





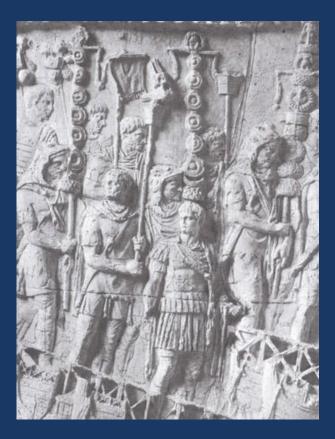
THE EUROPEAN STANDARDS

HAEMOPHILIA CENTRE CERTIFICATION SYSTEMS ACROSS EUROPE Rome, July 11, 2013

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1. "A flag or figurehead attached to a pole and raised to indicate a rallying point. The distinctive ensign of a sovereign, commander, nation or army".

2. "Authoritative or recognized exemplar of quality or correctness"

Background

409 facilities in Europe, of widely varying size and expertise, calling themselves "Haemophilia Centres"

Great disparities in EU Member States in terms of:

- ✓ facilities available for treatment;
- ✓ types of products used;
- ✓ amount of factor VIII and IX concentrates used;
- ✓ number of patients treated in individual centres

Only a small number of countries have accreditation systems of HCs



Aims

European guidelines for the certification of Haemophilia Centres To set quality standards for European HCs and criteria for their certification

To ensure equity of treatment throughout Europe

07 June 2013



European guidelines for the certification of Haemophilia Centres

07 June 2013

Target patient group

The document refers to the management of patients with <u>inherited bleeding</u> <u>disorders</u>, including:

- haemophilia A and B (including female carriers);
- the rarer congenital deficiencies of other coagulation factors (such as fibrinogen and factors II, V, VII, X, XI and XIII);
- von Willebrand disease;
- Inherited platelet defects.

The standards apply to both adult and paediatric patients.

Delivery of haemophilia care

The document sets the standards for the designation of two levels of European Haemophilia Centres:

European Haemophilia Treatment Centres (EHTCs)

providing local routine care



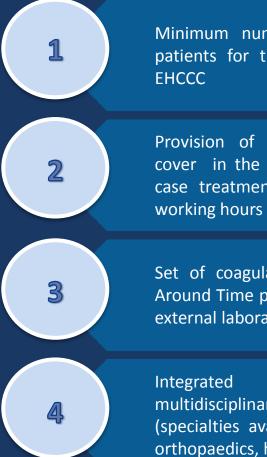
European Haemophilia Comprehensive Care Centres (EHCCCs)

providing specialized and multidisciplinary care and functioning as tertiary referral Centres

All patients should have access to a comprehensive care programme.

This may be provided by a EHCCC or by a EHTC which has established a formal relationship with one or more EHCCCs.

Functions and activities



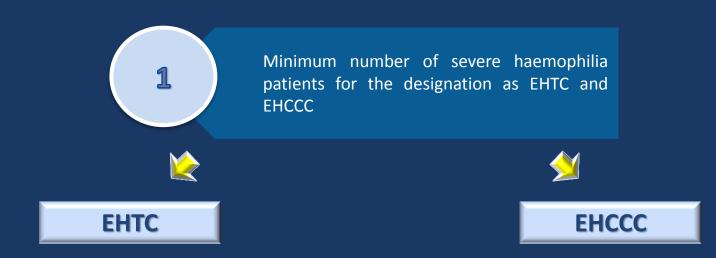
Minimum number of severe haemophilia patients for the designation to EHTC and EHCCC

Provision of expert haemophilia medical cover in the event of an emergency or in case treatment is needed outside normal working hours

Set of coagulation tests and related Turn Around Time performed by either internal or external laboratories

Integrated approach to patient multidisciplinary comprehensive care (specialties available include physiotherapy, orthopaedics, hepatology, etc.)

Functions and activities



Should normally care for at least 10 people with severe haemophilia A or B or VWD type 3.

Should normally care for at least 40 people with severe haemophilia.

Functions and activities

Provision of expert haemophilia medical cover in the event of an emergency or in case treatment is needed outside normal working hours



EHTC

2

Provides a 24 hour emergency treatment service

Carries out the <u>additional</u> following functions and activities:

EHCCC

- Provides a 24 hour advisory service for patients, families, hospital doctors, general practitioners and affiliated EHTCs health care professionals.
- Provides a 24 hour laboratory service for clotting factor assays and inhibitors screens.

Functions and activities

Set of coagulation tests and related Turn Around Time performed by either internal or external laboratories



3



Carries out the following functions and activities:

- Provides basic diagnostic and monitoring laboratory support during normal working hours for the more common inherited bleeding disorders.
- Offers specific treatment for patients with inhibitors and immune tolerance in collaboration with a EHCCC

Carries out the <u>additional</u> following functions and activities:

- Provides specialist care for patients with inhibitors, including surgery.
- Provides a diagnostic and reference laboratory service with a full repertoire of tests for the diagnosis and monitoring of inherited disorders of haemostasis.

Functions and activities



Set of coagulation tests and related Turn Around Time performed by either internal or external laboratories



\bigstar	
EHCCC	

Tests	EHTC			
1. PT, APTT, Thrombin time and mixing studies	□ Yes □ No	TAT*: within 3 hours	□ Yes	
			□ No	
		Comments:		
2. Factor VIII and IX assays	□ Yes			
	□ No			
	Comments:			
3. Inhibitor screen	□ Yes			
	□ No			
	Comments:			
4. Fibrinogen and factor V, VII, X, XI and XIII assays	□ Yes			
	□ No			
	Comments:			

Tests			EHCCC		
1. PT, APTT, Thrombin time and mixing studies	□ Yes □ No	TAT*: within 3	□ Yes	24 hr	🗆 Yes
		hours	🗆 No	service	🗆 No
		Comments:			
2. Factor VIII and IX assays	□ Yes □ No	TAT*: within 6	□ Yes	24 hr	□ Yes
		hours	🗆 No	service	🗆 No
		Comments:			
3. Inhibitor screen		TAT*: within 12	□ Yes	24 hr	□ Yes
	□ Yes □ No	hours	🗆 No	service	🗆 No
		Comments:			
4. Fibrinogen and factor V, VII, X, XI and XIII assays	🗆 Yes	TAT*: within 12	□ Yes	24 hr	□ Yes
	🗆 No	hours	🗆 No	service	🗆 No
	Comments:				
5. Platelet aggregation	🗆 Yes				
	🗆 No				
	Comments:				
	🗆 Yes				
6. VWF multimers	🗆 No				

Functions and activities



Integrated approach to patient multidisciplinary comprehensive care (specialties available include physiotherapy, orthopaedics, hepatology, etc.)



 Has access to multidisciplinary support, locally or in conjunction with EHCCC (physiotherapy and orthopaedics, surgery, dental care, hepatology, infectious diseases, obstetrics and gynaecology, paediatric facilities if children are treated, genetics, clinical psychology and social worker). Carries out the <u>additional</u> following functions and activities:

Has access to orthopaedic and/or rheumat. service with provision of surgery.

EHCCC

- Has access to physiotherapy service.
- Has access to a specialised obstetric and gynaecological service for the management of haemophilia carriers and women with vonWD Disease and other hereditary bleeding disorders.
- Has access to paediatric facilities if children are treated.
- Has access to a genetic diagnosis service providing also carrier detection and antenatal diagnosis.
- Has access to dental service.
- Has access to hepatology and infectious diseases service for patients with HIV and/or viral hepatitis.



Functions and activities







Should normally care for at least **10 people with** severe haemophilia A or B or VWD type 3.

Carries out the following functions and activities:

- Provides care for patients, including diagnosis, treatment, follow-up and rehabilitation.
- Provides patients with safe and effective treatment products.
- Provides a 24 hour emergency treatment service.
- Provides basic diagnostic and monitoring laboratory support during normal working hours for the more common inherited bleeding disorders.
- Has access to multidisciplinary support, locally or in conjunction with EHCCC (physiotherapy and orthopaedics, surgery, dental care, hepatology, infectious diseases, obstetrics and gynaecology, paediatric facilities if children are treated, genetics, clinical psychology and social worker).
- Offers specific treatment for patients with inhibitors and immune tolerance in collaboration with a EHCCC.
- Provides advisory service, including genetic counselling, to patients and healthcare professionals.
- Promotes information and training programs on inherited bleeding disorders to patients and healthcare professionals.

Should normally care for at least **40 people with severe** haemophilia.

Carries out the following <u>additional</u> functions and activities:

- Co-ordinates the delivery of haemophilia services both in hospital and in the community including liaison with affiliated EHTCs.
- Provides a 24 hour advisory service for patients, families, hospital doctors, general practitioners and affiliated EHTCs health care professionals.
- Provides specialist care for patients with inhibitors, including surgery.
- Provides a diagnostic and reference laboratory service with a full repertoire of tests for the diagnosis and monitoring of inherited disorders of haemostasis.
- Provides a 24 hour laboratory service for clotting factor assays and inhibitors screens.
- Has access to orthopaedic and/or rheumat. service with provision of surgery.
- Has access to physiotherapy service.
- Has access to a specialised obstetric and gynaecological service for the management of haemophilia carriers and women with vonWD Disease and other hereditary bleeding disorders.
- Has access to paediatric facilities if children are treated.
- Has access to a genetic diagnosis service providing also carrier detection and antenatal diagnosis.
- Has access to dental service.
- Has access to hepatology and infectious diseases service for patients with HIV and/or viral hepatitis.
- Offers professional psychological support.
- Has access to social worker and welfare advice.
- Collates data (e.g. product usage, patient demographics).
- Participates in research, including clinical trials.

Standard requirements



Focus on organizational issues

1. General requirements

- **1.1 Facility** (disabled car parking spaces; appropriate disabled access; secretariat)
- 1.2 General policy and objectives (mission; policies; quality improvement objectives)
- 1.3 Information about the Centres (documents with information for patients)
- 1.4 Organization and staffing (multidisciplinary team; organizational chart; meetings; data manager)
- **1.5 Policies and procedures** (required procedures; management of documents)
- 1.6 Record-keeping and data collection (patient register; medical records; data management)
- **1.7 Personnel appraisal and continuing education** (professional qualifications; training; periodic assessment of the staff's skills)
- **1.8 Supply and management of therapeutic products, reagents and medical devices** (management of therapeutic products; laboratory reagents and medical devices)
- **1.9 Quality planning, evaluation and improvement** (systematic monitoring of the quality of performance; management of adverse events and complaints; periodic surveys of patients' opinions; clinical and quality audits; corrective or preventive actions; periodic analysis and global assessment of the Centre's quality-related data by the Director)

1.10 Participation in registries related to inherited and acquired bleeding disorders

1.11 Participation in clinical research

Standard requirements

2. Patient care

- **2.1 Awareness, information and education of patients and their families** (events for the education/training of patients and their families including home therapy/self-infusion; information to patients and their families)
- **2.2 Diagnosis of haemophilia and other related bleeding disorders and all the forms of acquired haemophilia** (tests in cases of suspected bleeding disorders; minimum elements to be included in diagnosis, time within diagnosis must be formalized, medical emergency card)

2.3 Therapy of haemophilia and other related bleeding disorders and all forms of acquired haemophilia (treatment programme; prophylaxis; home treatment plan; treatment of acute bleeds and prevention; emergencies, treatment outside normal working hours; elective surgery; treatment of patients with inhibitors, including immune tolerance; treatment of patients with chronic viral infections; treatment of patients with acquired haemophilia and acquired vWD)

- **2.4 Periodic clinical and multi-disciplinary review** (organization of periodic reviews; protocols for multidisciplinary evaluation; monitoring of patients with complications, patient's clinical records)
- **2.5 Genetic services** (identification of the mutation or other underlying genetic abnormality within a family affected by haemophilia; formal relationship with a genetic laboratory; access to genetic counselling for families and individuals; written informed consent before performing of genetic tests)
- **2.6 Outcome indicators** (Units of coagulation factor concentrate used by each patient per year, Number of new bleeding episodes, Adverse events possibly related to treatment,)

Standard requirements

3. Advisory service

- Continuous emergency medical advisory service (EHCCC).
- Advisory service during normal working hours to patients, their families, other professionals and caregivers who treat the patients.

4. <u>Network of clinical and specialised services in conjunction with</u> <u>the haemophilia team</u>

- Formal relationship of EHTC with one or more EHCCCs .
- Integrated approach to patient multidisciplinary comprehensive care. Availability of the following <u>specialist services</u>: Physiotherapy and orthopaedics, Surgery; Dental care; Paediatrics; Hepatology; Infectious diseases; Obstetrics and Gynaecology; Genetics; Psychosocial support. Specific formal agreements with structures providing specialist services.
- Access to a laboratory, internal or external to the Centre, performing specific coagulation tests (Standards also stipulates the turnaround time allowed for each test) and participating in an accredited external quality assurance scheme in haemostasis.
- Periodic <u>training events</u> and updates for associated services in order to optimize diagnostic and therapeutic approaches