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® H. Depasse

Haemophilia Centres certification system across Europe : The Belgian experience

Disclosures

- Consultancy – Advisory board
  - Baxter, Bayer, Pfizer, CAF-DCF, SOBI, Ipsen, LFB, CSL-Behring, Novo Nordisk, Octapharma

- Research grants / Lecture Chairs
  - Baxter, Bayer, Pfizer, CAF-DCF, CSL-Behring, Novo Nordisk, Octapharma, Ipsen

Haemophilia in Belgium

• Haemophilia A	800*
• Haemophilia B	200*
• Medical doctors	40,000
GPs	15.000

Population : 10.600.000 inhabitants
FVIII annual consumption : 60 millions units/year – 6 units per capita

* Association des Hémophiles AH-VH

Cost of clotting factor concentrates to treat patients with haemophilia in Belgium

Therapeutic agent	Cost in € 2002	Cost in € 2009
Factor VIII	27 839 925	61 670 978
Factor IX	2 139 053	5 883 035
Novoseven	3 054 971	2 583 762
FEIBA	150 084	570 127
Total	33 184 033 €	70 707 902 €

The paradox of haemophilia care in Belgium

- Availability of plasma-derived and recombinant FVIII or FIX concentrates
  - No prescription restriction
  - No limitations of use of concentrates
  - Home treatment and prophylaxis widely available
  - Cost per FVIII unit : 0.7-0.9 Euro

- Absence of official treatments centres
- No specific funding for haemophilia care
- No national registry
- No certification
- No auditing

Haemophilia care in Belgium

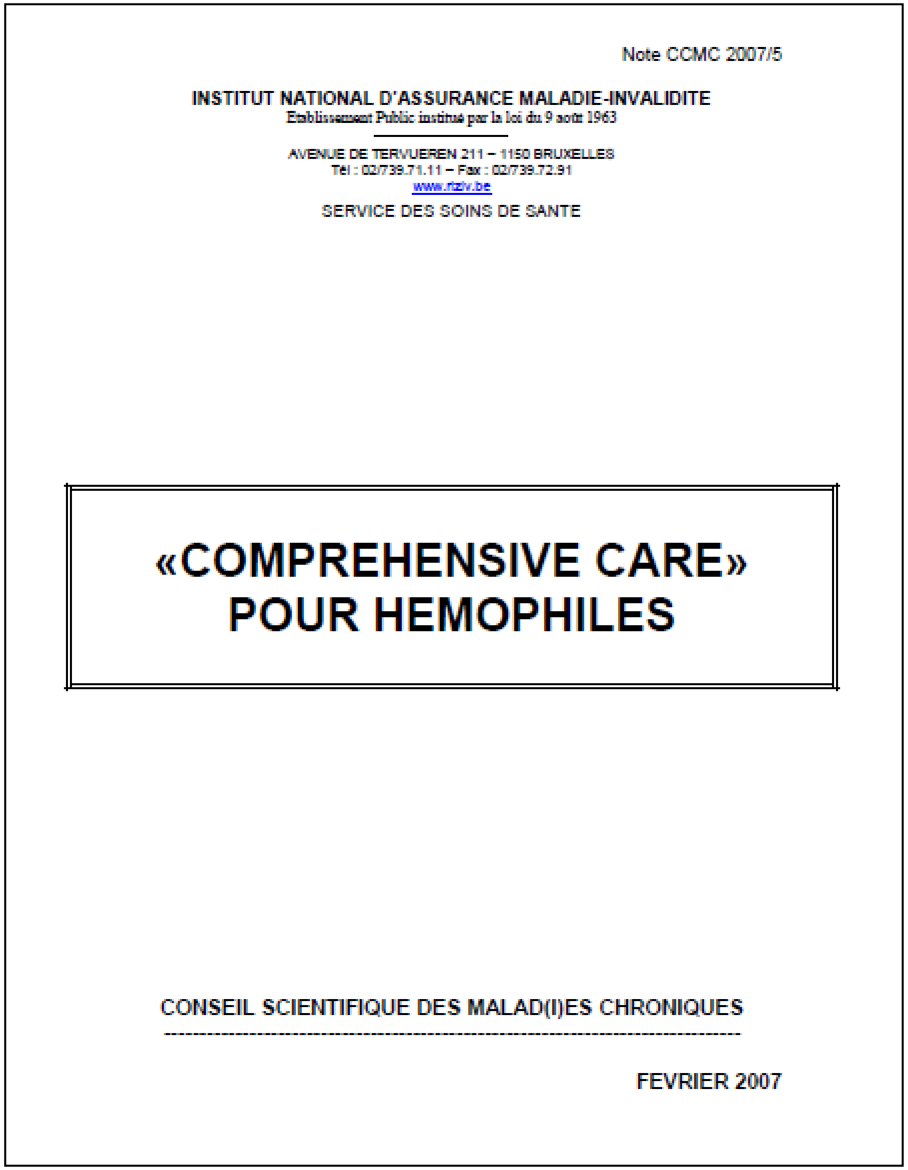
- Since factors concentrates can be prescribed by the local GPs, there is no incentive for a significant proportion of attend regularly specialised clinics.
- The proportion of belgian patients with haemophilia not regularly followed in haemophilia centres is unknown.
- The physical health, quality of life and life expectancy of these patients could be markedly improved if they were regularly referred to specialised centres.

Haemophilia Treatment Centres

Passport 2013 / Global treatment centre directory (WFH)

- Antwerp (n=1) (North)
- Brugge (n=1) (North)
- Gent (n=1) (North)
- Leuven (n=1) (North)
- Brussels (n=4)
- Liège (n=1) (South)

None of these centres is officially recognised by the Belgian Health Ministry
None of these centres is audited and funded for haemophilia care.



Note CCMC 2007/5

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Etablissement Public institué par la loi du 9 août 1963

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POUR HEMOPHILES

CONSEIL SCIENTIFIQUE DES MALAD(I)ES CHRONIQUES

FEVRIER 2007

Initiative launched in 2007 to recognize and fund HTCs

Not implemented so far

Last meeting took place in June 2013

Haemophilia care organisation in Belgium : new model (Proposed in 2007 – never implemented)

- **One single national coordinating centre**
  - > 150 patients with severe HA or HB
  - Publications +++ (cumulative impact factor over 5 years > 100)
  - Expertise +++

- **Several haemophilia treatment centres (number not defined)**
  - > 10 patients with severe HA or HB (adult or children)
  - Expertise +
  - Geographical distribution

Implementation of the haemophilia care organisation in Belgium

- Access to concentrates
  - Prescription will be restricted to haemophilia specialists (to be defined)

- Creation of a network of haemophilia centres
  - Applications have been submitted by several hospitals since 2007 (No specific application forms available)

  - Until today, there has been no feedback from the health ministry

Why is it so difficult to improve haemophilia care organisation in Belgium ?

- Rarity and complexity of haemophilia

- Financial implications :
  - Major investments and sponsorings from the pharmaceutical industry even in very small centres following a few patients

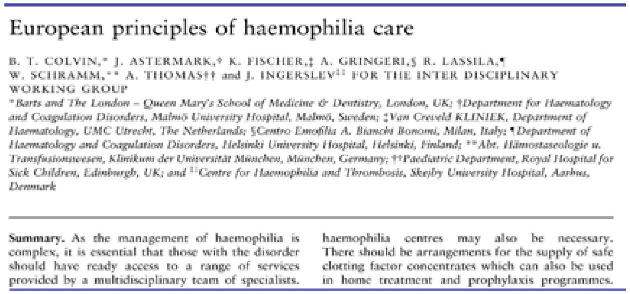
- Competition between hospitals / difficulties to reach a consensus

- Political reasons
  - Many centres do not fulfill the well-recognised requirements (> 40 patients with severe disease)
  - Complex belgian political situation
  - Real political willingness questionable (personal opinion)

The 10 European Principles of Hemophilia Care

1. A central hemophilia organisation with supporting local groups
2. National hemophilia patient registries
3. Comprehensive care centres and hemophilia treatment centres
4. Partnership in the delivery of hemophilia care
5. Safe and effective concentrates at optimum treatment levels
6. Home treatment and delivery
7. Prophylaxis treatment
8. Specialist services and emergency care
9. Management of inhibitors
10. Education and research

Colvin BT, Astermark J, Fischer K, et al. *Haemophilia* 2008; 14: 361-374



European principles of haemophilia care

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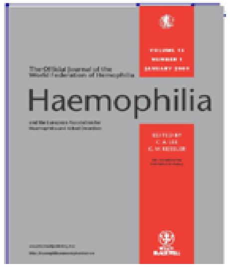
Summary. As the management of haemophilia is complex, it is essential that those with the disorder should have ready access to a range of services provided by a multidisciplinary team of specialists. haemophilia centres may also be necessary. There should be arrangements for the supply of safe clotting factor concentrates which can also be used in home treatment and prophylaxis programmes.



Haemophilia

Practice versus Principles

- The level of service provision within different countries in Europe compared to the recommendations set out in the Principles of Care has recently been audited by two studies;
  - Patients' organisations
  - Physicians

EHTSB

Haemophilia

Haemophilia (2010), 1–6

DOI: 10.1111/j.1365-2516.2010.02362.x

ORIGINAL ARTICLE

Haemophilia care in Europe: a survey of 19 countries

B. O'MAHONY,* D. NOONE,* P. L. F. GIANGRANDE† and L. PRIHODOVA‡

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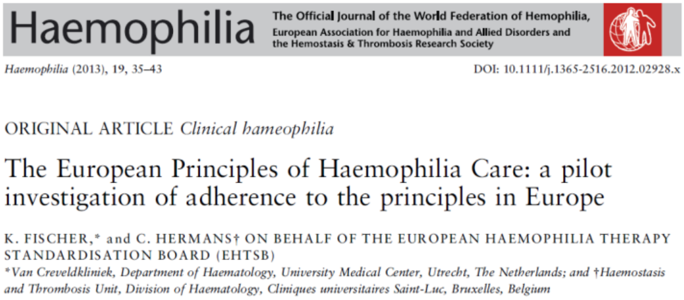

Haemophilia

The Official Journal of the World Federation of Hemophilia, European Association for Haemophilia and Allied Disorders and the Hemostasis & Thrombosis Research Society

Haemophilia (2013), 19, 35–43

DOI: 10.1111/j.1365-2516.2012.02928.x

ORIGINAL ARTICLE *Clinical haemophilia*

The European Principles of Haemophilia Care: a pilot investigation of adherence to the principles in Europe

K. FISCHER,* and C. HERMANS† ON BEHALF OF THE EUROPEAN HAEMOPHILIA THERAPY STANDARDISATION BOARD (EHTSB)

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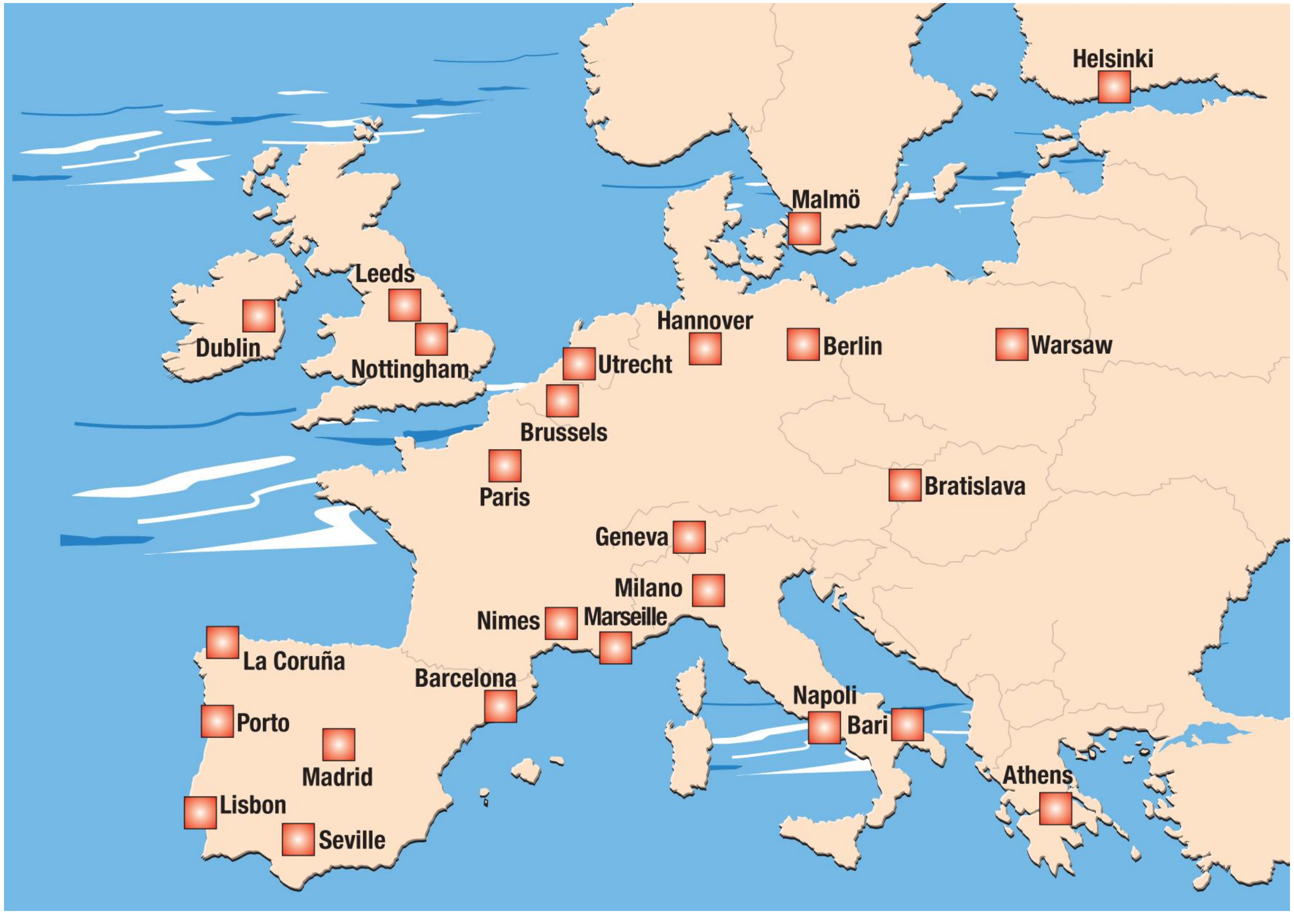
O'Mahony B, Noone D, Giangrande PL, Prihodova L. Haemophilia care in Europe: a survey of 19 countries. Haemophilia 2011 Jan;17(1):35-40.
Fischer K, Hermans C. The European Principles of Haemophilia Care: a pilot investigation of adherence to the principles in Europe. Haemophilia 2013 Jan;19(1):35-43.

The European Principles of Haemophilia Care: A pilot investigation of adherence to the principles in Europe

Translation of guidelines into practice

Objective	Current standard of services for haemophilia across Europe ? Extent of adherence to the Principles of Haemophilia Care ?
Setting	European Haemophilia Therapy Standardisation Board (EHTSB) (25 haemophilia treaters from 14 European countries)
Questionnaire	Derived from the audit tool designed by the UKHCDO and the published Principles of Haemophilia Care
Participation	Completed questionnaires obtained from 21/25 (84%) members of the EHTSB, representing the situation in all 14 member countries.

The European Haemophilia Therapy Standardisation Board (EHTSB) Centres



Severe Haemophilia A < 1%	Severe Haemophilia B < 1%
3.052	552

Summary of adherence to Principles 1,2 and 3 and 7 according to country

Country	No of Centres	Principle 1 Central Organisation	Principle 2 Patient Registry	Principle 3 All patients treated in CCC/HTC	No of CCC/HTC per Million inhabitants	Principle 7 % of Children on prophylaxis	Principle 7 % of Adults on prophylaxis
Belgium	1	No	No	No	0.83	75-100	50-75
France	1	Yes	Yes	Yes	0.71	75-100	1-25
Germany	2	Yes	Yes	No	0.89	75-100	50-75
Greece	1	Yes	Yes	Yes	0.37	75-100	1-25
Italy	3	Yes	Yes	Yes	0.81	75-100	1-25
Netherlands	2	Yes	No	Yes	0.78	75-100	50-75
Norway	1	Yes	No	Yes	0.40	75-100	50-75
Poland	1	Yes	No	No	0.84	75-100	1-25
Portugal	1	No	No	No	3.77	75-100	1-25
Slovakia	1	Yes	Yes	Yes	7.78	75-100	1-25
Spain	3	No	Yes	Yes	0.91	75-100	1-25
Sweden	1	Yes	No	Yes	0.32	75-100	75-100
Switzerland	1	Yes	Yes	No	1.27	75-100	1-25
United Kingdom	2	Yes	Yes	Yes	1.06	75-100	50-75
	Total 21	**79% Yes**	**57% Yes**	**64% Yes**	**Median 0.84 IQR0.62-1.11**		

Conclusions

- ☺ Clotting factor concentrates are available without restriction
- ☺ Home treatment and prophylaxis are widely available
- ☺ All patients have access to immune tolerance induction (ITI) if needed
- ☺ Active role played by the patients organisation (AH-VH) which is pro-active to implement an official network of HTCs

Conclusions

- ☹ No national registry
- ☹ No official recognition, funding, auditing and accreditation of HTCs
- ☹ Not all patients are followed in designated HTCs
- ☹ High dependency of HTCs on external funding provided by the Pharma Industry
- ☹ Very difficult to produce valid national data (use of resources, outcomes, incidence of INH,…) and implement a national tender process

EAHAD

Annual meeting

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Thank you for your attention