Tenders and Procurement: Challenges and Opportunities

Brian O Mahony
Tenders

- 19 European Countries
- Brazil
- Canada
- Australia
- South Africa
- Mauritius
- Iraq
- Central America
- Saudi Arabia and Gulf States

Other Procurement

- 19 European Countries
- USA
- China
- Thailand

Haemophilia

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

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Europe: Clinician Involvement in Tender/Alternative Process

- **Tender:** clinicians involved in 14/19 countries
  - formally involved in 5
  - scientific and technical aspects in 4
  - informally involved/observer in 5
  - not involved in 5

- **Alternative process:** Clinicians involved in 12 countries
  - formally involved in 0
  - scientific and technical aspects in 3
  - informally involved or observers in 9
  - not involved in 7

O Mahony B, Noone D et al
Haemophilia, 2015; 21(4); 436-443
Europe: Patient 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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Clinician and Patient Involvement outside Europe

- **USA** - Clinicians/ HTC’s involved in 340B Drug Pricing Program
- **Canada** - informal involvement in Canadian tender. More formal involvement in Quebec tender
- **South Africa** - no involvement
- **China** - no involvement
- **Mauritius** - clinicians involved
Clinician and Patient Involvement outside Europe

- **Thailand** - clinicians involved
- **Honduras** – clinicians involved
- **Iraq** - clinicians and patients involved
- **Central America tender** - no involvement
- **Saudi Arabia and Gulf states** - no involvement
Challenges

• Increased involvement by HTA bodies and economic evaluation of new products
• Challenge for new EHL factor concentrates
• Payers generally do not understand haemophilia and potential benefits of EHL CFC
• Companies applied for orphan drug status on basis of convenience
• Payers will not pay more for convenience
HTA / Economic Evaluation

• If cost of treatment greater than current cost HTA will look at ICER per QALY
• Utility value for adult on prophylaxis close to 0.90* – limited room for improvement
• EHL products will not pass a HTA process in many countries if cost significantly higher
• Need clear clinical data to demonstrate significant benefit

*D. Noone, B. O Mahony and L. Prihodova
HAEMOPHILIA, Volume 19, Issue 1, January 2013, Pages: 44–50
Payers Eye’s – Trial Data
Which Product is the EHL?

On-Demand  Prohylaxis

EHL

Bleeds treated with 1-2 infusion

43.2
33
33.7
58.8

Declan Noone 2015
IQWIG - Germany

• New product has to demonstrate significant additional benefit to achieve higher reimbursement
• To date, 2 recombinant FVIII products (not EHL) found NOT to have significant additional benefit
• Interesting to see outcome of their evaluation of EHL products
• Convenience not seen as a significant benefit
• Recent report also questioned evidence for prophylaxis
Challenges

• As EHL products come to market- price of current recombinant products decreasing
  - opportunity for some countries to increase per capita use of CFC
  - challenge to ability to purchase EHL CFC’s

• Decisions made by payers, insurance companies, tender boards without clinician or patient involvement and based on HTA assessments
Challenges

• Current low cost in some countries may make it difficult to use EHL products if cost significantly higher
• Cost expectations from payers always based on last tender/ current cost
• Budget savings through tender not kept within haemophilia- underinvestment in elements of comprehensive care staff and infrastructure
Challenges

• Tender system to encompass both current and EHL CFC’s
  - tender for both ?
  - separate tenders ?
  - selection criteria ?
  - decision on which patients to treat with which product ?
Opportunities

• **Solution** – ensure that clinicians and patient organisation formally involved
• Clinicians and patient representatives understand the value of products as well as the cost
• Optimum assessment of all products examining efficacy, safety, quality, supply and scientific support in addition to cost
• Clinician and patient involvement also cost effective
• Tender system preferable to HTA led decision
Specific Legal Structure for Purchasing factor

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Haemophilia, 2015; 21(4): 436-443
Clinical Involvement

Significant reduction also noted in price of bypassing agents when clinicians are involved

O Mahony B et al
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Patient Involvement

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Price per IU (€)</th>
<th>Patient Involvement</th>
<th>No Patient Involvement</th>
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<tbody>
<tr>
<td>rFVIII*</td>
<td>€0.55</td>
<td>€0.73</td>
<td>€0.55</td>
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<tr>
<td>allpdFVIII</td>
<td>€0.42</td>
<td>€0.57</td>
<td>€0.42</td>
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<tr>
<td>rFIX</td>
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<tr>
<td>pdFIX</td>
<td>€0.44</td>
<td>€0.52</td>
<td>€0.44</td>
</tr>
</tbody>
</table>

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Opportunity

• Very significant difference in cost of CFCs from country to country
• Availability of EHL products should mean lower cost of current CFC’s
• Opportunity for developing and emerging countries to increase use of CFC
• *Treatment for all* will not become a reality unless affordable
<table>
<thead>
<tr>
<th></th>
<th>Tender</th>
<th></th>
<th>Alternative Process</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Median (€)</td>
<td>Range (€)</td>
<td>n</td>
</tr>
<tr>
<td><strong>Recombinant FVIII</strong>*</td>
<td>12</td>
<td>0.56</td>
<td>0.28 -1.05</td>
<td>17</td>
</tr>
<tr>
<td><strong>Plasma-Derived FVIII</strong></td>
<td>15</td>
<td>0.40</td>
<td>0.16 -1.16</td>
<td>16</td>
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<tr>
<td><strong>Recombinant FIX</strong></td>
<td>6</td>
<td>0.73</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td><strong>Plasma-Derived FIX</strong>*</td>
<td>15</td>
<td>0.40</td>
<td>0.18 -0.83</td>
<td>17</td>
</tr>
</tbody>
</table>

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Opportunity

• Product donation programmes through WFH Humanitarian aid
• Look again at agreed twin track pricing system
• Countries could collaborate on tenders to purchase larger amount collectively and pool expertise for tender board
  - Central America (COMISCA)
  - Saudi Arabia and Gulf States
  - Baltic countries?
Collaborative Tenders

Central America
• COMISCA:
• Belize
• El Salvador
• Honduras
• Panama
• Costa Rica
• Nicaragua
• Guatemala
• Dominican Republic

Saudi Arabia and Gulf States
• Saudi Arabia
• Qatar
• Bahrain
• Oman
• UAE
• Kuwait
Baltic Countries

Lithuania, Latvia, Estonia

• Separate tenders
• Estonia-population 1.4 million and 3 separate CFC tenders
• Estonia and Latvia- flawed tender process with no patient or clinician involvement
• Collaborative tender would be beneficial if clinicians and patient organisations involved
• Lower cost, better selection process and higher per capita use
Opportunity

• Encourage national CFC Budget and link to haemophilia budget
• Proportion of any savings re-invested in haemophilia treatment or care
• **UK**- Price main selection criteria. Price decreased by 50% over 6 year period*. Factor use increased significantly but additional savings not re-invested in haemophilia care

Opportunity

- **Ireland**- Price not the main scoring criteria.
- Cost decreased by 70% over 10 years
- FVIII use increased from 3.7 to 8.2 IU/capita
- Proportion of savings re-invested:
  - new comprehensive care centre
  - new in patient unit
  - home delivery and electronic patient record systems
  - additional staff
Ireland: total units of factor use and cost 2002 - 2012
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 €300,000 haemophilia centre was developed, patients with the genetic disorder which impairs the body's ability to form blood clots 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 areas. All the specialist staff, including medical, nursing and administrative 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," he said.

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 Horowitz, chairman 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 standard of care which the National Haemophilia Council advises for the Cork region to be provided," he said.
Opportunity- New EU Procurement Directive

2014/24/EU

• Increased discussion under competitive dialogue procedure with negotiation
• Life cycle costs – could tender for CFC and HTC support staff and home delivery
• Full electronic submission
• Shorter time intervals
• Potential for cross border tenders
• Encourage move away from price as sole selection criteria
• Example could be utilised outside Europe
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

Brian O Mahony 2015
Procuring Longer Acting Factors

• Cost per IU – with weighing factor?
• Cost of treatment per severe PWH per year?
• Tender for treatment of all severe PWH for prophylaxis for year to trough level of X%?
• Capped cost per PWH per year
• Cost to treat all PWH to a defined ABR
• Capped cost to provide all CFC country would require for year up to a defined limit

Brian O Mahony 2015
First tender to include current and EHL

• Initial Scoring- 50% Quality, 50% other
• Product had to score > 70% in quality to be considered and > 70% overall
• Following this, price was considered with Quality/ Other scoring 70% and price 30%
• Correction factor applied to EHL based on estimate of lower number of units required
Quebec Tender 2015

Quality Criteria
- Half life
- Shelf life and storage temp.
- Inhibitor rates
- Approved indications
- Quality of clinical data
- Adverse reactions
- Potential for product to be withdrawn from market
- Barcoding
- Range of vial formats
- Quality of administration device
- Product history of recall, withdrawal or quarantine

Other Criteria
Included:
- 5% for company profile and anticipated manufacturing enhancements
- 15% for company QA systems
- 10% for company infrastructure
- 20% for supply and logistics capability
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.”

Conclusions

• Good tender or procurement systems have to include appropriate clinicians and patients
• Tender system preferable to decision made solely by payers, insurance or HTA body
• Availability of EHL products present significant opportunity to improve care and access to CFC
• Budget savings should be re-invested
• Clinicians and patient leaders require training in tenders and procurement
Concepts In Factor Replacement Therapy

Coagulation factor concentrates (CFCs) tender and procurement procedures in 38 European countries

Brian O’Mahony
Declan Noone
Lucia Prihodova