



Methods for Health Technology Assessment of Medical Devices: a European Perspective

Work Package 4: Cost-Effectiveness Work Package 5: Uncertainty and Value of Information analysis

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What is cost-effectiveness?

New technologies

- -Health gained
- -Additional Cost

Resource constrained health care system

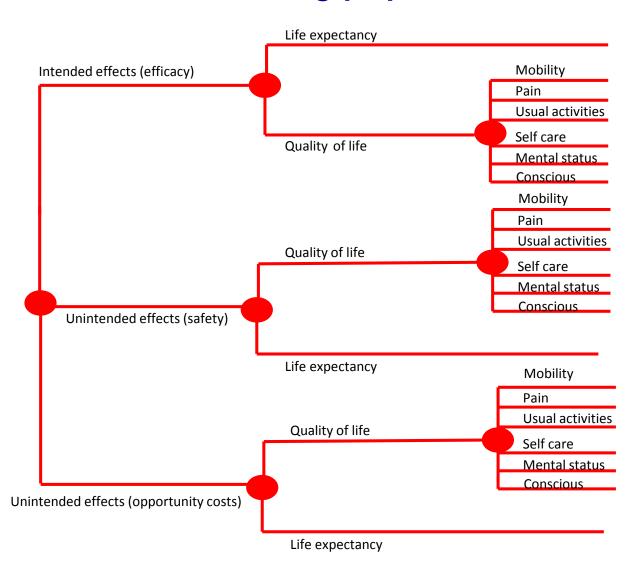
Displaced services

- -Health forgone
- -Resources released
- Therapeutics
- Diagnostics
- Care
- Service and delivery

Is the health gain from the new treatment greater than the health foregone through displacement (opportunity costs)?



Estimating population health effects





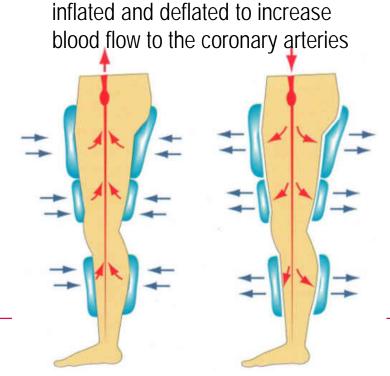
Case study: EECP for chronic stable angina

- ➤ Enhanced external counterpulsation (EECP) is a non-invasive procedure used to treat chronic stable angina
- Primary outcome is the symptomatic relief of angina symptoms
- EECP has large initial upfront costs of treatment (£4,347 per patient), which are

irrecoverable once treated

➤ EECP as adjunct to standard therapy vs. standard therapy alone

- ➤ One RCT showed evidence of improved HRQoL at 12 months
- Uncertain whether HRQoL benefits are sustained beyond 12 months



Long inflatable pressure cuffs are



Is EECP expected to be cost-effective?

> Assessment of effectiveness, potential for harm and costs over a patient time horizon

EECP:

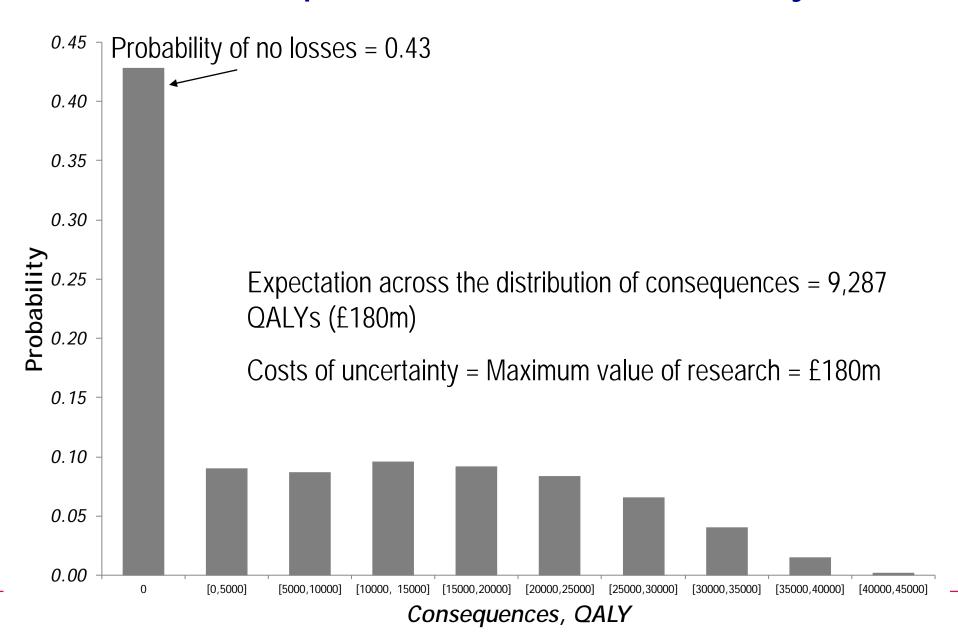
Prevalent population, 110,000

Future incidence, 9,500 per annum

Expected co	ost-effective	ness at popu	Cost-effectiveness threshold at £20,000 per QALY		
Treatment	Costs (£m)	QALY	ICER (£/QALY)	NHE QALYs	Incremental NHE QALY
EECP	896	1,435,787	£19,391	1,391,001	1,405
Standard	-	1,389,596		1,389,596	



Extent and consequences of evidential uncertainty



Framework for characterising uncertainty

Assessments

Decision options

Expected cost-effectiveness

- Cost-effectiveness based on existing evidence
- Is health gained > health forgone elsewhere?

Evidential uncertainty

- Parameter uncertainty
- Learning curve effects
- Incremental device innovation
- Significant investment or irrecoverable costs

Decision uncertainty

- Risk of funding wrong decision
- Adverse consequences on health outcomes

Further research to reduce consequences of uncertainty

- Value of further research
- Type and design of research
- Likelihood research is conducted
- Costs of conducting research
- Time taken for research to report

Incentivising research

- Who pays for research?
- Value of research to manufacturer
- Value of research to health sector
- Value of early access to manufacturer

Future changes

- Change in price of technology or comparators
- Incremental or new technological innovation
- Other changes expected over time

Coverage decision

- Is research possible with early access?
- Are benefits of approval > opportunity costs?
- Value of research forgone by early access
- Opportunity cost of reversing decision

Rejection

- restricts access to promising new technology

vs.

Approval

- impacts on the prospects of acquiring research to resolve uncertainty

vs.

Only in research (OIR)

- restricts access until further research establishes value

vs.

Approval with research (AWR)

- may result in subsequent withdrawal when further research is completed



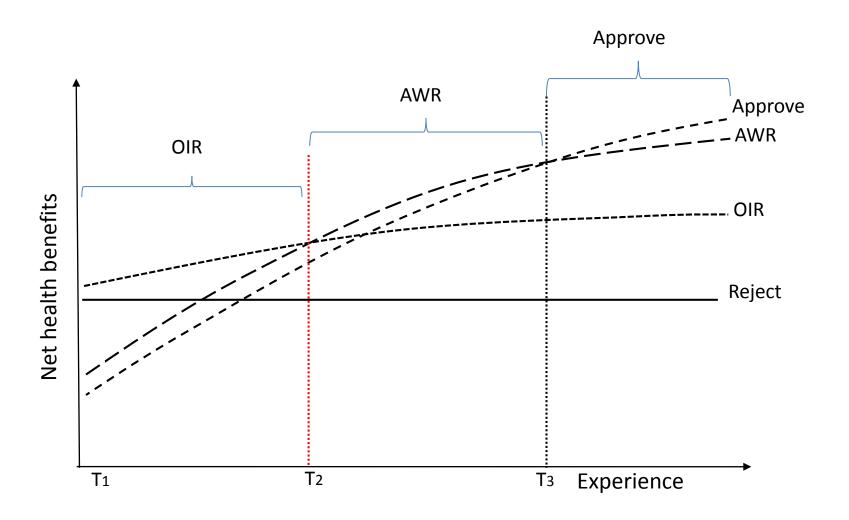


Comparing decision options for EECP

						Uncertainty	Value of				
EECP	Approvo	OIR	AWR	Reject	Value of	resolved	evidence				
EEGP	Approve	OIK	AWK	Reject	AWR	at launch	at launch				
Expressed in QALY											
T=3	1,391,001	1,397,192	1,393,578	1,389,596	-3,614	1,400,288	3,096				
T=7	1,391,001	1,393,608	1,392,030	1,389,596	-1,578	1,400,288	6,680				

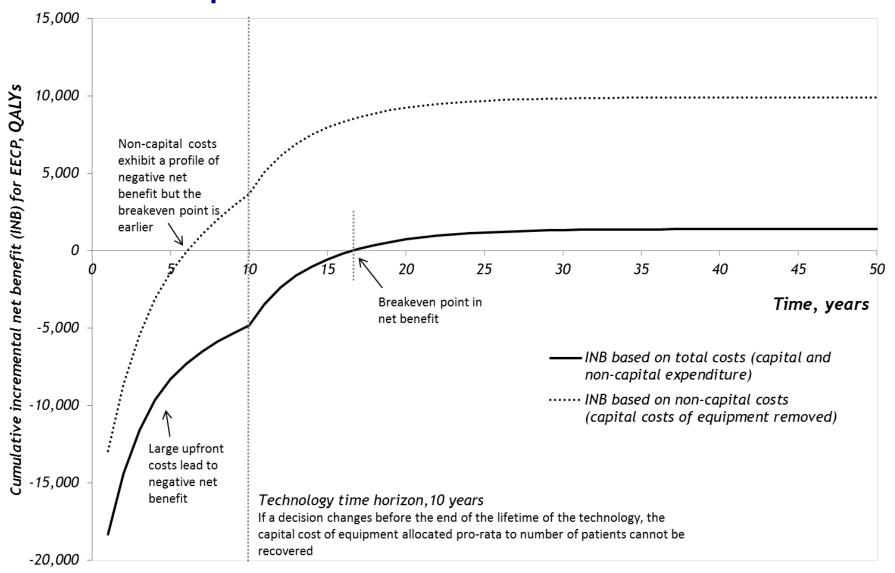


Implications of learning curve on coverage decisions



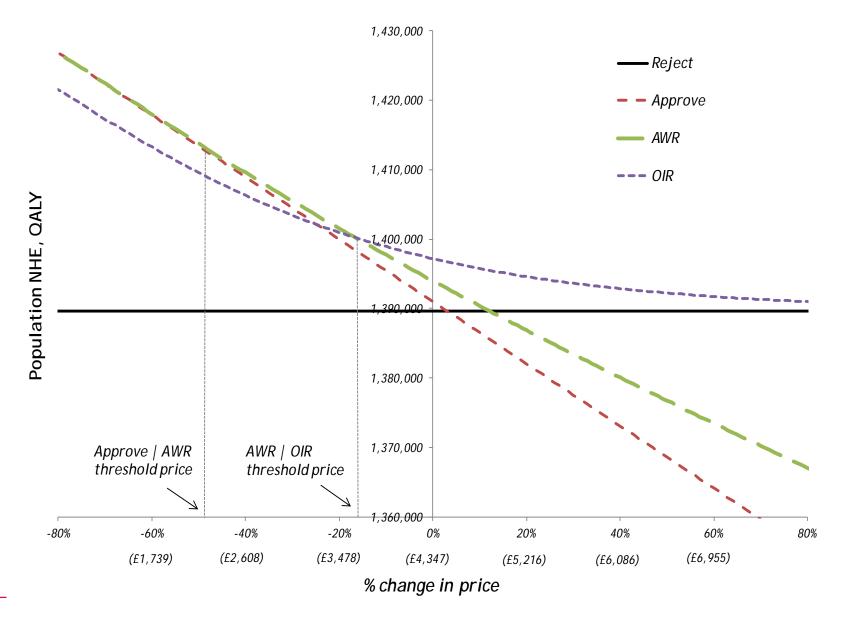


Investment profile for EECP





Price thresholds for EECP





Conclusions

- Value = cost-effectiveness = maximising population health
- Evidential uncertainty => decision uncertainty => population health loss
- Need to assess the value of research and policies most suitable to result in valuable research
- Key features of devices need to be factored into these assessments