Results of the EHC survey on Tender's and Procurement: a survey of 38 countries

Brian O Mahony

President, EHC

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Haemophilia(2015),1-8
DOI:10.1111/hae.12720

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EHC Survey

- Survey carried out in late 2014- sent to all 45 National Haemophilia patient Organisations
- 38 completed surveys received
  - 20 by patient organisations
  - 11 by patient organisations/clinicians
  - 7 by clinicians
- Clarifications received from doctors nominated by EAHAD from 5 countries

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Haemophilia
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the Hemostasis & Thrombosis Research Society

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ORIGINAL ARTICLE

Survey of coagulation factor concentrates tender and procurement procedures in 38 European Countries

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Procurement method

Tender		Alternative		Both
Albania	Poland	Austria	Kyrgyzstan	Bulgaria
Azerbaijan	Portugal	Belgium	Latvia	Lithuania
Belarus	Romania	Croatia	Netherlands	
Bosnia & Herzegovina	Russia	Estonia	Norway	
Czech Republic	Serbia	Finland	Spain	
Denmark	Slovak Republic	France	Sweden	
Hungary	Slovenia	Germany	Switzerland	
Ireland	Ukraine	Greece	Turkey	
Moldova	United Kingdom	Italy		
Montenegro				

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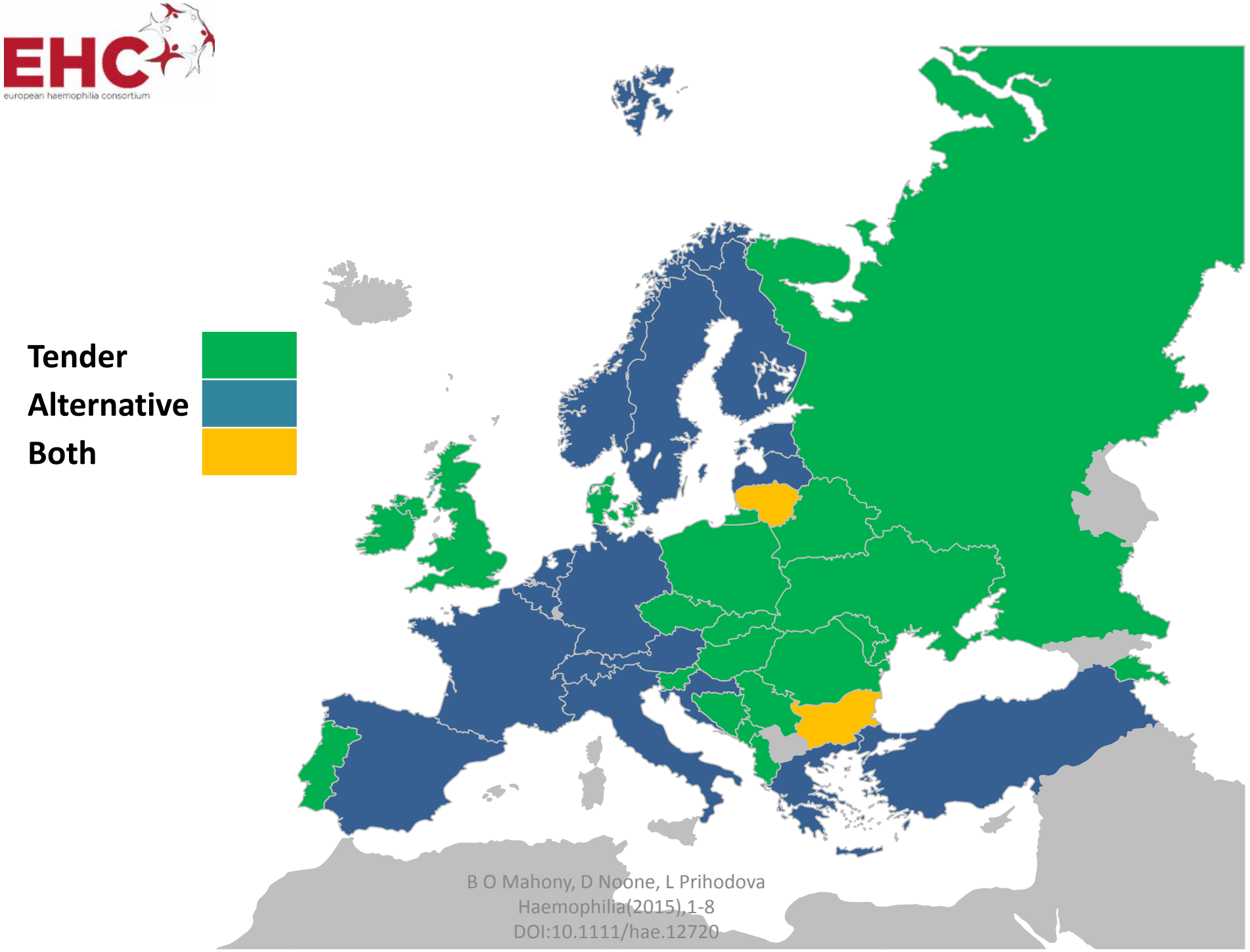

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Main Criteria

Tender Countries

- Most important- Safety
- Main criteria used is Price – 14 countries

Alternative procurement Countries

- Most important - Safety
- Main criteria used is Price – 6 countries

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Ireland: Recombinant FVIII Score sheet 2012

Safety	Human albumin in culture medium	15
	Additional human or animal protein (eg monoclonal antibiodies)	5
	Viral inactivation	10
	Inhibitors	30
	Prion Removal	5
	Others	10
	Total for Safety	75
Efficacy	Recovery/Half Life (adult/paedriatric)	12
	Clinical Response (adult/paedriatric)	18
	Total for Efficacy	30

Quality	Stability	5
	Volume of Administration	3
	Instructions for Use & Handling	3
	Ease of Administration	3
	Application of Unique Bar-Code	5
	Total for Quality	19

Scoring Criteria		Total Marks Available
Security of Supply/ Availability	Number of Manufacturing Plants	4
	Security of Supply	6
	Total for Supply/ Availability	10
Scientific Support	Clinical Opinion	2
	Consumer Opinion	2
	Tender	2
	Total for Scientific Support	6
Total Scores Awarded: Phase 1		140
Phase 2		
Cost	Total for Cost	60
Total Scores Awarded: Phase 2		200

Selection Criteria

Tender (19)

- Price 18
- Safety 14
- Quality 12
- Efficacy 12
- Supply 10
- Convenience 8

Alternative/ Combined(19)

- Price 12
- Safety 9
- Quality 8
- Efficacy 10
- Supply 6
- Convenience 3

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Products Tendered for

- 18/19 tender for plasma derived FVIII
- 16 tender for recombinant FVIII
- 17/19 tender for plasma derived FVIII
- 8 tender for recombinant FIX
- 13 tender for plasma derived FVIII/VWF
- 11 tender for PCC's
- 11 tender for bypassing agents
- 7 tender for products for rare bleeding disorders

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Main Representatives on Tender Boards

Health Insurance funds	Medicines agencies or pharmacies	Hospitals or blood centres	Ministries of Health	Clinicians or Haemophilia Centres	Patient Organisation
Involved in all aspects of the Process					
Bosnia& Herzegovina	Denmark	Albania	Albania	Ireland	Ireland
Hungary	United Kingdom	Czech Republic	Azerbaijan	Denmark	Serbia
Montenegro, Serbia Slovak Rep.	Azerbaijan Romania Belarus	Ireland Portugal Romania	Belarus Ireland Russia	Montenegro Serbia United Kingdom	
Involved only in Scientific and Technical aspects of the process					
				Romania Portugal Bosnia & Herzegovina Moldova	Portugal Slovenia United Kingdom

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Main Representatives Procurement Boards

Health Insurance funds	Medicines agencies or pharmacies	Procurement Agencies	Ministries of Health or Local authorities	Clinicians or Haemophilia Centres	Patient Organisation
Involved in all aspects of the Process					
Kyrgyzstan	France		Kyrgyzstan		Kyrgyzstan
	Belgium		Italy		
Croatia	Kyrgyzstan				
	Sweden				
Involved only in Scientific and Technical aspects of the process					
			Turkey	France	
				Kyrgyzstan	
				Estonia	

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Tender /Procurement Boards

Terms of Office and Contracts Awarded

		N	Years
Term of office of the committee	Tender	9	2.3
	Alternative	3	1.5
Typical duration of the contract awarded	Tender	18	1.4
	Alternative	7	1.9

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Involvement in Tender Process

19 Countries

- All have a legal framework for tender
- 16 have a tender board
- Clinicians involved in 16/19 countries

  - formally involved in 5

  -scientific and technical aspects in 6

  -informally involved or observers in 5

  - not involved in 2

  - no response from 1

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Involvement in Alternative /Combined Process

19 Countries

- 14 have a legal framework for tender
- 8 have a procurement board
- Clinicians involved in 12/19 countries

  -scientific and technical aspects in 3

  -informally involved in 9

  - not involved in 7

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Involvement in Tender/Alternative Process

- **Patient organisation involved in 15/19 countries**
  - formally involved in 2
  -scientific and technical aspects in 3
  -informally involved/observer in 5
  - not involved in 9

- **Alternative process- Patient organisation involved in 6 countries**
  - formally involved in 1
  - informally involved in 5
  - not involved in 13

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Tender v Alternative process

Tender system resulted in lower prices for:

- Recombinant FVIII (23%)
- Plasma derived FVIII (21%)
- Plasma derived FIX (30%)

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	Tender			Alternative Process		
	n	Median (€)	Range (€)	n	Median (€)	Range (€)
Recombinant FVIII*	12	0.56	0.28 -1.05	17	0.69	0.39 -1.06
Plasma-Derived FVIII	15	0.40	0.16 -1.16	16	0.64	0.18 - 0.90
Recombinant FIX	6	0.73		12	0.72	
Plasma-Derived FIX*	15	0.40	0.18 -0.83	17	0.54	0.38 -0.88

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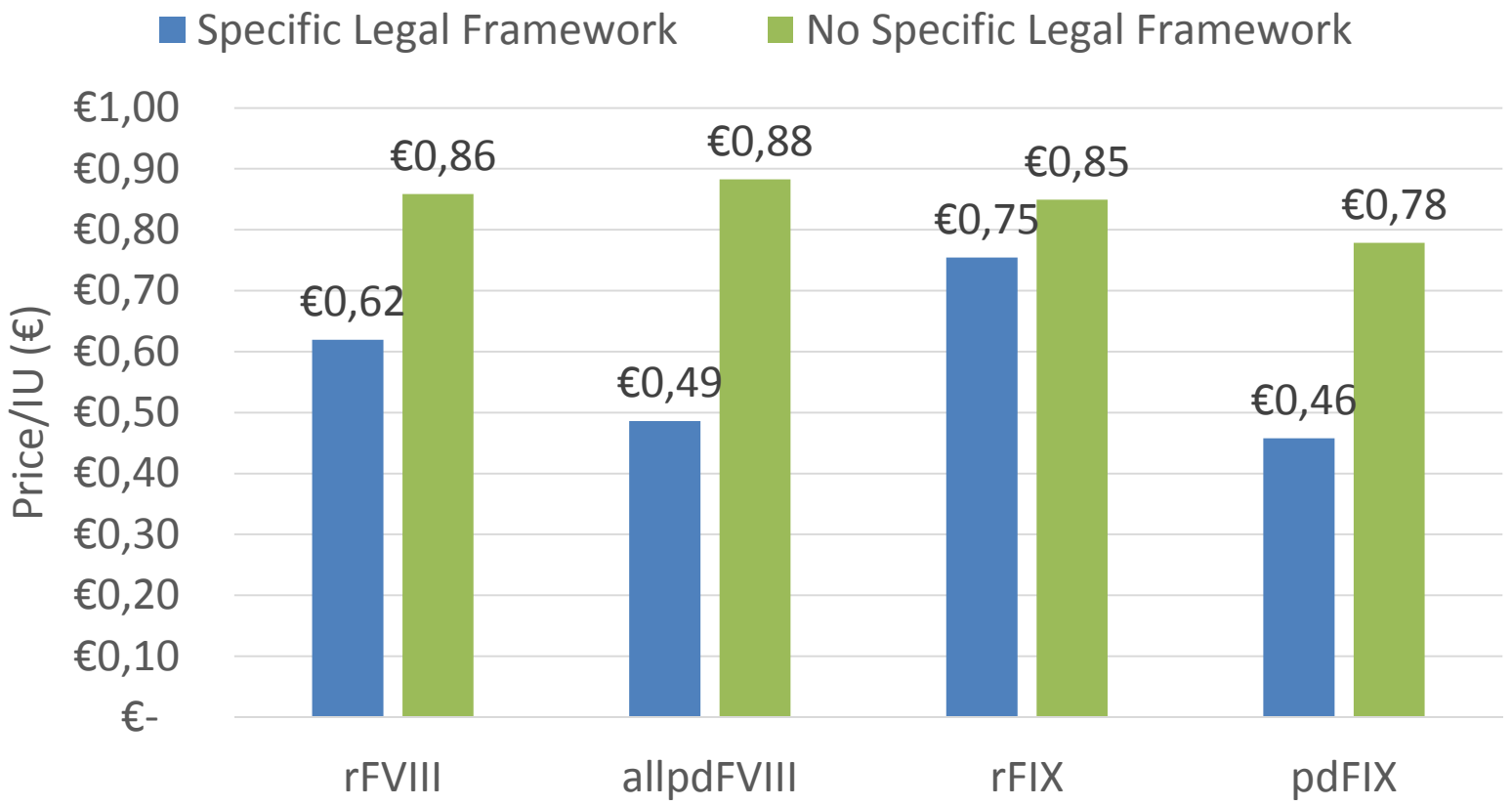
Use of Specific Legal Framework



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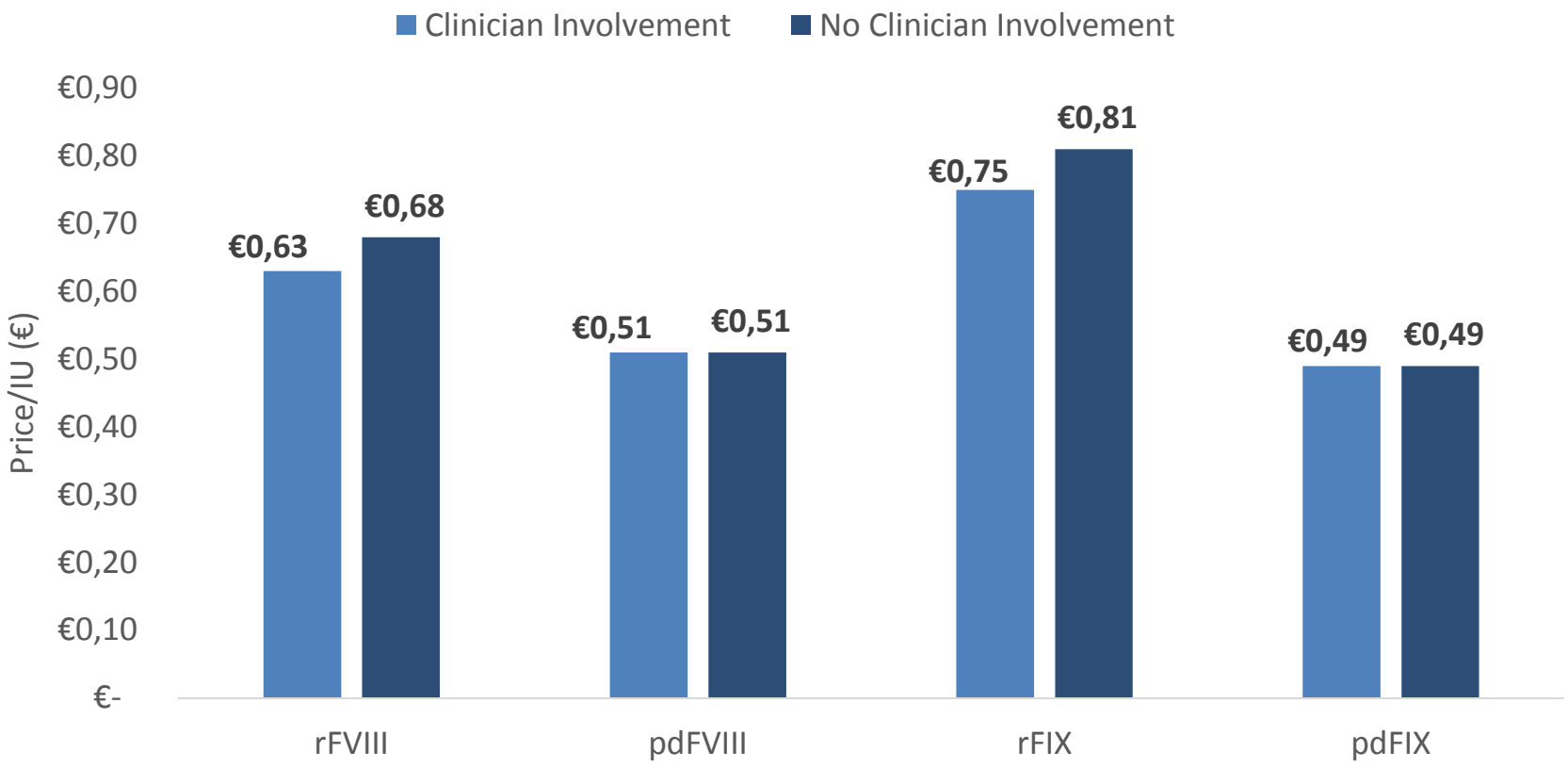
Clinician Involvement



- Significant reduction also noted in price of By-passing agents when clinicians are involved

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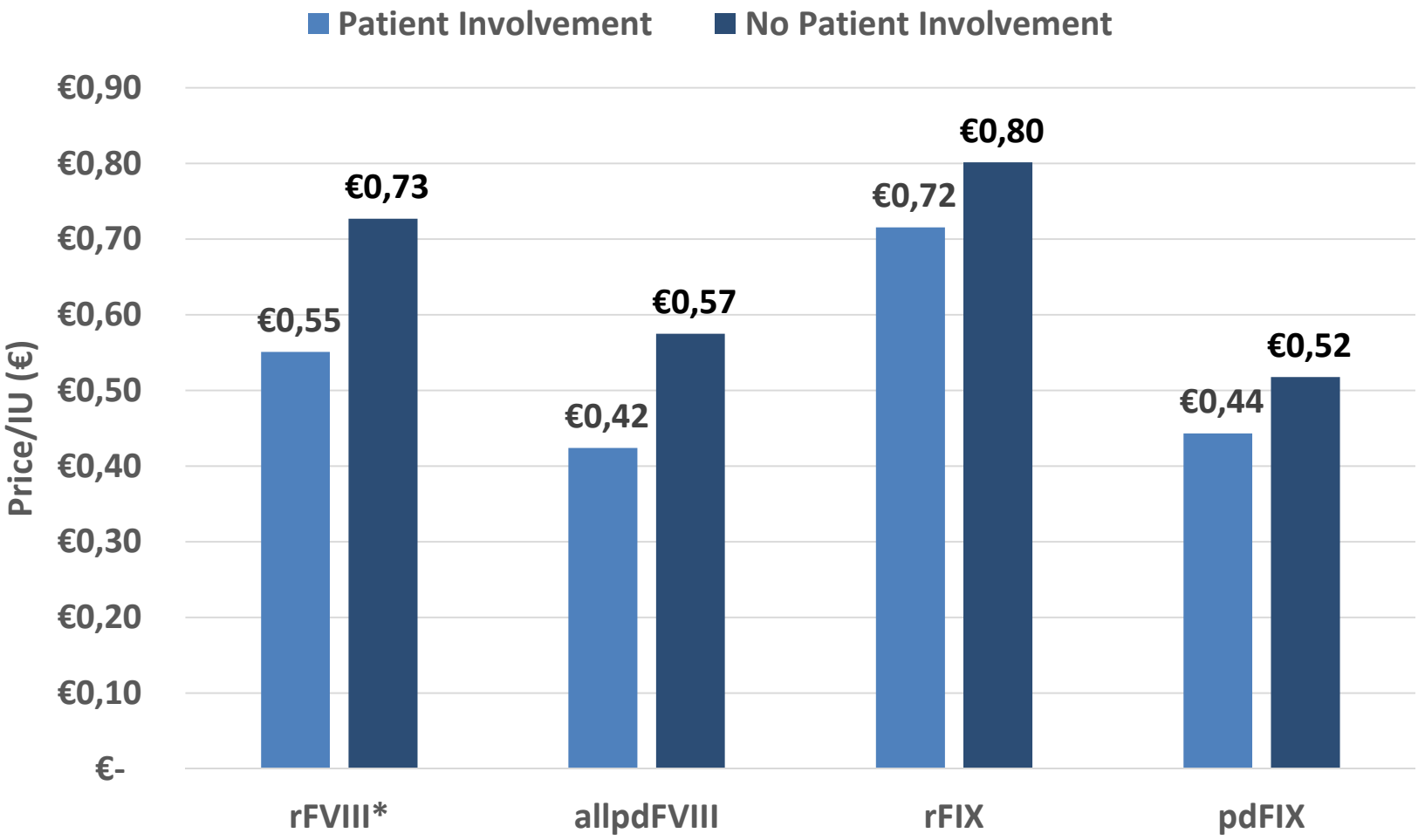
Patient Involvement



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Conclusions

- Tender process results in lower prices
- Clinician involvement improves outcomes
- Patient organisation involvement with clinician involvement delivers best outcomes
- Where both are involved, prices are lower for all products
- Impact of volume purchased to be analysed

Conclusions

- Co-ordinated national system delivers best outcomes
- Specific legal framework
- Use of registry to predict demand
- Promotes real competition
- No difference observed if contract awarded to 1 or more than 1 company
- Not as significant where there is a product monopoly

Clinician and patient organisation involvement

- Better more appropriate selection criteria
- Better assessment of tenders
- Lower prices
- More open and transparent process
- Knowledge and involvement are the key- not just focus on price

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Clinician and patient organisation involvement

United Kingdom*

- Clinician involvement and informal patient organisation involvement
- Price main scoring criteria
- Prices decreased by 50% over 6 years

Ireland

- Clinician involvement and formal patient organisation involvement
- Price not the main scoring criteria
- Total Prices decreased by 70% over 10 years

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Concerns

- Have to ensure that proportion of any savings made are used for development of comprehensive care
- Ireland:

- increased resources for comprehensive care infrastructure: new centres in Dublin and Cork

- lower unit costs and elimination of handling fees allowed FVIII use to increase from 3.7 IU to 8.2 IU p.c. over 12 years

Cork haemophilia centre 'inadequate'

IRISH TIMES 15/09/08

EITHNE DONNELLAN,
Health Correspondent

THERE ARE major deficiencies at the centre which provides care to people with haemophilia in Cork, according to external auditors.

The auditors, who visited the facility at Cork University Hospital in 2006 and are due to return again at the end of this month, found the infrastructure at the unit "very poor and grossly inadequate".

They found no dedicated space for the care
mophilia. "
to be move
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short notice due to lack of a place," their report said.

It added: "The facilities significantly hamper the delivery of effective and efficient care for patients with inherited bleeding disorders."

The UK auditors recommended that dedicated space be found for the haemophilia centre and that a consultant be employed to take overall responsibility for the unit.

The auditors also inspected the paediatric haemophilia centre at

for a clinician to lead the haemophilia service and at St James's the need for protected beds for in-patients with haemophilia.

The audits were ordered by the National Haemophilia Council, which was established following the recommendations of the Lindsay Tribunal, which inquired into the infection of haemophiliacs with HIV and hepatitis C by contaminated blood products.

Its chairman Prof John Bonnar said yesterday the recommendations of the auditors had been

has now passed the design stage. But the infrastructural problems in Cork have still to be addressed.

Brian O'Mahony, chief executive of the Irish Haemophilia Society, said, however, that the HSE was now examining a proposal for a modular centre in Cork.

He pointed out that the activity on these recommendations had only taken place in recent months, as a fresh audit was about to begin to check what had been acted on.

Meanwhile, a European haemo-

embryos to be implanted in their
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Minister opens treatment centre for blood disorders

by Eoin English

MINISTER for Health Dr James Reilly officially opened a new dedicated treatment centre at Cork University Hospital (CUH) yesterday which will deliver vast improvements in the quality of care for people with bleeding disorders.

Before the €430,000 haemophilia centre was developed, patients with the genetic blood disorder which impairs the body's ability to control blood clotting were treated in CUH's emergency department or were admitted to an in-patient bed. But since the new centre opened in March, these patients can be seen daily, if necessary, in the new facility.

Located on the ground floor of the hospital, it has four treatment rooms, an education and meeting room, office space, its own external entrance, and waiting area.

All the specialised staff including medical, nursing and administration are located on the one site.

"There are approximately 375 patients with bleeding disorders in the HSE South area and, since the centre opened, services have greatly improved," CUH Group CEO Tony McNamara said.

"Staff can administer blood clotting factor replacement therapy to patients before they go for dental or other day-case surgical procedures, which avoids the need for in-patient admission."

The centre provides a service to adults and children with bleeding disorders, including investigation, diagnosis and management at its outpatient review, treatment and genetic counselling clinics.

Professor John Bonnar, chairperson of the National Haemophilia Council, said he was delighted that people with bleeding disorders in the Cork region now have the appropriate facilities.

"This was a much needed requirement for the haemophilia community and will allow the standards of care which the National Haemophilia Council advises for the Cork region to be provided," he said.

Minister for Health Dr James Reilly meets clinical nurse specialists as he visited Cork University Hospital to officially open their new Haemophilia Centre. Picture: GMC Photography

Concerns

- Have to ensure that price is not the only criteria used – safety, efficacy, quality, supply
- Need clinician and patient participation to ensure these included
- This requires advocacy- data demonstrating economic benefit of clinician and patient participation

Portuguese Association of Hemophilia denounces economic criteria in the treatment of disease

"This way, health of people with hemophilia has become dependent on cheaper products and not necessarily the most effective and safe products. On the other hand, medical experts in hemophilia who should be the a very important voice in the scientific and medical choice of these products have been relegated to a completely secondary role in the choice of therapies that will be administered to their patients."

Press release, APH, World Haemophilia Day 2015

New EU Directive

2014/24/EU

- Increased discussion under competitive dialogue procedure with negotiation
- Life cycle costs
- Full electronic submission
- Shorter time intervals
- Potential for cross border tenders:
  - COMISKA ,Gulf States*
  - Baltic countries ?
  - Bulgaria, Romania ?

B O Mahony. Guide to Factor Concentrate Tender and Procurement,WFH 2015. In press

Procuring Longer Acting Factors

- Scoring criteria for comparing different classes of products
- US Launch prices increased unit cost almost in line with increase in half life
- Differences in half life
- Treating to specific trough levels
- Importance of peaks and troughs
- Individual pharmacokinetics

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Procuring Longer Acting Factors

- Treatment protocols for Prophylaxis v On demand
- Treatment protocols for surgery – bolus or continuous infusion
- Total factor requirement for country
- Average annual cost per severe patient per year
- Outcome based – treat to defined annual bleed rate

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Conclusions

- National system with formal involvement by clinicians and patient organisation delivers the best results
- Safest and most efficacious products at best economic cost
- Allows for increased per capita use
- Good economic outcome- decision more likely to stay with group rather than with HTA agency.
- Requires training and preparation

TRAINING COURSE

REPLACEMENT THERAPY CONCEPTS

Dates: 22nd to 25th May 2009

Venues: Dunboyne Castle Hotel,
Dunboyne,
Co. Meath.
Ireland.

and

Irish Haemophilia Society,
Cathedral Court,
New Street,
Dublin 8.
Ireland.

Concepts In Factor Replacement Therapy

Irish Haemophilia Society
2011

A Training Course in Factor Replacement Therapy Concepts for Haemophilia Organisation Leaders

Author: Brian O'Mahony – Irish Haemophilia Society

National Haemophilia Patient Organisations are encouraged to seek representation on their tender commissions or procurement committees. In several countries including Ireland, Canada and Brazil, patient representatives play an integral part of the procurement process. The concepts can be intimidating for those with limited experience or scientific knowledge. There is no training pathway for key opinion leaders in National Haemophilia Patient Organisations to develop their knowledge in this area. The majority of patient leaders do not have a scientific background and may lack understanding of the basic concepts. The training course was organised as a means of educating participants in the concepts relating to Factor Replacement Therapy. The course was organised around two (basic and advanced) three day modules, ideally held one year apart.

Basic course

Focused on Introduction to the Basic Concepts in Replacement Therapy, Safety, Economics, National Tender Procurement Systems and Mock tenders. The lectures on the basic aspects are interactive and care is taken to ensure that the participants are encouraged to ask questions and receive clear answers in terminology that they can comprehend. The terminology is demystified and the concepts are explained clearly.

Mock Tenders

The third day of the course is primarily based around carrying out a number of mock tender evaluations.
Separate mock tenders are carried out for both plasma derived and recombinant factor concentrates.
The examples of products used and the specifications and characteristics are based loosely on real products but alterations have been made to make the choice more difficult and also to ensure that the knowledge imparted on the course from the previous two days is used during the selection process.
The mock tender process and the discussions during the mock tender process embed the information that people have listened to for the previous two days and demonstrate to the participants the practical benefits of the course.

Evaluation

Participants were given a multiple choice pre-evaluation questionnaire of 25 questions. This was completed at the beginning and at the end of the course. In the pre training course questionnaire the average number of correct answers was 12.5 of 25 (50%) The range of correct answers ranged from 9-19. At the conclusion of the course, correct answers from the same participants averaged 17.7 (71%) with a range from 13-21. The most notable change was from one participant who prior to the course answered ten out of 25 (40%) questions correctly and by the end of the course was able to answer 21 out of 25 (84%) questions correctly. This individual now participates in his countries tender process for factor concentrates.

Advanced course

Focused on Manufacturing and Regulation, Economics and Health Technology Assessments, Update on Safety, Current and Future Developments.

Mock Tenders

In addition to carrying out two further mock tenders participants were also asked to devise the selection criteria for these tenders prior to carrying out the mock tenders.

Evaluation

In an evaluation survey carried out 9 months following the completion of the advanced course: 6 of the 7 respondents categorised the course as extremely useful to them and one as very useful. The course directly assisted 3 participants from 2 of the countries to become formally involved in their National Tender Process. Other participants were assisted by the course in their involvement with their Ministries for Health and Regulatory Authorities in relation to issues including: vCJD, Health Technology Assessments and European Directives and Guidelines. Participants also greatly valued the networking opportunity and exchange of information with each other. Ongoing contact between participants has been encouraged and facilitated by the provision of information from the course organisers on a regular basis. In evaluating the course, participants stated they now had a more in depth knowledge of the relevant issues, increased confidence presenting the views of their organisations and they believe themselves now to be more effective advocates for their communities on these issues.

Attendees

The initial basic and advanced courses were carried out in 2008 and 2009 for participants from 6 European Countries; France, Sweden, UK, Ireland, Germany and Italy. The basic course has also been attended by program staff from the World Federation of Hemophilia and by members of the Haemophilia Patient Organisation in New Zealand.

Acknowledgements

- Declan Noone

- Lucia Prihodova

- Clinicians and NMO's who responded to the survey