Perspectives on cost-effectiveness thresholds in the United States

Moderated by:
• Dr. Steven Pearson, President
• Dr. Rick Chapman, Director of Health Economics

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Webinar 4: Opportunity cost as a basis for a cost-effectiveness threshold in the United States

Main Presentation:

Karl Claxton
Professor of Economics,
Centre for Health Economics,
University of York
Fair prices, fair access and future innovation

Karl Claxton
26/7/2019
What is a fair price?

Health opportunity costs $K_h = £20,000$ per QALY

Price = $P^*$
- Surplus to the HCS £20,000
- Cost £40,000

Price > $P^*$
- Cost £60,000

Price < $P^*$
- Cost £20,000

Net Health Benefit
- 1 QALY
- -1 QALY

QALYs gained

Cost

Price = $P^*$
- £20,000 per QALY
- £30,000 per QALY
- £20,000 per QALY
- £10,000 per QALY
What is a fair price?

Health opportunity costs
\[ K_h = £20,000 \text{ per QALY} \]

Consumption value of health
\[ V_h = £30,000 \text{ per QALY} \]

Price = \( P^* \)
- £40,000
- £20,000

Price > \( P^* \)
- £60,000

Price < \( P^* \)
- £20,000

Net Consumption Benefit
- £30,000
- £60,000
- £90,000

£ Value of QALYs gained
£ Value of QALYs gained
**What is a fair access?**

<table>
<thead>
<tr>
<th>Thresholds and prices</th>
<th>Plan 1</th>
<th>Plan 2</th>
<th>Plan 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>$P^*<em>1 (K</em>{h1}, \text{and} \ V_{h1})$</td>
<td>$2 \times £60,000 - 2 \times £60,000 = 0$</td>
<td></td>
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</tr>
<tr>
<td>$P^*<em>2 (K</em>{h2}, \text{and} \ V_{h2})$</td>
<td>$2 \times £30,000 - 2 \times £30,000 = 0$</td>
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</tr>
<tr>
<td>$P^*<em>3 (K</em>{h3}, \text{and} \ V_{h3})$</td>
<td>$2 \times £20,000 - 2 \times £20,000 = 0$</td>
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</tbody>
</table>

$K_{h1} = £30,000$ per QALY

$V_{h1} = £60,000$ per QALY

$K_{h2} = £20,000$ per QALY

$V_{h2} = £30,000$ per QALY

$K_{h3} = £10,000$ per QALY

$V_{h3} = £20,000$ per QALY

£ Value of QALYs gained
What about future innovation?

Threshold for decision = health opportunity costs ($P^*$)
Patent expires and generic entry at $t=15$
Generic prices are 25% of the brand
All prescribing switches to generic
Or new brands compared to generic versions of old brands
Discounted (3.5% for UK Treasury)
How is value shared?

- 15 years of patent
- Generic 25% of brand
- Discount 3.5%

Proportion of total surplus retained by HCS

Cost per QALY ‘threshold’ used for pricing and reimbursement

Health opportunity costs

15 years of patent
Generic 25% of brand
Discount 3.5%
How is value shared?

Cost per QALY ‘threshold’ used for pricing and reimbursement

Proportion of total surplus retained by HCS

- **15 years of patent**
  - Generic 25% of brand
  - Discount 3.5%

- **10 years of patent**
  - Generic 25% of brand
  - Discount 1.5%

Health opportunity costs
How is value shared?

- Proportion of total surplus retained by HCS
- Cost per QALY ‘threshold’ used for pricing and reimbursement
- 15 years of patent
  - Generic 25% of brand
  - Discount 3.5%
- 10 years of patent
  - Generic 75% of brand
  - Discount 3.5%
- 10 years of patent
  - Generic 25% of brand
  - Discount 1.5%
- Health opportunity costs
How is value shared?

Proportion of total surplus retained by HCS

Cost per QALY ‘threshold’ used for pricing and reimbursement

Incidence grows at 2% pa
10 years of patent
Generic 25% of brand
Discount 1.5%

10 years of patent
Generic 75% of brand
Discount 1.5%

15 years of patent
Generic 25% of brand
Discount 3.5%

Health opportunity costs
How should value be shared?

- Proportion of total surplus retained by HCS
- Cost per QALY "threshold" used for pricing and reimbursement

- 15 years of patent
  - Generic 25% of brand
  - Discount 3.5%

- 10 years of patent
  - Generic 25% of brand
  - Discount 1.5%
  - Generic 75% of brand
  - Discount 1.5%

Incidence grows at 2% pa

- 10 years of patent
  - Generic 25% of brand
  - Discount 1.5%
TA391 Cabazitaxel for prostate cancer

- Consumer surplus does not rise above zero due to high approval norm
- Consumer surplus will be lower if initial approval within the Cancer Drugs Fund taken in to account
Recent UK estimates

- Scale of health opportunity costs
- Type of health effects (mortality, survival and morbidity)
- Where these are likely to occur (disease, age, gender)
- Severity of disease (burden, absolute and proportional)
- Net production effects (marketed and non marketed)
- Impact on health inequality
- Affordability and the scale of budget impact
- Elicitation from clinical and policy experts (surrogacy and extrapolation assumptions)
- Re-estimated for all waves of data
- Other categories of non NHS expenditure (public health, social care)

- Love-Koh J, Cookson R, Claxton K, Griffin S. Who gains most from public healthcare spending? Estimated health impacts of changes in English NHS expenditure by age, sex and socioeconomic status. Re-submission MDM
### What are the expected health consequences of £10m?

<table>
<thead>
<tr>
<th></th>
<th>Change in spend</th>
<th>Additional deaths</th>
<th>LY lost</th>
<th>Total QALY lost</th>
<th>Due to premature death</th>
<th>Quality of life effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Totals</strong></td>
<td>10 (£m)</td>
<td>51</td>
<td>233</td>
<td>773</td>
<td>150</td>
<td>623</td>
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<td>Cancer</td>
<td>0.45</td>
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<td>Circulatory</td>
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<td>116.0</td>
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<td>Respiratory</td>
<td>0.46</td>
<td>13.37</td>
<td>16.1</td>
<td>229.4</td>
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<td><strong>219.3</strong></td>
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<td>Gastro-intestinal</td>
<td>0.32</td>
<td>2.62</td>
<td>24.7</td>
<td>43.9</td>
<td>16.2</td>
<td>27.7</td>
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<td>Infectious diseases</td>
<td>0.33</td>
<td>0.72</td>
<td>5.3</td>
<td>15.7</td>
<td>3.6</td>
<td>12.1</td>
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<td>Endocrine</td>
<td>0.19</td>
<td>0.67</td>
<td>5.0</td>
<td>60.6</td>
<td>3.2</td>
<td>57.3</td>
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<td>Neurological</td>
<td>0.60</td>
<td>1.21</td>
<td>6.5</td>
<td>109.1</td>
<td>4.3</td>
<td><strong>104.8</strong></td>
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<td>Genito-urinary</td>
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<td>2.25</td>
<td>3.3</td>
<td>10.6</td>
<td>2.1</td>
<td>8.5</td>
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<td>Trauma &amp; injuries*</td>
<td>0.77</td>
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<td>Maternity &amp; neonates*</td>
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<td>Disorders of Blood</td>
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<td>0.36</td>
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<td>Mental Health</td>
<td>1.79</td>
<td>2.83</td>
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<td>Learning Disability</td>
<td>0.10</td>
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<td>0.2</td>
<td>0.7</td>
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<td>Problems of Vision</td>
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<td>Problems of Hearing</td>
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<td>14.0</td>
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<td>Dental problems</td>
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<td>0.0</td>
<td>6.8</td>
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<td>Skin</td>
<td>0.20</td>
<td>0.24</td>
<td>1.1</td>
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<td>Musculo skeletal</td>
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<td>Poisoning and AE</td>
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<td>0.04</td>
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<td>Healthy Individuals</td>
<td>0.35</td>
<td>0.03</td>
<td>0.2</td>
<td>0.7</td>
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<td>Social Care Needs</td>
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<td>0.0</td>
<td>0.0</td>
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<td>Other (GMS)</td>
<td>1.01</td>
<td>0.00</td>
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<td>0.0</td>
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<tr>
<td>Proportionate Shortfall (% QALY loss)</td>
<td>Absolute Shortfall (QALY loss)</td>
<td>Wider Social Benefits (net production)</td>
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<tr>
<td>C22 Liver cancer 73%</td>
<td>C22 Liver cancer 10.70</td>
<td>M05 Rheumatoid arthritis £30,034</td>
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<tr>
<td>C25 Pancreatic cancer 73%</td>
<td>C25 Pancreatic cancer 9.97</td>
<td>E11 Diabetes £27,421</td>
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<td>C34 Lung cancer 71%</td>
<td>C34 Lung cancer 9.68</td>
<td>M45 Ankylosing spondylitis £26,190</td>
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<tr>
<td>C62 Myeloid leukaemia 38%</td>
<td>F20 Schizophrenia 7.62</td>
<td>F30 Depression £23,489</td>
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<tr>
<td>G20 Parkinson’s disease 31%</td>
<td>G35 Multiple sclerosis 6.18</td>
<td>F20 Schizophrenia £22,697</td>
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<tr>
<td>C90 Myeloma 31%</td>
<td>C92 Myeloid leukaemia 6.15</td>
<td>J45 Asthma £20,100</td>
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<td>C64 Kidney cancer 22%</td>
<td>G20 Parkinson’s disease 4.60</td>
<td>M81 Osteoporosis £17,910</td>
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<tr>
<td>G35 Multiple sclerosis 18%</td>
<td>C90 Myeloma 4.45</td>
<td>G35 Multiple sclerosis £15,482</td>
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<tr>
<td>J43 Emphysema and COPD 17%</td>
<td>J43 Emphysema and COPD 3.80</td>
<td>J43 Emphysema and COPD £14,525</td>
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<td>G30 Alzheimer’s disease 14%</td>
<td>C64 Kidney cancer 3.75</td>
<td>E11 Diabetes £14,245</td>
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<tr>
<td>F03 Dementia 14%</td>
<td>C64 Kidney cancer 3.63</td>
<td>F40 Epilepsy £11,890</td>
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<tr>
<td>F20 Schizophrenia 12%</td>
<td>M05 Rheumatoid arthritis 2.83</td>
<td>F40 Epilepsy £11,890</td>
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<tr>
<td>M05 Rheumatoid arthritis 11%</td>
<td>E11 Diabetes 2.68</td>
<td>Displaced Average of displaced QALYs £11,611</td>
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<tr>
<td>C61 Prostate cancer 11%</td>
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<td>Displaced Average of displaced QALYs 2.07</td>
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<tr>
<td>I26 Embolisms, fibrillation, thrombosis 11%</td>
<td>J45 Asthma 1.86</td>
<td>K50 Irritable Bowel Syndrome £6,284</td>
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<tr>
<td>E11 Diabetes 11%</td>
<td>G30 Alzheimer’s disease 1.68</td>
<td>J30 Allergic rhinitis £5,234</td>
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<tr>
<td>C18 Colon cancer 10%</td>
<td>F03 Dementia 1.68</td>
<td>G20 Parkinson’s disease £3,102</td>
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<tr>
<td>I21 Acute myocardial infarction 9%</td>
<td>G40 Epilepsy 1.32</td>
<td>C50 Breast cancer £2,888</td>
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<td>I64 Stroke 8%</td>
<td>C18 Colon cancer 1.28</td>
<td>C30 Alzheimer’s disease £351</td>
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<td>I26 Embolisms, fibrillation, thrombosis 1.16</td>
<td>A40 Streptococcal septicaemia £513</td>
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<td>F30 Depression 6%</td>
<td>C61 Prostate cancer 1.06</td>
<td>F03 Dementia £2,430</td>
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<td>G40 Epilepsy 4%</td>
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<td>I64 Stroke £6,949</td>
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<td>J45 Asthma 4%</td>
<td>I21 Acute myocardial infarction 1.00</td>
<td>C18 Colon cancer £8,961</td>
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<td>C50 Breast cancer 3%</td>
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<td>C61 Prostate cancer £10,602</td>
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<td>C53 Central cancer 3%</td>
<td>C53 Central cancer 0.60</td>
<td>C64 Kidney cancer £13,211</td>
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<td>L40 Psoriasis 2%</td>
<td>C50 Breast cancer 0.55</td>
<td>I26 Embolisms, fibrillation, thrombosis £16,752</td>
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<td>J10 Influenza 2%</td>
<td>A40 Streptococcal septicaemia 0.38</td>
<td>I21 Acute myocardial infarction £14,395</td>
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<td>M81 Osteoporosis 2%</td>
<td>J30 Allergic rhinitis 0.30</td>
<td>I26 Embolisms, fibrillation, thrombosis £16,752</td>
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<tr>
<td>J30 Allergic rhinitis 2%</td>
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<tr>
<td>A40 Streptococcal septicaemia 2%</td>
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<tr>
<td>K50 Irritable Bowel Syndrome 1%</td>
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<tr>
<td>E66 Obesity 0%</td>
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<td>Displaced Average of displaced QALYs 8%</td>
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<tr>
<td>M45 Ankylosing spondylitis 0%</td>
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</tbody>
</table>

What type of QALYs are lost/gained and what are the other effects of changes in expenditure?

The effects of 1 QALY gained or lost in each ICD code.
Re-estimated for all waves of data

Alternative approach to identification


Other estimates using within country data

- **Australia (Edney et al)**
  - $28,033 per QALY AUD ($20,758 to $37,667)
- **Spain (Vallejo-Torres et al)**
  - 22,000€ to 25,000€ per QALY
- **Netherlands (van Baal)**
  - 41,000€ per QALY (CVD hospital care only)
- **Sweden (Siverskog and Henriksson)**
  - 39,000€ per QALY
- **Indonesia (Kreif et al)**
  - $331 per DALY averted (USD)
- **South Africa (Edoka and Hofman)**
  - $3,000 per DALY averted (USD)
Evidence of health opportunity costs

L/M IC = 2% - 56%
M/H IC = 20% - 77%

Evidence of health opportunity costs

Evidence of health opportunity costs

Average and range of estimates of cost per DALY averted by LIC

Evidence of health opportunity costs


USA ###
(### -#### US$ 20##)
Estimating health opportunity costs in Canada

<table>
<thead>
<tr>
<th>Province/Region</th>
<th>Claxton et al (-1.028)</th>
<th>Andrews et al (-0.705)</th>
<th>Bokhari et al (-0.193)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Canada</strong></td>
<td>$19,914</td>
<td>$29,032</td>
<td>$97,321</td>
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<tr>
<td>Alberta</td>
<td>$26,060</td>
<td>$37,991</td>
<td>$125,997</td>
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<td>British Columbia</td>
<td>$19,227</td>
<td>$28,029</td>
<td>$96,042</td>
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<td>Manitoba</td>
<td>$21,722</td>
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<td>New Brunswick</td>
<td>$18,265</td>
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<td>Newfoundland and Labrador</td>
<td>$21,392</td>
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<td>Ontario</td>
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<td>$23,945</td>
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<td>Saskatchewan</td>
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<td>Yukon</td>
<td>$30,633</td>
<td>$44,659</td>
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</table>

Cost per DALY averted ≈ QALY gained for (2015 US$)

<table>
<thead>
<tr>
<th>Province/Region</th>
<th>Claxton et al (-1.028)</th>
<th>Andrews et al (-0.705)</th>
<th>Bokhari et al (-0.206)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>USA</strong></td>
<td>$16,048</td>
<td>$23,397</td>
<td>$80,234</td>
</tr>
</tbody>
</table>
What are the health effects of additional health care costs in the USA?

• Single payer health care systems (marginal productivity of expenditure)
  • Medicaid (50 systems), federal and state $
  • Veterans Administration, federal $
  • Medicare (not allowed make decisions, still good to know you what get for federal $)

• Private health insurance plans
  • Health effect of being ‘priced out’ at plan choice or point of care
  • Costs net of the co-pay are passed on
    • Co-pay for the new drug has health (at point of care), consumption, and federal $ (HAS) effects
  • Employers or employees may decide
    • Stop offering/buying coverage (has health and consumption effects)
    • Reduce the benefits offered to control costs (has health and consumption effects)
    • Increase in co-pays and deductibles (has health, consumption, and federal $ effects)
    • Health and consumption effects likely greater for lower income and greater health need
Estimating health opportunity costs for private plans in the USA

• Dave Vanness iHEA 2017
  • Proportion insured by age
  • 100% pass through
  • Elasticity coverage wrt premium
  • Mortality effects of loss of coverage
    • Quality adjusted survival effects
  • Morbidity effects of loss coverage
    • Quality life effects of survivors
  • QALY effects of additional costs
  • = £100,000 per QALY
Estimating health opportunity costs for private plans in the USA
What are the effects of approving a new drug

- New drug 1 QALY gained ppt (100 patients)
- Costs additional $200,000 ppt
- 20% co-pay
- 10% have HAS, will be topped up
- Marginal costs of public finance is 1.2 ($1 federal = $1.20 in your pocket)
- Marginal income tax 25%
- Health opportunity costs, $h = $100,000 per QALY (Dave)
- Consumption value of health $h = $100,000 per QALY (Chuck)
- 10,000 initially in the plan
- Probability drop coverage 0.1

<table>
<thead>
<tr>
<th></th>
<th>New drug</th>
<th>Opportunity costs</th>
<th>Net value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health effects</td>
<td>1</td>
<td>1.6</td>
<td>- $60,000</td>
</tr>
<tr>
<td>Consumption effects HSA</td>
<td>-$3,000</td>
<td></td>
<td>- $3,000</td>
</tr>
<tr>
<td>Consumption effects</td>
<td>-$36,000</td>
<td></td>
<td>- $36,000</td>
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<tr>
<td>Total consumption costs</td>
<td>-$39,000</td>
<td>$2,222.22</td>
<td>-$41.222</td>
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<tr>
<td>Consumption value of Federal $ effects</td>
<td>-$1,200</td>
<td></td>
<td>- $1,200</td>
</tr>
<tr>
<td>Total cost (plan + consumption)</td>
<td>-$200,200</td>
<td></td>
<td>-$202,422</td>
</tr>
</tbody>
</table>
What else do we need?

• Courage
  • We use estimates of health opportunity costs because you don’t pay for your health care, other people do, sometimes with their lives and the lives and dignity of their loved ones

• Honesty (tell the truth)
  • $K_h$ and $V_h$ differ across your health care ‘systems’ and ‘plans’ or tell a story
    • Reduce health overall
    • Force those who can afford it least to pay too much for their health care
    • Impoverish those already struggling with non health care bills
  • Reveal the implications of current arrangements and add to the accountability of those responsible for them

• Humility
  • There is no such thing as a ‘decision rule’
  • But there can be accountable decisions
    • Accountable to reason, evidence and reasonably held, but disputed social values
Discussion

Responders: Lou Garrison, Anirban Basu
Comment: Opportunity Cost as a Basis for a U.S. Cost-Effectiveness Threshold for Innovative Medicines

July 30, 2019
ICER Webinar Series:
Perspectives on Cost-Effectiveness Thresholds in the United States
Webinar 4: Opportunity Cost as a Basis

Lou Garrison, PhD, Professor Emeritus
The CHOICE Institute, University of Washington, Seattle
Visiting Senior Fellow, Office of Health Economics, London
Comments: Opportunity Cost as a Basis for a U.S. Cost-Effectiveness Threshold for Innovative Medicines (1)

• Claxton and colleagues deserve credit for bringing societal opportunity cost estimation to the forefront of these threshold discussions.
• McCabe (2019) spoke about a “demand-side” threshold and a “supply-side” threshold: we seek equilibrium at that “extensive” margin.
  • WTP is a reasonable approach to thinking about thresholds in a consumer sovereignty-based (welfarist) system.
  • WTP could be seen as opportunity cost based: what are willing to give up (pay) in terms of “other consumption” to get greater well-being from improvements in the health?
• Value—and opportunity cost—vary across individuals (heterogeneity), across indications for the same medicine, and dynamically over time.
• It’s important to recognize that innovative (patented) medicines are unique medico-economic goods—with global public good properties. “The patent system is an effort to approximate a dynamically efficient price.” (Newhouse, 2004)
• There is a strong economic case for differential pricing of innovative medicines across countries (Danzon & Towse, 2003)—and even across individuals and population subgroups.
• Claxton et al. (2015) was an impressive, monumental econometric effort, but it has many limitations, especially related to the available data., as the authors caution.
  • See OHE (2018, 2019) for a discussion of these measurement challenges.
• It would be difficult to replicate this work in the U.S. given the lack of data on spending by disease category across different geographic areas.
• Given that U.S. is at 18% of GDP for health spending (by far the highest in the world) and has worse mortality outcomes. It’s clear that U.S is not cost-effective at that aggregate, extensive margin
  • Either we are maximizing something else (provider incomes?) or are very inefficient: it’s probably both.
  • Tax-subsidy for employer-based insurance distorts all U.S. spending.
• Our ISPOR Special Task Force on Value Assessment Frameworks identified a number of potential novel elements of value that could be used in augmented CEA: insurance value, value of hope, real option value, value of knowing, severity of disease, and fear of contagion.
• Other system-level factors can also affect value beyond the QALY: equity and scientific spillovers.
Comments: Opportunity Cost as a Basis for a U.S. Cost-Effectiveness Threshold for Innovative Medicines (3)

• It will be difficult to measure these in an empirical analysis for the different payer segments in the U.S.: but it’s certainly worth examining those trade-offs.
  • See Hadley (1988): "Medicare Spending and Mortality Rates of the Elderly"
• It’s complicated by the fact that we don’t have fixed annual budget: we can borrow from future generations (as U.S. and UK are doing).
  • See Paulden & Claxton (2012): “Budget allocation and the revealed social rate of time preference for health”
• It is important to remember the global public goods aspect of new medicines and the role of scientific spillovers: it’s a global enterprise and thus a global economic issue.
• What are the implications for ICER moving forward?
  • Support research on opportunity cost in US healthcare insurance systems, and apply thresholds flexibly for specific diseases. But think about science globally and long term.
  • And do this with “courage, honesty, and humility.”
Next webinar:

Thu, Aug 1, 2019 12:00 PM - 1:00 PM EDT

Final Webinar: Different thresholds, different perspectives? Equity considerations and the choice between health sector versus societal perspectives

**Host:** Rick Chapman

**Lead Presentation:** Steve Pearson

**Responders:** Karl Claxton, Anirban Basu, Patricia Danzon