Financial uncertainty in health technology appraisals

Developing risk sharing agreements

Didier Serre

June 27, 2016

IPEBLA IACA IAAHS PBSS Canadian Institute of Actuaries Institut canadien des actuaires

Presentation Overview

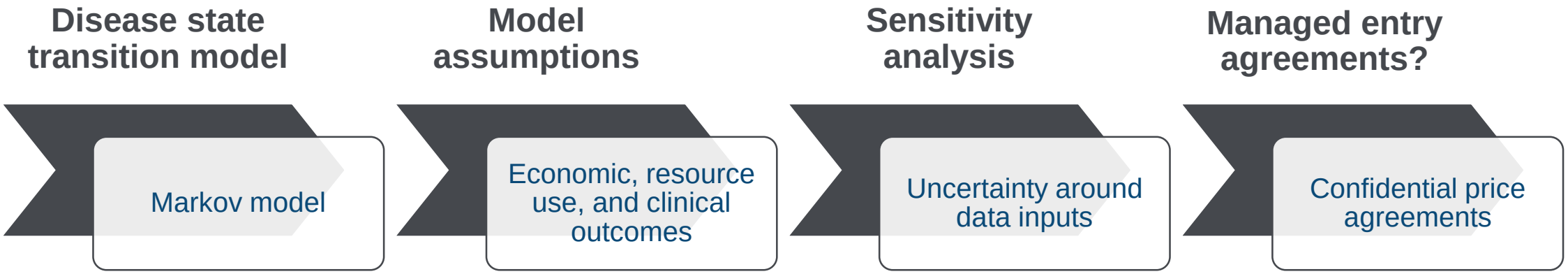
- Context on technology appraisal process in England
- Proposed methodological approaches
- Risk sharing opportunities & Hep C case study
- Key observations and next steps

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 heath 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.



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)**

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

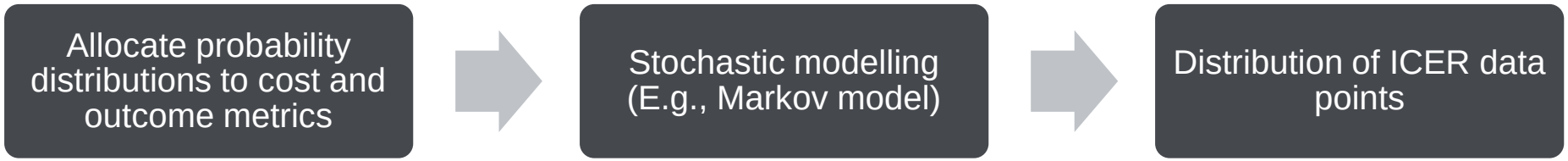
- Cost-effectiveness is measured in £ (or $) / Quality-Adjusted Life-Years (QALYs)

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

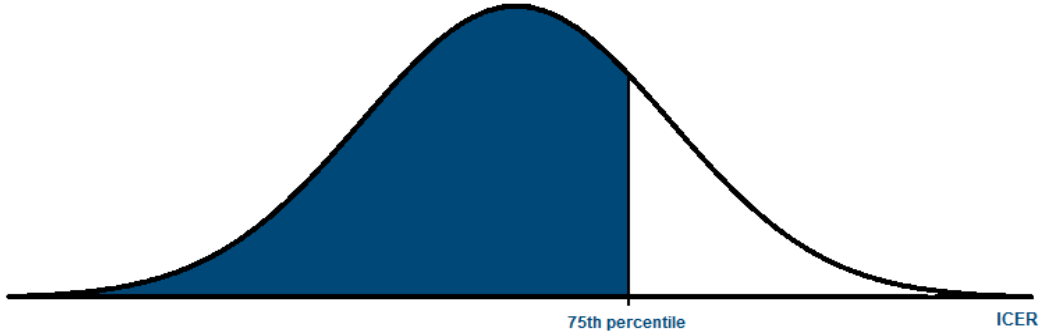
Add a measure of variability to the appraisal process

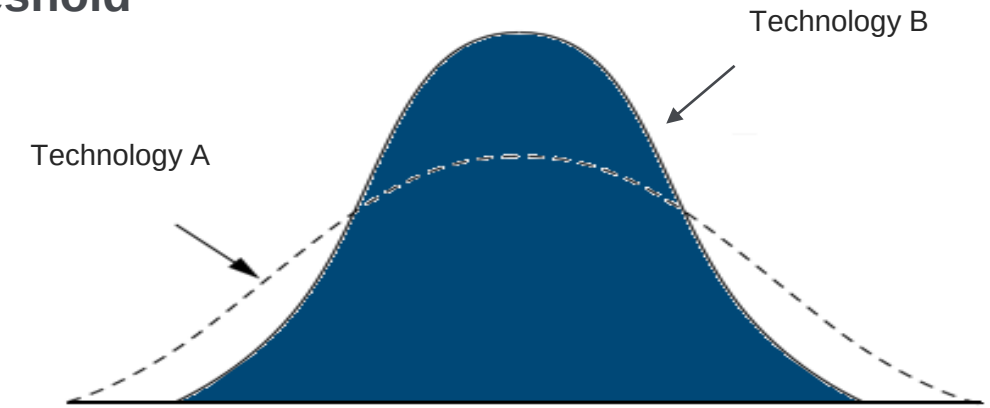


Aim is to present how different approaches can lead to different recommendations for reimbursement

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 ($\frac{\sigma}{\mu}$)**
  - 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

Technology A	Technology B	Coefficient of Variation - Threshold
μ_A = £18,000/QALY	μ_B = £14,000/QALY	0.350
σ_A = £8,000/QALY	σ_B = £9,000/QALY	
$\frac{\sigma}{\mu} = \frac{£8,000/QALY}{£18,000/QALY} = 0.444$	$\frac{\sigma}{\mu} = \frac{£9,000/QALY}{£14,000/QALY} = 0.643$	

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

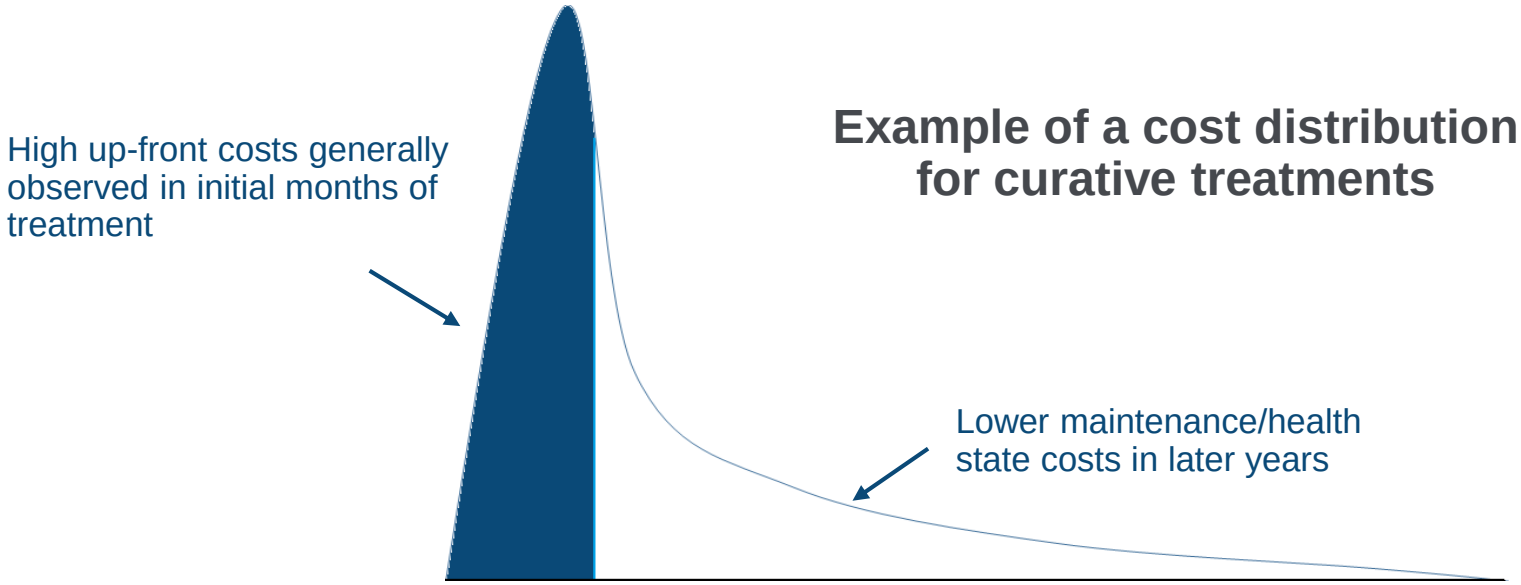
E.g. Modelling uncertainty in the probability of transitioning from mild to severe liver damage

	Annual transition probability	Corresponding ICER (£/QALY)
Expected	0.09	16,000
95% C.I.	[0.07 - 0.11]	14,000 – 19,000
Actual*	0.05	22,000

Two-way risk corridor

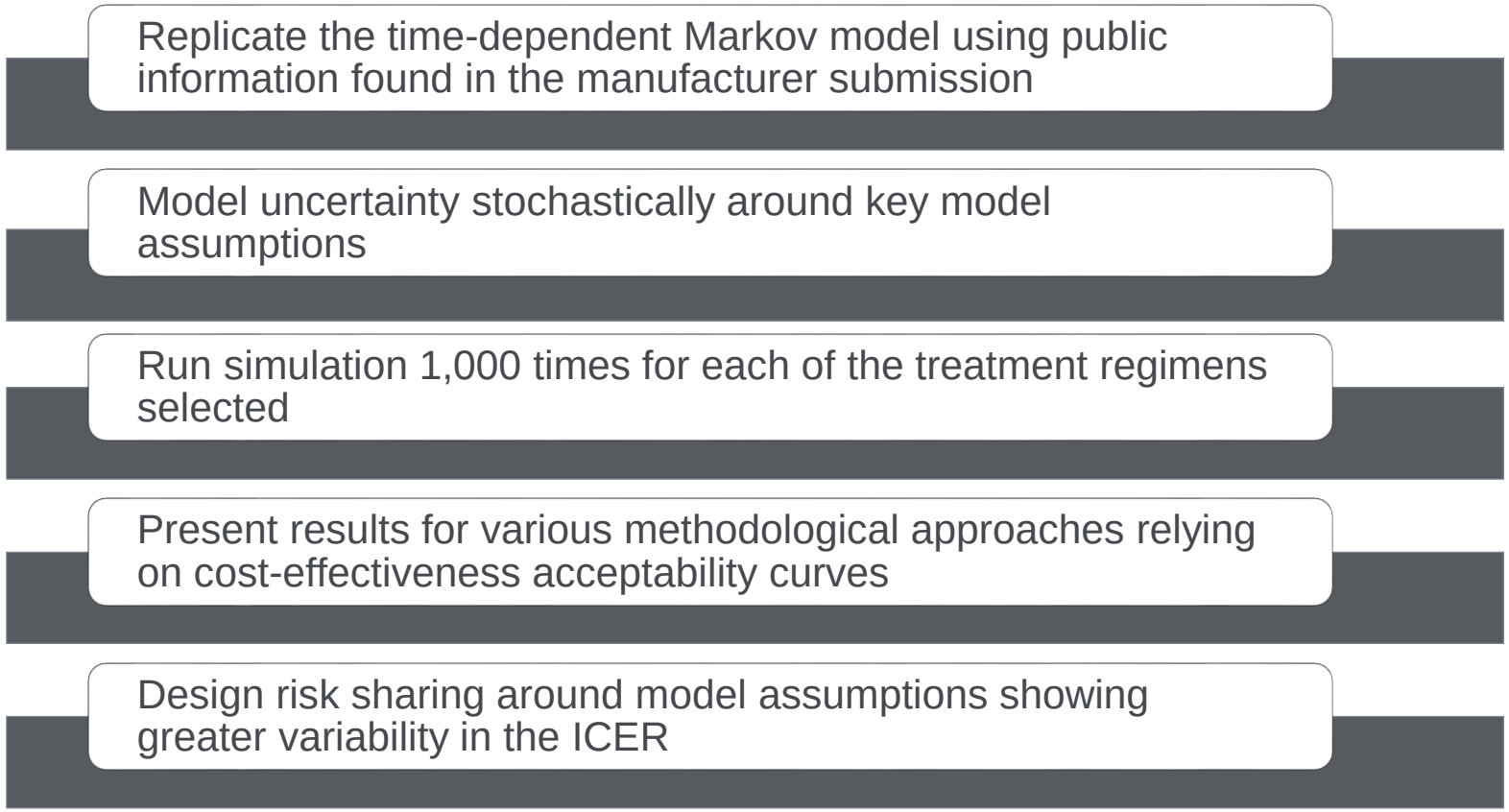
Stop-Loss Insurance Schemes

- **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**



Case Study: Hepatitis C Treatments Approved by NICE*

Approach



* 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**

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- **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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Questions and Comments are welcomed

Didier.Serre@milliman.com
London UK Health Practice