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ORIGINAL RESEARCH ARTICLE

Are Medical Devices Cost-Effective?

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Abstract

Objective Medical devices can offer important therapeutic advances but, as for any medical interventions, there are questions about their costs and benefits. We examined health benefits and costs for pre-market approved (PMA) devices approved by the US Food and Drug Administration (FDA) (1999–2015), grouping them by generic category (e.g., drug-eluting stents) and indication.

Methods We searched PubMed for incremental health gain estimates [measured in quality-adjusted life-years (QALYs)] and incremental costs for each device category compared to previously available treatments. We calculated incremental cost-effectiveness ratios by dividing the average incremental costs by the average incremental QALY gains. In sensitivity analysis, we repeated the analysis when excluding industry-funded studies.

Results We identified at least one relevant cost-utility or comparative-effectiveness study for 88 devices (15.9% of non-cosmetic devices approved from 1999 to 2015), and at least one device across 53 (26.2%) generic categories. The median (mean) incremental cost across generic device categories was $1701 ($13,320). The median (mean) incremental health gain across generic device categories was 0.13 (0.46) QALYs. We found that cost-effectiveness ratios for 36 of 53 (68%) and 43 of 53 (81%) device categories fell below (were more favorable than) $50,000 and $150,000 per QALY, respectively. Results were roughly similar when we excluded industry-funded studies.

Conclusions We found that roughly one-quarter of the major PMA medical device categories have published cost-effectiveness evidence accessible through a large, publicly available database. Available evidence suggests that devices generally offer good value, as judged relative to established cost-effectiveness benchmarks.

1 Introduction

Medical devices can offer important advancements in the prevention, diagnosis, monitoring, and treatment of a range of conditions, including cardiovascular, orthopedic, and gastroenterologic diseases. This study examines the value offered by devices across a range of conditions.

One prior study found that the economic benefits of medical devices for heart disease, colorectal cancer, diabetes, and musculoskeletal disease exceed their costs [1]. Many others have examined the value of individual devices [2–4]. Here, we take an alternative approach by grouping devices together in US Food and Drug Administration (FDA)-defined generic categories (e.g., drug-eluting stents, implantable cardio defibrillators, etc.), and then examining the value of each group.

Key Points for Decision Makers

Prior research has estimated that the economic benefits of medical devices for heart disease, colorectal cancer, diabetes, and musculoskeletal disease exceed their costs. Many other studies have examined the value of individual devices.

We take an alternative approach by grouping pre-market authorized medical devices together in FDA-defined generic categories (e.g., drug-eluting stents, implantable cardio defibrillators, etc.), and then examining the cost-effectiveness of each group.

This paper has two principal insights. First, only roughly one-quarter of the major PMA medical device categories have published cost-effectiveness evidence. Second, our study suggests that devices in these categories generally offer good value relative to established cost-effectiveness benchmarks.

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We focused on premarket approved (PMA) medical devices, which "support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury" [5]. We used the quality-adjusted life-year (QALY) as our health-benefit measure because it accounts for both survival and quality of life, and hence facilitates the comparison of devices indicated for different diseases. Researchers often use QALYs in cost-effectiveness analyses to calculate an intervention's incremental cost-effectiveness ratio (ICER). One QALY represents a year of life in perfect health, or a combination of improved quality of life and life extension that has the same value as a year of life in perfect health. The cost-per-QALY ICER is a commonly used metric of economic value that represents the amount of additional spending on an intervention that produces one QALY of additional health in the population [6].

Health technology assessment agencies in various countries use cost-per-QALY ICERs to characterize the value of new and existing healthcare interventions. These agencies may designate interventions to be favorably cost-effective if their ICERs fall below—i.e., are more favorable than—established benchmarks (e.g., interventions that cost less than $50,000 per QALY gained [7]).

We identified incremental health gain, costs, and cost-effectiveness estimates for major PMA generic device categories for devices first approved by the FDA from 1999 through 2015, relative to existing treatments, and compared these ICERs to established value benchmarks (e.g., $50,000 per QALY).

2 Study Data and Methods

We used the generic name FDA assigns to each PMA device to define our major categories and then assigned devices to each group. For example, we grouped different brands of cervical disc prostheses (FDA generic category, "Prosthesis, Intervertebral Disc"), for instance, the Prestige Cervical Disc System (Medtronic Sofamor Danek) and the Mobi-C Cervical Disc Prosthesis (LDR Spine, USA). We further grouped devices with respect to their indicated disease categories, as identified by the FDA advisory committee that reviewed the PMA application (e.g., cardiovascular, orthopedic, and so on).

2.1 Search Strategy and Data

We used the FDA website to identify PMA devices approved from 1999 through 2015 [5]. We excluded cosmetic devices (e.g., breast and dermal implants). Next, we searched a single medical literature database (PubMed) to identify estimates of incremental QALY gains and costs for these PMA devices [8]. Two researchers searched for cost-effectiveness and comparative-effectiveness studies that quantified benefits in terms of QALYs. This search included the FDA generic category for each device and the search phrase "quality-adjusted life year OR QALY". We performed additional searches that included PMA device brand names. For example, for the Cypher Sirolimus-eluting Coronary Stent, we first used the search terms "Coronary Drug-Eluting Stent" AND (qaly OR "quality-adjusted life-year"); second, we used the search terms Cypher AND "Drug-Eluting Stent" AND (qaly OR "quality-adjusted life-year"). We limited our search to studies involving human participants and published in English. Our searches took place in July 2018.

Studies satisfied inclusion criteria if they: evaluated a PMA device approved from 1999 through 2015; included an incremental QALY gain estimate; and compared the device to interventions available at the time the device received FDA approval. Hence, we excluded studies that compared devices to treatments that became available only after FDA approved the device. For example, if the FDA approved a device in 2012, we excluded studies that compared it to treatments FDA approved after 2012. We also excluded studies that compared devices to placebo, or no treatment, if it was apparent that an alternative treatment was available at the time the device received FDA approval.

For studies that compared devices to multiple treatments, we chose as the comparator the most effective alternative approved before the device of interest received approval. For example, in their study evaluating treatments for secondary stroke prevention, Reddy and colleagues [9] compared left atrial appendage closure (LAAC) (first approved in 2015, 6.09 QALYs) [10] to warfarin (1954, 5.66 QALYs), dabigatran (2010, 5.84 QALYs), and apixaban (2012, 5.82 QALYs). Because dabigatran was the most effective treatment available before the approval of LAAC, we estimated the incremental QALY gain for LAAC to be $6.09 - 5.84 = 0.25$ QALYs. Finally, we classified each cost-effectiveness and comparative-effectiveness study as industry-funded, non-industry funded, or unfunded.

We created a dataset of incremental QALY and incremental cost estimates extracted from the included studies. We relied on estimates reported in each study's base case. For studies that reported multiple base case values (e.g., when the study reported findings for different patient populations), we averaged these values. For example, Doble and colleagues [11] evaluated the use of the transcatheter heart valve for both operable and inoperable patients, reporting incremental QALY gains of -0.10 and 0.60 for these two groups, respectively; we therefore estimated the health gain for transcatheter heart valves to be 0.25 QALYs.

e converted currencies to US dollars using the US Federal Reserve website and inflated costs to 2018 using the US Consumer Price Index [12, 13].

2.2 Analysis

The unit of analysis in our base case was the FDA generic category. We therefore combined data for devices belonging to the same category. For example, we combined data for the Sapien Transcatheter Heart Valve (Edwards), and Corevalve System (Medtronic) because both of these devices belong to the FDA generic category "Aortic Valve, Prosthesis, Percutaneously Delivered".

Our base-case analysis excluded studies that estimated cost-effectiveness by comparing devices belonging to the same generic class. For example, we excluded one study [14] that compared the Heartware Ventricular Assist System (Medtronic) and the Heartmate II Left Ventricular Assist System (Thoratec) because both of these devices belong to the "Ventricular (Assist) Bypass" category.

We combined data from multiple studies and devices within the same FDA category by averaging the reported estimates. For example, if we identified five cost-effectiveness studies for three devices all belonging to the same generic category, we averaged the five reported incremental cost estimates and five reported incremental QALY estimates. We calculated the ICER for that category by dividing the average cost estimate by the average QALY gain estimate.

2.3 Benchmarking Cost-Effectiveness

We then compared generic product category ICER estimates to two benchmarks often referenced in the US: $50,000 and $150,000 per QALY gained [15, 16].

2.4 Sensitivity Analyses

Our first sensitivity analysis excluded industry-funded studies. Research suggests that these studies tend to report more favorable cost-effectiveness estimates than non-industry funded studies [17].

Our second sensitivity analysis used the individual device as the unit of analysis. For devices with multiple ICER estimates, we retained the estimate that compared the device to the most recently approved alternative that had received approval no later than the device of interest. Note that this sensitivity analysis retained cost-effectiveness estimates comparing devices belonging to the same generic category. For example, for this sensitivity analysis, we included one study [18] that compared the Endeavor zotarolimus-eluting stent (2008) and the Cypher sirolimus-eluting stent (2003), even though both stents belong to the "*Coronary Drug-Eluting Stent*" Category. Because the FDA approved Cypher before Endeavor, our sensitivity analysis designated Cypher as the comparator.

3 Results

The FDA approved 555 non-cosmetic PMA devices across 203 generic categories from 1999 through 2015. We identified at least one relevant cost-utility or comparative-effectiveness study for 88 devices (15.9%), and at least one device across 53 generic categories (26.2%) (Table 1). For 16 generic categories, we identified studies for multiple devices; for 37 generic categories, we identified studies for a single device. Devices in our sample most often belonged to the FDA category "*Prosthesis, Intervertebral Disc*" (15.1%), followed by "*System, Endovascular Graft, Aortic Aneurysm Treatment*" (11.3%), and "*Stimulator, Spinal-Cord, Totally Implanted For Pain Relief*" (7.5%). Our base-case dataset included 120 cost-utility studies and five comparative-effectiveness studies.

Most studies addressed devices indicated for cardiovascular disease ($n = 34$) and orthopedic disease ($n = 18$) (Fig. 1). We identified no cost-utility or comparative effectiveness studies for four broad technology categories (as defined by the FDA advisory committee): anesthesiology, dental, physical medicine, and toxicology.

Included studies spanned 13 countries and took one of three perspectives in their analyses (healthcare payer, healthcare system, or societal). Thirty-nine studies (40%) used a short-term (< 5 years) time horizon and 54 studies (55%) examined cost-effectiveness over a longer term (> 5 years); these thresholds have been previously established in the literature [19]. The time horizons used in five studies were not reported. A summary of study characteristics is available in Online Supplementary Material (OSM) Table S1.

3.1 Incremental Quality-Adjusted Life-Year (QALY) Gains

The median incremental health gain across generic device categories was 0.13 QALYs, corresponding to a quality-adjusted survival gain of roughly 7 weeks (Table 1). The mean QALY gain was 0.46 QALYs. We found seven of the 53 generic categories (13%) to have average QALY increments that were zero or negative—i.e., on average, devices in those categories made health worse in QALY terms (Table 1).

Across advisory committees, incremental QALY gains ranged from -0.098 (obstetrics/gynecology) to 1.98 (neurology).

3.2 Incremental Costs

The median (mean) incremental cost across generic device categories was $1701 ($13,320) (Table 1). We found 14

Table 1 Overview of findings: incremental device costs, quality-adjusted life-years (QALYs), and cost-effectiveness

	Device categories
Number of generic categories	53
QALY gain compared to previous treatment options	
Median	0.13
Interquartile range	(0.017–0.66)
Mean	0.46
Standard deviation	0.72
Additional costs ($)	
Median	1701
Interquartile range	(− 44 to 17,265)
Mean	13,321
Standard deviation	40,548
Aggregate incremental cost-effectiveness ratios	
Less expensive, equal or improved health	11
Less than $25,000	17
$25,000 to < $50,000	8
$50,000 to < $75,000	1
$75,000 to < $100,000	4
$100,000 to < $125,000	1
$125,000 to < $150,000	1
$150,000 or more	3
More expensive, equal or worse health	3
Less expensive, worse health	3
Cost data not available	1
Advisory committee	
Cardiovascular	18
Clinical chemistry	4
Ear nose, and throat	1
Gastroenterology/urology	3
General and plastic surgery	2
Immunology	2
Microbiology	3
Neurology	3
Obstetrics/gynecology	1
Ophthalmic	3
Orthopedic	8
Pathology	2
Radiology	3

(26%) generic categories to have lower average costs relative to comparator treatments (OSM, Fig. S2).

Across advisory committees, cost estimates ranged from a savings of $1012 (obstetrics/gynecology) to a cost of $36,163 (clinical chemistry).

3.3 Incremental Cost-Effectiveness

For 11 generic device categories, devices on average were equally or more effective and less costly than the comparator. For three categories, devices on average were equally or less effective and more costly than the comparator (Table 1). Devices in three generic categories were both less effective and less costly than the comparator. Further, 36 of 53 (67.9%) ICERs fell below (were more favorable than) the $50,000 per QALY benchmark, and 43 of 53 (81.1%) of ICERs fell below the $150,000 per QALY benchmark (Fig. 2).

Across advisory committees, cost-effectiveness ranged from saving money and improving health (microbiology) to $66,457 per QALY gained (radiology) (Fig. 3).

3.4 Sensitivity Analyses

Excluding industry-funded studies yielded results that differed little from the base-case results (see OSM Table S2). Using the individual device as the unit of analysis also yielded results broadly equivalent to the base case findings (see OSM Table S3).

4 Discussion

Devices in each broad category tended to produce good value. These findings were more favorable than the cost-effectiveness estimates reported in a study of medications approved by the FDA from 1999 to 2015 [20]. The medications included in that study had a median incremental QALY gain of 0.09 QALYs (vs. 0.13 QALYs estimated in the present study of devices), and an incremental cost of $6,085 (vs. $1,701 estimated in the present study for devices).

It is notable that we identified cost-effectiveness information for only 16% of the PMA devices approved by the FDA from 1999 through 2015. The lack of cost-effectiveness information for devices may be due to a number of factors [21, 22]. First, the lack of robust clinical trial data for medical devices makes performing cost-effectiveness analyses challenging. It is difficult to randomize patients in medical device clinical trials, and it can be unethical or impractical to blind trial participants. Second, it is difficult to account for operator variation and user learning curves. Third, disentangling the costs and benefits associated with a device embedded within a complex medical procedure can be a challenge.

Importantly, our results may reflect a preference among investigators to analyze devices they expect will have favorable ICERs.

The lack of cost-effectiveness evidence for medical devices is a problem for decision makers responsible for making reimbursement or procurement decisions,

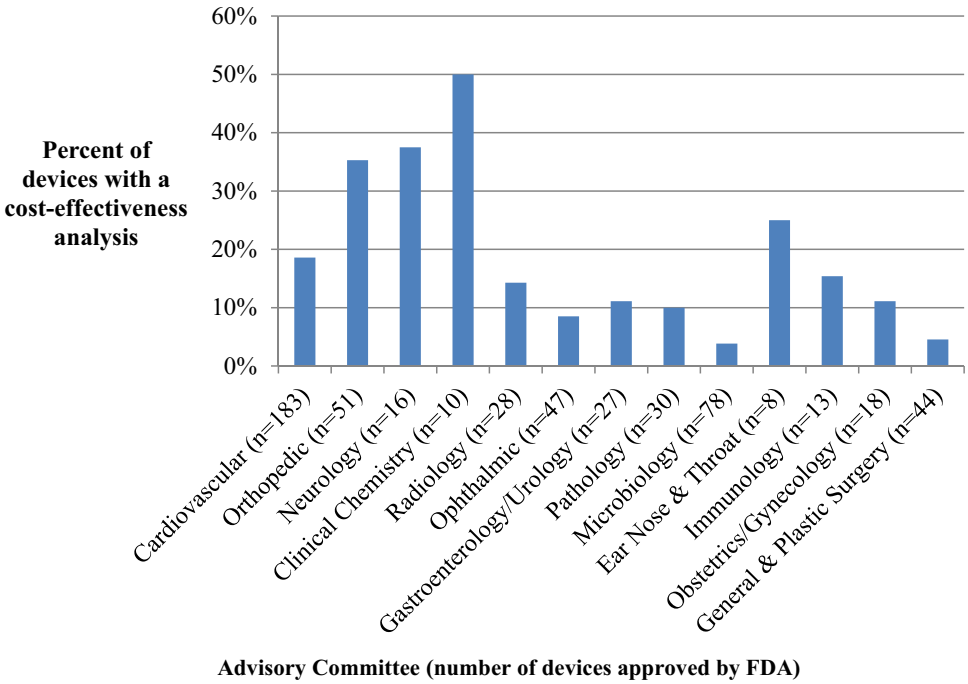

Fig. 1 Number of devices with a cost-effectiveness analysis by US Food and Drug Administration (FDA) advisory committee

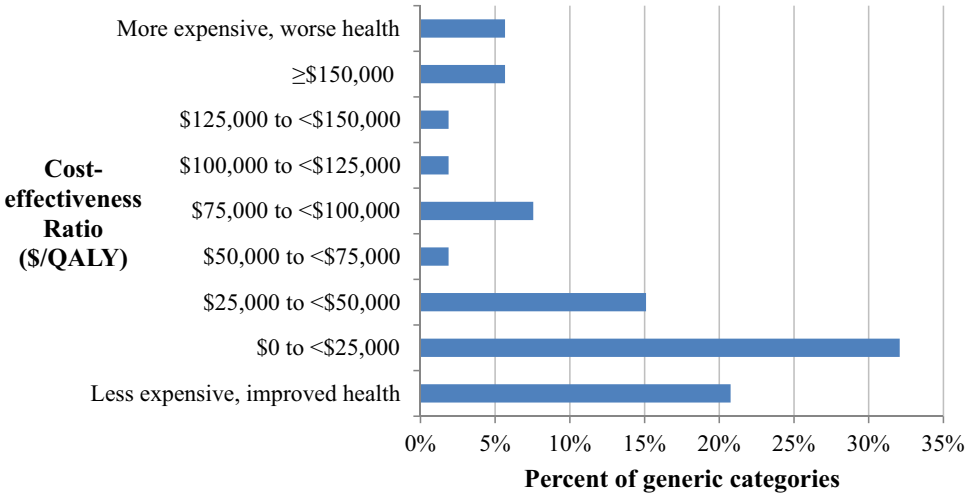

Fig. 2 Generic device category cost-effectiveness distribution ($n = 53$)

particularly for those that lack the sophistication to perform their own analyses. Without cost-effectiveness evidence, decision makers may be unable to accurately weigh the costs and benefits of competing treatments, thus hindering efficient resource allocation.

4.1 Limitations

Our study has a number of limitations. First, the studies we included used methods that were not strictly comparable. The studies varied with respect to the analytic perspective, time horizon, and so on (see OSM Table S1 for a summary of study characteristics). In these ways, we are at the mercy of authors' methodological approaches.

Second, we did not assess the quality of the included studies. Future research should account for study quality, for example, by applying the ISPOR Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Checklist [25].

Third, in some cases, different studies for the same device used different comparator treatments. However, when studies reported results for multiple comparator interventions, we mitigated this limitation by selecting the most effective comparator available at the time the FDA approved the device.

Fourth, the cost-effectiveness literature may inadequately reflect changes in the value of medical devices over time. Product manufacturers often update devices after they reach

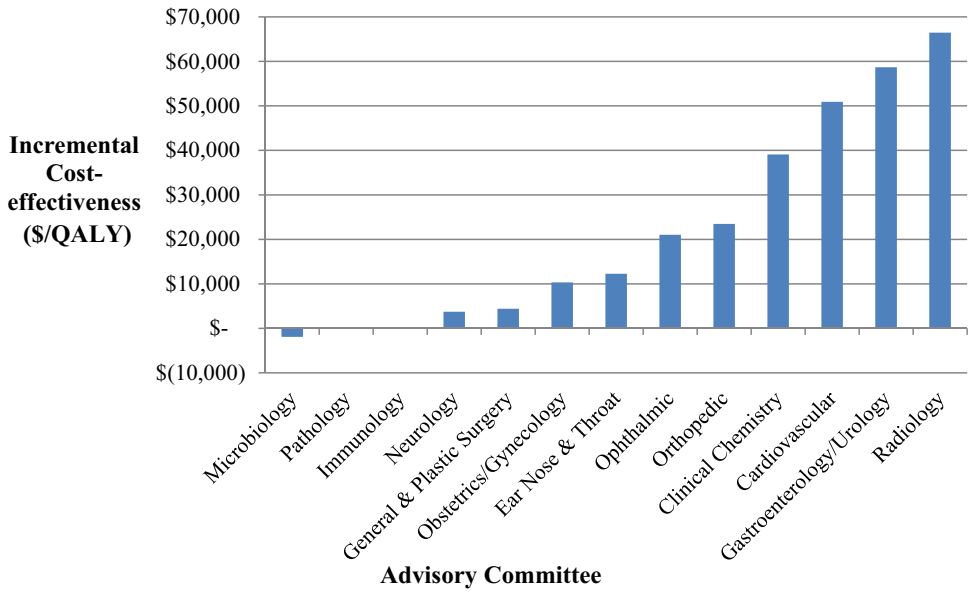

Fig. 3 Average incremental cost-effectiveness of devices by advisory committee

the market. These updates are often minor (e.g., device size reduction, improved battery performance, and so on) and do not trigger a novel PMA approval [26]. Nevertheless, incremental changes can confer meaningful improvements, thus diminishing the relevance of previously published cost-effectiveness analyses.

Fifth, our standardization of currencies across countries and over time was imperfect. A device's cost may vary across countries, as may other healthcare costs incorporated into the cost-effectiveness analyses. Converting other currencies to US dollars may not address all factors contributing to price differences across the 13 countries represented in the analysis. Further, the Consumer Price Index, which we used to inflate costs to 2018 values, may not fully account for price changes.

Sixth, we searched only the PubMed Database for medical device cost-effectiveness analyses. Future research should expand the literature search to additionally include alternative medical research databases.

Seventh, we cannot necessarily generalize our findings beyond PMAs and our results may not apply to all FDA PMA generic categories. However, we note that our aggregation of results by device category did not appear to substantially influence our findings. Moreover, although others have reported that industry funding can bias cost-effectiveness findings [17], the fact that our results did not differ substantially upon exclusion of industry-funded studies suggests that in this context, funding did not substantially bias the results.

As the healthcare system becomes more value-based, decision makers will want more robust and complete cost-effectiveness evidence. Without such information, decision makers risk underutilizing cost-effective technologies and overusing inefficient technologies. Our study highlights the need for more cost-effectiveness evaluations for medical devices, particularly for device categories with few cost-effectiveness studies.

5 Conclusion

Our search of a large biomedical literature database identified available cost-effectiveness evidence for roughly one-quarter of the major PMA medical device categories. Cost-effectiveness studies were most often available for devices approved by the Cardiovascular and Orthopedic FDA Advisory committees. Our study suggests that devices for which cost-effectiveness studies are available tend to offer good value, as judged relative to established cost-effectiveness benchmarks.

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Declarations

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Conflicts of interest/Competing interests The authors have no conflicts of interest to declare.

Availability of data and material Available upon request.

Code availability Available on request.

Ethics approval The authors obtained an institutional review board waiver for this study.

Consent to participate Not applicable.

Consent for publication Not applicable.

Author contributions All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by James D. Chambers, Madison C. Silver, and Flora C. Berklein. The first draft of the manuscript was written by James D. Chambers and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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