Assessing the Socio-Economic Value of Medical Devices: The Case of Cardiac Care

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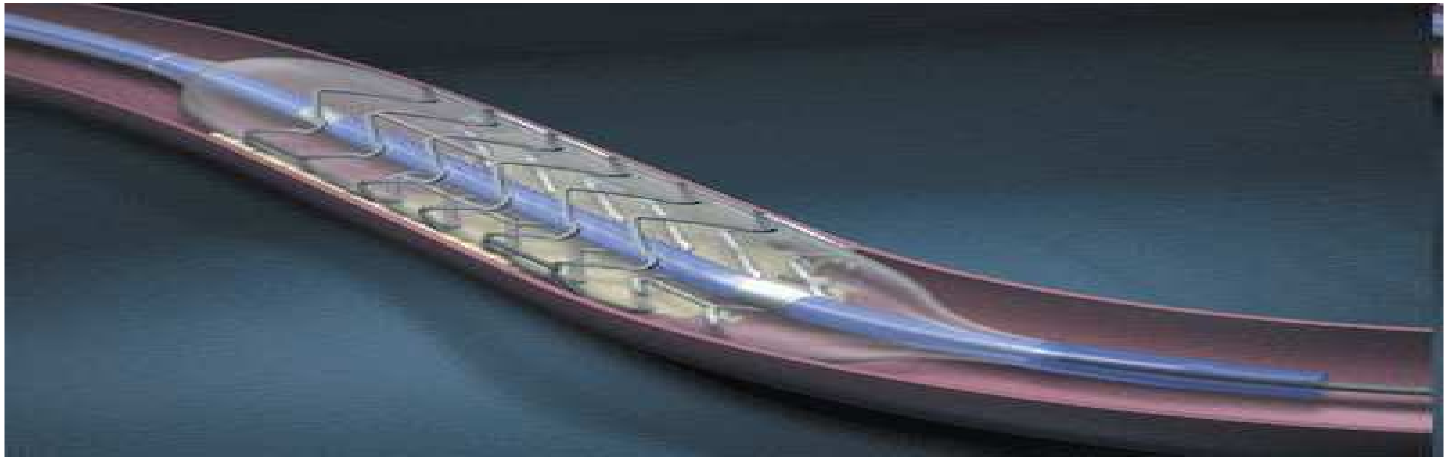
Background and Aims

Background

- Cardiovascular disease is a leading public health problem, associated with significant health, social and economic burden.
- Innovative medical technologies (e.g., stents, ICDs) introduced since the 1990s to treat cardiac conditions.
- However, minimal robust evidence exists on their socio-economic value and how such value is (or can be) ascertained.



Research Aims and Objectives

- Objective of research was to systematically evaluate the socio-economic value of medical technologies used in cardiac care.
- In particular, we sought to address four key questions:
  - How do these technologies impact various dimensions or measures of value – health outcomes, costs, productivity?
  - Under what circumstances do medical devices deliver maximum socio-economic value?
  - What are the methodological challenges in demonstrating such value?
  - In what primary ways do devices differ from medicines, and how can such variations be adequately taken into account in assessing value?

Provides value by contributing to an unexplored area of great interest to variety of stakeholders.

May contribute a framework for analysing value of MDs.

Methods

Methods – Search, Review, and Analysis

Systematic Literature Review

Review broadly followed the York Centre for Reviews and Dissemination (CRD) guidelines.

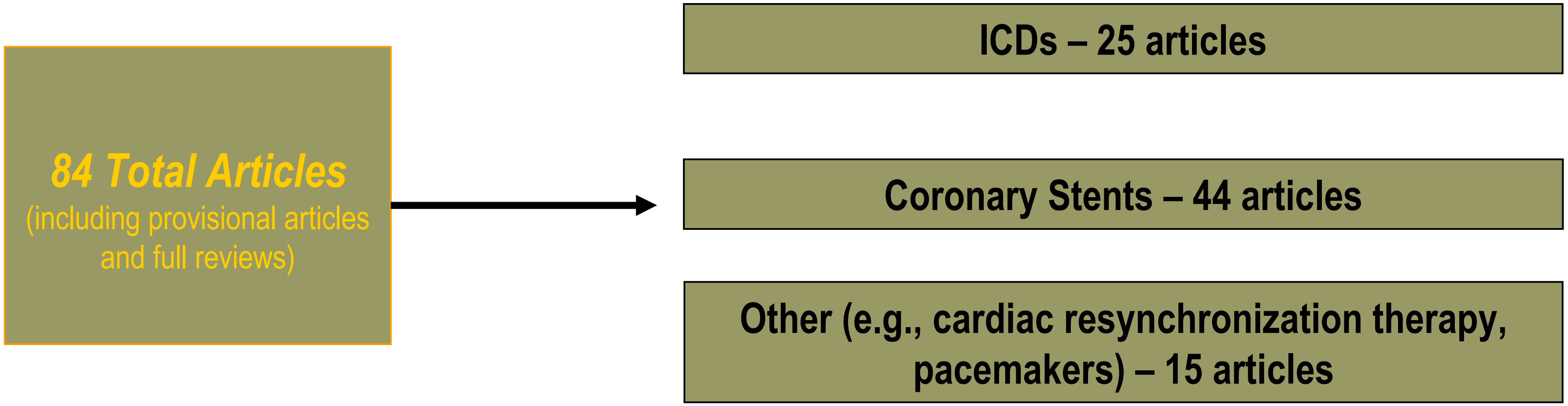
Search sources and strategy: Comprehensive inclusion of health and social science databases (e.g., MEDLINE, EMBASE, CINAHL, TRIP, NHS HEED, PsychInfo, Scopus). Grey literature also explored. Search terms for condition, intervention(s), outcome measures, and study type.

For this stage of the analysis, decided to focus on all economic evaluations published in NHS EED.

Data extraction and collection: Standardized template generated to guide the key information to be gleaned from each article (e.g., study aims, study population, methods, outcomes, etc.).

Data synthesis: Data analyzed across the four research domains.

Methods – Sketch of Selected Articles



Results

Overview of the Evidence

- Majority of studies:
  - Published in early to mid-2000s, with much of the data used in the analyses coming from the mid- to late 1990s.
  - Conducted from a payer or hospital/health service perspective; only 8 used a societal perspective.
  - Based in a hospital or other secondary care setting.
  - Funded by industry, followed by governmental bodies (where a sponsor was explicitly specified).

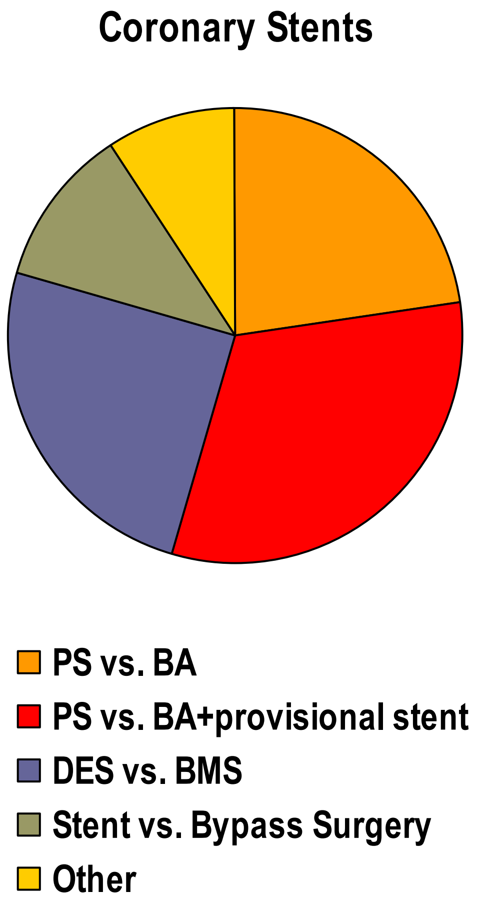
How is Value Measured?

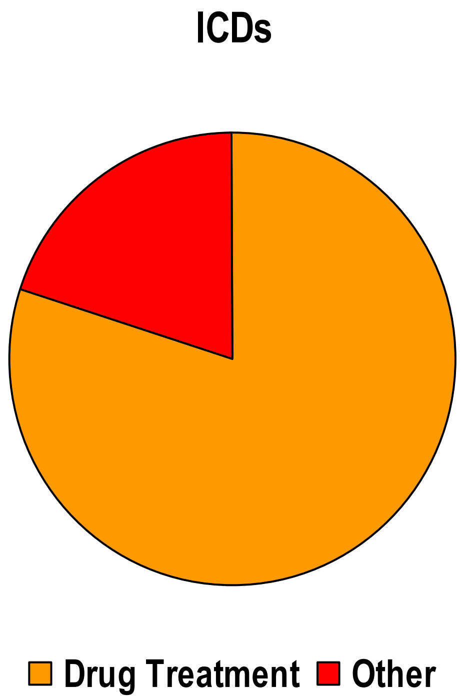
Type of Study

Type of Technology	Cost-Effectiveness Analyses				Review of Economic Studies
	CEA	CCA	CMA	CUA	
ICDs	14	1	1	5	4
Stents	26	7	3	6	2
Other	12	0	0	0	3

CEA analysis most frequently used to assess costs and benefits of cardiology technologies.

Comparator Interventions





Outcome Measures

- Multiple endpoints used to characterize value.
- Primary health outcomes included:
  - Mortality
  - Event-free survival (MI, revascularization, restenosis, repeat procedures, arrhythmia)
  - Complications (vascular, associated with cardioversion)
  - LOS
  - Frequency of replacement (in case of ICDs)
- Direct costs most often assessed (procedure, hospital, professional, and follow-up costs).
  - Limited number of studies examined long-term or lifetime costs.
  - Only one study included indirect costs.
- Summary measures used to combine costs and benefits:
  - Cost per additional MACE-free survivor, cost per revascularization avoided, cost per life year saved, cost per life year gained, cost per QALY.
  - Cost per QALY more frequently used in ICD studies.

How do these technologies impact various dimensions or measures of value?

Effectiveness

- Significant reductions in mortality.
  - ICD implantation led to a 13%-67% reduction; LE between 1.4 and 8.3 yrs vs. 2.7 and 5 yrs for drug treatment.
  - Additional LYs: 0.21-6.21.
- Improved event-free survival and adverse event/complication rates with technological innovation.
  - Average EFS: 85-88% (stents), 80-85% (BA+provisional stents), 60-65% (BA).
  - Revascularization rates: 8-15% (stents), 15-40% (BA); Compared to BMS, use of DES reduced RR by 30-60% at 12 months.
  - Restenosis: 17-20% (stents), 25-35% (BA+provisional stents), 45-50% (BA).
  - MACE: 8-10% (stents), 28-35% (BA); MACE lower in patients treated with DES (5-7%).
- Similar improvements were seen in reduced procedure times, hospital stays, and readmission rates.

Costs

Note to Eucomed: Figures are preliminary ranges. Need to re-confirm these are base case figures and adjust currency/year of values.

Cost Measure	[illegible]	[illegible]	[illegible]prov	BA
Initial cost of i[illegible]				
Initial [illegible]				
Average [illegible] costs	NA	$1,165-$9,055	$954-$4,500	$1,208-$3,000
Average follow-up costs	NA	$3,613-$8,048	$4,492-$10,300	NA
Total Costs	$22,000-$101,000	$13,800-$49,000 $3,542-$11,027 (pp)	$12,914-$20,000	$22,571-$40,683 $3,136-$14,713 (pp)
Lifetime Costs	$122,950-$147,000			

- Cost estimates highly variable, depending on technology, comparator, patient population, time horizon, costing methodology, etc.
- Initial (hosp. and procedure) costs often higher for newer technology (e.g., DES vs. BMS, Stenting vs. BA), but total costs are fairly comparable and, in some cases, lower.
  - Higher initial costs often recouped during follow-up period due to reduced revascularization.
- Cost of device often deemed as cost-driver.

Cost-Effectiveness

Note to Eucomed: Figures are preliminary ranges. Need to re-confirm these are base case figures, provide an average estimate with range (high-low estimates), and adjust currency/year of values.

CE Measure	[illegible]	[illegible]	[illegible]	[illegible]S vs. BA
Cost per LY G[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Cost p[illegible]	[illegible]	[illegible]		
Cost pe[illegible]	[illegible]-$235,000	$27,540-$261,000		
Cost per R[illegible]vasc Avoided	NA	$1,650-$23,067	$10,550	
Cost per MACE-free survivor (1 yr)				$962-$2,083

- Mixed results around cost-effectiveness of ICDs.
- Overall, evidence suggests that various stenting strategies provide good value for money, as compared to other accepted interventions.
- In both cases, CE often depended on use in certain patient populations.

Under what circumstances do cardiac medical devices deliver maximum value?

Sensitivity and Subgroup Analyses

- Parameters with greatest impact on results:
  - Stenting studies: cost of initial procedures, degree of patient risk, number of stents used, patient age, comorbidities (i.e., diabetes), revascularization and restenosis rates.
  - ICDs: Efficacy of device in reducing mortality, cost of ICD, frequency of replacement, patient age, function status (i.e., left ventricular ejection fraction) and time horizon.
- Increased CE under following circumstances:
  - In high-risk patients (vessel diameters <=2.5mm, lesion lengths >20mm, <=0.30 EF, diabetes, multivessel disease, previous history, older).
  - Fewer stents used.
  - In case of ICDs, if reductions in mortality lasted for 7 yrs or more; replacement not needed before 5-7 yrs.
  - Cost of device lowered below certain threshold.

What are the methodological challenges in demonstrating value?

Several Methodological Challenges Exist

- Most common limitations included:
  - Small patient sample
  - Short time horizon
  - Uncertainty or differences around data parameters
- Lack of randomization and long-term cost/effectiveness data, exclusion of all relevant endpoints, and limitations to study patient populations also issues.
- Costing methods not always robust and transparent.
- A few studies noted difficulty in adequately capturing the technology's value, given ongoing, iterative development.

Conclusions

Current Evidence Substantiates Value of Cardiac Devices, But More Research is Needed

- Medical technology innovation in cardiology brings significant benefits to patients.
  - Potential to save lives; reduce adverse events, complications, and repeat procedures; and, shorten time in hospital….
  - …under certain circumstances, at reduced costs.
- However, additional research is need to address the limitations of existing evidence and to fully measure the value of medical devices across a variety of perspectives – health care system, patients, payer, etc.
- In particular, more evidence is required on:
  - Longer-term cost and economic outcomes.
  - Indirect costs and benefits and patient perspectives on treatment.
  - Patient subgroups who would most benefit to improve treatment decision-making.
  - Impact on patient and carer QoL.
- Are there necessary incentives in place to obtain this evidence??

Next Steps

Subsequent To Dos

- Initial review of results – need to further refine and substantiate.
- Replicate methodology for orthopaedic devices.
- Address fourth area of inquiry – deepening understanding of devices vs. drugs in assessing value.
  - Will build upon current review(s) and recent conceptual work of Drummond et al. (2009).
  - Devise case studies to assess and illuminate if and how devices differ and potential methodological implications.

Many thanks!

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