD) - if applicable membership of any Regional or National Haemophilia Nurses Network	X		
Note	Documents regarding membership and educational activites by GTH were in place.			
2.3.13.5	The EHTC/EHCCC must have a record of the Haemophilia Nurse's research awareness, reviewed and updated annually: - the minimum being a completed GCP course and having knowledge of ongoing clinical trials within the centre - participation in ongoing nursing research at the EHTC/EHCCC		X	
Note	Not at the moment but there are plans for involvement of Haemophilia nurse in the clinical trials in near future.			

2.4 Periodic clinical and multi-disciplinary review

All registered patients must be offered a regular clinical review. The EHTC/EHCCC must have a system in place to organize these clinics

Standard	Description	Yes	No	Not appl.
2.4.1	EHTCs and EHCCCs that enter shared patient care arrangements must ensure that all registered patients with disorders classified as severe have a multidisciplinary review performed at least once a year, including remotely, where appropriate.	X		
Note	Regular routine appointments take place 2-4 times a year.			
2.4.2	Patients with frequent bleeding episodes, or complications such as inhibitors, arthropathy or chronic viral infections, as well as young children, may require more frequent review in the EHTC/EHCCC, in accordance with accepted guidelines.	X		
Note				
2.4.3	Patients with moderately severe or mild haemophilia must be invited by the EHTC/EHCCC for review at least once every two years.	X		
Note				
2.4.4	The EHTC/EHCCC must have a protocol in place for age and condition-appropriate multidisciplinary evaluation during each review designed to monitor complications (e.g. inhibitor, arthropathy, chronic liver disease, HIV infection) and any other comorbidities.		X	
Note	No protocol in place.			
2.4.5	A letter must be drafted after each follow-up which includes the following information: - current clinical problems; - treatment regimen, highlighting any changes since last review; - results of relevant laboratory and other tests such as imaging; - date of next review. This letter must be sent to the patient's general practitioner and other doctors involved in the management of the patient. Copies must also be filed in the patient's clinical records and sent to the patient.	X		
Note				
2.4.6	The EHTC/EHCCC must keep records of non-attendance. In case of non-attendant children, the child welfare institutions should be contacted when the situation does not improve after constructive conversations with the parent.	X		
Note				

2.5 Genetic services

Identification of the underlying genetic abnormality causing haemophilia and other inherited bleeding disorders in a family facilitates the identification of carriers in the wider family. This information can also be used to provide antenatal diagnosis in pregnant carriers (although there are both legal and cultural restrictions which may apply in some countries). Carriers of haemophilia may themselves have low levels of factor VIII (or IX) and thus may have clinical problems similar to mild haemophilia.

Standard	Description	Yes	No	Not appl.
2.5.1	The mutation (or other underlying genetic abnormality) within a family affected by haemophilia and other inherited bleeding disorders must be identified by the EHTC/EHCCC.	X		
Note				
2.5.2	The EHTC/EHCCC must have a formal relationship with a genetic laboratory allowing all patients and families access to genetic testing.	X		
Note	Collaboration with EHCCC Bonn.			
2.5.3	It is recognised that genetic testing requires sophisticated technology which is not universally available throughout countries within the territory of the European Union. The EHTC/EHCCC which cannot provide basic genetic services locally must establish collaborative links with other Centres (which may be located in other countries) to ensure the availability of these important tests to their own patients and their families.	X		
Note				
2.5.4	Families and individuals must have access to genetic counselling. Written informed consent needs to be documented by the EHTC/EHCCC before genetic tests are performed. This must include specific consent for storage of samples and to share relevant results with other family members.	X		
Note				
2.5.5	In the EHTC/EHCCC, each family must have a genetic file separate from the individual patient files and each individual must have a section of this file that can be kept confidential.	X		
Note				

2.5.6	In the EHTC/EHCCC, potential female carriers of haemophilia must be offered genetic counselling and testing to confirm their status when they are old enough to understand the issues involved and give informed consent. Genetic counselling and testing should comply with all legal requirements that may apply to provision of consent.	X		
Note				
2.5.7	The level of factor VIII or IX must be measured by the EHTC/EHCCC in all known or potential carriers of haemophilia. The factor FVIII of FIX levels should be measured preferably before the age of 2 years, as carriers with reduced levels of FVIII or FIX have an increased risk of intracerebral bleeding after minor trauma, but definitely before menarche and surgery or other invasive procedures.	X		
Note				
2.5.8	Pregnancy in known or potential carriers of haemophilia must be supervised in the EHTC/EHCCC that has specific expertise in the area. At all stages of pregnancy there must be close collaboration between the obstetric and haemophilia staff. A documented care plan for the delivery and aftercare of any infant at risk of having a bleeding disorder must be established. Appropriate haemostatic agents for both mother and infant must be available for immediate use if necessary. In the case of a male baby, diagnosis should be confirmed, ideally by cord blood testing as soon as possible after birth.	X		
Note				

2.6 Outcome indicators

Standard	Description	Yes	No	Not appl.
2.6.1	All Centres delivering haemophilia care must collect information concerning the outcome of treatment. In order for this to be possible, there should be a protocol for patients (or parents in the case of children) to consent to provide the raw data requested.		X	
Note	The MDT reviews do not cover collection of all required outcome measures at the moment.			

2.6.2	The EHTC/EHCCC must agree the precise parameters to be collected with the appropriate regional and/or national authorities. It is recommended that as a minimum the following be recorded: - Units of coagulation factor concentrate/non replacement therapy used by each patient per year. YES - Data on pharmacokinetics (minimum trough levels for patients on prophylaxis) YES - Number of new bleeding episodes (including breakthrough bleeds in the case of patients on prophylaxis), ABR and AJBR. YES - Number of days missed from school or work due to bleeds. NO - Adverse events possibly related to treatment (inhibitors, viral infections, poor efficacy of treatment, local reactions, etc.). YES - Data about surgery, if appropriate. NO - Assessment of joint health Not using scorings such as HJHS - Quality of life measurement. NO - Comorbidities. YES - Mortality and causes of death.		X	
Note	Outcome data are collected partially. There are plans for assessment of QoL by recruiting a phsycologist. The physiotherapist is also planning to do at least annual assessments of joints using HJHS. The director performs joint ultrasound at the clinic but not in a structured manner by annual evaluation of joints – HEAD-US. Haemophilia nurse is encouraged to collect data about number of days missed from school or work due to bleeds at the annual visits.			

3. Advisory service

Standard	Description	Yes	No	Not appl.
3.1	The EHCCC provides a continuous emergency medical advisory service.	X		
Note				
3.2	The EHTC/EHCCC provides an advisory service to patients and their families, as well as other professionals and caregivers who treat the patients during normal working hours	X		
Note				

4. 4. Network of clinical and specialised services in conjunction with the haemophilia team

Standard	Description	Yes	No	Not appl.

4.1	The EHTC must establish a formal relationship with one or more EHCCCs. Many smaller EHTCs play a critical role in providing effective emergency care at a local level for patients with haemophilia and other related bleeding disorders. However, patients may need to attend the EHCCC for more comprehensive elements of care (e.g. elective surgery in patients with inhibitors). The level of collaboration will depend upon the degree of expertise available in the EHTC.	X		
Note	Collaboration with EHCCC Bonn.			
4.2	The EHTC/EHCCC must guarantee between them an integrated approach to patient multidisciplinary comprehensive care. The support available must include at least the following specialities: - Surgery. - Dental care. - Paediatrics (children must be followed up by health care professionals specifically trained in the care of children). - Hepatology, Infectious diseases (patients exposed to HIV and chronic liver disease must be followed up by appropriate specialists). - Obstetrics and Gynaecology (known or potential carriers of haemophilia who are pregnant must be supervised in Centres that have specific expertise in the area). - Genetics (all people with haemophilia and related bleeding disorders must have access to specialised genetic services for inheritance counselling and mutational analysis to enable confirmation of diagnosis, determination of carrier status and antenatal fetal testing). - Psychosocial support, particularly regarding provision of social welfare, occupational therapy and counselling services (patients with haemophilia and related bleeding disorders and their family members often have complex psychological issues), and where appropriate, gene therapy monitoring and follow-up. If the above-mentioned specialist services are not provided by the EHTC, arrangements for their provision must be put in place by the EHCCC.	X		
Note				
4.3	The relationship between the EHTC/EHCCC and the structures that provide these specialist services must be regulated by specific formal agreements. Protocols must define how to access services and name the physicians involved in providing continuity of care. There must also be diagnostic and therapeutic protocols, protocols on the use of haemostatic agents and protocols to define the processes of exchange of medical information and data collection.	X		
Note				

4.4	The EHTC/EHCCC has access to a laboratory, which may be either internal or external to the Centre, which provides at least the following coagulation tests (see table below which also stipulates the TAT* allowed) (SEE TABLE IN STANDARDS) The Turnaround Time for laboratory tests carried out must be agreed in writing between the clinical and laboratory services and be subject to monitoring, as described in the Table. The laboratories that perform the above-mentioned tests must participate in an accredited external quality assurance scheme in haemostasis.	X		
Note				

Standard	Description	Yes	No	Not appl.
4.5	The EHTC/EHCCC, in collaboration with other Centres and/or patient associations, organizes periodic training events and updates for associated services in order to optimize diagnostic and therapeutic approaches (e.g. specialist services, emergency and other hospital departments, family physicians and paediatricians, pharmacy).	X		
Note				