CHAIRE FRANCQUI AU TITRE BELGE 2016-2017

UNIVERSITÉ LIBRE DE BRUXELLES,
ÉCOLE DE SANTÉ PUBLIQUE

L’ÉCONOMIE DE LA SANTÉ

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Principes et méthodes des évaluations économiques en matière de santé

Lieven Annemans

ULB, 30 Mars 2017
Outline

I. Basic principles and concepts of health economic evaluations
II. Medical decision trees and Markov models
III. Health economic evaluation in decision making: some problems and trends
I. Basic principles and concepts of health economic evaluations
Consequences of the crisis

Recent health spending growth follows economic growth more closely
Growth rates in GDP and health spending per capita in real terms, OECD average, 2001-2015

Note: Provisional estimates for 2015.
“Member states who **invest in health policy** today, contribute to the economic growth of tomorrow.

**Effective healthcare** is one of the **best possible investments** we can do.”

Dr. Vytenis Andriukaitis, EU commissioner of health

Reeves et al. 2013
Principles of ‘good’ healthcare
→ the goal of health care systems

• Primary goal of health care policy = to *optimise the health of the population within the limits of the available resources*, and within an *ethical framework* built on equity and solidarity principles.

Report of the Belgian EU Presidency, adopted by the EU Council of Ministers of Health in Dec 2010
What does it mean for innovative technologies?

- Innovative technologies can contribute to **improved health** but exert a continuous **pressure on health care budgets**

> “We need to stimulate and make available innovative technologies that offer a therapeutic benefit at an acceptable cost (i.e. are cost-effective), and fill unmet medical needs”

- Report of the Belgian EU Presidency, endorsed by the EU Council of Ministers of Health in Dec 2010
Cost-effectiveness

Cost

Health effect (QALYs)

Current care

“intervention”

Not C-EFF

Threshold

C-EFF

dominant
QALY = Quality Adjusted Life Years

INDEX ("utility level") → (based on EQ5D/SF36)
example: acute coronary syndrome

<table>
<thead>
<tr>
<th>Disease state</th>
<th>Utility level</th>
</tr>
</thead>
<tbody>
<tr>
<td>No further event (age 60-69)</td>
<td>0.877</td>
</tr>
<tr>
<td>No further event (age 70-79)</td>
<td>0.838</td>
</tr>
<tr>
<td>No further event (age 80-89)</td>
<td>0.773</td>
</tr>
<tr>
<td>After a stroke</td>
<td>0.143 decrease</td>
</tr>
<tr>
<td>After a myocardial infarction</td>
<td>0.068 decrease</td>
</tr>
</tbody>
</table>
Gain in QALY by avoiding an event

INDEX ("utility level")

Perfect health 1

0.5

Death 0

TIME

With standard of care

With better prevention

QALY gain

event
## Example Breast cancer

<table>
<thead>
<tr>
<th>Disease state</th>
<th>Utility level</th>
<th>St Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence Free</td>
<td>0.78</td>
<td>0.017</td>
</tr>
<tr>
<td>Local recurrence</td>
<td>0.78</td>
<td>0.04</td>
</tr>
<tr>
<td>Distant recurrence</td>
<td>0.69</td>
<td>0.03</td>
</tr>
<tr>
<td>Distant recurrence brain meta</td>
<td>0.60</td>
<td>0.12</td>
</tr>
</tbody>
</table>

Hall et al. Pharmacoeconomics 2011
Gain in QALY by delaying progression

INDEX ("utility level")

Perfect health

0.5

Death

TIME

With new treatment

Standard of care

QALY gain
Where is the threshold?

• BENCHMARKING
  – Example: cost-effectiveness of caring for a dialysis patient
    historically $50,000 per QALY
    now... >$100,000 per QALY
• WHO: Highly cost-effective (< GDP per capita); Cost-effective (between one and three times GDP per capita); (e.g. Belgium = +/- €37000)
• At the discretion of the decision maker (England: 30,000£ per QALY)
ICER threshold applied in the UK

ICER = incremental cost effectiveness ratio
= incremental cost / incremental effect

QALY = Quality Adjusted Life Years

Societal willingness to pay threshold = 30,000£
Examples of reimbursed medicines in Belgium

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Cost per QALY gained (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Champix for Smoking cessation</td>
<td>dominant</td>
</tr>
<tr>
<td>Procoralan Chronic Heart Failure</td>
<td>6,000</td>
</tr>
<tr>
<td>Brillique Acute Coronary Syndrome</td>
<td>14,000</td>
</tr>
<tr>
<td>Prezista HIV</td>
<td>16,000</td>
</tr>
<tr>
<td>Sovaldi HCV</td>
<td>18,000</td>
</tr>
<tr>
<td>Velcade multiple myeloma</td>
<td>30,000</td>
</tr>
<tr>
<td>Alimta NSCLC</td>
<td>40,000</td>
</tr>
<tr>
<td>Tysabri MS</td>
<td>47,000</td>
</tr>
</tbody>
</table>
### Real examples: “league table”

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Net cost</th>
<th>QALY gain</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training for caregivers of stroke patients</td>
<td>-6,000</td>
<td>0.00</td>
<td>Dominant</td>
</tr>
<tr>
<td>Diabetes education and self management for patients newly diagnosed with type 2 diabetes</td>
<td>200</td>
<td>0.04</td>
<td>5,000</td>
</tr>
<tr>
<td>Daily dialysis compared to dialysis every other day for 60 year-old men with kidney injury</td>
<td>13,000</td>
<td>2.14</td>
<td>6,000</td>
</tr>
<tr>
<td>ICD (implantable cardioverter defibrillator) for patients who are at risk for sudden death due to left ventricular systolic dysfunction</td>
<td>113,000</td>
<td>3.00</td>
<td>38,000</td>
</tr>
<tr>
<td>HIV counseling, testing, and referral compared to standard of care in high risk populations</td>
<td>1,000</td>
<td>0.03</td>
<td>44,000</td>
</tr>
<tr>
<td>Annual CT for 60 year-old heavy smokers</td>
<td>6,000</td>
<td>0.04</td>
<td>140,000</td>
</tr>
<tr>
<td>Screen &amp; treat osteoporosis for men age 65 and older with no prior fracture</td>
<td>4,000</td>
<td>0.03</td>
<td>150,000</td>
</tr>
</tbody>
</table>

ICER = Incremental Cost Effectiveness Ratio

[https://research.tufts-nemc.org/cear4/Resources/LeagueTable.aspx](https://research.tufts-nemc.org/cear4/Resources/LeagueTable.aspx)
Two methods for health economic evaluations

1. Prospective data: directly collecting economic data alongside clinical trial, but rarely applied. **WHY?**
   a) Artificial design
   b) Too short follow up
   c) “Ideal” patients (many excluded)
   d) Drop outs not followed
   e) ....

2. Combining different sources (clinical trials, epidemiology, retrospective data, expert opinion, ...) within a **decision model**
II. Medical decision trees
Decision tree – theoretical example

Cost treatment A (Standard of Care) = 1000
Cost new treatment B = 2000
Cost of “failure” = 10000*

* Needs separate study to obtain data

CALCULATE EXPECTED RESULT

Treat disease X

SoC A

Success
0.7
1000

Failure
0.3
11000

New B

Success
0.9
2000

Failure
0.1
12000

4000

3000
Calculation for treatment A, per 10 patients

€7000

€33000

€40000 for 10 patients

→ €4000 per patient

FASTER: 0.7 × 1000 + 0.3 × 11000 = 4000
Change inputs $\rightarrow$ new result

Cost treatment A = 1000
Cost new treatment B = 6000
Cost of Failure = 10000
What about the QALYs?

Cost treatment A = 1000
Cost medicine B = 6000
Cost of Failure = 10000

If disease: -2 QALYs*

* Needs again separate study to obtain data

ICER = 4000/0.2 = 20000 € /QALY gained

Incremental cost-effectiveness ratio
Example: fall prevention

McLean et al
BMC Geriatr. 2015; 15: 33
Example Acute Coronary Syndrome

Goeree, R; Economic evaluation of drug-eluting stents compared to bare metal stents using a large prospective study in Ontario. *Int. Journal of Technology Assessment in Health Care* 25.2 (Apr 2009): 196-207
Markov models

Principle:

- Patients are in disease specific health states
- Time is divided into periods (cycles)
- During each cycle the patient can move from one health state to another (transition).

The risk of this transition = “transition probability”

Note:
Medline citations [“QALY” AND “Markov”] up to now: > 3000 citations
Markov Model – simple example

- 3 health states (at risk, sick, death); 1 cycle = 1 year

Upon start | after 1 year | after 2 years | after 3 years
---|---|---|---
At risk | 1000 | 890 | 792 | 705
Sick | 0 | 100 | 169 | 214
Dead | 0 | 10 | 39 | 81
Total | 1000 | 1000 | 1000 | 1000

100 - 20 + 89 = 169
Changing the model

NEW PREVENTIVE TREATMENT: At risk $\rightarrow$ sick: **0.05 per year! (50% reduction)**

<table>
<thead>
<tr>
<th></th>
<th>Upon start</th>
<th>after 1 year</th>
<th>after 2 years</th>
<th>after 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>At risk</strong></td>
<td>1000</td>
<td>940</td>
<td>884</td>
<td>831</td>
</tr>
<tr>
<td><strong>Sick</strong></td>
<td>0</td>
<td>50</td>
<td>87</td>
<td>114</td>
</tr>
<tr>
<td><strong>Dead</strong></td>
<td>0</td>
<td>10</td>
<td>29</td>
<td><strong>56</strong></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
</tr>
</tbody>
</table>

Model predicts less deaths
How to calculate a Markov model? Like a decision tree (but repeated)

<table>
<thead>
<tr>
<th>CURRENT</th>
<th>Upon start</th>
<th>after 1 year</th>
<th>after 2 years</th>
<th>after 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk</td>
<td>1000</td>
<td>890</td>
<td>792</td>
<td>705</td>
</tr>
<tr>
<td>Sick</td>
<td>0</td>
<td>100</td>
<td>169</td>
<td>214</td>
</tr>
<tr>
<td>Dead</td>
<td>0</td>
<td>10</td>
<td>39</td>
<td>81</td>
</tr>
<tr>
<td>Total</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
</tr>
</tbody>
</table>

Example: Cost/yr At risk = €200; “Sick” = €3000  
\[ \text{yr 1} = 0.89 \times 200 + 0.10 \times 3000 = €478 \]  
\[ \text{yr 2} = 0.792 \times 200 + 0.169 \times 3000 = €665 \]

<table>
<thead>
<tr>
<th>NEW</th>
<th>Upon start</th>
<th>after 1 year</th>
<th>after 2 years</th>
<th>after 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk</td>
<td>1000</td>
<td>940</td>
<td>884</td>
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<tr>
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<td>0</td>
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<td>29</td>
<td>56</td>
</tr>
<tr>
<td>Total</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
</tr>
</tbody>
</table>

\[ \text{yr 1} = 0.94 \times 200 + 0.05 \times 3000 = €338 \]  
\[ \text{yr 2} = 0.884 \times 200 + 0.087 \times 3000 = €438 \]
Same approach for QALYs

<table>
<thead>
<tr>
<th></th>
<th>Upon start</th>
<th>after 1 year</th>
<th>after 2 years</th>
<th>after 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk</td>
<td>1000</td>
<td>890</td>
<td>792</td>
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<td>214</td>
</tr>
<tr>
<td>Dead</td>
<td>0</td>
<td>10</td>
<td>39</td>
<td>81</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1000</strong></td>
<td><strong>1000</strong></td>
<td><strong>1000</strong></td>
<td><strong>1000</strong></td>
</tr>
</tbody>
</table>

e.g. Utility at risk = 0.8; U “Sick” = 0.5 → yr 1 = $0.89 \times 0.8 + 0.10 \times 0.5 = 0.762$

yr 2 = ?

<table>
<thead>
<tr>
<th></th>
<th>Upon start</th>
<th>after 1 year</th>
<th>after 2 years</th>
<th>after 3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>At risk</td>
<td>1000</td>
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<tr>
<td>Sick</td>
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<td>50</td>
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<td>114</td>
</tr>
<tr>
<td>Dead</td>
<td>0</td>
<td>10</td>
<td>29</td>
<td>56</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1000</strong></td>
<td><strong>1000</strong></td>
<td><strong>1000</strong></td>
<td><strong>1000</strong></td>
</tr>
</tbody>
</table>

→ yr 1 = $0.94 \times 0.8 + 0.05 \times 0.5 = 0.777$

yr 2 = ?
Markov Modeling in HIV/AIDS

Miners et al, 2001
- Cost-effectiveness of HAART
- 12 months intervals
- 20 years

All start here

Miners et al, HIV Medicine (2001) 2, 52 - 58
‘transition matrix’ (probabilities per year)

<table>
<thead>
<tr>
<th>From state:</th>
<th>To state:</th>
<th>CD4 ≥ 200</th>
<th>CD4 &lt; 200</th>
<th>AIDS</th>
<th>Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dual NRTI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 ≥ 200*</td>
<td></td>
<td>#</td>
<td>0.15</td>
<td>0.05</td>
<td>0</td>
</tr>
<tr>
<td>CD4 ≥ 200</td>
<td></td>
<td>#</td>
<td>0.16</td>
<td>0.04</td>
<td>0.04</td>
</tr>
<tr>
<td>CD4 &lt; 200</td>
<td></td>
<td>0.11</td>
<td>#</td>
<td>0.11</td>
<td>0.05</td>
</tr>
<tr>
<td>AIDS</td>
<td></td>
<td>0.13</td>
<td>0.50</td>
<td>#</td>
<td>0.25</td>
</tr>
<tr>
<td>HAART</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CD4 ≥ 200*</td>
<td></td>
<td>#</td>
<td>0.02</td>
<td>0.01</td>
<td>0</td>
</tr>
<tr>
<td>CD4 ≥ 200</td>
<td></td>
<td>#</td>
<td>0.05</td>
<td>0.02</td>
<td>0</td>
</tr>
<tr>
<td>CD4 &lt; 200</td>
<td></td>
<td>0.43</td>
<td>#</td>
<td>0</td>
<td>0.03</td>
</tr>
<tr>
<td>AIDS</td>
<td></td>
<td>0</td>
<td>0.49</td>
<td>#</td>
<td>0.50</td>
</tr>
</tbody>
</table>
More finetuned

Colombo et al, 2011
Example: hpv vaccine

det: subjects with disease detected through screening: same pathways but different probabilities

Demarteau et al 2007
Output: predicted HPV prevalence

HPV yearly prevalence per 100,000 subjects

Age

Population non vaccinated
Population vaccinated
Output: predicted cancer incidence

Yearly incident cases of cervical cancer per 100,000 subjects

Population non vaccinated
Population vaccinated
Note: typical use of Markov models: 2 possibilities

- **Long-term large-scale trials**
  - Intermediate endpoint
  - **Total cholesterol level**
  - **CHD rate**
  - **Death**

- **Markov model**
  - **Short-term trials**
  - **Markov model**
HOW TO MAKE MODELS CREDIBLE AND RELIABLE?

1. Validation of structure: does the structure reflect real life? → *clinical experts*
2. Validation of calculations: → *peer review*
3. Validation of outcomes: compare outcomes predicted by the “current” arm with *real* observations
4. Show various sensitivity analyses
Example: HPV vaccine Belgium (basecase = €10 546 per QALY)

“Tornado” Diagram

Vaccine duration: 10 y + booster for 20 y
Vaccine duration: 20 y
Vaccine duration: 10 y + booster for lifetime
Pap sensitivity for CIN-2/3: 55–75%
Vaccine efficacy: 80–100%
Time with disease: ± 50%
Vaccine cost: €119.62–130.22
CC utilities
Treatment costs: ± 20%

Pharmacoeconomics 2009; 27 (3)
Probabilistic sens. Analysis (= Monte Carlo analysis): example

Available data:
- Purchase cost of no prevention = €0
- Purchase cost of prevention = €4000
- Cost of a heart attack = €10000
- Chance of a heart attack without prevention = 30%
- Chance of a heart attack with prevention = 20%
- QALYs without a heart attack = 10
- QALYs with a heart attack = 6

Deterministic result?

\[ \text{ICER} = 7500 \]

\[ \begin{align*}
\text{No MI} & \quad 0.700 \quad 10 \text{ QALY} \\
\text{MI} & \quad 0.300 \quad 6 \text{ QALY} \\
\text{No MI} & \quad 0.800 \quad 10 \text{ QALY} \\
\text{MI} & \quad 0.200 \quad 6 \text{ QALY}
\end{align*} \]

At risk for CHD

CHD = coronary heart disease
→ Prob distribution of inputs

- Suppose the cost of prevention is not €4,000 as was originally the case, but a normal distribution with average = €4,000 and standard error = €500.
- The cost of a heart attack is not €10,000, but a normal distribution with average = €10,000 and standard error = €1,000.
- The number of QALYs if there is no heart attack is not 10, but a normal distribution with an average of 10 and a standard error of 1.
- The number of QALYs in case of a heart attack is not 6, but a normal distribution with an average of 6 and a standard error of 1.

Computer runs the model **500** times. *For every new calculation, the computer takes a value chosen at random from the respective probability distributions.*

When the model is calculated for the first time, for example, the computer might use:

- Cost of prevention = €3,790 (and not €4,000)
- Cost of heart attack = €8,530 (and not €10,000)
- Number of QALYs without MI = 10.5 (and not 10)
- Number of QALYs with MI = 6.2 (and not 6).

→ With these inputs, the model leads to an ICER of €6,712 per QALY (check 😊)
Probabilistic sensitivity analysis
III. Health economic evaluations in decision making: some problems and trends
Problem 1: different perspectives
Different Payers, different questions

How much can you save elsewhere?

I want a meta-analysis, a cost per QALY estimate and a probabilistic analysis

What is the impact on my budget?

I don’t trust (= understand) your model

What is the cost per (cured) patient?

What discount can you give me?

1. NEED FOR OTHER PAYMENT MECHANISMS THAT REWARD QUALITY
2. NEED FOR PAYER EDUCATION
Problem 2: medical need. 
Is a QALY a QALY?

Same life expectancy
Same cost of drugs
Same prevalence

Drug X
Disease A

Drug Y
Disease B

E. Nord, person trade off method
Is a QALY a QALY? No!

Plus number, own responsibility, mortality?

E. Nord, person trade off method
“We conclude that Viagra is very cost-effective”

(3000 € /QALY ; Stolk et al, British Medical Journal)

Good ICER; Not Funded
Social reference point (Scitovsky)

- **Striving above SRP**
  - Pleasure seeking
  - Not necessary
  - No funding

- **Striving towards SRP**
  - Necessity depends on severity
  - Accept higher cost/QALY in worst conditions

Cost-effectiveness of some orphan drugs

Table 1. Preliminary cost per quality-adjusted life year incremental cost–effectiveness ratio estimates by NICE (2008).

<table>
<thead>
<tr>
<th>Condition</th>
<th>Prevalence (England)</th>
<th>Product</th>
<th>ICER (preliminary estimated £ per QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M. Gaucher type I and III</td>
<td>270</td>
<td>Imiglucerase (Ceredase®)</td>
<td>391,200</td>
</tr>
<tr>
<td>MPS type 1</td>
<td>130</td>
<td>Laronidase (Aldurazyme®)</td>
<td>334,900</td>
</tr>
<tr>
<td>M. Fabry</td>
<td>200</td>
<td>Agalsidase beta (Fabrazyme®)</td>
<td>203,000</td>
</tr>
<tr>
<td>Hemophilia B</td>
<td>350</td>
<td>Nonacog alpha (BeneFIX®)</td>
<td>172,500</td>
</tr>
<tr>
<td>M. Gaucher type I</td>
<td>270</td>
<td>Miglustat (Zavesca®)</td>
<td>116,800</td>
</tr>
</tbody>
</table>

These examples from England illustrate the mismatch between ultra-orphan drug cost and conventional cost–effectiveness benchmarks as adopted by NICE (i.e., £20,000 to £30,000 per QALY gained) [8].


Health Technology Assessment multiple criteria!

HTA seeks to inform health policy makers by using the best scientific evidence on the medical, social, economic and ethical implications of investments in health care.

HTA includes:

1. Synthesising health research findings about the effectiveness of different health interventions
2. Evaluating the economic implications and analysing cost and cost effectiveness
3. Appraising social and ethical implications of the diffusion and use of health technologies as well as their organisational implications
4. Identifying best practices in health care, thereby enhancing safety, improving quality and saving costs.

http://www.inahta.org/HTA/
Cost–effectiveness information should be used alongside other considerations – e.g. budget impact and feasibility considerations – in a transparent decision-making process, rather than in isolation based on a single threshold value.
Zorginstituut NL (ZIN): variable threshold

- €80,000 per QALY for severe condition, even up to €100,000 at end-of-life
- €50,000 per QALY for moderate burden
- €20,000 per QALY for mild burden
Problem 3: Budget impact

“The economic and equity rationale for carrying out budget impact analyses is opportunity cost, or benefits forgone by using resources in one way rather than another”

→ Need for estimates at population level!

BUT: not only budget impact !!!!

Birch and Gafni (2006); Cohen et al (2008)
Not recognizing the value goes against the objectives of health care policies; If we only look at budget impact, then we better let patients die.
How to link all of this?

Value Informed & Affordable Prices

Willingness to pay vs. Burden/therapeutical need

- Very low budget impact
- Low budget impact
- Moderate budget impact
- High budget impact
The Belgian solution for medicines

→ Class I: (claimed added value)

1. Added therapeutical value
2. Proposed price and reimbursement level
3. Medical therapeutical need
4. Impact on the Budget
5. Cost-effectiveness*

* NOT for orphan drugs
... and last but not least
Recommendations

FOR INDUSTRY
1. Increase transparency of cost-effectiveness and budget impact studies
2. Promote and foster the cost-effective use of your drugs

FOR PAYERS
1. Apply a broad health insurance (& societal) perspective
2. Be explicit about the motivation of reimbursement decisions & about our societal limits
3. Challenge also current healthcare use
4. Provide incentives for cost effective care
Recommendations

FOR PHYSICIANS & NURSES
1. Health economic considerations in clinical guidelines
2. Think also societal, avoid non cost-effective care

ALL
1. Work together (payers, physicians, industry, patients, …)
2. Invest in cost-effective prevention measures
3. Invest in health economic training, engage in health economics
Chaire Francqui: leçon 2

Principes et méthodes des évaluations économiques en matière de santé

Lieven Annemans

ULB, 30 Mars 2017
Leçons suivantes

• **Jeudi 20 avril 2017 | 17h - 19h**
  – La pharmaco-économie dans le cycle de développement des médicaments: opportunités et défis

• **Jeudi 27 avril 2017 | 17h - 19h**
  – Évolution des collaborations européennes en matière de politiques de santé et d’accès aux soins

• **Mercredi 17 mai 2017 | 17h - 19h**
  – Qu’est-ce que la santé ? Regard critique sur les QALYs et analyse d’autres paramètres pour mesurer les gains en santé

(Campus Erasme, École de Santé Publique, Auditoire Sand)