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

<table>
<thead>
<tr>
<th>Therapeutic agent</th>
<th>Cost in € 2002</th>
<th>Cost in € 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor VIII</td>
<td>27 839 925</td>
<td>61 670 978</td>
</tr>
<tr>
<td>Factor IX</td>
<td>2 139 053</td>
<td>5 883 035</td>
</tr>
<tr>
<td>Novoseven</td>
<td>3 054 971</td>
<td>2 583 762</td>
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<tr>
<td>FEIBA</td>
<td>150 084</td>
<td>570 127</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>33 184 033 €</strong></td>
<td><strong>70 707 902 €</strong></td>
</tr>
</tbody>
</table>
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.
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

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

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%

3.052

Severe Haemophilia B < 1%

552
## Summary of adherence to Principles 1,2 and 3 and 7 according to country

<table>
<thead>
<tr>
<th>Country</th>
<th>No of Centres</th>
<th>Principle 1 Central Organisation</th>
<th>Principle 2 Patient Registry</th>
<th>Principle 3 All patients treated in CCC/HTC</th>
<th>No of CCC/HTC per Million inhabitants</th>
<th>Principle 7 % of Children on prophylaxis</th>
<th>Principle 7 % of Adults on prophylaxis</th>
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</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>1</td>
<td>No</td>
<td>No</td>
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</tr>
</tbody>
</table>

### Total
- **79% Yes**
- **57% Yes**
- **64% Yes**

Median 0.84

IQR 0.62-1.11
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

European
Association

Haemophilia
Allied
Disorders

BRUSSELS – BELGIUM
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Thank you for your attention