

Conditional Reimbursement: Assessing Uncertainty and the Value of Research

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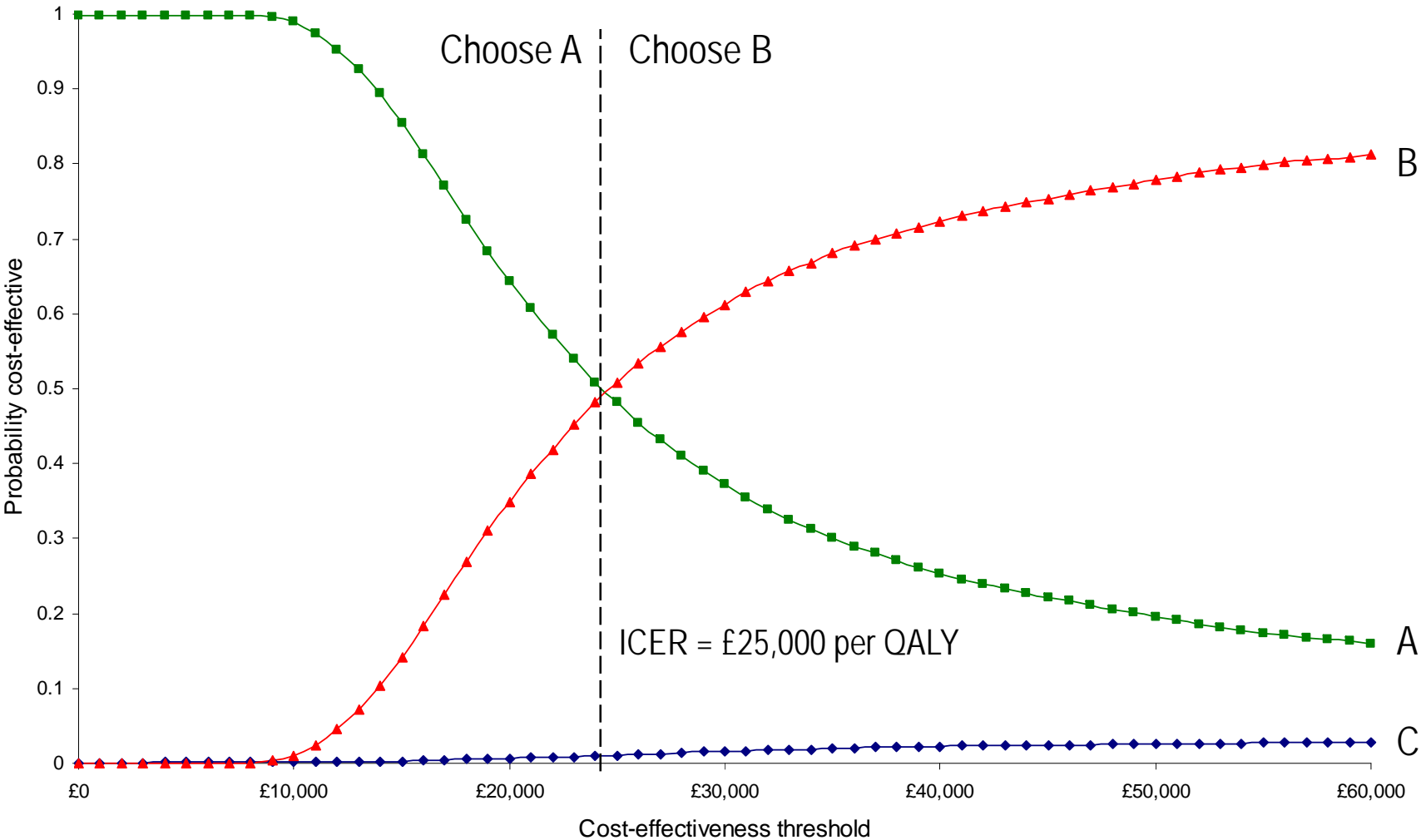
Background

- Increasing demands to assess new drugs closer to launch
- Inevitable uncertainty in evidence base
- Hence a series of linked questions
 1. Should a technology be adopted given existing evidence?
 2. How uncertain is this decision?
 3. Is more evidence required?
 4. Is conditional reimbursement appropriate?
- Need to address each question within an analytic framework

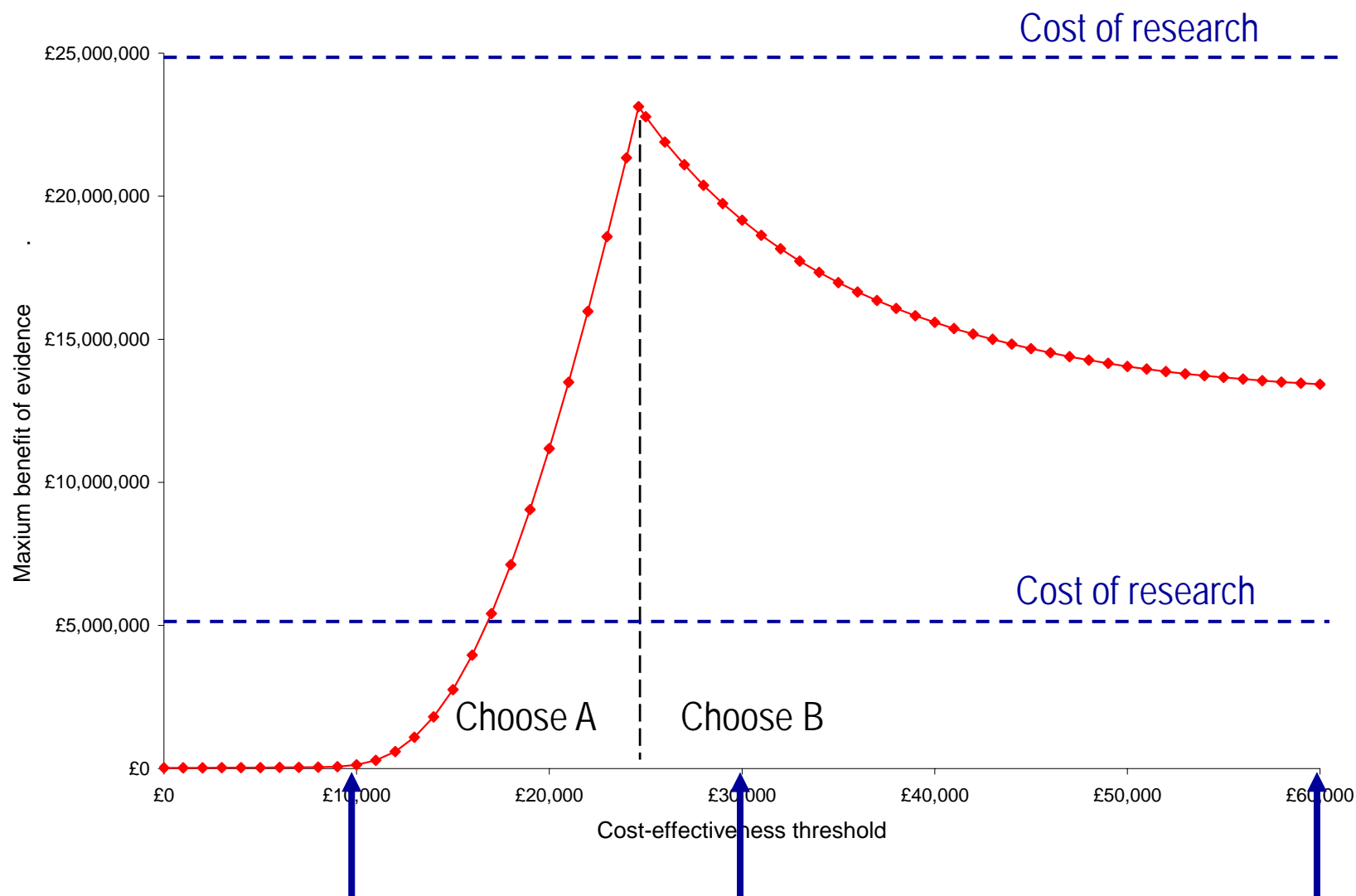
Decision 1: Should a technology be reimbursed given current evidence?

- Usual requirements for economic model: e.g. all appropriate comparators, all relevant evidence
- Would the use of a the new technology increase population health?
 - Would the additional health gain be greater than the health gain displaced?
 - Is the ICER < cost-effectiveness threshold?
- Is so, the technology should in principle be reimbursed

Decision 2: How uncertain is the reimbursement decision?



Decision 3a: Is more evidence required?



Decision 3b: If so, what type of research?

- Where are the key uncertainties (value of information pertaining to individual parameters)?
- Treatment effects
 - Needs evidence from RCTs
 - Registers have little role
- Other parameters can be estimated from non-randomised research
 - Baseline events
 - Utilities
 - Costs
 - Long-term prognosis

Decision 4a: Is reimbursement conditional on research appropriate?

- If $ICER > \text{threshold}$, no case for conditional reimbursement but research may still be of value
- If $ICER < \text{threshold}$ and evidence is potentially of greater value than the cost of research, conditional reimbursement may be appropriate
- But this depends on a series of further questions...

Question 4b: Does the reimbursement agency have a clear research role and have 'teeth'?

If the answer is 'no'

- Reimbursement can remove incentives for research for all parties
- Expected cost of reversing a decision can be high
- No research budget for agency to commission own research
- A 'no' decision required: evidence not sufficient
- In NICE language: 'only in research'
- Manufacturer could reduce price as an alternative to undertaking research

Question 4c: Does the reimbursement agency have a clear research role and have 'teeth'?

If the answer is 'yes'

- Would the research be considered ethical?
- Would recruitment be feasible?
- If so, conditional reimbursement has value
- Range of cost and risk sharing arrangements feasible
 - Share the cost of research? Need for price reduction?
- If not, unconditional reimbursement

Conclusions

- Conditional reimbursement potentially feasible when technology appears cost-effective on existing evidence
- The appropriateness of conditional reimbursement depends on
 - The value of research versus its cost
 - The reimbursement agency's role in research
 - The type of research
 - The ethics and feasibility of the research
- Who pays for research?
 - key role for risk sharing