Financial uncertainty in health technology appraisals

Developing risk sharing agreements

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Presentation Overview

- Context on technology appraisal process in England
- Proposed methodological approaches
- Risk sharing opportunities & Hep C case study
- Key observations and next steps

*Can the financial risk of recommending new drugs be better apportioned among the various stakeholders? How can this financial uncertainty be mitigated from the perspective of the health payers?*
Health Technology Appraisals - Overview

Following market authorization, the health technology goes through a process to seek reimbursement from the English National Health Service for routine commissioning.

Disease state transition model
- Markov model

Model assumptions
- Economic, resource use, and clinical outcomes

Sensitivity analysis
- Uncertainty around data inputs

Managed entry agreements?
- Confidential price agreements

Onus is on the manufacturer to justify premium pricing of the technology through cost-effectiveness
Health Technology Appraisals - Overview

Generally, new drugs and technologies offer superior outcomes, but at a higher cost than conventional treatments.

- Mean Incremental Cost-Effectiveness Ratio (ICER)

\[
\text{ICER} = \frac{\Delta \text{Cost (£)}}{\Delta \text{Effectiveness (QALY)}} = \frac{(\text{Cost treatment} - \text{Cost comparator})}{(\text{Effectiveness treatment} - \text{Effectiveness comparator})}
\]

- Cost-effectiveness is measured in £ (or $) / Quality-Adjusted Life-Years (QALYs)

The (implicit) ICER threshold provides a common framework to assess varying treatment interventions and promote an efficient use of resources.
Proposed Approaches & Key Elements

- Current approach: mean ICER below implicit threshold of £20,000/QALY
- Some ALTERNATIVE approaches that incorporate financial uncertainty more explicitly
  - Median ICER as criteria for reimbursement
  - Higher percentile ICER

Aim is to present how different approaches can lead to different recommendations for reimbursement

Allocate probability distributions to cost and outcome metrics → Stochastic modelling (E.g., Markov model) → Distribution of ICER data points

Add a measure of variability to the appraisal process
Median or Higher Percentile ICER

- Percentile ICER is compared against a pre-defined threshold
- Choice of percentile inversely correlated to risk appetite of risk-bearing entity
  - Potential unintended consequences linked to reducing uncertainty

*Two technologies with same mean may not exhibit the same variability around the ICER*
Risk Sharing
Developing mitigation strategies around selected model assumptions
Risk Sharing Schemes

- Inform the magnitude of the risk sharing agreement
  - Coefficient of variation

- Draw on tools and techniques prevalent in insurance settings
  - Risk corridors
  - Stop-loss insurance schemes

- Meet the specificities of model assumptions
  - Wider disease population
  - Treatment cohort
  - Individual patient
Measure of Variability

- Coefficient of variation \( \left( \frac{\sigma}{\mu} \right) \)
  - Adjust the variability around a value (i.e., ICER) relative to its mean
  - Apply in conjunction with any methodological approaches

Rule: If coefficient is above the threshold, implement risk sharing agreements

<table>
<thead>
<tr>
<th>Technology A</th>
<th>Technology B</th>
<th>Coefficient of Variation - Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \mu_A = £18,000/QALY )</td>
<td>( \mu_B = £14,000/QALY )</td>
<td>0.350</td>
</tr>
<tr>
<td>( \sigma_A = £8,000/QALY )</td>
<td>( \sigma_B = £9,000/QALY )</td>
<td></td>
</tr>
</tbody>
</table>

\[
\frac{\sigma}{\mu} = \frac{£8,000/QALY}{£18,000/QALY} = 0.444 \\
\frac{\sigma}{\mu} = \frac{£9,000/QALY}{£14,000/QALY} = 0.643
\]

Direct relationship between the threshold value and the risk tolerance of the payer

**High mean ICER / low variability potentially given preference over low mean ICER/ high variability**
Risk Corridors

- Risk mitigation tool used in the absence (or limitations) of data
- Margin for deviation of actual experience relative to projected/expected experience

**E.g. Modelling uncertainty in the probability of transitioning from mild to severe liver damage**

<table>
<thead>
<tr>
<th>Annual transition probability</th>
<th>Corresponding ICER (£/QALY)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expected</td>
<td>0.09</td>
</tr>
<tr>
<td>95% C.I.</td>
<td>[0.07 - 0.11]</td>
</tr>
<tr>
<td>Actual*</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Two-way risk corridor
Stop-Loss Insurance Schemes

- Limit the financial impact of providing care under extreme and volatile scenarios
  - Use in conjunction with 95th percentile of modelled lifetime costs of patients with Hepatitis C

- Partition time frame and analyse costs separately within each time interval

- Use with aggregate stop-loss to limit overall budget impact for particular treatment

Example of a cost distribution for curative treatments

High up-front costs generally observed in initial months of treatment

Lower maintenance/health state costs in later years
## Case Study: Hepatitis C Treatments Approved by NICE*

### Approach

- Replicate the time-dependent Markov model using public information found in the manufacturer submission
- Model uncertainty stochastically around key model assumptions
- Run simulation 1,000 times for each of the treatment regimens selected
- Present results for various methodological approaches relying on cost-effectiveness acceptability curves
- Design risk sharing around model assumptions showing greater variability in the ICER

* NICE: National Institute for Health and Care Excellence
Key Observations and Concluding Remarks
Key Observations

- Multiple risk sharing schemes can be implemented simultaneously

- Process requires:
  1) Early identification of model assumptions with a high potential budget impact
  2) Monitoring of assumptions over time
  3) Conducting retrospective reviews of historical medical services utilisation

- Designed with ‘win-win’ approach and incentives aligned

- Risk sharing is growing particularly in countries with a single national health payer

- Move from financial-based to outcomes-based schemes
Next Steps

- **Leverage of big data and health analytics**
  - Rely on empirical data to inform appraisals and supplement evidence from clinical studies
  - Post-appraisal: to inform risk sharing deals through derivation of empirical population-level data

- **Need to monitor key assumptions over time**
  - Incorporate this step into “feedback loop” process to reduce uncertainty
  - Potential to inform the guidance review process

- **Actuarial cost model**
  - 5-year or 10-year model broken out by service category and adjusted for population characteristics
  - Project healthcare costs and resources to each payer in the health system and **under various trend scenarios**
  - Support quantifying the budget impact of recommending new drugs and health technologies
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