Health economics for device developers: *a framework for assessing commercial viability*

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Outline

1. Economic Evaluation for Health Technology Assessment (HTA)
2. Early HTA for development decisions – the headroom method
3. WHO compendium of innovative health technologies for low-resource settings
   • Case study: Cervical Cyroablation
4. Conclusion
1. Economic Evaluation for HTA

- To help decision-makers determine whether a new intervention represents value for money.
- Economic evaluation is simply a comparison which involves a trade-off.

<table>
<thead>
<tr>
<th>∆Cost (£)</th>
<th>Reimbursement Threshold</th>
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<tbody>
<tr>
<td>More expensive and worse</td>
<td>‘Willingness to pay’</td>
</tr>
<tr>
<td>Cheaper and better</td>
<td>UK: £20-30,000</td>
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Reimbursement Threshold = ‘Willingness to pay’

QALYs gained / DALYs averted
**1. Economic Evaluation for HTA**

- **Reimbursement thresholds...** Based on the **opportunity cost** of spending, so will differ by country according to **healthcare budgets** and **current coverage**
- Thresholds can be explicit (e.g. NICE), or determined implicitly from past decisions

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Cost-Effectiveness in Low- and Middle-Income Countries:
A Review of the Debates Surrounding Decision Rules

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Cost-Effectiveness is often measured in terms of **$US 150 / Disability-Adjusted Life-Year (DALY)**

2 x gross national income
2. Early HTA for development decisions – the headroom method

- Early HTA: “...is aimed at improving development of cost-effective new technologies, preventing development of technologies that are of doubtful value for the health system” [The ‘Headroom Method’]
2. Early HTA for development decisions – the headroom method

- The application of health economic principles **early** on in the development process, to assess product development opportunities
- Assessing **commercial viability**: Estimating potential value to the healthcare provider

Late-stage HTA

*Is there enough healthcare value to justify price?*

Early-stage HTA

*Can I produce the device at a price acceptable to the healthcare provider?*
2. Early HTA for development decisions – the headroom method

New device is not viable unless the price headroom is sufficient to cover costs of development and production.

Net Health Gain ($\Delta QALY$)

Reimbursement Threshold

Headroom: MRP

$\Delta$ Cost (£) = SC + Price

Standard practice

Net Health Gain ($\Delta QALY$)

Service cost saving ($\Delta$Cost)

New device

$\Delta$ Health Benefit

New device is not viable unless the price headroom is sufficient to cover costs of development and production.
2. Early HTA for development decisions – the headroom method

- Application to 20 medical devices in UK context
  - [Horizon Scanning Centre](https://www.horizon-scanning.org/) 2000-2009
    - Headroom calculated
    - Followed-up to present day

- Could this be a useful tool for assessing device development opportunities within a low income setting?
  - Some anticipated challenges:
    - Often no baseline service (so not direct replacement)
    - Scarcity of data
    - Uncertainty around reimbursement thresholds (no constant opportunity cost)
    - …..but a setting where it’s even more important to get this right!!
3. WHO compendium of innovative health technologies for low-resource settings

WHO Call for Innovative health technologies (2010)

• WHO compendium of innovative health technologies for low-resource settings

"...to identify and promote innovative technologies addressing global health concerns and to stimulate their further development"

Innovative technologies

Successful healthcare delivery requires effective medical devices as tools for prevention, diagnosis, treatment and rehabilitation. Despite the exponential growth of scientific and technological development, low- and middle-income countries are still largely excluded from access to appropriate and affordable health technologies.

In the medical device programme the term “Innovative technologies” refers to novel medical device solutions developed to address health problems and improve quality of life. Of particular interest are technologies suitable for use in low- and middle-income countries that have the ability to enhance access to essential health services and contribute further to improving health outcomes.

WHO is pleased to announce the outcome of the call for innovative technologies that address global health concerns. Eight medical devices in the category of commercialized or commercialisable stage products and seven in the category of non-commercialized or non-commercialisable stage products were selected.

To contribute to the achievement of that goal the Department of Essential Health Technologies has launched a call for "Innovative Technologies that address global health concerns". The call aims at identifying and evaluating innovative medical devices, either commercialized or under development, which focus on global health concerns by being accessible, affordable and appropriate for both low- and middle-income countries.

...potential to offer value for money?

‘Not yet commercialized’ technologies

Innovative health technologies under development for low-resource settings

Not recommendations.
Potential to improve health outcomes

2012
3. WHO compendium of innovative health technologies for low-resource settings

<table>
<thead>
<tr>
<th>Technology</th>
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<tbody>
<tr>
<td>Cervical cryoablation equipment</td>
</tr>
<tr>
<td>Combination HIV/T.pallidum Ab test</td>
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<tr>
<td>Digital pen technology for partographs</td>
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<tr>
<td>Hand-powered centrifuge</td>
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<tr>
<td>Human powered nebulizer</td>
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<tr>
<td>Integrated resuscitation solution</td>
</tr>
<tr>
<td>Jaundice treatment blanket</td>
</tr>
<tr>
<td>Low-cost fluorescence cell imager</td>
</tr>
<tr>
<td>Pouch to prevent childhood HIV</td>
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<tr>
<td>Ultrasensitive p24 antigen test</td>
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Cervical cancer results in 120 deaths per million women in the world’s poorest countries

This is 3x higher than in Western Europe and North America

Much of this difference is due to absence of screening in lowest-income countries

- Pre-cancerous lesions exist for approximately 15 years
- Need for effective programmes for screening and treating pre-cancerous lesions

Cryoablation is used to remove pre-cancerous lesions

Its use must be embedded in a screening programme:

- Visual inspection after application of acetic acid
- PAP smear

3. WHO compendium of innovative health technologies for low-resource settings
Case study: Cervical cryoablation
3. WHO compendium of innovative health technologies for low-resource settings
Case study: Cervical cryoablation

- Device in development: claims to simplify existing cryoablation technology and save on consumables

- What is the “headroom”...

...Will depend on setting...

a) Screening programme in operation in target setting
   - Comparator: Standard cryo-guns (inefficient CO₂ use)
   - Headroom: ↓Cost of consumables

b) No screening programme in target setting
   - Pre-cancerous lesions not identified
   - Would this device make screening cost-effective, if it’s not already?
3. WHO compendium of innovative health technologies for low-resource settings
Case study: Cervical cryoablation

a) Screening programme in operation in target setting
   • Conventional cryo-gun
     • Capital cost $1,000; Lasts 2 years
     • 45 patients per year
     • Discount rate: 3%

Cost of Cryoablation [in low-income setting] per patient

≈$25 [2;3]  How much of this is ‘headroom’?

• New device just as effective AND claims to use 90% less CO₂

3. WHO compendium of innovative health technologies for low-resource settings

Case study: Cervical cryoablation

b) No screening programme in target setting

- No longer cost-saving territory! Need to think about health benefits
- Evidence suggests VIA and PAP screening programmes might not be cost-effective for poorest countries [4]
- Questions become...
  - % of overall cervical screening & treatment cost = cryotherapy?
  - Might a reduction send it under the threshold?
  [some provisional calculations...]
  - ...turns on the proportion of women in whom pre-cancerous lesions are identified
    - Just under $200
    - $ (even if free, would not make it a cost-effective policy)

4. Conclusion

- Assesses the commercial viability of a new device idea
- Helps articulate what is *affordable* and to *demonstrate value* (won’t necessarily need/want to charge the MRP!)

- **A word of warning** for ‘frugal innovations’: choose the right comparator!
- Biomedical engineers / developers can use as part of the development decision to....
  - Rule out unpromising technologies
  - Assess the relevant patient population
  - Inform product design

....but wouldn’t it be better if.....
Thank you

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