Conditional Reimbursement: Assessing Uncertainty and the Value of Research

Mark Sculpher

Centre for Health Economics, University of York, UK
**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 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?

ICER = £25,000 per QALY

Cost-effectiveness threshold
Decision 3a: Is more evidence required?

- £25,000,000 Cost of research
- £20,000,000 £15,000,000 £10,000,000 £5,000,000 Maximum benefit of evidence

Cost of research

Choose A

Choose B

Cost-effectiveness threshold
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 > threshold, no case for conditional reimbursement but research may still be of value
- If ICER < 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