Quantification Of Lifecycle Value using Early Modelling to Support R&D & Strategy Decisions: A Case Study of a Polymeric Heart Valve

EE624

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BACKGROUND

Decisions about investment in research and development activities and pricing can be optimised for manufacturers by considering that funding and uptake of new technologies by health systems depends on clinical and economic value to health systems and on uncertainty over this value.

A novel heart valve for aortic position made from **styrene-*block*-ethylene/butylene-*block*-styrene copolymers** (SEBS) is in development. The valve is expected to improve patient mortality, reoperation, and symptomatic disease outcomes while being significantly cheaper to produce than its bioprosthetic valve comparators.

OBJECTIVES

- Estimate the SEBS valve's lifecycle value
- Examine maximum investment costs for the manufacturer under alternative scenarios for product and evidence development
- Examine alternative health system policy levers to reduce uncertainty and maximize value

METHODS

- Early decision modelling: estimate clinical and economic value
- Structured Expert Elicitation (SEE) of relative treatment effects
- Lifecycle value calculations: using cost-effectiveness and value of information analysis

METHODS FOR LIFECYCLE VALUE CALCULATIONS

- **Payoffs** – calculated from early decision model :
  - Manufacturer: Profit per unit sold, from calculations of Value Based Price (Figure 1) or price at which there is no decision uncertainty minus manufacturer's costs
  - Health system: Expected Net Health Benefit, under different scenarios of uncertainty and pricing $Net Health Benefit (NHB) = \Delta QALYs - (\Delta Costs/k)$, k=£20,000/QALY
- **Lifecycle value calculations**: apply payoffs to yearly patient cohorts
  - 20-year time horizon (10 years on-patent)
  - Discount Rates: Manufacturer 11%, Health System 3.5%
  - Research reports after 3 years
- Max R&D Cost: Present Value of total Profit(Benefit) discounted to 5 years prior, when development is assumed to begin

	HEALTH SYSTEM POLICY LEVERS	MANUFACTURER CHOICES
S1	DO NOT mandate perfect information to access market	Invest in perfect information prior to launch
S2		DO NOT invest in perfect information prior to launch. Launch with current information
S3	Mandate perfect information to access market. Negotiate price before research (with current information). Do not adjust price following report of research.	Negotiate price based on current information. Conduct research before accessing market. Not allowed to adjust price when research reports.
S4	Mandate perfect information to access market. Negotiate price following research	Conduct research before accessing market. Negotiate price when research reports.
S5	Allow market access with current information but mandate price cut such that there is no decision uncertainty. Allow price adjustment ***if*** manufacturer conducts research	Do not conduct further research. Market at reduced price for entire patent period.
S6		Market at reduced price while conducting further research. Renegotiate price when research reports

RESULTS

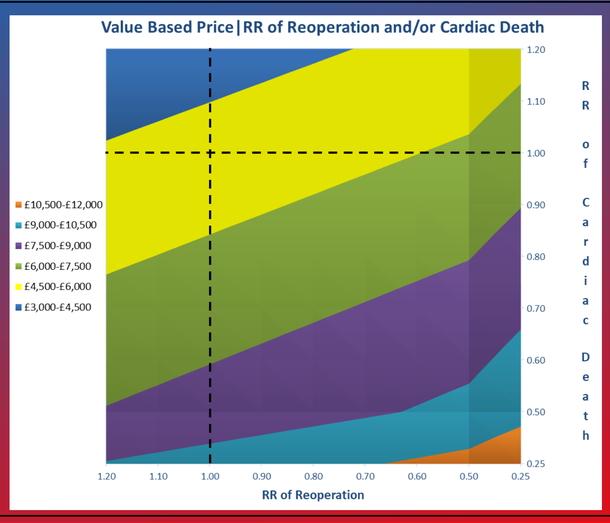

Figure 1 – Value-Based Price for alternative Relative Risks (RR) of reoperation and cardiac death

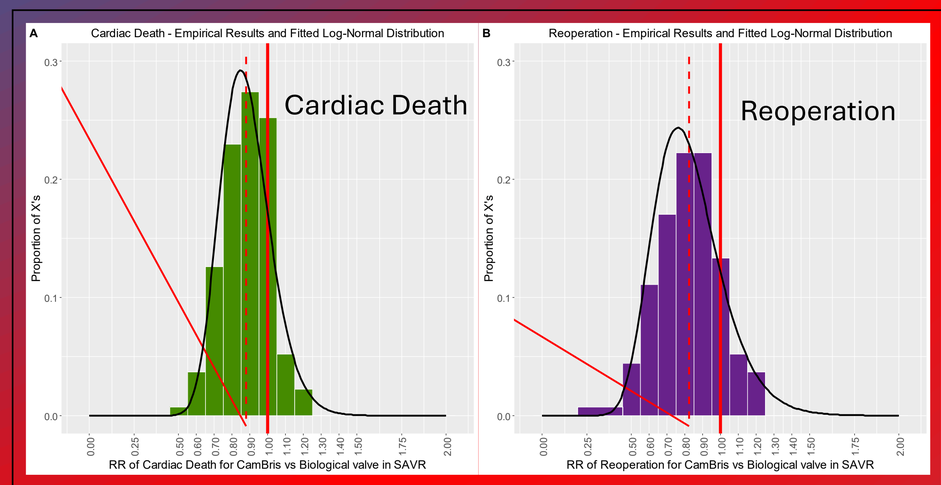

Figure 2 – Elicited distributions of RRs for cardiac death and reoperation

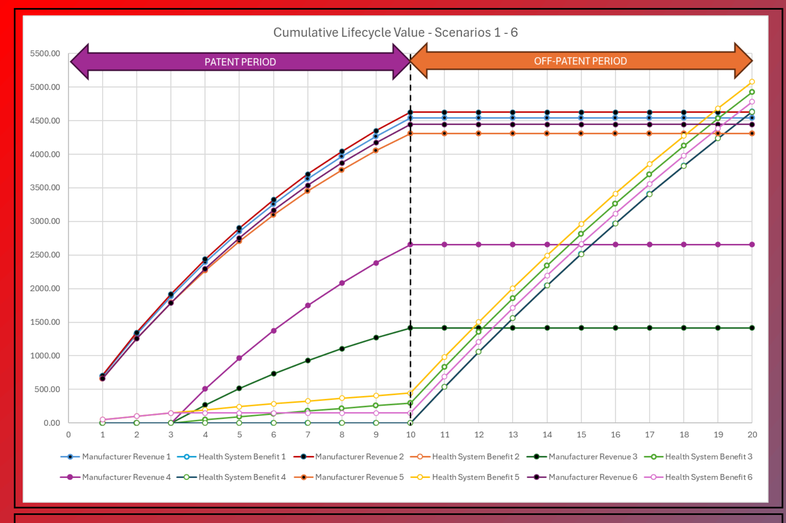

Figure 3 – Cumulative lifecycle value to the manufacturer and the health system

SUMMARY OF KEY RESULTS

Early decision modelling

The early decision model in conjunction with clinical advice provided the basis for understanding which prosthetic valve-influenced patient outcomes drive the most value. This is represented by the value-based price, the price at which the SEBS valve can be cost effective given its relative clinical effectiveness (Figure 1).

Structured Expert Elicitation

The expected relative clinical effectiveness of the SEBS valve compared to standard of care bioprosthetic valves given its in-vitro and in-vivo (juvenile sheep model) material safety results was elicited from clinical experts. The experts' combined responses for relative risk of cardiac death (mean - 0.88) and reoperation (mean - 0.82) are presented in Figure 2.

Lifecycle Value Case Study

If the manufacturer has a choice between launching with current information (S2) or perfect information (S1), then they choose S2. The manufacturer has no incentive to conduct further research before launch. The health system is indifferent as they receive the same benefit in the post-patent period in both S1&S2.

If the health system mandates perfect information for market access and it takes 3 years for research to report (S3&S4), lower manufacturer profit in S3&S4 compared to S1&S2 suggests that manufacturers have no incentive to conduct further research post launch whether they can adjust prices following research(S4) or not(S3). The low manufacturer profit in these scenarios results in significantly lower ceilings for R&D costs. The health system receives at least as much benefit in S3&S4 as in S1&S2.

If the health system allows market access at a reduced price when the manufacturer launches with current information but allows price adjustment *if* manufacturer conducts further research (S5&S6), the manufacturer is better off conducting the research (S6). The health system benefits most in S5&S6 due to the reduced price until research reports coupled with the maximum market access period.

PAYOFFS		MANUFACTURER PROFIT	HEALTH SYSTEM BENEFIT
SCENARIO 1	Patent	0.2683	0.0000
	Off-Patent	0.0000	0.2737
SCENARIO 2	Patent	0.2737	0.0000
	Off-Patent	0.0000	0.2737
SCENARIO 3	Patent	0.1429	0.0187
	Off-Patent	0.0000	0.2737
SCENARIO 4	Patent	0.2683	0.0000
	Off-Patent	0.0000	0.2737
SCENARIO 5	Patent	0.2550	0.0187
	Off-Patent	0.0000	0.2737
SCENARIO 6	Patent	0.2550 ; 0.2683	0.0187 ; 0.0000
	Off-Patent	0.0000	0.2737

Table 1 – Payoffs for manufacturer and health system in patent- and off-patent periods by scenario

	MANUFACTURER PROFIT	HEALTH SYSTEM BENEFIT	MAX R&D COST MANUFACTURER
SCENARIO 1	4,537	4,633	£53,852,343
SCENARIO 2	4,627	4,633	£54,922,359
SCENARIO 3	1,413	4,928	£16,773,182
SCENARIO 4	2,655	4,633	£31,506,515
SCENARIO 5	4,312	5,078	£51,177,083
SCENARIO 6	4,444	4,783	£52,742,254
Expected Value	3,665	4,781	£43,495,623

Table 2 – Present value of total manufacturer profit and health system benefit over 20-year lifecycle of the SEBS valve in health units . Max R&D Costs are further discounted an assumed 5 years for product development.

CONCLUSIONS

Through early economic modelling, manufacturers can identify product improvements that maximize net value to the health system, and estimate maximum R&D costs which allow maximum expected profit given expected health system market access policy decisions. The health system can maximize benefits received through utilizing alternative market access policy levers.

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