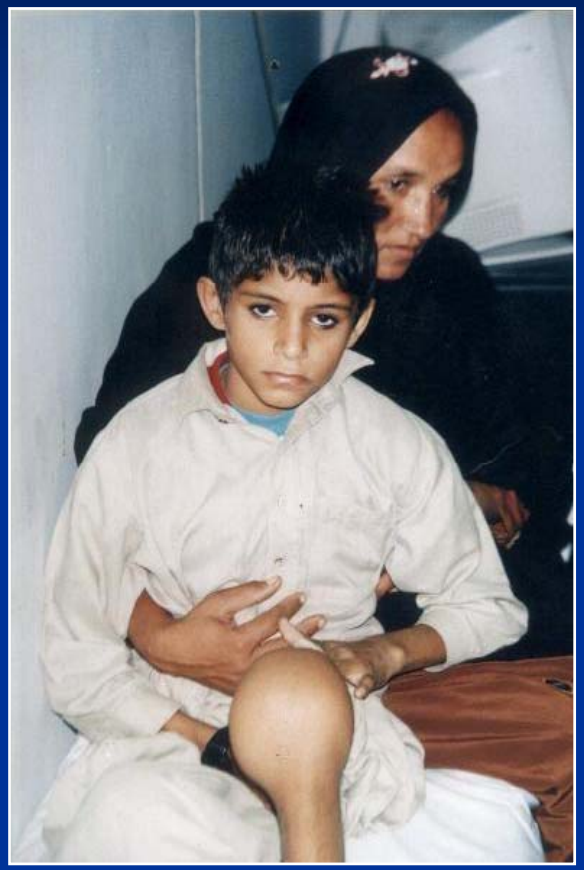
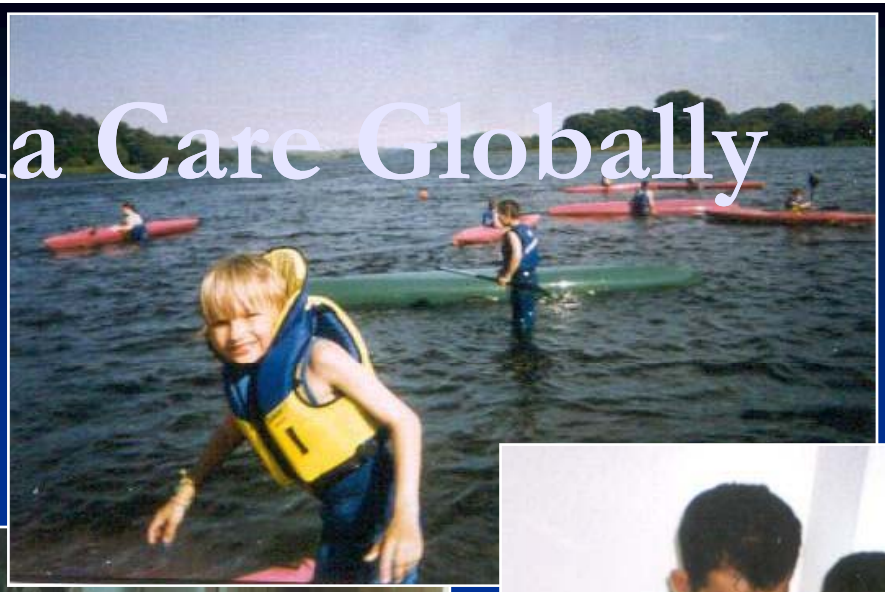
Economic Reality and the Development of Haemophilia Care

Brian O'Mahony, CEO
Irish Haemophilia Society
Esfahan, Iran
April 2009

Haemophilia Care Globally





- **70% not diagnosed, 75% not treated**
- Many die in childhood or grow-up severely disabled
- **High cost, low priority for most governments**

Setting National Objectives for Care

- **Linked to Economy**
- **Realistic in light of Global economic downturn**
- Practicable, Achievable
- Organisation and Resources
- Incremental development

National Haemophilia Program…Organisation

- National Haemophilia program with Government support
- Integrated within healthcare system
- National Register
- National treatment protocols
- Organised network of treatment centre's
- National purchase of replacement therapy

National Haemophilia Program…Organisation

- Strong National Patient Organisation for Advocacy and Education
- Doctors and Patient Organisation Co-operate
- National Haemophilia Committee

  : Statutory or Formal Basis

  : National Tender Commission

  : Doctors and Patient organisation included

Objectives of Treatment-
As Access to replacement Therapy increases:

Objective	Per Capita FVIII use
Survival	0 – 1
Functional Independence	1 – 3
Joint Integrity	3 – 6
Full integration into Society	5 – 7

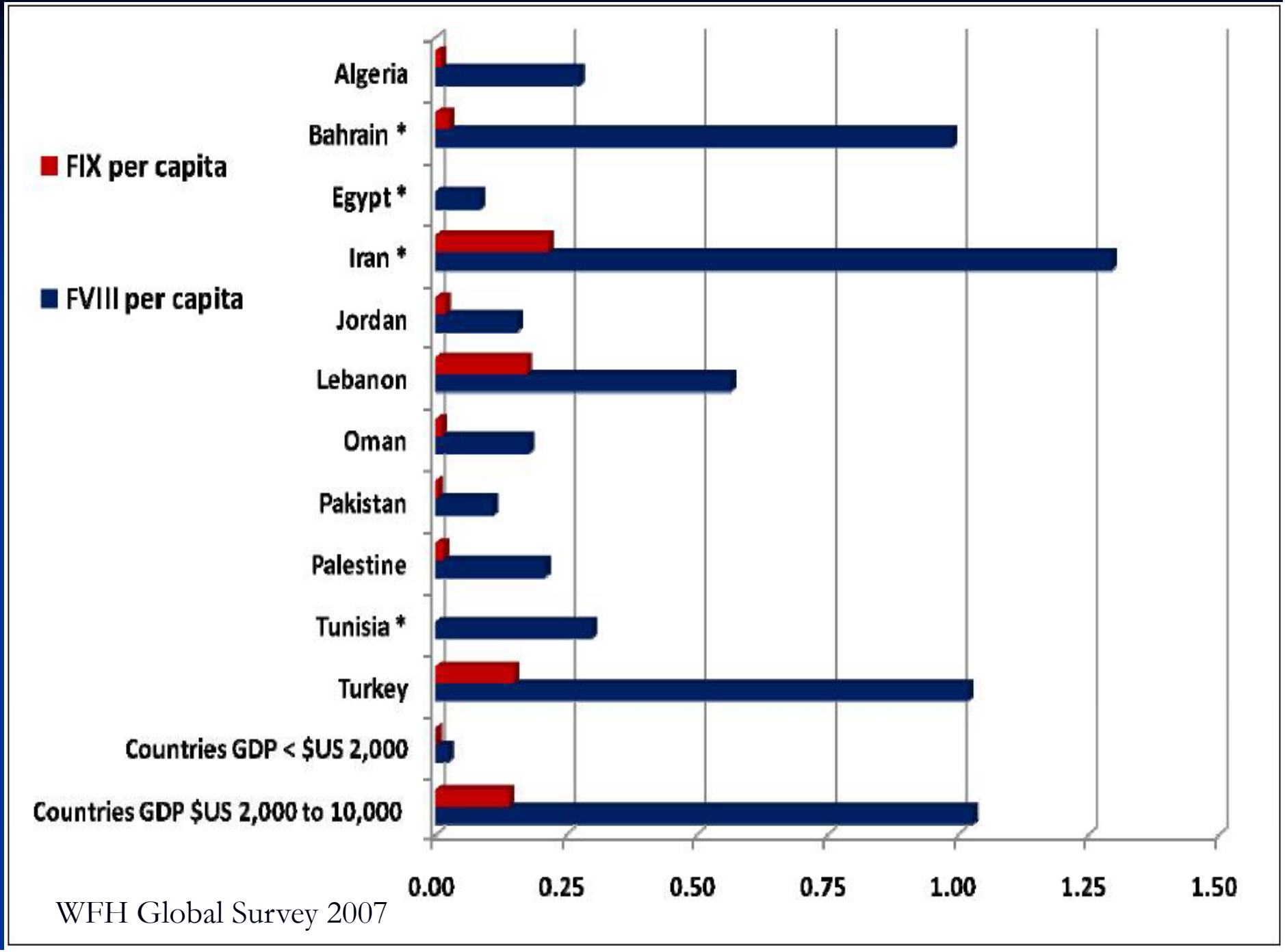
Factor Use relates to Economy

GNP	FVIII use	FIX use
>US$10,000	3.47	0.39
US$2 – 10,000	0.31	0.06
< US$ 2,000	0.02	0.001

IRAN * **Close to 2.0 iu/capita**

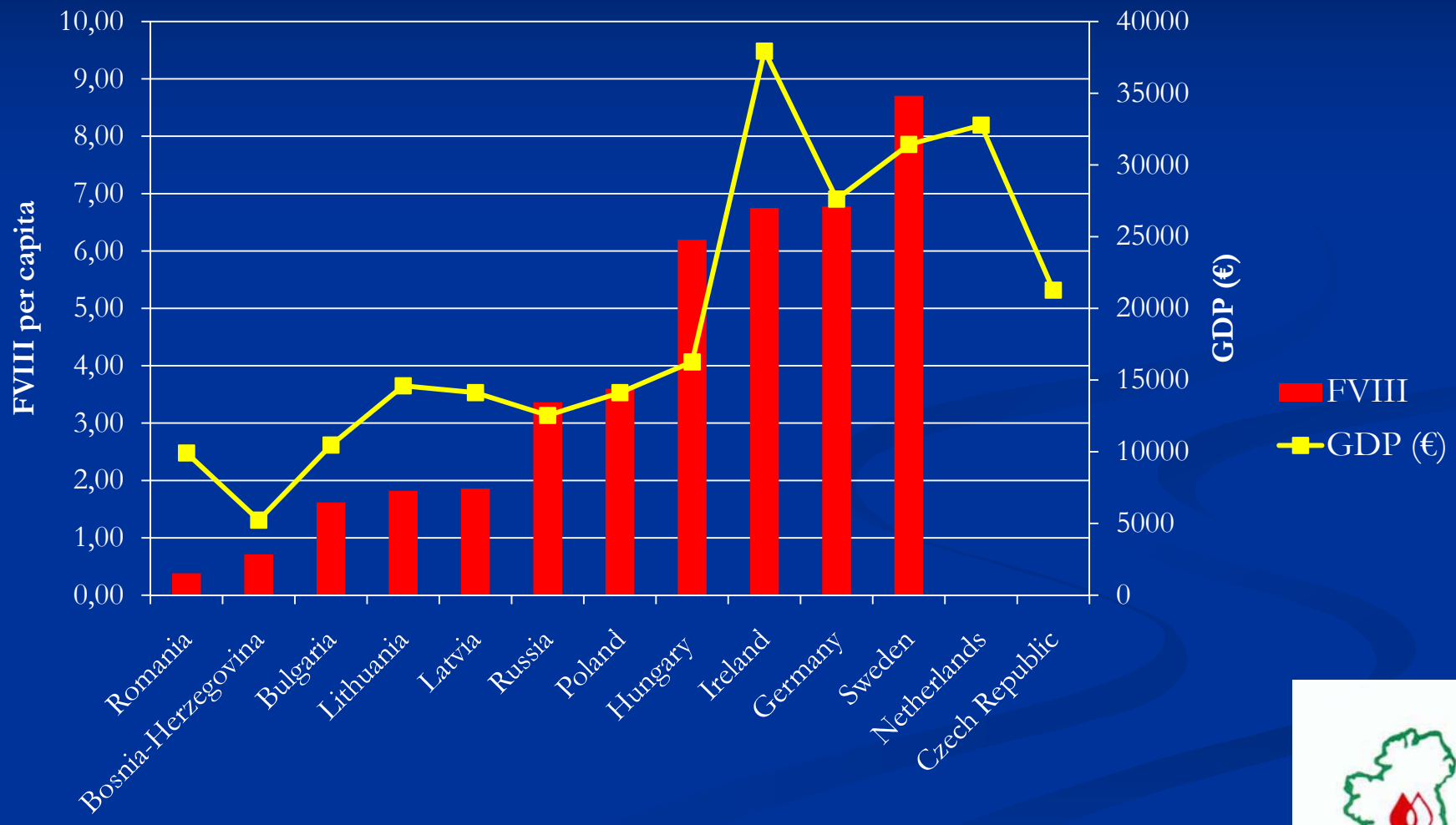
WFH Global Survey 2007 data

* 2009



WFH Global Survey 2007

Concentrate Use per capita



Minimum "Survival" standard

- Treatment in a care centre
- Safe and efficacious replacement therapy
- Factor concentrates for:
  - Life / Limb threatening bleeding episodes
  - Surgery
  - Major bleeding episodes

Good Standard of Care

- Treatment in a comprehensive care centre
- Provision of safe and efficacious replacement therapy
- Home treatment
- 'On Demand' therapy

Optimum Haemophilia Care

- Treatment in a comprehensive care centre
- Provision of safe and efficacious replacement therapy
- Home treatment
- Prophylaxis
- Strong co-operation between Doctors and Haemophilia Society

Prophylaxis

- Prevent bleeds from occurring
- Prevent joint damage
- Eliminate need for Orthopaedic surgery in later years
- Physical and psychological freedom
- Recognised as the current Optimum therapy

Prophylaxis Study 2007

- 65 Children with haemophilia- 5 year study
- 32 on Prophylaxis, 32 on-demand
- Normal Joint Function;
  - 93% of those on prophylaxis
  - 55% of those On-demand

M Manco Johnson et al, 2007

Factor replacement therapy in haemophilia

Outcome at different doses

	France ('on demand')	The Netherlands (intermediate-dose prophylaxis)	Sweden (high-dose prophylaxis)
Numbers	116	21	19
Age at study analysis	23	21	16–22
Age at start of home treatment	8.9	9.1	NA
Age at start of prophylaxis	NA	4.6	2.6
Annual number of joint bleeds	**16.3**	**5.3**	**3**
Pettersson score	18.8	6.0	6.5
Orthopaedic joint score	7.7	2.0	2.4
Clotting consumption (IU/kg/year)	1634	1828	3713

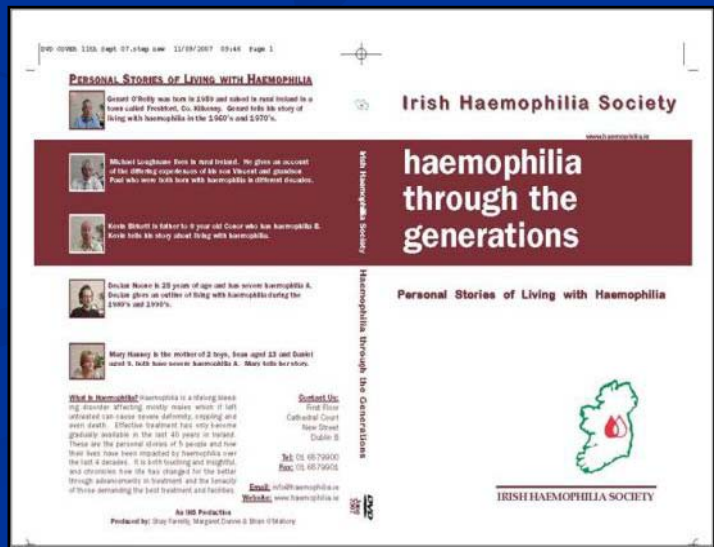
Different Reality and perception – Optimum Care

Children on Prophylaxis

- For many, no joint damage
- Severe haemophilia changed to mild

: Do not know what untreated haemophilia is like

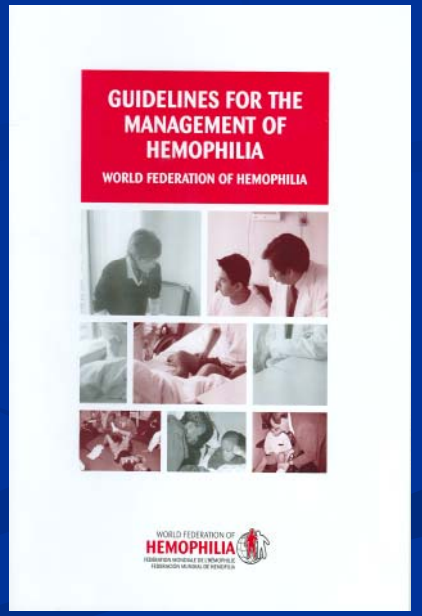
: Compliance with prophylaxis ?



Appropriate National Treatment Protocols

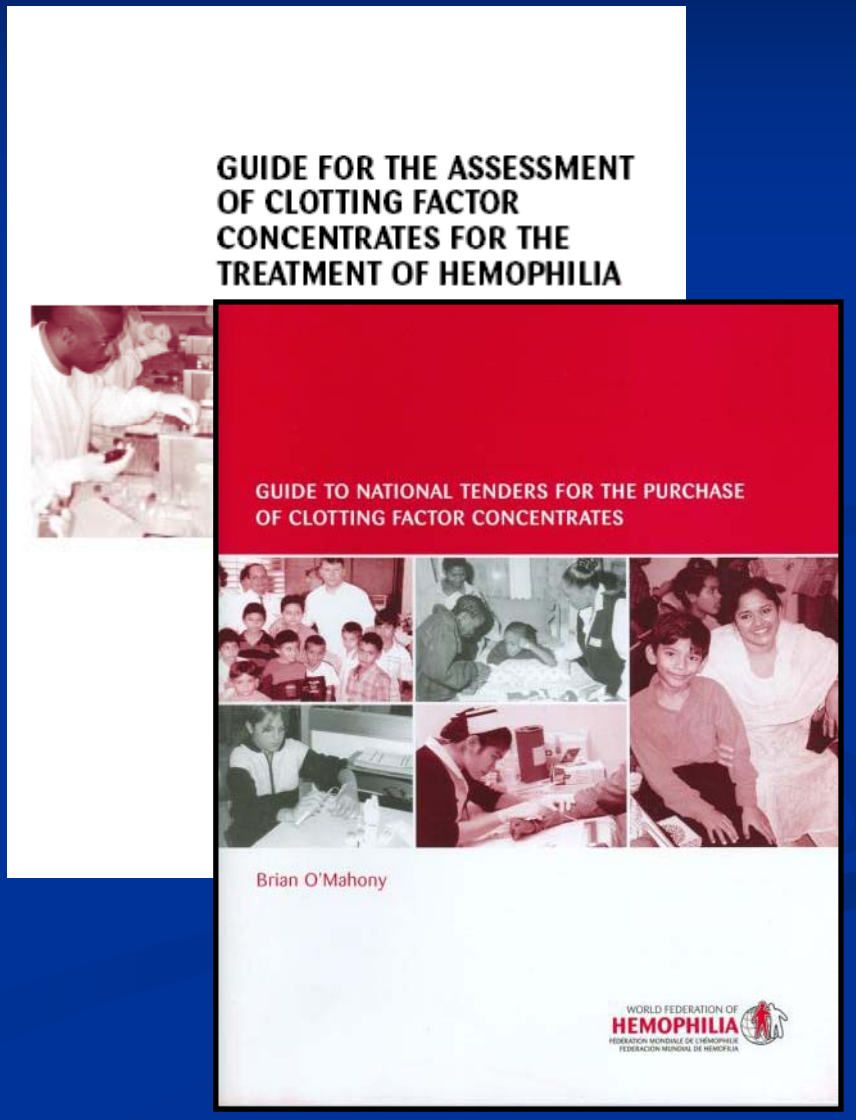
- **Recommended Dosage**

	Optimum	v Resource Constrained
Joint Bleed	40 - 60%	10-20%
Muscle	40 - 60%	10-20%
Iliopsoas	80 - 100%	20-40%
CNS/Head	80 - 100%	50-80%
Gastrointestinal	80 - 100%	30-50%
Major Surgery		
- Pre op	80 -100%	60-80%
- Post op	60 - 80%	30-40%



Choice of Replacement Therapy

- Safety
- Efficacy
- Quality
- Supply / Availability
- Cost
- National Purchasing



Factor Concentrate Safety

- Plasma derived, recombinant, excellent safety profile
- Plasma derived:
  - Improved donor selection
  - Improved donor screening
  - Viral inactivation, / removal
  - Post marketing surveillance

BBC NEWS

First case of haemophiliac vCJD

The Health Protection Agency has confirmed the first case of the human form of "mad cow disease" in a patient with haemophilia.

A post-mortem showed the man, who was "over 70" and had received plasma products before rules were introduced to limit contagion, died infected.

However he died of other causes and had not shown any symptoms, the HPA said.

Up to 4,000 haemophilia sufferers have been warned they could be at risk of variant Creutzfeldt-Jakob disease.

The HPA says it is still unclear how the man became infected with the prion protein that causes vCJD, but it is known that he was treated with several batches of UK blood plasma products before 1999, when the risk of transmission was not known.

Specifically, he was treated with a

Professor Mike Catchpole HPA

While this is the first case involving plasma products, three people have died after being infected with vCJD linked to blood transfusions.

"This new finding may indicate that what was until now a theoretical risk may be an actual risk to certain individuals who have received blood plasma products, although the risk could still be quite low," said Professor Mike Catchpole of the agency's Centre for Infections.

"We recognise that this finding will be of concern for persons with haemophilia who will be awaiting the completion of the ongoing investigations and their interpretation."

Chris James, the chief executive of the Haemophilia Society, said the Department of Health needed to now act "swiftly to give people the full details and offer them the appropriate support.

"Detailed information about recent developments must be made available immediately to all those who have been treated with potentially-infected plasma products."

David Allsop, professor of neuroscience at Lancaster University, said there was no need for widespread concern among haemophilia sufferers.

"The only real cause for concern is for other haemophilia patients who received clotting factors from the same infected human donor, at

guardian.co.uk

Haemophiliac caught CJD from plasma donor

Patient given clotting factors from UK blood is first haemophiliac thought to have human form of BSE

Staff and agencies
guardian.co.uk, Tuesday 17 February 2009 11.50 GMT
Article history

An elderly man with haemophilia contracted the human form of BSE after being treated with a blood-clotting agent from an infected donor, experts said today.

The patient had shown no symptoms of the disease but a post-mortem revealed evidence of variant Creutzfeldt - Jakob disease (vCJD) in the spleen.

The patient, who was over 70 and who died from an unrelated condition, is the first haemophiliac to be identified with vCJD.

Investigations are ongoing to

symptoms of vCJD six month after donating it in 1996.

The Health Protection Agenc (HPA) said today th investigations were ongoing b that it was working with the U Haemophilia Centre Docto Organisation to inform patients with bleeding disorde of the finding.

In 2004, all patients wit bleeding disorders, includin haemophilia, treated with UI sourced pooled plasma produc between 1980 and 2001 we classed as "at risk" of vCJD du to the possibility of infection.

The HPA said today that th atest discovery would n

Fears over UK blood

FIFTY Irish haemophiliacs have been warned they are at risk of the human form of mad cow disease after a sufferer became the first to contract the condition.

A postmortem revealed that a 70-year-old British man received infected blood products and had died with the disease.

The man, who died of other causes, became infected with Creutzfeldt-Jakob disease (vCJD) from a blood transfusion using UK-sourced plasma.

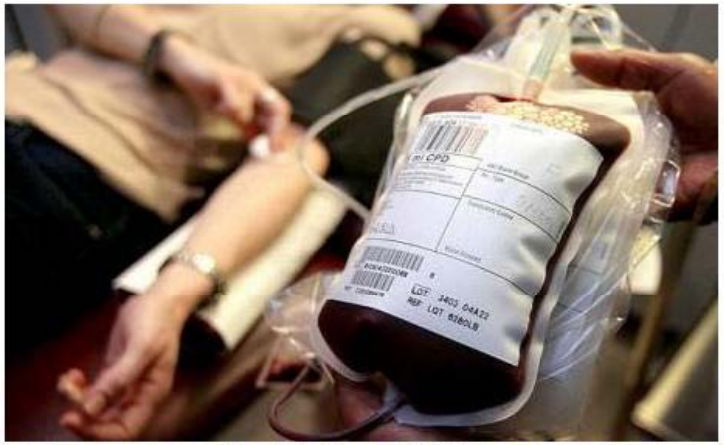
Fifty people with haemophilia a

Telegraph.co.uk

Thousands at risk of human form of mad cow disease af haemophiliac's death

Thousands of haemophiliacs are at risk of developing vCJD after the death of a man who had receive infected blood clotting products.

by Rebecca Smith, Medical Editor
Last Updated: 4:28PM GMT 17 Feb 2009



http://www.telegraph.co.uk/health/healthnews/4680483/Thousands-at-risk-of-human-form-of-mad-cow-disease-after-haemophiliacs-death.html

Irish Examiner

Wednesday, February 18, 2009

Blood test for vCJD may be here by summer

By Evelyn Ring

A NEW blood test for the human form of mad cow disease, Creutzfeldt-Jacob Disease (vCJD), could be available this summer.

The Irish Blood Transfusion Service's national medical director Dr William Murphy said yesterday he is hopeful EU approval for the test could be secured soon.

The blood bank would be asking for e3 million a year in Government funding to include the test in its screening process. Currently, blood donations are tested for a range of different conditions, including syphilis, hepatitis and HIV.

Dr Murphy said the Canadian manufacturer, Amorfix Life Sciences, claims it can detect infected people who have not developed the disease but may be able to transmit it through their blood.

The blood bank is looking at how it will manage concerns, in particular the number of false positives that it is likely to throw up.

"When we test people for HIV we get a number of false positives every year but we know they are false positives because there are additional tests we can do. We do not have that kind of back-up test for vCJD."

The blood bank will only be able to tell donors they tested positive for vCJD.

"That has implications for people. It is going to cause anxiety and it is going to cause issues around insurance and social life as well."

He was speaking at a press conference organised by the National Haemophilia Council to reassure people with haemophilia about the risk of infection of vCJD from clotting products made in the past from donors.

A man in his 70s with haemophilia, who recently died in Britain, had evidence of vCJD infection. A postmortem found evidence of vCJD in his spleen.

About 50 Irish patients who used British plasma-derived products, have been informed of the news.

Chief executive of the Irish Haemophilia Society Brian O'Mahony said it might indicate that what was until now a theoretical risk might be an actual one.

"We are keeping this in perspective, however, because there have been a couple of thousand people with haemophilia in Britain who have received these products in the 1980s and 1990s and we have not seen a single clinical case of vCJD anywhere in the world."

The National Centre for Hereditary Coagulation Disorders in St James's Hospital, Dublin, has set up a helpline (1800 200 849) for anyone with concerns.

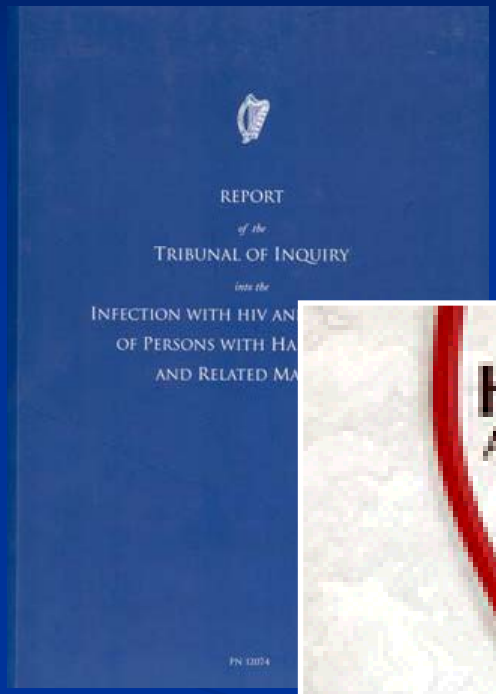
www.haemophilia.ie.

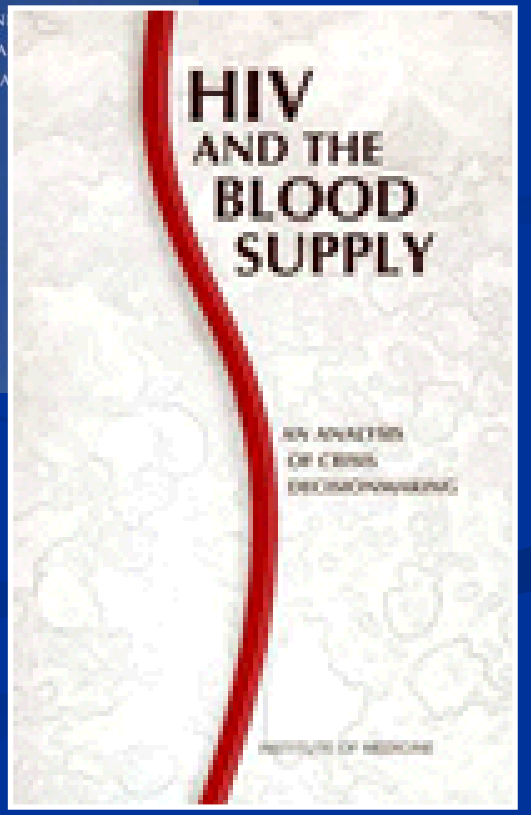
Economic Benefits of Factor Concentrates

- Faster recovery
- Less joint damage
- Less requirement for orthopaedic surgery in future
- Less time lost work, education
- Contribute to society

Economic Cost of Not providing Safe Treatment

- HIV
- Hepatitis A, B, C
- Cost of treatment
- Hospitalisation cost
- Cost of Inquiries
- Cost of Compensation





Early Treatment

- Home Treatment
  - Less treatment required
  - Minimise joint damage- decreased by 30%
  - Less disruption to individual
  - Eases burden on hospitals
  - Preserves functional independence

Benefits of Home Therapy

- 400% decrease in clinic visits
- Increase lifespan and Quality of Life
- Optimal use of factor concentrates

Mexico: Home therapy, 47% annual reduction in cost of treatment

Survival Analysis of Thai Hemophiliacs

	First decade 1971-1980	Second decade 1981-1990	Third decade 1991-2000
No. of patients	47	58	59
No. of patients receiving home treatment	15 (31.9%)	30 (51.7%)	40 (67.8%)
Age at starting home treatment	16.5 ± 7.7	9.1 ± 4.2	7.2 ± 8.4
Age at initial joint deformity	14.4 ± 8.5	10.7 ± 5.0	19.9 ± 11.8

Chuansumrit A, et al. Haemophilia 2004; 10:542-9.

Survival Analysis of Thai Hemophiliacs

	First decade 1971-1980	Second decade 1981-1990	Third decade 1991-2000
No. of patients with			
joint deformity	10 (21.3%)	12 (20.7%)	4 (6.8%)
1 - 2 joint	11 (23.4%	15 (25.9%)	6 (10.2%)
> 2 - 4 joints			
No. of patients with	27 (62.8%)	43 (75.4%)	49 (84.5%)
unaided proper walking			

Chuansumrit A, et al. Haemophilia 2004; 10:542-9.

The Way Forward

- Doctors / Patient organisations work together – Formal involvement
- National approach in collaboration with Government
- National protocols and Register
- Planned steady incremental improvement in diagnosis, treatment and comprehensive care.

Economic Reality

- Global Economic Recession / Depression
- Iceland had highest FVIII per capita use in world - country now bankrupt
- More examination of cost effectiveness
- Treatment parameters may increasingly be set by funding available and not by clinical need
- Health Technology Assessment (HTA)
- First HTA in Haemophilia in Sweden – 2009
- Result may have Global implications / utility

Annual Cost Data- Ireland

- Severe Haemophilia € 125 - €215,000
- Haemophilia € 55 - €63,000
- Bleeding Disorder € 26,500
- Bleeding/Clotting disorder (or average annual cost per patient) € 15,600

- **Integrated approach reduces average cost per patient by 88% compared to severe FVIII deficiency**

Most expensive substances

Swedish national pharmaceutical registry data

Substance and area of use	Total cost Million € July 2007–June 2008	Increase vs last year (%)	Number of patients Sweden	Pat /1000	Average cost per patient €
1. Etanercept (rheumatoid arhtritis etc)	65	19	6648	0,73	9834
2. Test strips blood glucose (diabetes)	51	3	210507	23,1	242
3. Factor VIII (Haemophilia)	48	1	355	0,04	134019

Source: the National Board of Health and Welfare (2008)

Targets for Cost Analysis

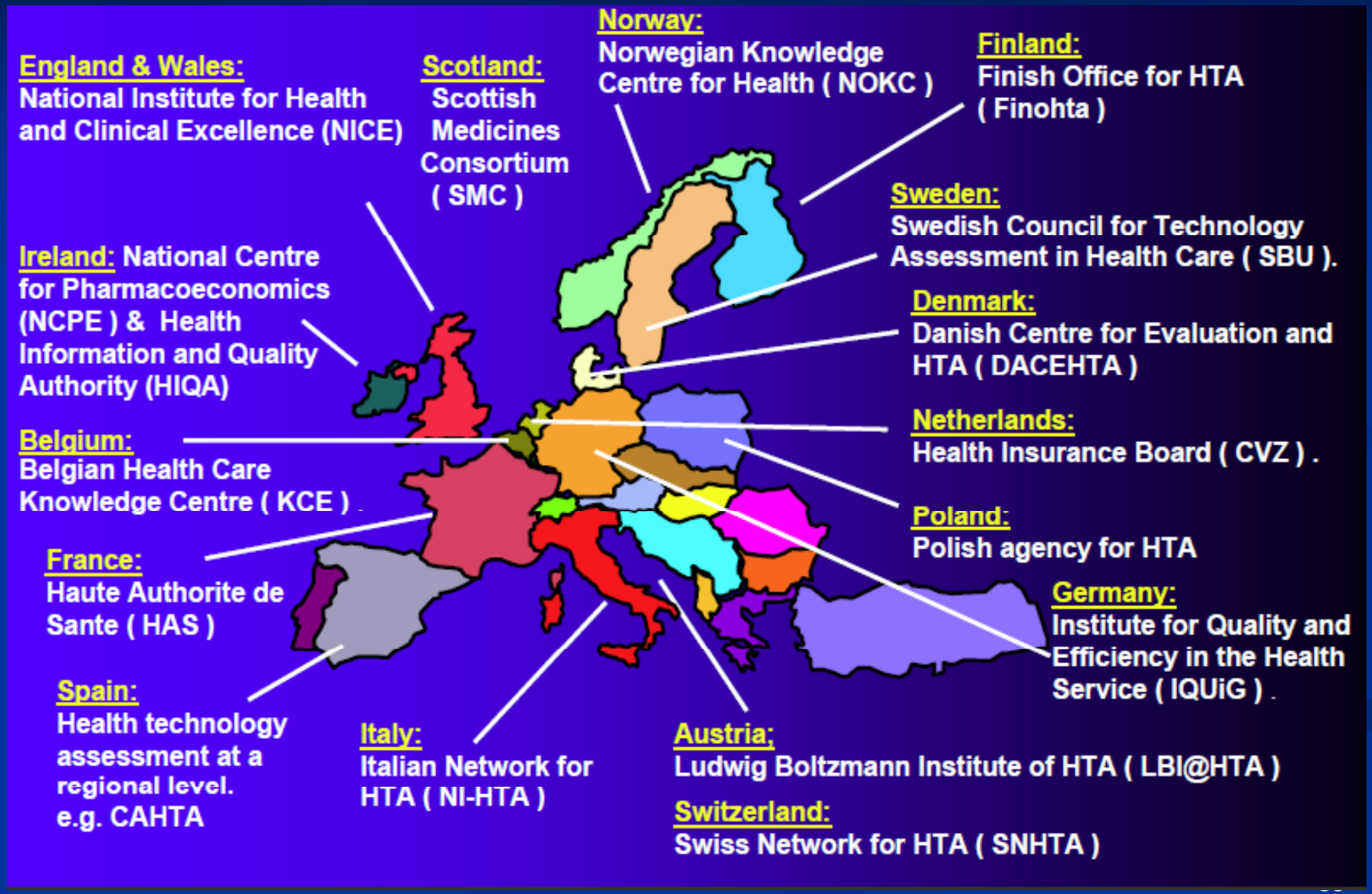
- Prophylaxis v on demand
- Prophylaxis in adults
- Inhibitor treatment regimes
- Plasma derived v Recombinant
- Different generations of Recombinant
- Recombinant products from new companies

Health Technology Assessments

- HTA is concerned with the medical, organizational, economic and societal consequences of implementing health technologies or interventions within the health system.

- Evidence based systematic study of benefits, costs and harms of a health technology.

HTA Agencies in Europe 2008



Dealing with Economic Threats

- Need to define and agree on what is required – Guidelines
- If not, competing priorities win
- Coming battles will be as much about advocacy and assertiveness as availability and adequacy

Quality-Adjusted Life Year **(QALY)**

- A **quality-adjusted life year** (QALY) is a measure of disease burden, including both the quality and the quantity of life lived.
- It is a means of assessing the value for money of a medical intervention.
- The QALY is based on the number of years of life that would be added by the intervention
- **Each year in perfect health is assigned a value between 0.0-1.0 with 0.0 for death and 1.0 being full health.**

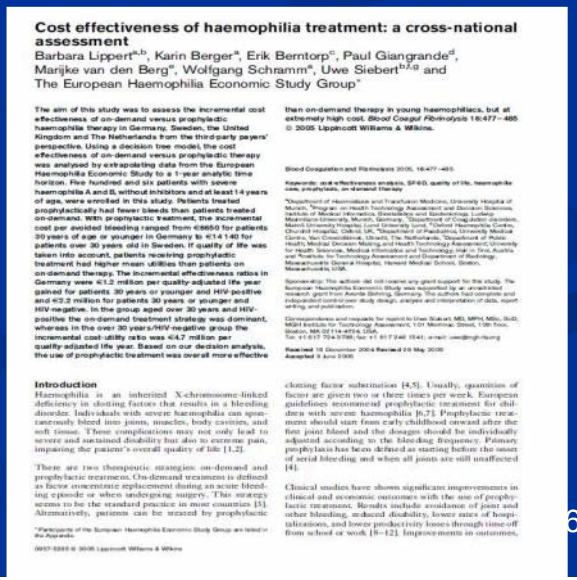
Haemophilia and Cost Effectiveness

- E.G. Germany
  - A **QALY** of a person under 30 with on-demand Treatment (HIV negative) is **0.7427** and costs **€85,451**
  - A **QALY** of a person under 30 on Prophylaxis (HIV negative) is **0.7754** and costs **€157,972**
  - Effectiveness of the Treatment is the difference in **QALY's**

    0.7754 – 0.7427 = 0.0328
  - Incremental Cost of a QALY :

    Cost Difference = **€2,212,749**

    QALY Difference



Cost effectiveness of haemophilia treatment: a cross-national assessment

Barbara Lippert[a,b], Karin Berger[a], Erik Berntorp[c], Paul Giangrande[d], Marijke van den Berg[e], Wolfgang Schramm[a], Uwe Siebert[b,f,g] and The European Haemophilia Economic Study Group*

The aim of this study was to assess the incremental cost effectiveness of on-demand versus prophylactic haemophilia therapy in Germany, Sweden, the United Kingdom and The Netherlands from the third-party payers' perspective. Using a decision tree model, the cost effectiveness of on-demand versus prophylactic therapy was analysed by extrapolating data from the European Haemophilia Economic Study to a 1-year analytic time horizon. Five hundred and six patients with severe haemophilia A and B, without inhibitors and at least 14 years of age, were enrolled in this study. Patients treated prophylactically had fewer bleeds than patients treated on-demand. With prophylactic treatment, the incremental cost per avoided bleeding ranged from €9650 for patients 30 years of age or younger in Germany to €14 140 for patients over 30 years old in Sweden. If quality of life was taken into account, patients receiving prophylactic treatment had higher mean utilities than patients on on-demand therapy. The incremental effectiveness ratios in Germany were €1.2 million per quality-adjusted life year gained for patients 30 years or younger and HIV-positive and €2.2 million for patients 30 years or younger and HIV-negative. In the group aged over 30 years and HIV-positive the on-demand treatment strategy was dominant, whereas in the over 30 years/HIV-negative group the incremental cost-utility ratio was €4.7 million per quality-adjusted life year. Based on our decision analysis, the use of prophylactic treatment was overall more effective than on-demand therapy in young haemophiliacs, but at extremely high cost. *Blood Coagul Fibrinolysis* 16:477–485 © 2005 Lippincott Williams & Wilkins.

Blood Coagulation and Fibrinolysis 2005, 16:477–485

Keywords: cost effectiveness analysis, SF-6D, quality of life, haemophilia care, prophylaxis, on-demand therapy

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Introduction

Haemophilia is an inherited X-chromosome-linked deficiency in clotting factors that results in a bleeding disorder. Individuals with severe haemophilia can spontaneously bleed into joints, muscles, body cavities, and soft tissue. These complications may not only lead to severe and sustained disability but also to extreme pain, impairing the patient's overall quality of life [1,2].

There are two therapeutic strategies: on-demand and prophylactic treatment. On-demand treatment is defined as factor concentrate replacement during an acute bleeding episode or when undergoing surgery. This strategy seems to be the standard practice in most countries [3]. Alternatively, patients can be treated by prophylactic clotting factor substitution [4,5]. Usually, quantities of factor are given two or three times per week. European guidelines recommend prophylactic treatment for children with severe haemophilia [6,7]. Prophylactic treatment should start from early childhood onward after the first joint bleed and the dosages should be individually adjusted according to the bleeding frequency. Primary prophylaxis has been defined as starting before the onset of serial bleeding and when all joints are still unaffected [4].

Clinical studies have shown significant improvements in clinical and economic outcomes with the use of prophylactic treatment. Results include avoidance of joint and other bleeding, reduced disability, fewer rates of hospitalizations, and lower productivity losses through time-off from school or work [8–12]. Improvements in outcomes,

The Incremental Cost can be calculated on bleeds avoided

- . **EG. Germany**
  - A person under 30 with on-demand Treatment has an average of 16.7 bleeds a year at a cost of **€85,451**
  - A person under 30 on prophylaxis has an average of 5.9 bleeds a year at a cost of **€157,972**
  - Effectiveness of the Treatment is the difference in bleeds avoided

    16.7 – 5.9 = 10.8

  - Incremental Cost:

    $$\frac{\text{Cost Difference}}{\text{Difference in bleeds avoided}} = \text{€6,653}$$

Cost effectiveness of prophylaxis

Published cost per QALY estimates of FVIII prophylaxis in children

Study	Cost per QALY estimate ($)
Miner 2002	65,000
Roosendahl 2007	300,000
Risebrough 2008	420,000
Lippert 2005	1.2m – 2.7m

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*Participants of the European Haemophilia Economic Study Group are listed in the Appendix.

0957-5235

HTA - Prophylaxis

- **Prophylaxis:** proven efficacy
- Early prophylaxis can decrease risk of inhibitors
- Severe into Moderate- increases QOL and Life expectancy
- Cost per bleeding episode avoided is relatively low
- Better economic studies now available

Economics and Haemophilia

- Know the relevant data
- Prepare case based on economic AND Human criteria
- Pharmacoeconomic and QOL data increasingly important
- Stress societal support – any person can develop an "expensive" condition
- Prepare to counter likely approach of emphasising most expensive cases.

“Attacking” most Expensive cases

Hospital Charges W1.8 Bil. to Hemophiliac

By Lee Jin-woo
Staff Reporter A general hospital in Seoul has charged a record-high 1.87 billion won ($1.8 million) to a pat for receiving intensive medical treatments for 97 days. Kyung Hee Medical Center in northeastern Seoul sai Saturday that it has issued the bill to its patient, identified by his family name Bae, 37, who suffers from hemophilia. According to a revised law concerning medical insurance for patients who require expensive treatments, Bae should pay up to 10 million won and the hospital should receive the remaining sum from tl National Health Insurance Corp. The hospital, an affiliate of Kyung Hee University, needs to get approval fr

Family defend boy's health bill

Related Video

Family defend boy's health bill (07.02)

Mar 21, 2005

Treatment for patient cost €4m so far this year

MARTIN WALL AND **RICHARD OAKLEY**

TREATMENT for one patient in a Dublin public hospital has s[illegible] this year cost the state o[illegible]m, health chiefs in the capital have told the government.

The Sunday Tribune has learned that the Eastern Regional Health Authority (ERHA) is seeking the government to provide up to €12m in supplementary funding to St James's Hospital to defray the enormous costs of providing care for a small number of patients requiring hugely expensive blood products.

The ERHA told the Department of Health on Friday week last that the hospital had spent over €35m in the first eight months of the year on certain forms of blood products. The authority said that the bill for one patient was €4.044m, while blood products for three other patients had cost over €1m each.

It is [illegible]erstood that all the patient[illegible]ncerned have a hereditary blood disorder.

A spokesman for St James's Hospital stressed that the products were essential for the well-being of the patients involved.

The ERHA told the Department of Health last week that various hospitals and agencies which it funds were over budget by some €29m at the end of August. It expressed unease at a surge in spending by the three constituent health boards in the eastern region in the late summer.

"Within the Area Health Boards the levels of reported expenditure are a cause for some concern in that they have risen sharply compared with the average monthly expenditure up to July. The authority is querying the nature of the expenditure and the related issue of accruals and standard accounting practice," the ERHA told the department.

The report said that the main financial overruns were recorded in the acute hospitals and in the Northern Area Health Board.

The ERHA said that the main Dublin acute hospitals were €36m in the red by the end of August while the health board covering the northern part of Dublin had an overrun of almost €14m.

The report said that the main financial pressures were coming from blood products, medical overtime and nurse recruitment costs, as well as bills for drugs, insurance, security emergency replacement of equipment and lower than anticipated revenue as a result of the winter vomiting bug.

The report said that the Northern Area Health Board expected to make savings of €7m as a result of cost containment initiatives.

St James's Hospital: costly

Thank You