THE METHODOLOGY FOR DEFINING THE EUROPEAN STANDARDS

HAEMOPHILIA CENTRE CERTIFICATION SYSTEMS ACROSS EUROPE

Rome, July 11, 2013

Fabio Candura

WP4

Objective:

Development of a

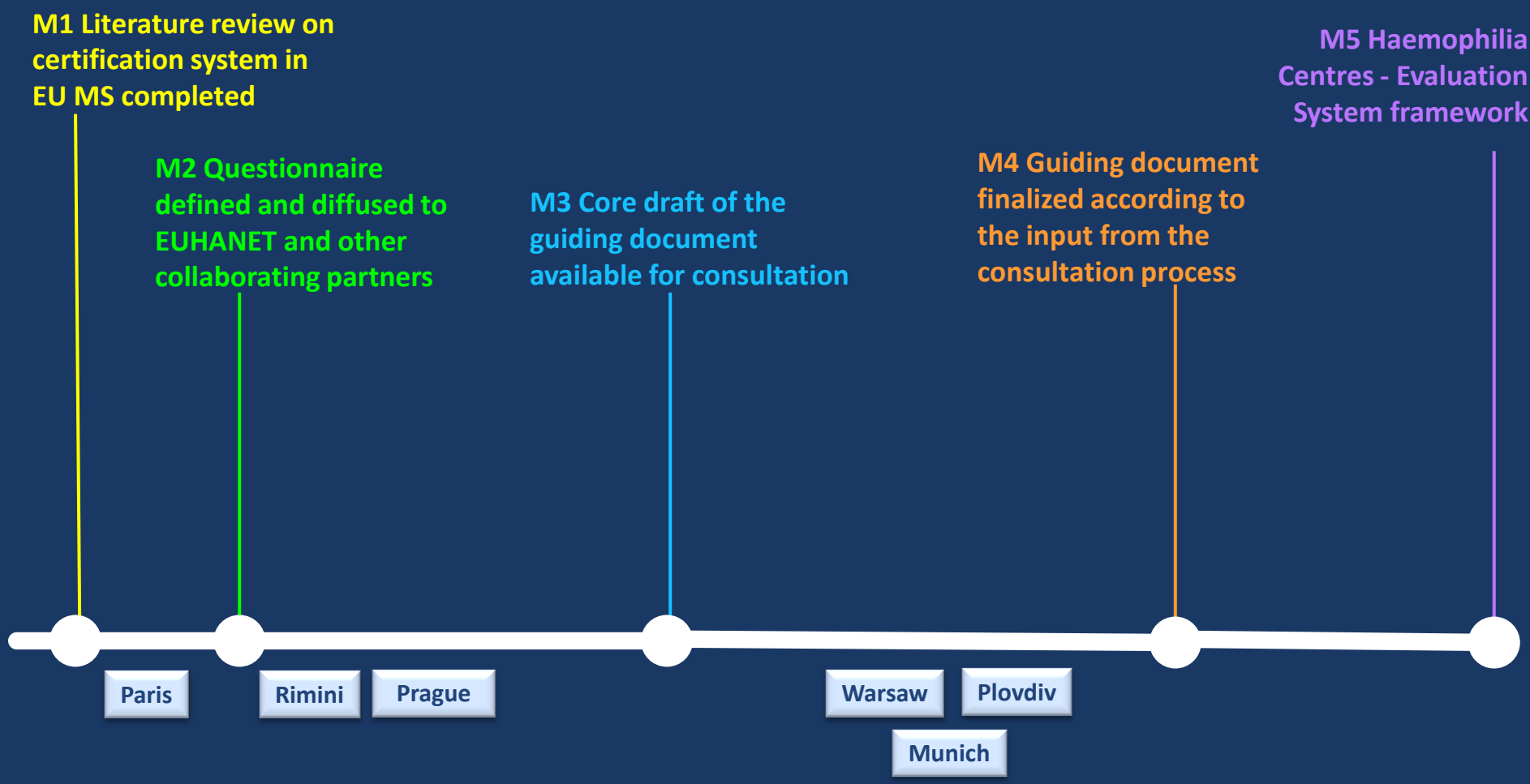
Guideline document

setting criteria for the certification of the

- European Expert Haemophilia Centres (EU-EHC)
- European Haemophilia Centres (EU-HC)

in EU MS, in order to promote standardization of quality of diagnosis and treatment in the European Haemophilia Centres

WP4 Flow of activities



WP4 Flow of activities

2012 July 31st

Milestone 1 → Milestone 2 → Milestone 3 → Milestone 4 → Milestone 5

OBJECTIVE

<u>Shared principles and criteria</u>

(scopes, approaches and rules)

for the production of a common set of EU standards on Haemophilia Centres

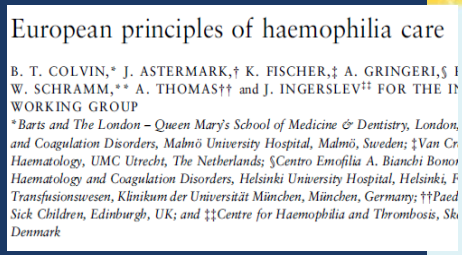
for European countries through a situation analysis on certification systems

WP4 Flow of activities

2012 July 31st

Milestone 1 → Milestone 2 → Milestone 3 → Milestone 4 → Milestone 5

1 Literature review and analysis


European principles of haemophilia care

B. T. COLVIN,* J. ASTERMARK,† K. FISCHER,‡ A. GRINGERI,§ I
W. SCHRAMM,** A. THOMAS†† and J. INGERSLEV‡‡ FOR THE IN
WORKING GROUP

*Barts and The London – Queen Mary's School of Medicine & Dentistry, London,
and Coagulation Disorders, Malmö University Hospital, Malmö, Sweden; ‡Van Cr
Haematology, UMC Utrecht, The Netherlands; §Centro Emofilia A. Bianchi Bonor
Haematology and Coagulation Disorders, Helsinki University Hospital, Helsinki, F
Transfusionswesen, Klinikum der Universität München, München, Germany; ††Paed
Sick Children, Edinburgh, UK; and ‡‡Centre for Haemophilia and Thrombosis, Sk
Denmark

2 Identification of strategic partners to be involved in

EAHAD | EHC | EUHASS | EUHANET

WP4 Flow of activities

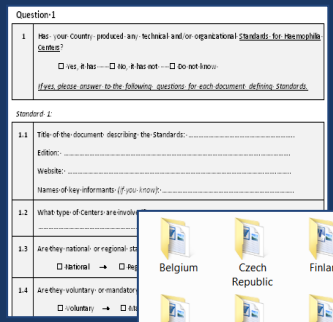
Milestone 1

2012, July 31st

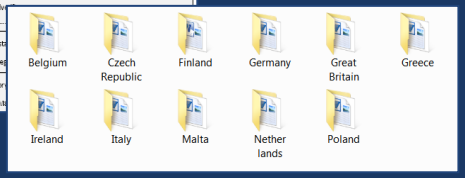
3 Collection and review of certification/accreditation systems in EU MS through the Preliminary questionnaire

1ST CONSULTATION PROCESS

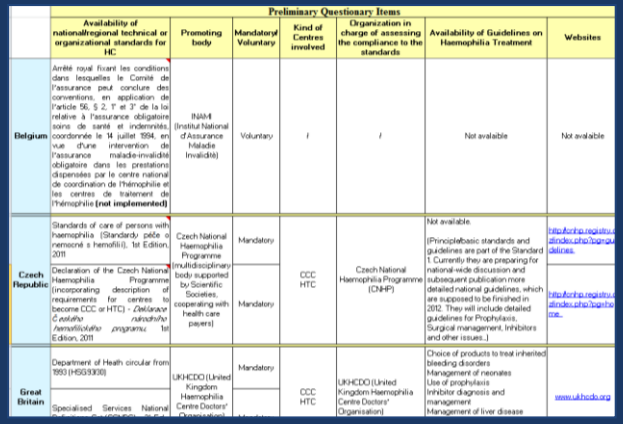
17 questionnaires collected out of 27 sent



National Standards and Guidelines on Haemophilia Treatment



4 Preliminary Questionnaires results and Literature cross match



	Preliminary Questionary Items						
	Availability of national/regional technical or organizational standards for HC	Promoting body	Mandatory/ Voluntary	Kind of Centres involved	Organization in charge of assessing the compliance to the standards	Availability of Guidelines on Haemophilia Treatment	Websites
Belgium	Arrêté royal fixant les conditions dans lesquelles le Comité de l'assurance peut conclure des conventions, en application de l'article 56, § 2, 1° et 3° de la loi relative à l'assurance obligatoire soins de santé et indemnités, coordonnée le 14 juillet 1994, en vue d'une intervention de l'assurance maladie-invalidité obligatoire dans les prestations dispensées par le centre national de coordination de l'hémophilie et les centres de traitement de l'hémophilie (not implemented)	INAMI (Institut National d'Assurance Maladie Invalidité)	Voluntary	/	/	Not available	Not available
Czech Republic	Standards of care of persons with haemophilia (Standardy péče o nemocné s hemofilií), 1st Edition, 2011	Czech National Haemophilia Programme (multidisciplinary body supported by Scientific Societies cooperating with health care payers)	Mandatory	CCC HTC	Czech National Haemophilia Programme (CNHP)	Not available. (Principle/basic standards and guidelines are part of the Standard 1. Currently they are preparing for national-wide discussion and subsequent publication more detailed national guidelines, which are supposed to be finished in 2012. They will include detailed guidelines for Prophylaxis, Surgical management, Inhibitors and other issues..)	http://chhp.registry.cz/index.php?sign[1]=delines
	Declaration of the Czech National Haemophilia Programme (incorporating description of requirements for centres to become CCC or HTC) - Deklarace České národního hemofilického programu, 1st Edition, 2011		Mandatory				http://chhp.registry.cz/index.php?sign[1]=ce..
Great Britain	Department of Health circular from 1993 (HSG(93)30)	UKHCDO (United Kingdom Haemophilia Centre Doctors' Organisation)	Mandatory	CCC HTC	UKHCDO (United Kingdom Haemophilia Centre Doctors' Organisation)	Choice of products to treat inherited bleeding disorders Management of neonates Use of prophylaxis Inhibitor diagnosis and management Management of liver disease	www.ukhcdo.org
	Specialised Services National						

Milestone
1

2012, July 31st

WP4 Flow of activities

5

Definition of a proposal of criteria/principles to be adopted for the standards production

PROPOSAL: 7 CRITERIA

Crit. 1: Types of structures involved
Crit. 2: Types of diseases
Crit. 3: Age groups of patients
Crit. 4: Reference sources
Crit. 5: Types of standards
Crit. 6: Assessment
Crit. 7: Issues to be developed

Public Health

EUHANET

Principles and criteria

a) **Type of structures involved:**
Two levels, in relation to different functions assigned:
- CCC (Comprehensive Care Centres: provide specialized and multidisciplinary care and function as tertiary referral centres).
- HTC (Haemophilia Treatment: provide local routine care).

b) **Type of disease treated by Centres:**
- Haemophilia and other inherited and acquired coagulation disorders.

c) **Type of patients managed by Centres:**
- Both adults and paediatric patients.

d) **Definition of criteria for eligibility of CCC/HTC:**
- minimum number of patients
- functions
- etc.

e) **Definition of Standards on the basis of current scientific evidence on the management of inherited coagulation disorders:**
- European principles of haemophilia care
- EUCERD Recommendations on Centres of Excellence
- Relevant Regulations, guidelines, recommendations, best practices, etc., developed by EU MS

f) **Standards with focus on:**
- Organizational issues
- Identification, application and monitoring of relevant Guidelines (Centres will be requested to identify scientific references at the base of the clinical protocols applied, in adherence to available European and National Guidelines. Standards don't aim to take the place of scientific references, but their purpose is to ensure their correct identification, application and supervision).
- General Standards for Quality System management (see EUCERD)
- Quality Indicators to be monitored and related targets (e.g. set of quality indicators that should be routinely measured and evaluated by the Centres to confirm that the clinical outcome reaches the requested standards - see EUCERD)

g) **Definition of Standards that can be assessed objectively**
Objective evidence can be collected during an audit by reviewing documents, examining records, evaluating results, observing operations, interviewing people, etc.

Milestone
2

2012 August 31st

WP4 Flow of activities

OBJECTIVE

Consensus building on the preparation of the guiding document

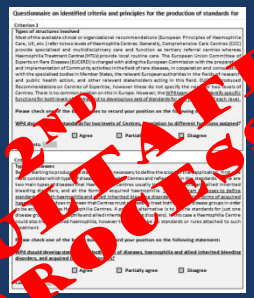
Criteria and Principles validated

WP4 Flow of activities

Milestone 2

2012, August 31st

1. Definition and diffusion of a Questionnaire on principles and criteria to EUHANET and other collaborating partners



CONSULTATION PROCESS

2. Questionnaires collection and analysis

56 Questionnaires collected from 26 EU and non-EU MS

3. Criteria and Principles validation

WP4 Flow of activities

2013 January 31st

Milestone 1 | Milestone 2 | Milestone 3 | Milestone 4 | Milestone 5

OUTPUT

Core draft of the Guiding document available for consultation

WP4 Flow of activities

Milestone 3

2013 January 31st

1 Standards and guiding document production

- **a** Definition of Standards index and framework
- **b** Cross reference of EU MS Standards, if available
- **c** Development of Standards

Standard Index

Contents

GENERAL REQUIREMENTS

Facility

ENGLAND (HCs)	BELGIUM (HCs)	NETHERLANDS	ITALY (MEC 1-2)	ITALY (AICE)
There should be dedicated **disabled car parking** spaces for patients/parents in the vicinity of the haemophilia centre. There should be appropriate **disabled access** throughout the haemophilia treatment area. The clinical treatment of patients with haemophilia should take place in a **dedicated clinical area** that should be comfortable, quiet and appropriately equipped. These areas must have a facility to **allow confidential interviews** between staff and patients particularly those with HIV and hepatitis virus infections.	Article 13-1 The centre is an organizational unit established and functional within a hospital and on a single site hospital. It has spaces for consultation and individual service required, a **meeting room** and a secretariat where records of individual functional rehabilitation of patients are kept available to the multidisciplinary team and emergency department.			

Information about Centre (for patient)

ENGLAND (HCs)	BELGIUM (HCs)	NETHERLANDS	ITALY (MEC 1-2)	ITALY (AICE)
				0.1.1 Il Centro mette a disposizione degli utenti un documento di presentazione del Centro che indica almeno: - i servizi offerti; - le modalità di accesso al Centro; - il responsabile del Centro ed il personale dedicato con le relative funzioni; - i presidi collaboranti con il Centro ed i principali referenti.

Organization and staffing

ENGLAND (HCs)	BELGIUM (HCs)	NETHERLANDS	ITALY (MEC 1-2)	ITALY (AICE)
		1.2 Structures and appointments 1.2.1 The management of HTC is known: a. how the organizational structure of the centre is embedded in the hospital structure b. the roles, responsibilities and authorities within the HTC c. how responsibilities are regulated in the region, including with other hospitals. *Explanation* *1.2.1.c For example, one may think of:* • *Agreements on inclusion in or transfer to the hospital including the HTC* • *Agreements on discharge from hospital* • *Agreements on the location where the birth of a wearer will occur.*		**0.2.1** La direzione del Centro definisce e formalizza le responsabilità, le deleghe e le funzioni assegnate all'interno della Struttura.

Cross reference

WP4 Flow of activities

Milestone 3

2013 January 31st

2 Launch of a consultation process on key points

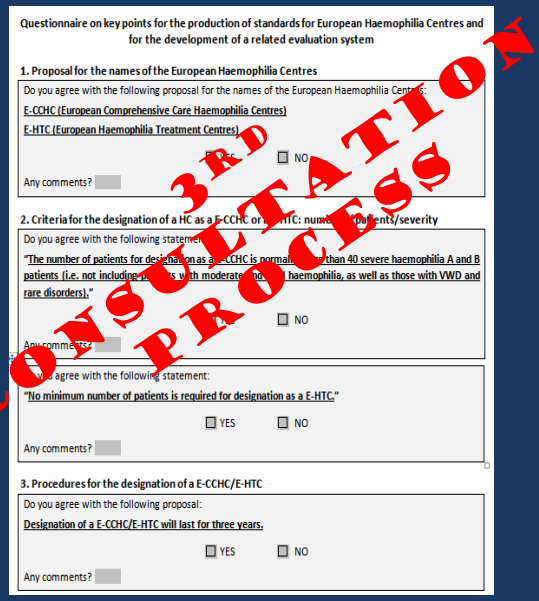
a Identification of key points

b Definition and diffusion of a Questionnaire on key points to EUHANET and other collaborating partners

Key points

- Names of the European HCs
- Number of patients/severity for designation of E-HCCC and E-HTC
- Procedures for the designation of E-HCCC/E-HTC
- Provision of 24-h expert haemophilia medical cover in E-HCCC
- Provision of 24-h medical cover in E-HTC by formalized arrangements with other departments and/or E-CCHC
- Formal relationship between E-HTCs and E-HCCCs
- Network of clinical and specialised services in conjunction with the haemophilia team
- Coagulation tests provided by Laboratory
- Availability of non-confidential information about the Centres

Key points Questionnaire


Questionnaire on key points for the production of standards for European Haemophilia Centres and for the development of a related evaluation system

1. Proposal for the names of the European Haemophilia Centres

Do you agree with the following proposal for the names of the European Haemophilia Centres:

E-CCHC (European Comprehensive Care Haemophilia Centres)

E-HTC (European Haemophilia Treatment Centres)

☐ YES ☐ NO

Any comments?

2. Criteria for the designation of a HC as a E-CCHC or E-HTC: number of patients/severity

Do you agree with the following statement:

"The number of patients for designation as a E-CCHC is normally more than 40 severe haemophilia A and B patients (i.e. not including patients with moderate and mild haemophilia, as well as those with VWD and rare disorders)."

☐ YES ☐ NO

Any comments?

Do you agree with the following statement:

"No minimum number of patients is required for designation as a E-HTC."

☐ YES ☐ NO

Any comments?

3. Procedures for the designation of a E-CCHC/E-HTC

Do you agree with the following proposal:

Designation of a E-CCHC/E-HTC will last for three years.

☐ YES ☐ NO

Any comments?

WP4 Flow of activities

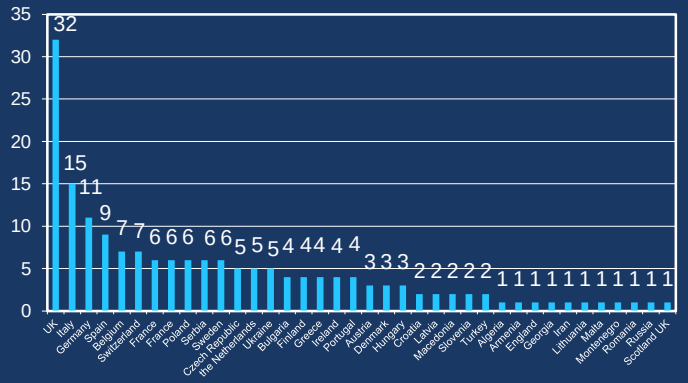
Milestone 3

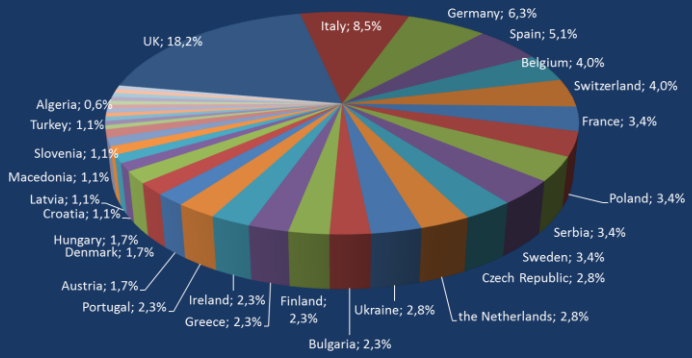
2013 January 31st

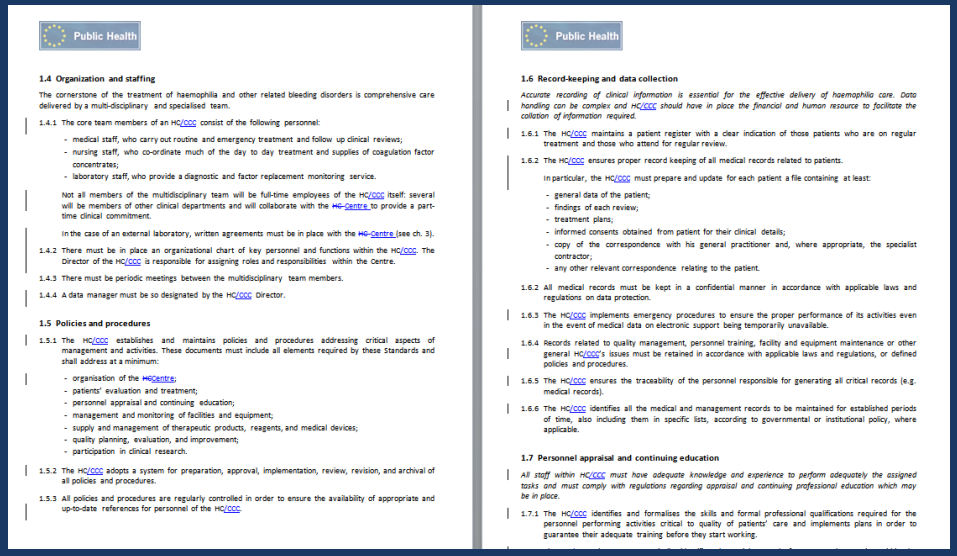
3 Questionnaires collection and analysis

4 Revision of the document according to the results of the consultation process

170 Questionnaires







Public Health

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.

1.4.1 The core team members of an HC/CCC consist of the following personnel:

- medical staff, who carry out routine and emergency treatment and follow up clinical reviews;
- nursing staff, who co-ordinate much of the day to day treatment and supplies of coagulation factor concentrates;
- laboratory staff, who provide a diagnostic and factor replacement monitoring service.

Not all members of the multidisciplinary team will be full-time employees of the HC/CCC itself: several will be members of other clinical departments and will collaborate with the ~~HC~~ Centre to provide a part-time clinical commitment.

In the case of an external laboratory, written agreements must be in place with the ~~HC~~ Centre (see ch. 3).

1.4.2 There must be in place an organizational chart of key personnel and functions within the HC/CCC. The Director of the HC/CCC is responsible for assigning roles and responsibilities within the Centre.

1.4.3 There must be periodic meetings between the multidisciplinary team members.

1.4.4 A data manager must be so designated by the HC/CCC Director.

1.5 Policies and procedures

1.5.1 The HC/CCC establishes and maintains policies and procedures addressing critical aspects of management and activities. These documents must include all elements required by these Standards and shall address at a minimum:

- organisation of the ~~HC~~Centre;
- patients' evaluation and treatment;
- personnel appraisal and continuing education;
- management and monitoring of facilities and equipment;
- supply and management of therapeutic products, reagents, and medical devices;
- quality planning, evaluation, and improvement;
- participation in clinical research.

1.5.2 The HC/CCC adopts a system for preparation, approval, implementation, review, revision, and archival of all policies and procedures.

1.5.3 All policies and procedures are regularly controlled in order to ensure the availability of appropriate and up-to-date references for personnel of the HC/CCC.

Public Health

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 HC/CCC should have in place the financial and human resource to facilitate the collation of information required.

1.6.1 The HC/CCC maintains a patient register with a clear indication of those patients who are on regular treatment and those who attend for regular review.

1.6.2 The HC/CCC ensures proper record keeping of all medical records related to patients.

In particular, the HC/CCC 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;
- copy of the correspondence with his general practitioner and, where appropriate, the specialist contractor;
- any other relevant correspondence relating to the patient.

1.6.2 All medical records must be kept in a confidential manner in accordance with applicable laws and regulations on data protection.

1.6.3 The HC/CCC implements emergency procedures to ensure the proper performance of its activities even in the event of medical data on electronic support being temporarily unavailable.

1.6.4 Records related to quality management, personnel training, facility and equipment maintenance or other general HC/CCC's issues must be retained in accordance with applicable laws and regulations, or defined policies and procedures.

1.6.5 The HC/CCC ensures the traceability of the personnel responsible for generating all critical records (e.g. medical records).

1.6.6 The HC/CCC 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.

1.7 Personnel appraisal and continuing education

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

1.7.1 The HC/CCC identifies and formalises the skills and formal professional qualifications required for the personnel performing activities critical to quality of patients' care and implements plans in order to guarantee their adequate training before they start working.

WP4 Flow of activities

2013 May 31st

Milestone 1 | Milestone 2 | Milestone 3 | **Milestone 4** | Milestone 5

OUTPUT

Final document approved

WP4 Flow of activities

Milestone 4

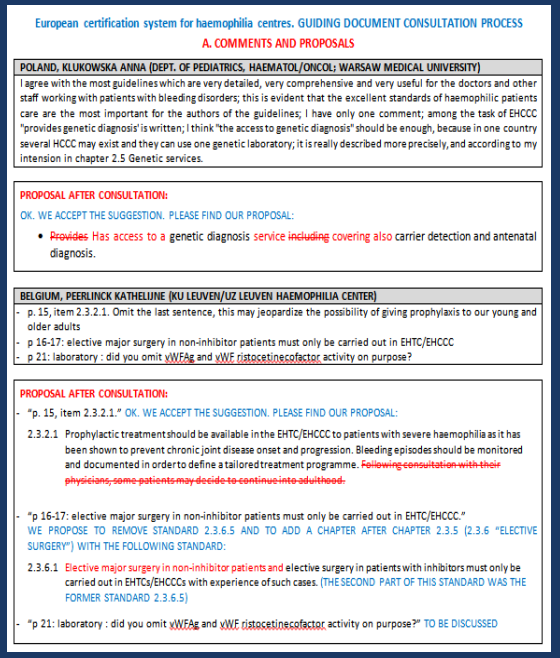
2013, May 31st

5 Launch of a consultation process on guiding document

4TH CONSULTATION PROCESS

6 Collection and analysis of comments

7 Revision of the document according to the results of the consultation process



European certification system for haemophilia centres. GUIDING DOCUMENT CONSULTATION PROCESS

A. COMMENTS AND PROPOSALS

POLAND, KLUKOWSKA ANNA (DEPT. OF PEDIATRICS, HAEMATOL/ONCOL; WARSAW MEDICAL UNIVERSITY)

I agree with the most guidelines which are very detailed, very comprehensive and very useful for the doctors and other staff working with patients with bleeding disorders; this is evident that the excellent standards of haemophilic patients care are the most important for the authors of the guidelines; I have only one comment; among the task of EHCCC "provides genetic diagnosis' is written; I think "the access to genetic diagnosis" should be enough, because in one country several HCCC may exist and they can use one genetic laboratory; it is really described more precisely, and according to my intension in chapter 2.5 Genetic services.

PROPOSAL AFTER CONSULTATION:

OK. WE ACCEPT THE SUGGESTION. PLEASE FIND OUR PROPOSAL:

- ~~Provides~~ Has access to a genetic diagnosis service ~~including~~ covering also carrier detection and antenatal diagnosis.

BELGIUM, PEERLINCK KATHELIJNE (KU LEUVEN/UZ LEUVEN HAEMOPHILIA CENTER)

- p. 15, item 2.3.2.1. Omit the last sentence, this may jeopardize the possibility of giving prophylaxis to our young and older adults
- p 16-17: elective major surgery in non-inhibitor patients must only be carried out in EHTC/EHCCC
- p 21: laboratory : did you omit vWFAg and vWF ristocetinecofactor activity on purpose?

PROPOSAL AFTER CONSULTATION:

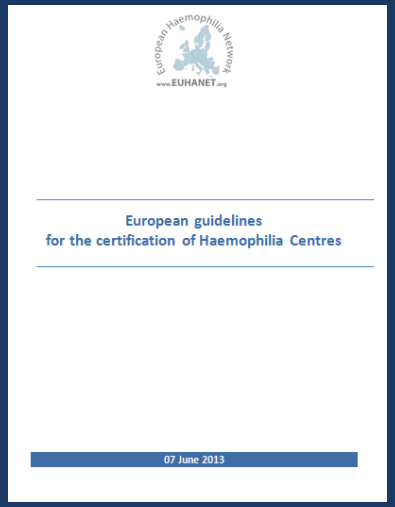
- "p. 15, item 2.3.2.1." OK. WE ACCEPT THE SUGGESTION. PLEASE FIND OUR PROPOSAL:

  2.3.2.1 Prophylactic treatment should be available in the EHTC/EHCCC to patients with severe haemophilia 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. ~~Following consultation with their physicians, some patients may decide to continue into adulthood.~~

- "p 16-17: elective major surgery in non-inhibitor patients must only be carried out in EHTC/EHCCC."
  WE PROPOSE TO REMOVE STANDARD 2.3.6.5 AND TO ADD A CHAPTER AFTER CHAPTER 2.3.5 (2.3.6 "ELECTIVE SURGERY") WITH THE FOLLOWING STANDARD:

  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. (THE SECOND PART OF THIS STANDARD WAS THE FORMER STANDARD 2.3.6.5)

- "p 21: laboratory : did you omit vWFAg and vWF ristocetinecofactor activity on purpose?" TO BE DISCUSSED



European Haemophilia Network
www.EUHANET.org

European guidelines
for the certification of Haemophilia Centres

07 June 2013

WP4 Flow of activities

2013 May 31st

Milestone 1 → Milestone 2 → Milestone 3 → Milestone 4 → Milestone 5

OUTPUT

Proposal of an Evaluation System framework

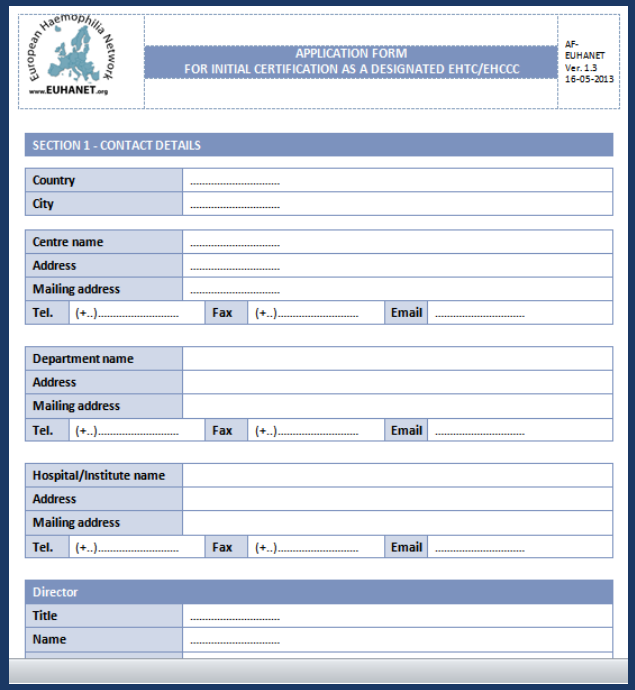
WP5

Milestone 4

2013, May 31st

WP4 Flow of activities

1. Definition of an Evaluation System framework
2. Production of the Application form



European Haemophilia Network
www.EUHANET.org

APPLICATION FORM
FOR INITIAL CERTIFICATION AS A DESIGNATED EHTC/EHCCC

AF-EUHANET Ver. 1.3 16-05-2013

SECTION 1 - CONTACT DETAILS

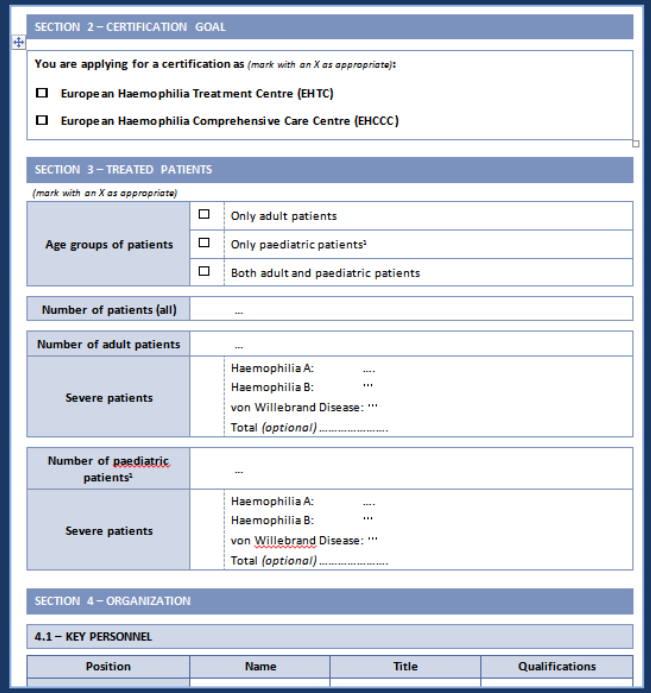
Country	.....
City	.....

Centre name	.....
Address	.....
Mailing address	.....
Tel. (+..).....	Fax (+..)..... Email .....

Department name	
Address	
Mailing address	
Tel. (+..).....	Fax (+..)..... Email .....

Hospital/Institute name	
Address	
Mailing address	
Tel. (+..).....	Fax (+..)..... Email .....

Director	
Title	.....
Name	.....



SECTION 2 – CERTIFICATION GOAL

You are applying for a certification as *(mark with an X as appropriate)*:

- ☐ European Haemophilia Treatment Centre (EHTC)
- ☐ European Haemophilia Comprehensive Care Centre (EHCCC)

SECTION 3 – TREATED PATIENTS

(mark with an X as appropriate)

Age groups of patients	☐	Only adult patients
	☐	Only paediatric patients[1]
	☐	Both adult and paediatric patients

Number of patients (all)	...
Number of adult patients	...
Severe patients	Haemophilia A: .... Haemophilia B: ''' von Willebrand Disease: ''' Total *(optional)* .....
Number of paediatric patients[1]	...
Severe patients	Haemophilia A: .... Haemophilia B: ''' von Willebrand Disease: ''' Total *(optional)* .....

SECTION 4 – ORGANIZATION

4.1 – KEY PERSONNEL

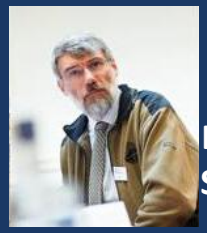
Position	Name	Title	Qualifications

EUHANET WP4 MEMBERS

Gabriele Calizzani
WP4 Leader

Brian O'Mahony
WP4 EHC Official Delegate

Paul Giangrande
WP4 Haemophilia Expert



Jo Eerens
EHC Bruxelles Staff Member

Amanda Bok
EHC Bruxelles
WP4 Staff member

Fabio Candura
WP4 Coordinator

Ivana Menichini
WP4 Consultant Methodologist