

Evaluation pathway for medical technologies: Value of information

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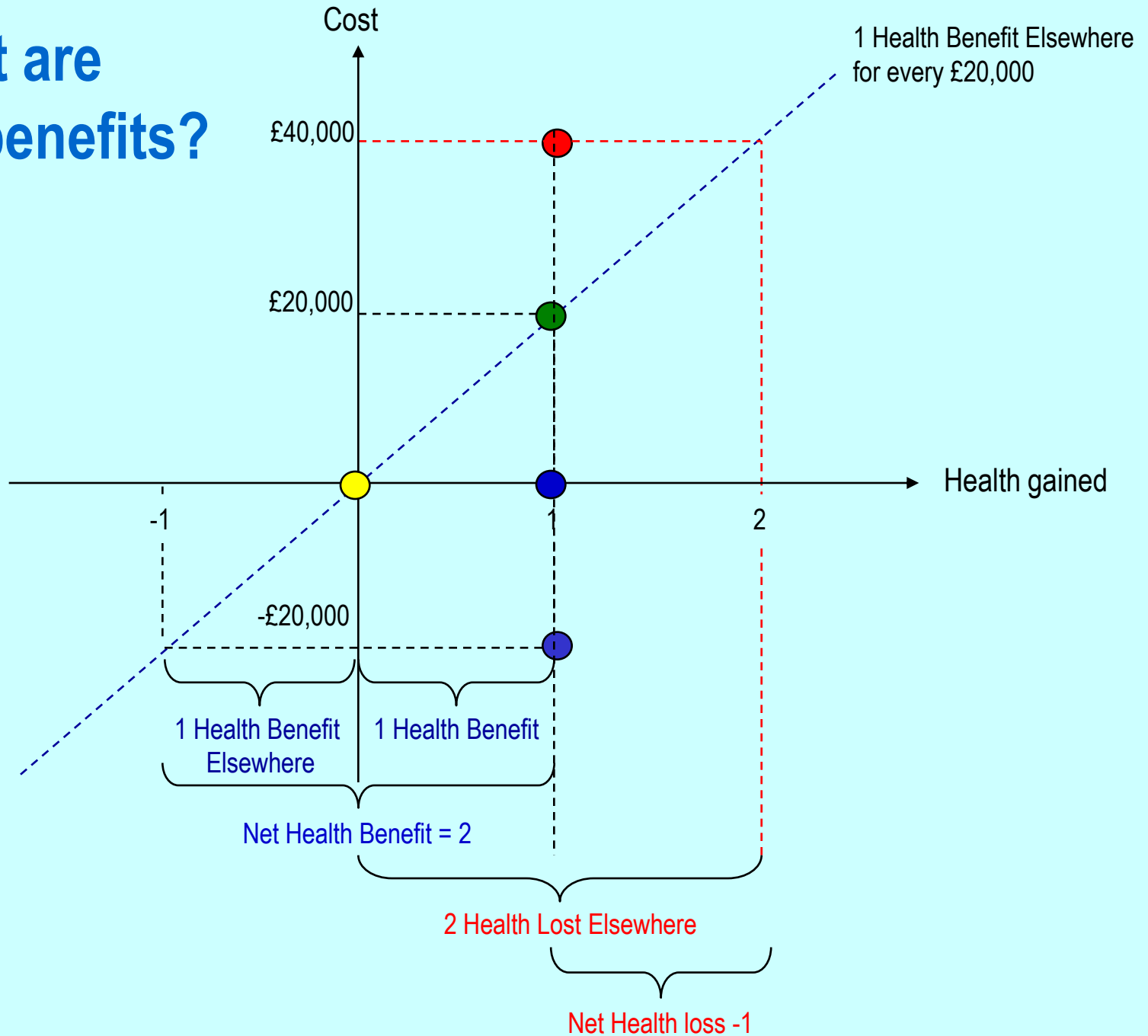
Judging methods

- What assessments need to be made?
 - Either implicit or explicit judgements informed by analysis
- Which methods might be most useful?
 - Do they directly address the assessments which will be made?
 - Are they feasible within the resource, time and process constraints?
- No formal analysis can capture everything that might be important
 - But do they capture enough to be a useful starting point for deliberation?
 - Is the quality, transparency and accountability of assessment (judgements required) likely to be better with or without explicit analysis?

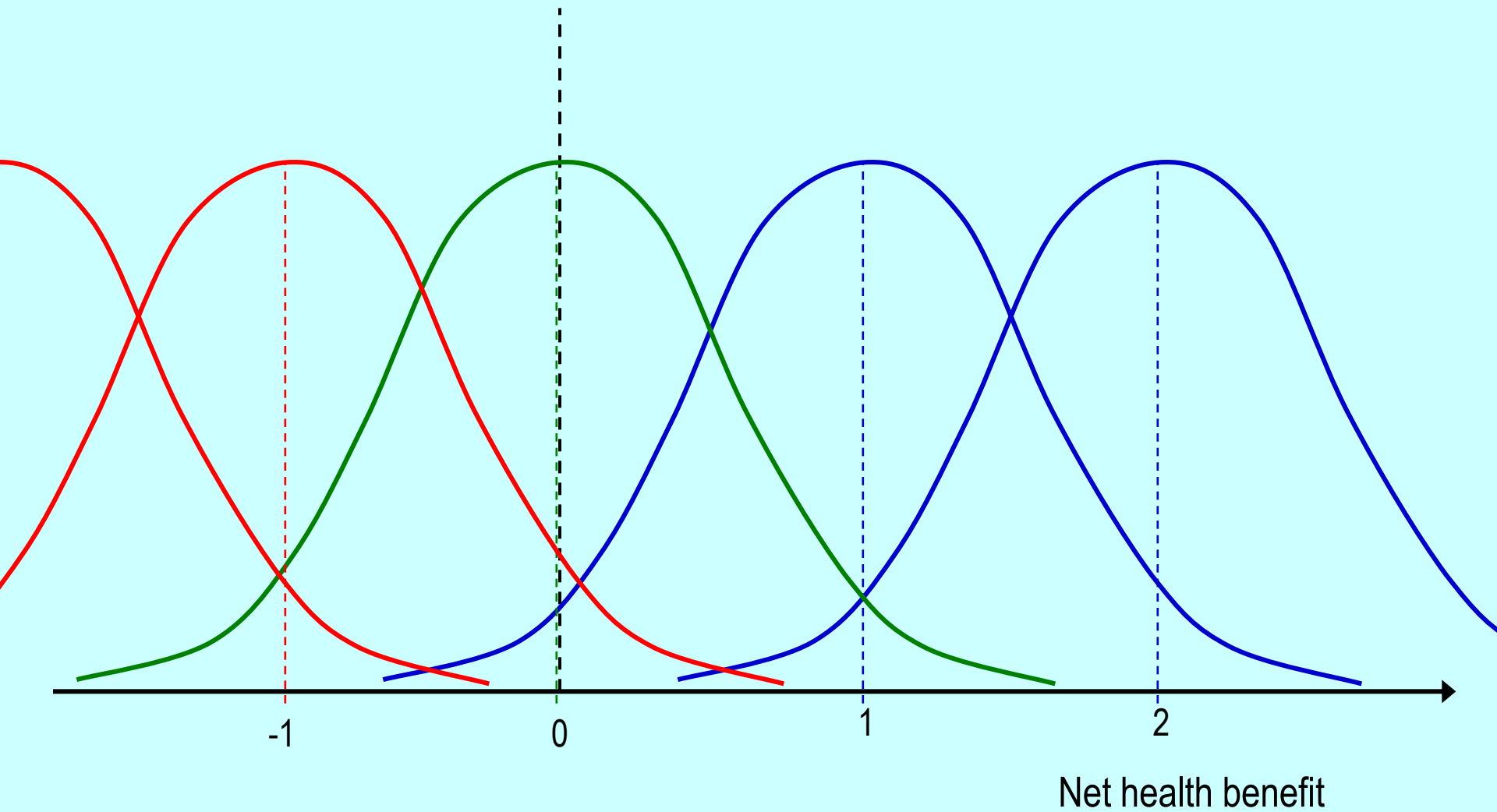
What assessments are needed?

- Do we expect benefits for the NHS?
 - Improve health?
 - Save resources?
 - How should they (and others) be weighted?
- Is more evidence required?
 - How uncertain are the expected benefits
 - Does this uncertainty matter (will it change the decision)
 - How much does it matter (consequences of getting it wrong)

What are the benefits?



Does this uncertainty matter?



Would more evidence improve health?

How things could turn out	Net Health Benefit			Best we could do if we knew
	Treatment A	Treatment B	Best choice	
Possibility 1	8	12	B	12
Possibility 2	16	8	A	16
Possibility 3	9	14	B	14
Possibility 4	12	10	A	12
Possibility 5	10	16	B	16
Average	11	12		14

What's the best we can do now?

Choose B

Expect 12 units, gain 1

But uncertain

Wrong decision 2/5 times

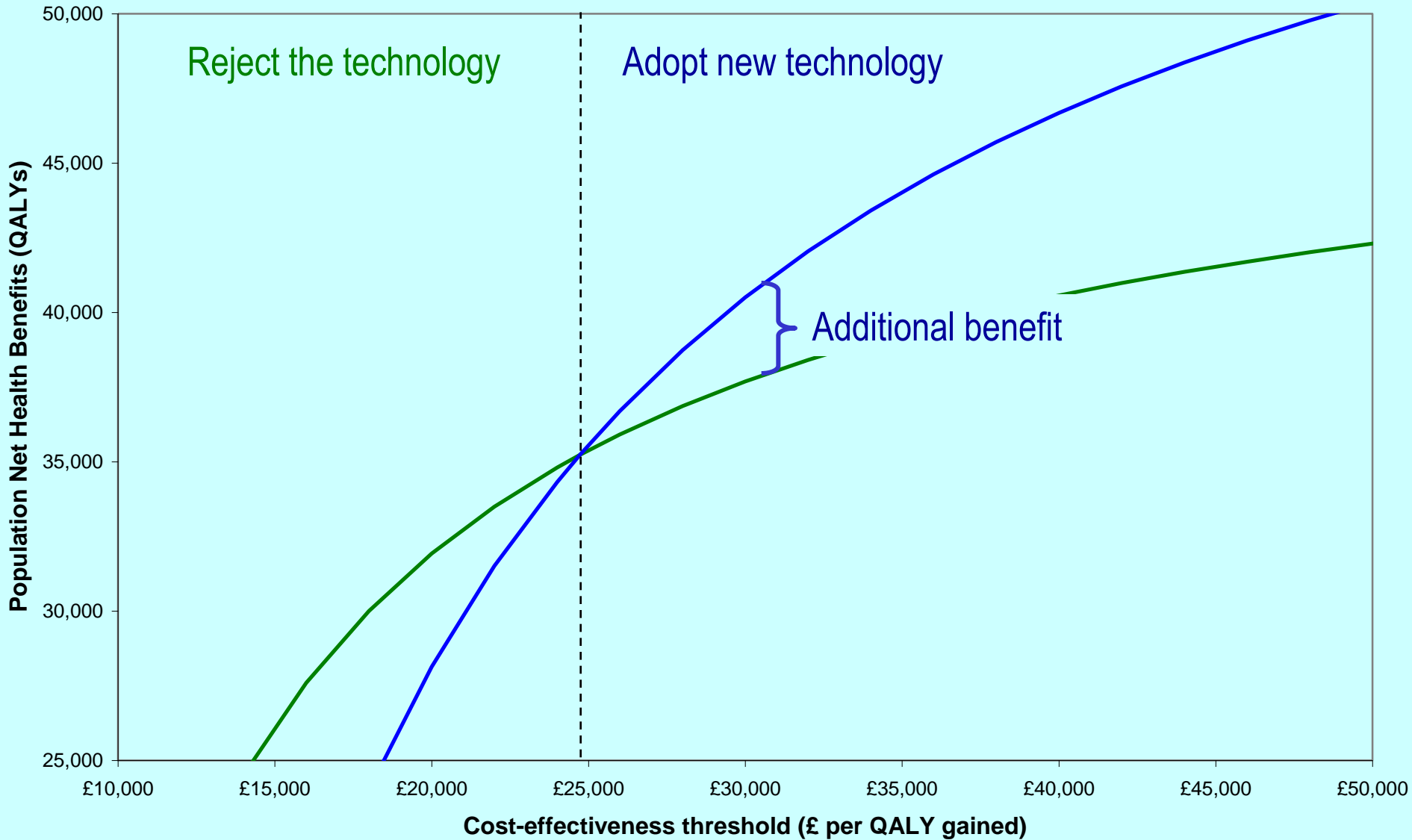
Could we do better?

If we knew

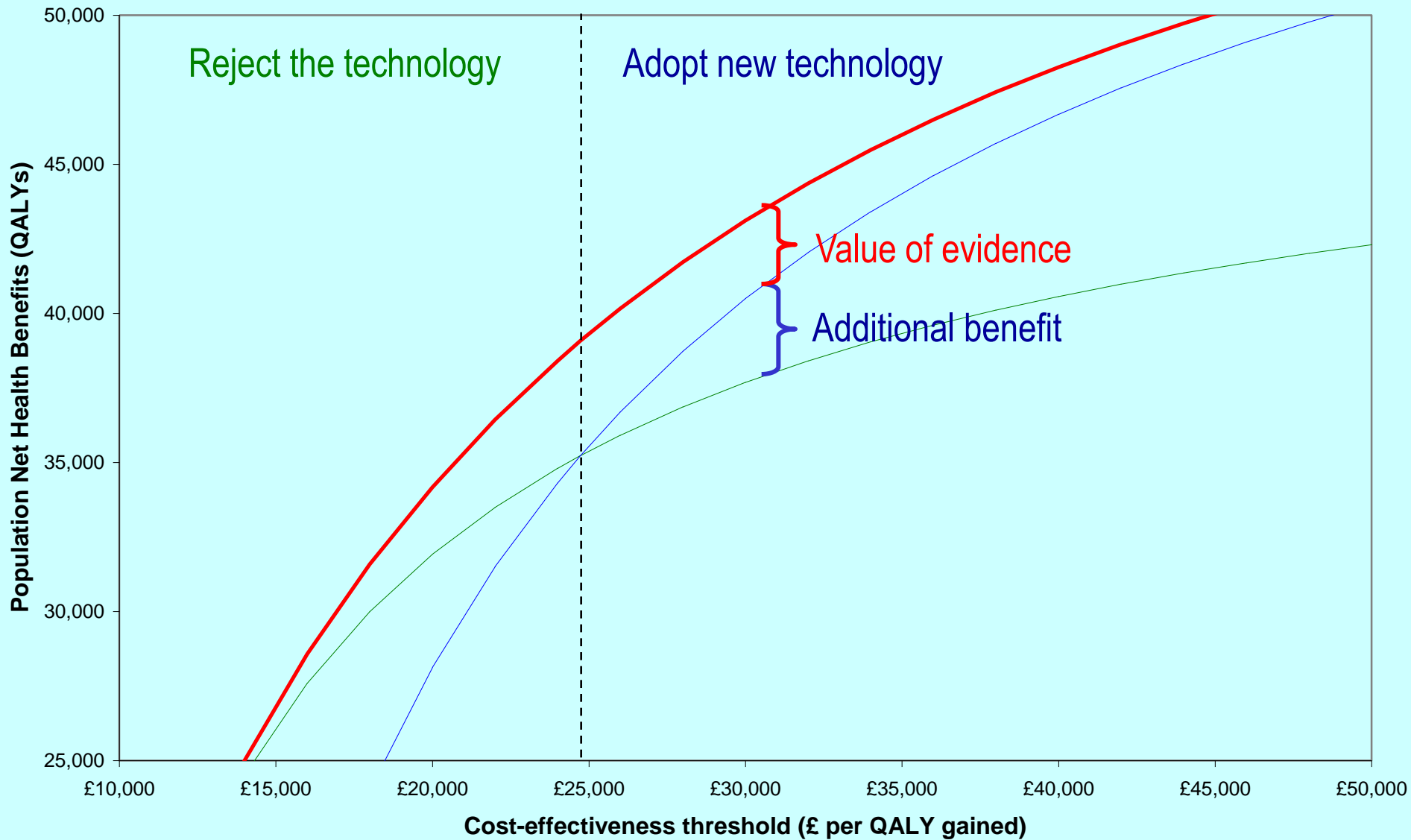
Expect 14 units

Maximum value of more evidence is 2 units per patient

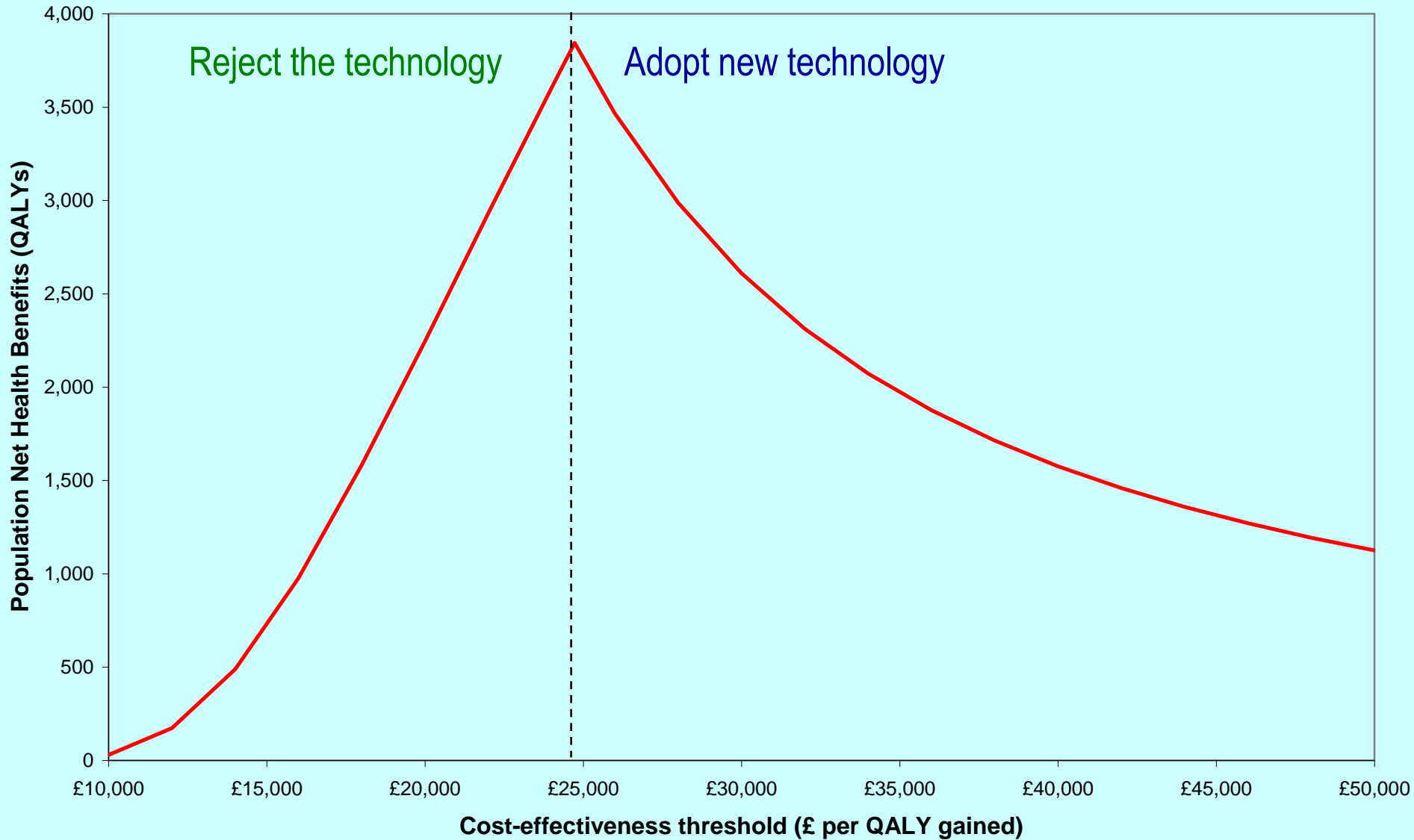
Adopt the new technology?



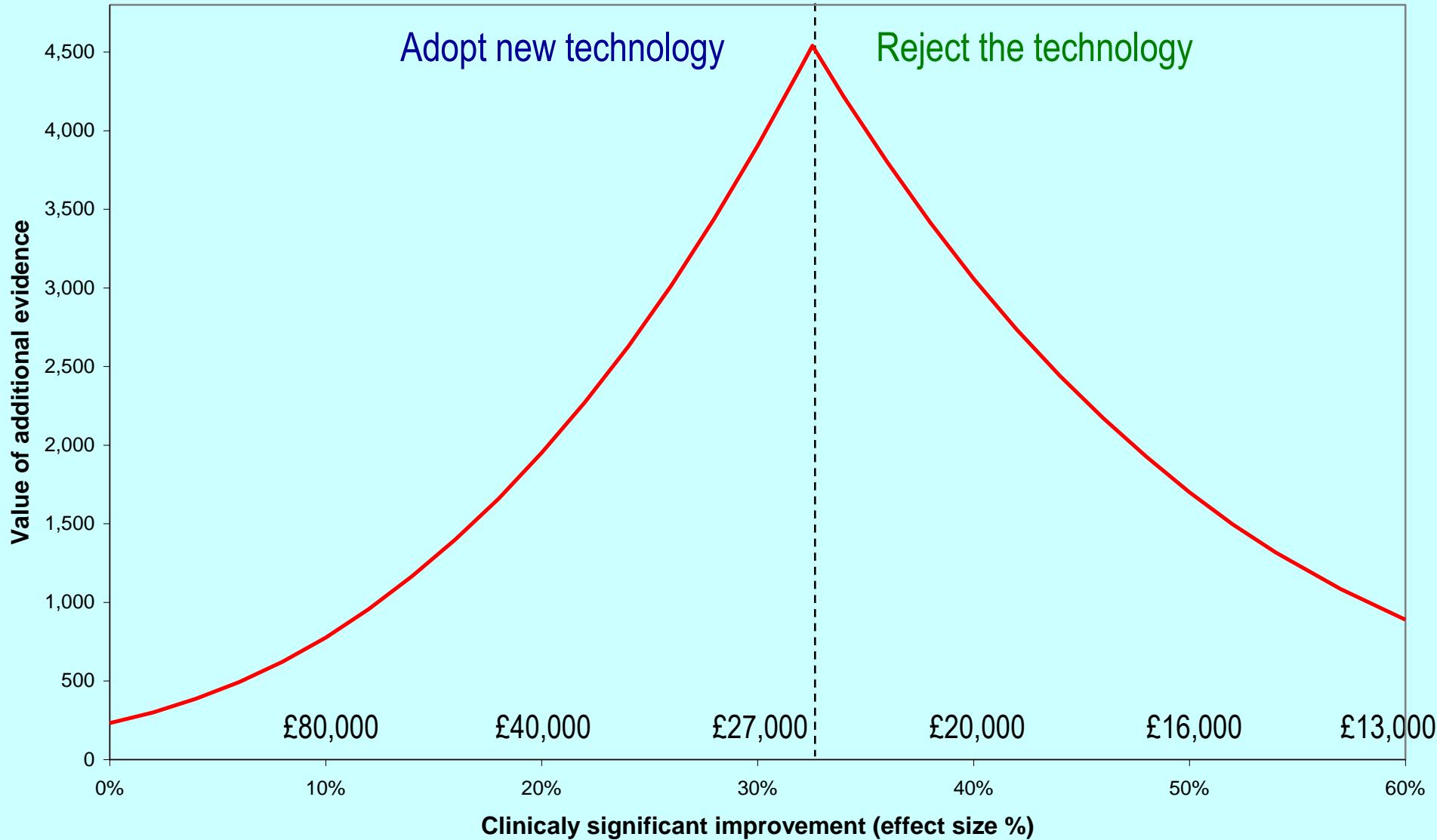
Value of additional evidence



Value of additional evidence



Is this only about cost-effectiveness?



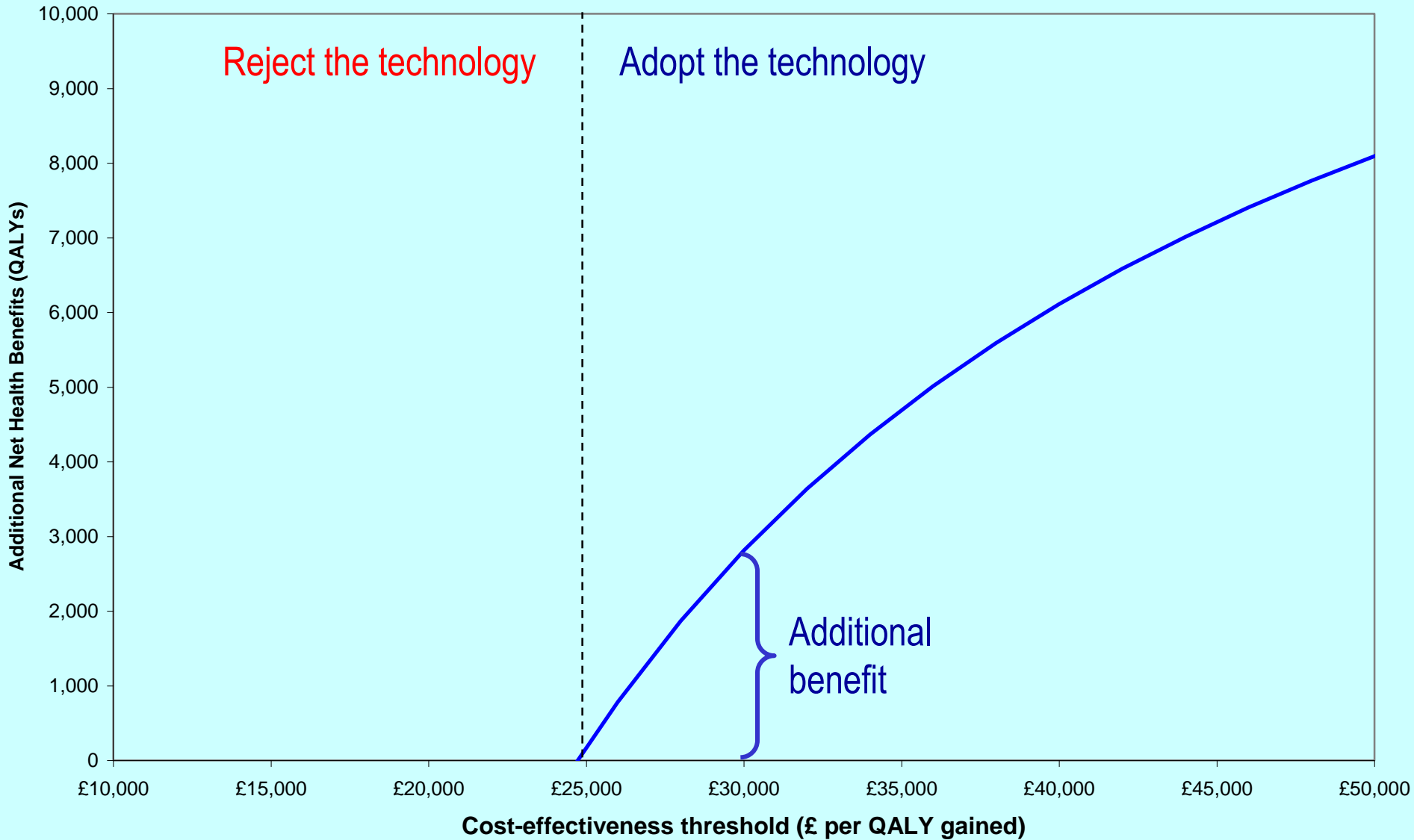
Coverage (guidance) with evidence?

- Questions to ask
 - Is additional evidence needed?
 - What type of evidence is needed?
 - Can this evidence be provided once approved?
- What type of research is possible?
 - Observational/registry
 - Experimental research generally not possible
- How and who should pay?
 - Sponsor
 - Promises to provide the evidence?
 - Public sector
 - Other more valuable priorities (without a sponsor)
 - Should account for research costs (price discount)
 - Price so additional research not needed

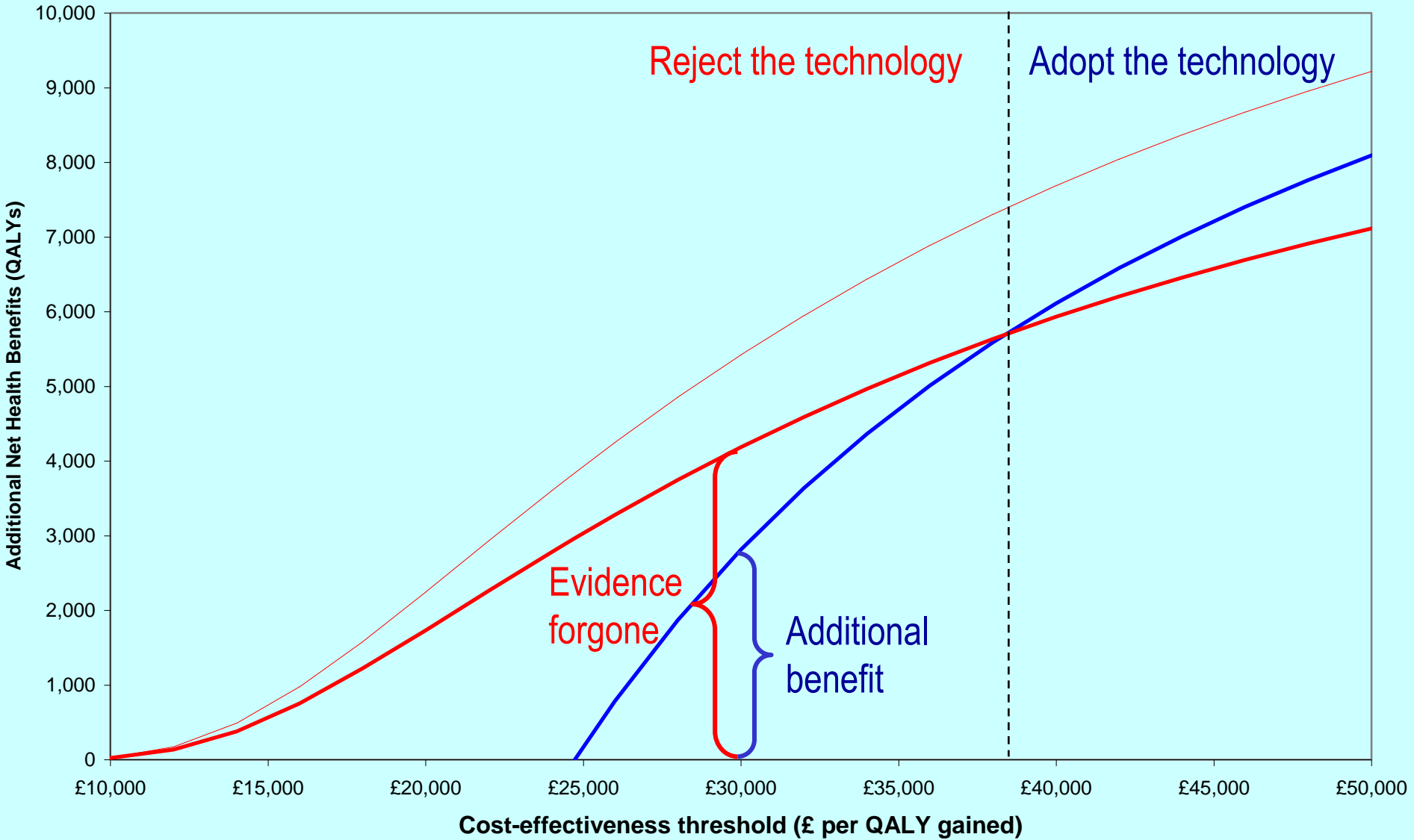
Coverage without evidence?

- Coverage with evidence not possible
 - Sponsor unwilling or unlikely to provide it
 - Type of research needed is not possible
- Early approval?
 - Net benefits of early access
 - Evidence base is least mature
- Impact on future research
 - Incentives for manufacturers
 - Ethics of experimental research
- Compare costs and benefits to all patients?
 - Benefit of access to the technology
 - Value of the evidence forgone

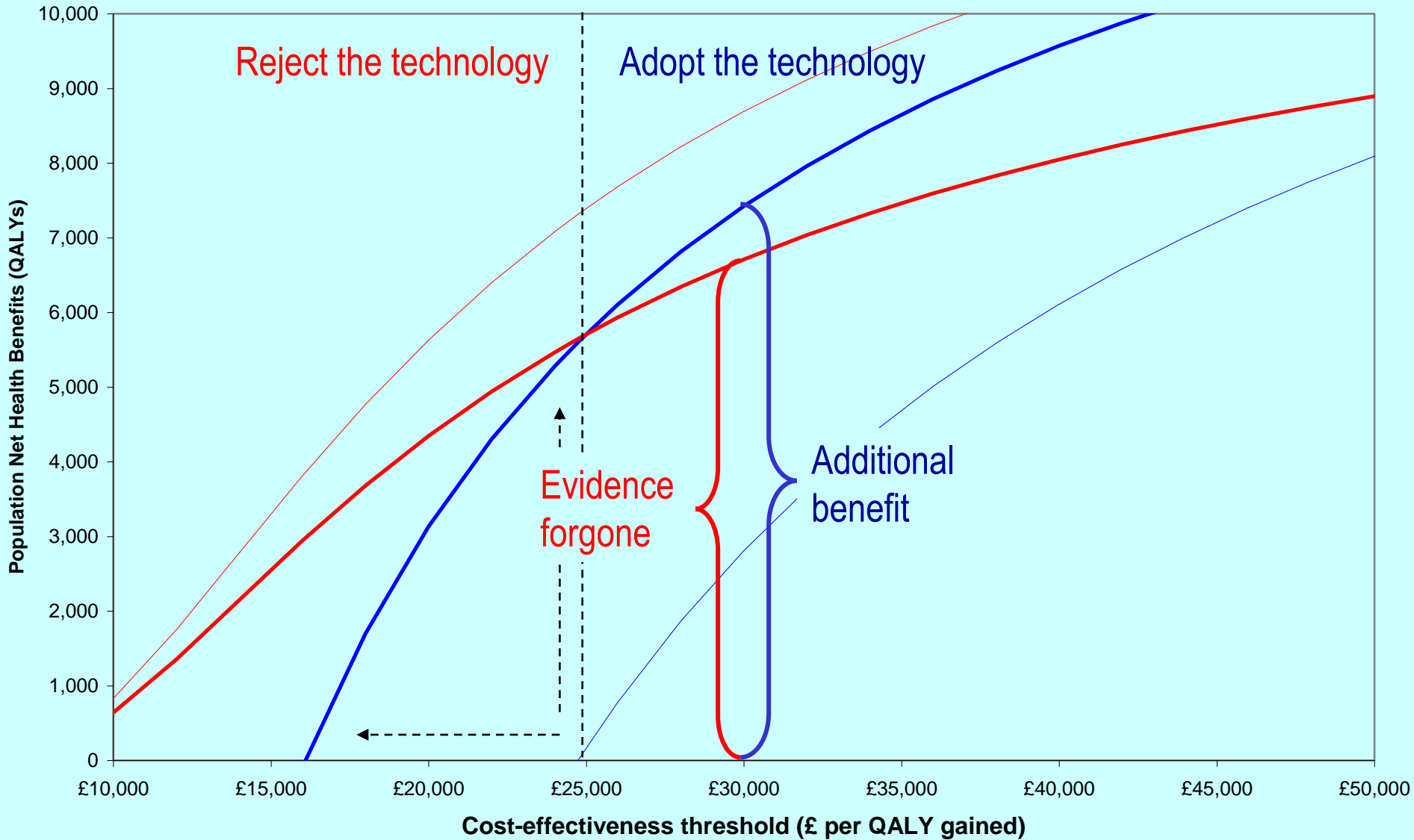
Benefits of early access



Value of evidence forgone



Price and evidence



What assessments are needed

- Are the benefits uncertain?
- Does the uncertainty matter?
 - Change the decision
- How much does it matter?
 - Impact on health benefit of changing the decision
 - For how many patients?
 - For how long?
- What type of research is needed?
- Can this be conducted with positive guidance?
- Are the benefits likely to exceed the costs
 - Direct resource costs
 - Costs of delay
 - More important than other research priorities

Simple to sophisticated methods

- Scenarios based on sensitivity analysis
 - Probability of each (explicit judgement)
 - Uncertainty, its consequences and EVI
- Analysis of clinical effectiveness
 - EVI directly from meta-analysis/synthesis
 - e.g., reanalysis of CRASH
- Full analysis
 - Synthesis and elicitation
 - Cost-effectiveness and uncertainty
 - EVPI, EVPPI, EVSI and research design
 - e.g., EECP and VAC

But are medical devices really that different?

- We can and do subject devices to the same assessments
 - Assessment of effectiveness, cost and uncertainty
 - Hip replacement and joint resurfacing, bi ventricular pacing, ICDs, stents, monitoring systems for diabetes, inhaler systems for childhood asthma, digital hearing aides, EVAR, IDET
 - Assessment of the value of evidence
 - Dressing systems for leg ulcers (EVPI), CPAP (EVPI), cochlear implants (EVPI), EECP (EVPI, and EVSI), Vacuum assisted closure (EVPI and EVSI)
- Surely the same assessments are needed?
 - Subject to the same principles and methods of assessment as any other technology or intervention
 - Account for the benefits of access and the net benefits of evidence

Keep it simple, transparent and efficient

- Adoption decision
 - Expected cost, effect, NHB and EVPI (in health)
 - Population EVPI (range of time horizons)
 - Is the EVPI is 'high'?
 - Report EVPPI for groups relevant to research designs
- Provide information about
 - Estimates of investment costs
 - On going research, planned research
 - Is there a price at which no further research is needed?
- Different scenarios
 - Iterative process or not?
 - The thing you didn't measure might be the most valuable

Keep it simple, transparent and efficient

- Research decision
 - Is it 'high' compared to other publicly funded claims?
 - Critically review the EVI analysis with clinical experts
 - Estimate opportunity cost of research
 - Are costs low and benefits high?
 - Commission now
 - Are costs high and benefits high?
 - Conduct commission EVSI for range of agreed designs
 - Iterative process with experts
 - Is research the *only* way to change practice?
 - Include the value of implementation