How does haemovigilance link with quality management and cost savings?

21 / 2 / 2013
International Haemovigilance Seminar, Brussels

Philippe Vandekerckhove
Haemovigilance: recurring elements in the definitions

- Organized surveillance
- Collecting and evaluating information
- On serious adverse or unexpected events or reactions in donors or recipients
- Epidemiological follow-up of donors
Content

- Evolution in the sector

- Health economics
  - introduction
  - blood products & QALY
  - blood products & costs considered

- Conclusions & Recommendations
Safety measures ever increase – product

• Lab tests
  • Syphilis (1961)
  • HBsAg (1971)
  • anti-HIV1 As (1985); anti-HIV1,2 As (1992)
  • anti-HCV As (1990)
  • ALT (1994; eliminated 2007)
  • Bacterial testing (1999)
  • NAT HIV1 en HCV (2002)
  • NAT HBV / HIV2 / HIV O (2010)
  • HLA As screening of donors (2010)

• Other measures
  • Viro inactivation plasma (1992)
  • no pooling (2004)
  • Only male donors without transfusion antecedents (2004)
    • Irradiation of blood products (since 20 jaar, in 2009 reimbursed)
    • Universal leukoreduction (2005)
    • Platelets
      • in PAS instead of plasma (2008)
      • Pathogen Reduction Technology (2009)
Safety measures ever increase – process

- Donor selection
  - Exclusion criteria
- Quality norms
  - Inspections
- Haemovigilance
  - Formal reporting procedure (by competent authority, 2005)
  - ...
Number of inspections ever increases
Blood products become ever safer
But... blood becomes ever more expensive

1986 - 2011

LR = Leukoreduced
**Blood “incidents” in Belgium**

<table>
<thead>
<tr>
<th></th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process-related</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious adverse events</td>
<td>156</td>
<td>145</td>
</tr>
<tr>
<td>Serious adverse reactions</td>
<td>153</td>
<td>142</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>309</td>
<td>287</td>
</tr>
<tr>
<td><strong>Product-related</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>in %</td>
<td>4,5</td>
<td>3,1</td>
</tr>
</tbody>
</table>

*source: annual report FAGG*
Our instinct & tradition is to make blood ever safer

- The precautionary principle: in the interest of public health, risk management action should be taken in the absence of certainty about risk

New challenge is to balance this with sustainability

- The principle of risk based decision making: risk management actions should be proportionate with the level of demonstrated risk
Evolution in the sector

Health economics
  - introduction
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Conclusions & Recommendations
A “unit” of health effect

- Number of symptom-free days
- Number of days with good life quality
- Number of patients cured
- Number of complications avoided
- Number of years without complication
- Number of years with responder status
- Number of life years gained (LYG)

- Disability adjusted life years (DALY) (adjusted for handicap)
- Quality adjusted life years (QALY) (adjusted for quality)
# Different Types of Economic Analysis

<table>
<thead>
<tr>
<th>Type of analysis</th>
<th>Objective determines</th>
<th>Technique</th>
<th>Outcome Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost minimization</td>
<td>which of 2 options with equal benefits has lowest costs</td>
<td>Compares costs between different options thought to be equally effective</td>
<td></td>
</tr>
<tr>
<td>Cost effectiveness</td>
<td>how a given goal is achieved most efficiently</td>
<td>Relates costs to some measures of outcome</td>
<td>Natural units (e.g. LYG, life-years gained (saved) or treatment - specific terms e.g. reduction in LDL level)</td>
</tr>
<tr>
<td>Cost utility</td>
<td>the best way of spending given health care budget</td>
<td>Relates cost to healthy years gained</td>
<td>Healthy years (e.g. quality-adjusted life years (QALY), healthy years equivalent)</td>
</tr>
<tr>
<td>Cost benefit</td>
<td>how much more or less of societies’ resources should be allocated to achieve a defined goal</td>
<td>Compares input and output in monetary units</td>
<td>Benefits converted into monetary terms</td>
</tr>
</tbody>
</table>

Schematic representation of QALY: the concept

A. Index

0.6 \times 10 = 6

B. Index

0.6 \times 10 = 6

0.6 \times 12 = 7.2

C. Index

0.7 \times 10 = 7

D. Index

0.6 \times 10 = 6

0.7 \times 12 = 8.4
Schematic representation of QALY: real-life

New therapy

Old therapy
How to measure QALY? the EQ5D questionnaire

**Mobility**
No problems walking (score 1)
Some problems walking (score 2)
Bedridden (score 3)

**Selfcare**
No problems washing - getting dressed
Some problems washing - getting dressed
Not capable to wash or dress myself

**Daily activities** (f.i. work, study, spare time, ...)
No problems doing my daily activities
Some problems doing my daily activities
Not capable to do my daily activities

**Pain**
No pain or other complaints
Moderate pain or other complaints
Severe pain or other complaints

**Mood**
No anxiety or depression
Moderate anxiety or depression
Severe anxiety or depression

$3^5 = 243$ possibilities
Utilities corresponding to EQ5D profielen

$3^5 = 243$ possibilities

<table>
<thead>
<tr>
<th>Status</th>
<th>Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>11111</td>
<td>1.000</td>
</tr>
<tr>
<td>11112</td>
<td>0.7444</td>
</tr>
<tr>
<td>11113</td>
<td>0.3847</td>
</tr>
<tr>
<td>11121</td>
<td>0.7641</td>
</tr>
<tr>
<td>11122</td>
<td>0.6607</td>
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<tr>
<td>11123</td>
<td>0.3010</td>
</tr>
<tr>
<td>..</td>
<td>..</td>
</tr>
<tr>
<td>33321</td>
<td>0.1320</td>
</tr>
<tr>
<td>33322</td>
<td>0.0286</td>
</tr>
<tr>
<td>33323</td>
<td>-0.0748</td>
</tr>
<tr>
<td>33331</td>
<td>0.0484</td>
</tr>
<tr>
<td>33332</td>
<td>-0.0550</td>
</tr>
<tr>
<td>33333</td>
<td>-0.1584</td>
</tr>
<tr>
<td><strong>Death</strong></td>
<td>0.0000</td>
</tr>
<tr>
<td><strong>In coma</strong></td>
<td>-0.0163</td>
</tr>
</tbody>
</table>
## Limit of willingness to pay per QALY

<table>
<thead>
<tr>
<th>Country</th>
<th>Currency</th>
<th>Limit (local currency)</th>
<th>Limit (Euro)</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>USD</td>
<td>50.000-100.000</td>
<td>36.600-73.200</td>
</tr>
<tr>
<td>Sweden</td>
<td>SEK</td>
<td>50.000</td>
<td>54.000</td>
</tr>
<tr>
<td>UK</td>
<td>GBP</td>
<td>30.000</td>
<td>44.500</td>
</tr>
<tr>
<td>Australia</td>
<td>AUSD</td>
<td>42.000-76.000</td>
<td>26.200-47.400</td>
</tr>
<tr>
<td>Canada</td>
<td>CND</td>
<td>20.000-100.000</td>
<td>13.700-68.700</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>EURO</td>
<td>20.000</td>
<td>20.000</td>
</tr>
<tr>
<td>New Zealand</td>
<td>NZD</td>
<td>20.000</td>
<td>11.200</td>
</tr>
</tbody>
</table>

* Conversion based on exchange rates August 1, 2007
Double barrier of societal willingness to pay per QALY
Cost per QALY (1,000 $)

- General measures
- Medical procedures
Content

- Evolution in the sector
- Health economics
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  - blood products & QALY
  - blood products & costs considered
- Conclusions & Recommendations
Cost per QALY (1,000 $)

- General measures
- Medical procedures
Cost per QALY (1,000 $)

### General measures
- Airbag
- HBV vaccinatie
- Pap smear (4 jaar)
- Bypass operatie
- Hemodialyse
- Mammografie (jaarlijks)
- Bar code
- RFID wristband
- HCV NAT
- HIV / HCV NAT
- HBV NAT
- PRT Bloedplaatjes

### Medical procedures
- Verplichte motorkhelm

### Product-related
Incremental increase in cost-effectiveness

- F.i. HIV-tests
  - 1st generation (Ab): $ 3,600/QALY
  - 2nd generation (NAT): > $2 million/QALY
- Cost – result curve
Cost per QALY (1,000 $)

- General measures
- Medical procedures
- Process related
- Product-related
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### Perspectives of Economic Analyses and Costs Considered

<table>
<thead>
<tr>
<th>Perspective</th>
<th>Costs of primary interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Societal</td>
<td>• All medical and nonmedical costs:</td>
</tr>
<tr>
<td></td>
<td>o Hospitalization</td>
</tr>
<tr>
<td></td>
<td>o Long-term care</td>
</tr>
<tr>
<td></td>
<td>o Home care</td>
</tr>
<tr>
<td></td>
<td>o Social welfare services</td>
</tr>
<tr>
<td></td>
<td>• Productivity losses (indirect costs)</td>
</tr>
<tr>
<td></td>
<td>• Intangible costs</td>
</tr>
<tr>
<td>Third party payer</td>
<td>• Charges that pertain to reimbursement of providers</td>
</tr>
<tr>
<td></td>
<td>• Average, not marginal cost</td>
</tr>
<tr>
<td>Health care provider</td>
<td>• Variable costs that influence the expenses of providing health care</td>
</tr>
<tr>
<td>Patient</td>
<td>• Costs that affect out-of-pocket payments</td>
</tr>
<tr>
<td></td>
<td>• Lost wages (indirect costs)</td>
</tr>
<tr>
<td>Employer</td>
<td>• All insurable direct costs</td>
</tr>
<tr>
<td></td>
<td>• Lost wages (indirect costs)</td>
</tr>
</tbody>
</table>

### Cost of a transfusion: cost types

<table>
<thead>
<tr>
<th>Cost Type</th>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Direct costs</strong></td>
<td>cost of the blood product itself</td>
<td></td>
</tr>
<tr>
<td><strong>Indirect costs</strong></td>
<td>storage, testing, release, costs of administration (working time, disinfection, disposables, ...)</td>
<td>€ 407 - € 923 (average € 593)</td>
</tr>
<tr>
<td><strong>Costs due to the extra care needed by a transfusion patient</strong></td>
<td>increased length of hospital stay</td>
<td>3 -5 days (on average 2 days)</td>
</tr>
<tr>
<td><strong>Costs due to transfusion reactions and inherent risks of a red cell transfusion</strong></td>
<td>Increased for infection, to die</td>
<td></td>
</tr>
</tbody>
</table>

Shander et al. 2010
Cost of red cell transfusion: the case of Belgium

<table>
<thead>
<tr>
<th></th>
<th>Current</th>
<th>Reduction to 45</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion rate (/1000 inwoners)</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>Direct costs (million €/year)</td>
<td>67</td>
<td>6.7</td>
</tr>
<tr>
<td>Indirect costs (million €/year)</td>
<td>310</td>
<td>31</td>
</tr>
<tr>
<td>Costs for extra care (million €/year)</td>
<td>228</td>
<td>22.8</td>
</tr>
<tr>
<td>Costs of transfusion reactions (million €/year)</td>
<td>???</td>
<td></td>
</tr>
<tr>
<td>Total cost (million €/year)</td>
<td>605</td>
<td>60.5</td>
</tr>
</tbody>
</table>
Cost of inspections?

[Graph showing the cost of inspections over time for different organizations, with the x-axis representing years from 2004 to 2012 and the y-axis representing cost from 0 to 45.]
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Willingness to pay per QALY for our sector is extremely high: contributing factors

- Emotional issue with the broader public
  - Blood has a symbolic value
- Personal career risk for politicians
  - Incidents are often acute and mono-factorial as opposed to most other health intervention incidents
- Lack of good data & clear conclusions
  - Cost models are not widely used and health economics analyses are not applied as they are in the rest of health care.
  - As a result, blood safety interventions and outcomes cannot be compared between jurisdictions nor with other health care measures.
Factors that contribute to slow adaptation of a Health Economics approach

- Outside the sector: willingness to pay is very high

- Inside the sector:
  - Instinct & tradition is to make blood ever safer
  - Every additional (expensive) measure to approach zero-risk allows blood operators to grow revenue without growing output (which is comfortable to manage)
Link between haemovigilance and health economics should be bi-directional

1. In the past, HV has contributed greatly to HE by collecting data to evaluate effectiveness
2. For the future, HE should contribute to HV
   1. HV should expand to include also cost-effectiveness
      1. With a particular focus on process improvements; as these are least studied
   2. HV is in itself (probably) a more cost-effective approach to achieve defined safety levels than many technical improvements
      1. But we need more studies to prove this
      2. Complex to calculate