

Measuring the Value of Firm-level Innovation in the Medical Device Industry

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Abstract

The medical device industry delivers value to providers and patients by creating new innovative devices. Many policy discussions related to the device industry are often framed in terms of how a proposed change will affect firms' development of innovative devices. In order to evaluate these policy proposals and describe innovation in the medical device industry, researchers need a variety of measures that characterize specific dimensions of value within the broad category of innovation. This white paper provides a brief overview of the medical device industry, describes different dimensions of the value of innovation relevant to the medical device industry, summarizes the strengths and weaknesses of currently used measures of firm-level innovation in the medical device literature, and finally offers some suggestions for applying pre-existing methodologies to new settings in order to develop new measures of firm-level medical device innovation. Current measures of firm-level innovation either describe innovation broadly without focusing on a specific dimension of value or describe the scientific or producer value of innovations. More work is needed to describe firms' development of innovations that are valuable from a clinical or population health perspective.

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Introduction

The medical device industry provides life-saving and life-improving therapy to millions of patients every year¹. The industry is characterized by the constant development and improvement of innovative devices. When policymakers and thought leaders discuss changes to either the taxation or regulation of the device industry, they often frame the effects of policy changes in terms of innovation trade-offs^{2,3}. This necessarily raises the question of whether current empirical measures are up to the task of describing innovation in the medical device industry in a meaningful way that captures the different dimensions of innovation relevant to different stakeholders.

This white paper offers an overview of different firm-level measures of innovation in the medical device industry. It begins by briefly describing the medical device industry to frame what innovation in the device space looks like; those interested in a more substantial discussion of institutional details affecting innovation in the medical device space should consider reading MedPAC's 2017 report on the device industry⁴ and Dr. James C. Robinson's *Purchasing Medical Innovation: The Right Technology, For the Right Patient, At the Right Price*⁵. The paper then offers an overview of four different dimensions of the value of innovation in the medical device industry. The rest of the paper is devoted to examining the advantages and challenges of currently used measures of firm-level innovation in the medical device literature, as well as discussing potential new measures to describe different dimensions of value not adequately covered by current measures.

Overview of the Medical Device Industry in the United States

The U.S. Food and Drug Administration (FDA) defines a medical device as, “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other

similar or related article...intended to affect the structure or any function of the... which does not achieve its primary intended purposes through chemical action within or on the body of man...”⁶. Given the broad definition of what constitutes a medical device, medical devices range in complexity from surgical gloves and tongue depressors to cardiac pacemakers and fMRI scanners. Exact estimates of the size of the medical device industry in the United States vary, but analyses suggest at least 3.5 million patients will receive an implantable medical device every year¹ and that spending on medical devices makes up roughly 5% of total health care spending in the United States^{7,8}.

The medical device industry has two unique characteristics that shape how innovation takes place: how devices are approved for market entry and how devices are reimbursed. In terms of regulation, there are three primary mechanisms by which the FDA allows medical devices to enter the market⁹. High-risk devices such as cardiac pacemakers and coronary stents must apply for a Premarket Approval (PMA). Applicants must demonstrate through human clinical trials that their device is safe and effective. The PMA process mirrors the FDA’s process for approving new pharmaceutical products, although by comparison the FDA often requires less rigorous evidence to approve a new high-risk medical device compared to a new drug¹⁰. For moderate-risk devices such as hip replacements and blood glucose monitors, firms will most often submit Premarket Notifications, often referred to as 510(k) submissions. During the 510(k) process, firms must demonstrate that their device is “substantially equivalent” to a legally marketed “predicate” device; both devices already approved by the FDA through the 510(k) process and devices that predate the FDA’s authority to regulate medical devices can serve as predicates. Firms sometimes establish substantial equivalence through human clinical data, but often do so through in vitro or bench testing. Of devices reviewed by the FDA, the 510(k)

process is the most common approval mechanism¹¹. Finally, most low-risk devices such as toothbrushes are entirely exempt from FDA review. There are several other approval mechanisms by which medical devices enter the market that are not covered here, but these are relatively rare^{9,11}.

In terms of reimbursement, providers are often reimbursed for the cost of medical devices implants in a lump sum payment, covering both the cost of the device itself and the resources that went into performing the procedure (e.g. a DRG payment)⁵. This means a medical device company must assure providers that they can bill insurers for the company's medical devices under pre-existing coding schemes, or else the device company must petition for the introduction of new coding for physician reimbursement. If medical device companies fit their new devices into pre-existing coding, device companies can frame value claims around how reimbursement will change for providers if providers use their devices in relatively certain terms. For example, in promotional material for OrthoSense's VeraSense system, the company argues that providers can avoid unprofitable knee replacement DRGs by using their device:

Analysis of facility costs and Medicare reimbursements shows over 90% of hospitals lose money on revision [total knee arthroplasty]... VeraSense multi-center study patients showed an almost 75% lower rate of revision [total knee arthroplasty] compared to national averages. This reduction represents clinical and financial benefit to both patients and providers¹².

Device companies face far more uncertainty in reimbursement (and thus have a harder time encouraging physician adoption) if their device is novel enough that it requires its own unique coding. Firms often need to recruit physician champions to advocate for the use of devices at specialty society meetings, and specialty societies in turn create recommendations and guidance

that influence insurers' reimbursement decisions. Navigating the roles of these different stakeholders to ultimately gain insurer coverage and physician adoption is a difficult process that can take years¹³.

A consequence of the regulatory and reimbursement environments for medical devices in the United States is that innovation is highly incremental in the device industry. When firms develop novel devices without clear predicates, firms place both greater regulatory hurdles (PMA rather than 510(k)) and more uncertainty in the reimbursement process. Put simply, device firms face greater risk when they pursue truly novel innovations. As such, unlike the pharmaceutical industry which is often characterized by “blockbuster” innovations, innovation in the device industry tends to be characterized by continuous small improvements of pre-existing technologies⁴. Ideally, measures of firm-level innovation in the medical device industry should capture the iterative nature of developing new medical devices.

Dimensions of the Value of Innovation

Innovation is not a monolithic phenomenon. Rather, the creation of new products and ideas have different implications for different stakeholders. Patients, providers, insurers, and medical device companies all have different hopes and expectations for new innovative devices. As such, researchers may need different measures of innovations when they consider research questions from different perspectives. Prior studies have taxonomized innovation in different ways. For example, Kogan and colleagues focused on the distinction between the “private economic” value of innovation and the “scientific” value of innovation; they note that technologies may be novel but not lucrative for their developers, or conversely that new technologies may help restrict market competition and increase company profits without actually

being scientifically novel¹⁴. Similarly, in a study of pharmaceuticals by Dranove and colleagues, the authors focused on the distinction of the “scientific” value of new drugs, or their molecular novelty, versus the “therapeutic” value of drugs, as measured by whether a drug offers new treatment options to patients when previously options were limited¹⁵. This paper focuses on four dimensions of value relevant to the medical device industry and uses these dimensions to characterize different measures of innovation:

- Producer value: a new medical device has producer value if it generates profits for the individual or firm that created the device
- Scientific value: a new medical device has scientific value if it is technologically novel (i.e. new mechanical instrument, new software, new power source) or if it facilitates the development of new follow-on innovations
- Clinical value: a new medical device has clinical value if it improves the quality or duration of life for a patient who receives the technology; devices with clinical value have higher levels of safety or efficacy relative to the the pre-existing standard of care
- Population health value: a new medical device has population health value if it improves the total quality or duration of life for all patients who have indications for the device; devices with population health value either have higher levels of safety or efficacy relative to the pre-existing standard of care or offer a similar level of efficacy and safety to more patients

These dimensions of value are not mutually exclusive. Some devices may excel in one particular dimension of value, while other devices may demonstrate all four dimensions. Furthermore, the same device can offer different degrees of value over time. For example, a new device can enter

the market at a price point that is prohibitive for most patients but decrease in cost over time, which would in turn increase patient access and population health benefits.

The following are examples of how different devices can all be “innovative” yet offer different types of value to different stakeholders. Inevitably, some readers will assess the value of the following examples differently than the ad hoc analyses presented here; the point of the examples is to simply clarify the significance of individual dimensions of value and to illustrate that any single dimension of value is neither a necessary nor sufficient condition for another any of the other dimensions of value. Disagreements over the magnitude of value in any of these devices underscore the need for precise measures of each of the listed dimensions of value, which is discussed in greater detail in the next section of the paper.

Example 1: Micra Leadless Pacemaker



Figure 1: Micra leadless pacemaker¹⁶

A traditional cardiac pacemaker involves implanting a battery in a patient’s chest and threading “lead wires” through patients veins and into the heart. Conversely, Medtronic’s Micra leadless pacemaker uses a tine fixture system to secure a small battery directly to the heart, eliminating the need for lead wires¹⁶. In traditional pacemakers, both the pocket created for the

battery and the lead wires can become infected. By eliminating these infection risks, Micra has lower rates of complications compared to traditional pacemakers¹⁷. However, Micra can only provide pacing to a single area of the heart; most patients who receive traditional pacemakers receive “dual chamber” pacemakers that provide pacing to multiple areas of the heart¹⁸.

Evaluating Micra in terms of the four list listed dimensions of innovation value, Micra clearly represents an advance in clinical and producer value but is limited in its scientific and population health value. In terms of clinical value, the Micra improves upon traditional pacemaker modalities by reducing infections and complications. Micra has also been highly lucrative to Medtronic¹⁸, demonstrating producer value. However, due in part to Micra’s high price point and part to its inability to provide dual chamber pacing, Micra has not substantially penetrated the overall pacemaker market¹⁸, limiting its current ability to provide substantial population health benefits. In terms of scientific value, different analysts will come to different conclusions about the scientific value of Micra. On the one hand, Micra relies on the same basic principles as a traditional pacemaker, meaning one could make the case that Micra is not particularly scientifically innovative. On the other hand, the act of miniaturizing pacemakers involved rethinking the engineering of a pacemaker from the ground up¹⁹, and these new processes may in turn generate new follow-on innovations¹⁸.

Example 2: Lung Biopsy Tool



Figure 2: A small lung biopsy tool²⁰

Bronchoscopes are used to biopsy tumors in the bronchial tubes of the lung. Standard bronchoscopes are relatively large and have difficulty extracting biopsies from narrower parts of the bronchial tubes. Physicians can use electromagnetic navigation bronchoscopes to extract biopsies from the narrower parts of the bronchial tubes that traditional bronchoscopes cannot reach, but such electromagnetic system requires a substantial capital investment that smaller medical centers may not be able to afford. Engineers at the University of Minnesota have taken advantage of the decreasing size of cameras to develop a smaller version of the traditional bronchoscope that can reach the narrower portions of the bronchial tubes previously only reachable through electromagnetic navigation²⁰.

The University of Minnesota small lung biopsy tool offers little in terms of clinical or scientific value but may generate value at the producer and population health levels. The ability to create a smaller biopsy device is largely a consequence of prior reductions in the size of cameras (meaning there is little scientific value to the device), and the new biopsy tool does not provide any additional clinical value relative to traditional or electromagnetic bronchoscopes; it takes the same biopsies as the current standard of care. However, the ability to take the same biopsies as electromagnetic navigation bronchoscopes without a costly capital investment may

allow more providers to offer biopsies of smaller bronchial tubes and thus may increase overall patient access, resulting in population health benefits. Given that the smaller device effectively creates a new market for lung biopsy tools (smaller health systems), the device will likely generate value for its producer.



Example 3: Proton Beam Therapy for Prostate Cancer

Figure 3: Proton Beam Facility at Mayo Clinic²¹

Proton beam therapy is a form of radiation therapy that relies on a directed beam of protons rather than X-ray energy used in typical radiation therapy modalities. Differences in how protons dissipate energy result in proton therapies delivering less radiation to non-targeted areas compared to X-ray radiation therapy. Proton beam therapy was originally conceived of as an alternate treatment modality in cases where tumors are adjacent to very sensitive non-cancerous areas (e.g. eye, spinal cord) but in recent years have been extended to other conditions, including prostate cancer²². Establishing a proton beam center costs roughly \$200 million, and treatment via proton beam therapy can cost as much as \$50,000²³.

Proton therapy may be scientifically novel, but physicians and financial analysts have called the clinical, population health, and producer benefits of proton therapy into question. Despite the theoretical promise of less extraneous radiation, research has not demonstrated that proton therapy reduces harm relative to traditional radiation therapy, meaning the therapy does not deliver any meaningful clinical value²². Furthermore, because proton therapy is so expensive and offers little to no therapeutic benefit, many insurers tend to deny coverage of the therapy, thus limiting the ability of the therapy to deliver any population health benefits. Finally, proton therapy may not even be profitable for proton therapy centers. Many proton therapy centers have reported substantial losses or declared bankruptcy in the last several years, suggesting a lack of producer value associated with the therapy²³.

Measures of Firm-level Innovation

The current literature on firm-level innovation in the medical device industry relies on several measures available in public databases: research and development (R&D) spending, receipt of venture capital funding, and counts of FDA-approved devices. There are also several measures from the broader literature on innovation that could be easily applied to studies of medical device firms: citation-weighted patent counts and the market value of patents approvals. In addition to these measures, there are other sources potential new measures that researchers could use, but current challenges in data availability or quality prevent their immediate usage: cost-effectiveness measures including quality-adjusted life year (QALY) gains and incremental cost-effectiveness ratios (ICERs), and citation-weighted 510(k) approvals.

Pre-existing Measures

R&D Spending

R&D spending measures firms' spending "aimed at developing or significantly improving a product or service"²⁴. R&D spending notably excludes any customer or government-sponsored research activities as well as research assets acquired through business combinations. Measures of R&D spending are available for publicly traded medical device firms through individual firm annual financial reports housed in free online portals such as EDGAR²⁵ or in more research-ready panel formats through paid subscription services such as CompuStat Capital IQ²⁶.

Several studies have used R&D spending to measure innovative activity in the medical device industry. Santerre and Schmutz estimated the relationship between medical device firms' cash flow, market value, and R&D spending²⁷. They then used the estimated relationship to speculate on changes in R&D spending and years of human life following the passage of the Affordable Care Act. Lee investigated a similar question and employed a difference-in-differences approach to investigate the effects of the Affordable Care Act²⁸

R&D spending is an easily accessible measure for describing the overall extent of innovative activity among publicly traded firms. However, R&D spending is value agnostic; simply spending on developing new products does not always translate into the creation of new products that generate clinical, population health, scientific, or producer value. Furthermore, R&D spending only captures a portion of total innovative activity in the medical device space. Privately held firms do not face the same reporting requirements as publicly held firms. This is a crucial limitation in measuring medical device innovation, as many larger public firms often supplement their innovation portfolios through acquisitions or joint ventures with smaller private

firms^{4,5}. These activities make up an important part of the innovation landscape in the medical device industry but are not captured in R&D spending.

Venture Capital Valuations and Time to Venture Capital Receipt

Various metrics related to the venture capital process can be used to assess the innovativeness of a firm's product portfolio. Researchers could hypothetically use either the time between a firm's founding and the receipt of its first round of venture capital funds or the valuation of a firm at any given round of funding. Metrics related to the venture capital funding process can be accessed via paid subscription services such as Dow Jones' VentureSource database or Thomson Financial's VentureXpert²⁹.

Chatterji examined the effect of prior industry experience on medical device start-ups' speed in receiving their first round of funding as well as their valuation in their final non-public round of funding³⁰. Chatterji's methodological approach in the particular paper highlights some of the challenges in using funding data. Both VentureSource and VentureXpert rely on surveys of firms identified through press releases, website, or other media. This creates the possibility both that firms included in the sample could have misreported certain information and that relevant firms were excluded from the sample because they were not properly identified²⁹. As such, Chatterji conducted concurrent analyses in both data sources. While conducting analyses of venture capital funding in multiple datasets may increase the validity of a study, doing so may be cost prohibitive for researchers without institutional access to these databases.

Using venture capital-based measures has two unique advantages. First, these measures specifically focus on privately held firms in early stages of development. These firms make up an important part of the larger medical device innovation environment but are often excluded from other datasets derived from public financial reports and stock activities. Second, these measures

provide a clear measure of producer value by directly quantifying how investors perceive the profitability of the firm.

FDA Approvals

FDA approvals are counts of the number of new devices cleared for market entry by the FDA; researchers could hypothetically count all FDA approvals or break counts out based on the FDA's different clearance mechanisms. The FDA provides readily downloadable datasets of all medical devices cleared through both the PMA and 510(k) review processes with records going all the way back to the start of the FDA's statutory authority to review medical devices³¹. However, adding other firm-level characteristics to this dataset inevitably requires a non-trivial amount of data cleaning due to the way imprecise way the FDA records firm names. For example, the 510(k) file includes the following values with "Boston Scientific" in the applicant name: "BOSTON SCIENTIFIC", "Boston Scientific", "BOSTON SCIENTIFIC – PRECISION VASCULAR", " "BOSTON SCIENTIFIC CORP.", "Boston Scientific Corporation", "BOSTON SCIENTIFIC CORPORATION", "BOSTON SCIENTIFIC EP TECHNOLOGIES", and "BOSTON SCIENTIFIC IVT"³¹. There are likely many cases where a researcher would be interested in treating all these applicants as one firm unit and would need to organize these manually before combining the FDA data with another dataset.

Despite the initial data challenges, several studies have used firm-year level counts of devices approved by the FDA as measure of a firm's innovative activity^{30,32,33}. As an example, a working paper by Ball and colleagues looked at how product recalls affect firms' development of "major innovations" (as measured by the number of devices clearing the PMA review process) and "minor innovations" (as measured by the number of devices clearing the 510(k) review process).

The primary advantage of using device approvals as a measure of innovation is the breadth of innovative activity that it covers. Unlike many other measures of innovations, both public and private firms have their devices reported in the FDA databases, and changes in device counts can be tracked longitudinally for as long as devices have been approved by the FDA. However, the main challenge is characterizing the quality of the innovation associated with approved devices. The “major innovation/minor innovation” taxonomy is a rough gradation in practice. In terms of clinical value, devices cleared through the 510(k) process may improve on a pre-existing technology, or they may effectively duplicate devices already on the market and not innovate in a meaningful sense. Similarly, while devices approved through the PMA process must demonstrate evidence of safety and efficacy, these devices need not improve on any pre-existing standard of care⁹.

Furthermore, after receiving FDA approval, firms must still go through the difficult process of receiving insurer coverage for novel devices. Device approval does not guarantee that firms can sell their devices to customers and reach patients, limiting the ability of FDA approvals to describe the producer value or population health value of new devices. In summary, counts of approved devices should be viewed as measure of the overall extent of innovative activity for a medical device firm without drilling into specific dimensions of value.

Citation-weighted Patents

Many metrics exist that measure firms’ patent approvals weighted by citations associated with the firms’ patents. Perhaps the most common measure is forward patent counts. A forward citation-weighted patent count for a firm is the number of patents attributed to a firm in a given year weighted by the number of future patents that cite the firms’ patents, “plus a fractional weight multiplied by the number of citations received by those citing patents... important patents

are those that are cited a lot, and are cited by patents that are themselves relatively highly cited”³⁴. Other citation weighting schemes exist to capture different nuances in how patents shape follow-on innovations^{34,35}. Previous researchers have organized citation-weighted patent metrics in panel formats and made them publicly available³⁶.

To date, no researchers have directly employed citation-weighted patent metrics in the study of medical devices. However, given the availability of the data, there is nothing prohibiting a researcher from constructing a panel of medical device firms by subsetting other data sets based on SIC/NAICS codes²⁷ to study innovation in the device industry specifically.

In general, citation-weighted patents are often considered a clear measure of the technical or scientific value of innovations^{14,34,37} and have the advantage that they can be easily tracked longitudinally. The main challenge with using patents to measure innovation in the medical device industry comes in assessing the overlap of scientific value and other types of value. Many types of patents go into devices³⁸, meaning the process of mapping patents (which establish scientific value) to devices (which generate clinical value) is likely a difficult one. For example, a study using citation-weighted patent metrics may be able to show that some factor is associated with changes in firms’ development of scientifically-valuable innovations, but that study would not be able to comment on the development of clinically-valuable innovations without aggregating some other unit of analysis to the firm-level.

Market Value of Patents

Developed by Kogan and colleagues, the market value of a patent measures the performance of a firm’s stock relative to overall market performance in the days following the firm’s receipt of a patent. Intuitively, if a firm’s new patent is deemed valuable by investors, then the firm’s stocks will do better than the overall market in the days immediately after their receipt

of a patent¹⁴. This patent-based metric can easily be aggregated to the firm-year level, and previous research has interpreted this aggregation as a measure of the value to producers associated with their innovation in a given year^{14,39}. Like the citation-weighted patent metric, the researchers behind the market value metric have made a research-ready firm-year panel with the measure publicly available³⁶.

To date, researchers have not used the market value of patents to measure firm-level innovation in the device industry, but researchers could easily observe the market value of medical device patents by focusing on a subset of firms with specific SIC/NAICS codes in prior datasets²⁷. The core strength of the market value of patents metric is its ability to describe both the value of innovation to producers and relationship between producer value and scientific value. The researchers behind the market value metric found that overall patents with greater market value generate more forward citations¹⁴. However, the observed correlation between scientific value and producer value could be weaker or stronger in the medical device industry specifically. Assessing the relationship between producer value and scientific value in the device industry could provide greater insights into the current incentives that exist within the industry and guide more nuanced policy interventions.

Summary of Existing Measures

Overall, the current available measures of firm-level innovation in the medical device industry either broadly characterize the extent of innovation without drilling down into specific dimensions of value or focus on the scientific or producer value of innovations. R&D spending and FDA approvals effectively describe firms' development of innovations, but it is unclear what types of value are specifically associated with these measures. Venture capital valuations and the market value of patents precisely characterize the value of innovations to producers while

citation-weighted patents characterize the scientific value of innovations, but these measures do not describe whether firms are developing new products that benefit patients. More work is needed to specifically characterize firm-level innovation that generates clinical value or population health value in the medical device industry.

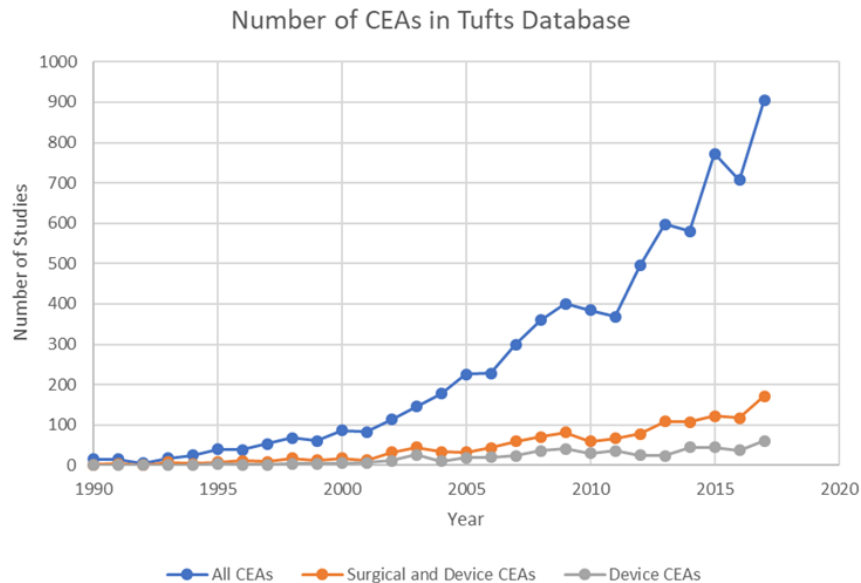
Potential New Measures

QALYs and ICERS

Researchers could aggregate incremental quality adjusted life years (QALYs) to the firm-year level to describe whether firms develop innovations that improve or extend patient lives. Alternatively, one could aggregate the number of devices with low incremental cost effectiveness ratios (ICERs) to describe whether firms develop devices that improve or save lives at a cost-effective price. Incremental QALYs measure improvements in duration and health-related quality of life derived from new technologies, while ICERs measure the incremental cost associated with a new technology and divide the cost by its incremental QALYs⁴⁰. A firm-year QALY metric would sum incremental QALYs gains generated by a firm's devices approved by the FDA in a given year, while a firm-year ICER metric would count the number of a firm's devices approved by the FDA with a low ICER (e.g. less than \$100,000 per QALY) in a given year. The intuition would be that firms with higher sums of incremental QALYs have generated more clinical value for patients in that year compared to firms with low sums of QALYs, while firms with more low ICER devices have generated more cost-effective clinical value for patients in that year compared to firms with fewer low ICER devices. To the extent that cost-effective technologies are more accessible⁴¹, one could view a count of low ICER devices as an approximate measure of the population health value generated by a firm in a given year.

Using incremental QALYs or ICERs to measure the value of medical devices is not a new concept, but to date researchers have not aggregated either measure to the firm-level. The Tufts University Center for the Evaluation of Value and Risk in Health (CEVR) maintains a database describing all English-language cost-effectiveness analyses; researchers can access the database if their institution supports CEVR with a paid sponsorship⁴². In the pharmaceutical literature, Chambers and colleagues have aggregated QALYs to the level of FDA approval mechanisms and discussed in detail the challenges that go with such an aggregation⁴³.

One could employ an aggregation similar to Chambers and colleagues’ approach at the medical device firm-level, but there are two related challenges that come with such an aggregation. First, the literature on cost-effectiveness analysis in medical devices is relatively sparse compared to other types of interventions⁴⁴. As demonstrated in Figure 4 below, the use of cost-effectiveness analysis to study medical devices has grown modestly over time, but there are



still fewer than 70 medical device cost-effectiveness analyses published every year.

*Figure 4: Cost-effectiveness Analyses in the Tufts Database by Study Type*⁴²

This leads to the challenge of interpreting the value of a medical device without a published cost-effectiveness analysis. Companies are not required to publish cost-effectiveness analyses, as only certain European insurers condition coverage on cost-effectiveness results. A device may not have an associated cost-effectiveness analysis because a company feels QALYs or ICERs are not necessary tools for expressing the value of their devices. Alternatively, some publication bias could be at work where less favorable results are less likely to be published⁴⁵. Any researcher aggregating QALYs to the firm-level will need to carefully consider how they treat devices with no published cost-effectiveness analysis.

Second, there are data cleaning challenges associated with attributing results from cost-effectiveness analyses to device firms. The Tufts CEA database does not report the names of devices or the firms that created the devices. As such, any researcher looking to aggregate cost-effectiveness results to the firm-level will need to read through each individual publication and then assign the publication to a specific device and/or company. This will be further complicated by the fact that cost-effectiveness analyses will not necessarily study individual devices but rather types of devices. Researchers will need to make decisions about whether to assign cost-effectiveness results to individual firms or multiple firms depending on their exact research question of interest.

Overall, incorporating QALYs and ICERs into measurements of firm-level innovation in the medical device industry holds promise but presents substantial data challenges. QALYs and ICERs measure the clinical and population health value of innovations in a way that currently employed measures do not. However, actually aggregating QALYs and ICERs to the firm-level requires the development and validation of new methodologies. These methodologies may vary

depending on the research question of interest, but they must to accurately attribute device-level outcomes to firms while thoughtfully interpreting the value of firms’ devices when no cost-effectiveness analyses are available.

Citation-weighted 510(k) Approvals

Citation-weighted 510(k) metrics would apply “genealogical” techniques from the patent literature to devices approved through the FDA’s 510(k) mechanism. Since almost all 510(k) cleared devices have a predicate device, it is possible to create a “family tree” for 510(k) devices. For example, Zargar and Carr mapped all of the predicate relationships for surgical meshes approved by the FDA and generated a family tree of all devices originating from a single predicate⁴⁶:

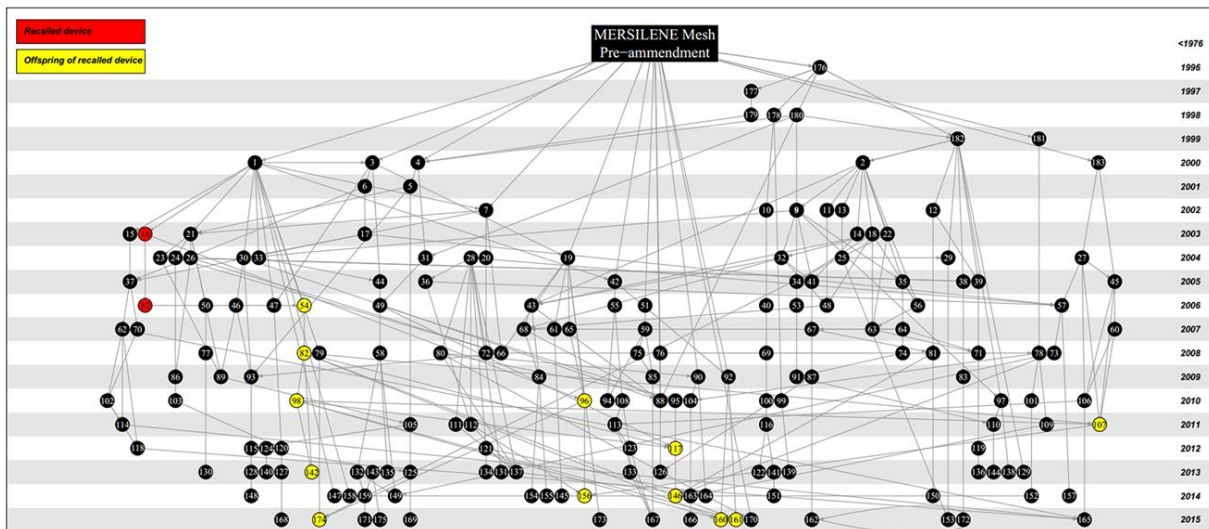


Figure 5: Ancestral Network of MERSILENE Mesh⁴⁶

Given the structure of these predicates, researchers could hypothetically assess the scientific value of firms’ FDA-approved devices in a given year by weighting the firms’ devices by future devices that cite the firms’ devices as predicates. It would also be feasible to modify other genealogical patent methodologies^{34,35} and apply them to these 510(k) devices.

A citation-weighted 510(k) measure would have the advantage of providing an alternative measure of scientific value derived from device-level data that directly captures the iterative nature of innovation in the device industry. Deriving a measure from device-level data would enable researchers to make statements about the overlap of different dimensions of value, particularly clinical value. For example, a study could assess whether firms that develop scientifically valuable devices (as measured by forward predicate citations) also develop clinically valuable devices (as measured by incremental QALYs) and whether policy interventions encourage firms to disproportionately focus more on scientifically valuable devices or clinically valuable devices.

There are two main disadvantages associated with constructing 510(k) citation-weighted measures. First, while 510(k) devices are clear examples of iterative innovations that characterize the device industry and make up the vast majority of devices reviewed by the FDA, they are not likely to be the most innovative devices; higher risk devices that are more likely to truly advance standards of care will be reviewed through the PMA mechanism. Researchers will need to think carefully about the relevance of 510(k) devices when studying innovation. Second, the data describing device predicates is very messy. The FDA does not maintain a single database describing all the predicates used in 510(k) decisions. Instead, this information is stored across many individual inconsistently formatted (and sometimes missing) PDF files⁴⁷. Zargar and Carr created the family tree diagram in Figure 5 by looking through each of these records manually⁴⁶. Currently, studies interested in device predicates would need to implement a similar manual approach. However, Karaca-Mandic and colleagues are in the process of using natural language processing techniques to extract predicate information from 510(k) documents and offer the information in a research-ready format⁴⁸.

Overall, citation-weighted 510(k) approvals have the potential to describe the scientific-value of firms' innovations. Since such a measure would be derived from device-level outcomes, using citation-weighted 510(k) approvals would allow for easier comparisons between different dimensions of value in the medical device industry. However, researchers should think carefully about whether studying 510(k) devices is relevant to their research question of interest, and challenges in how predicate data is maintained by the FDA mean that creating citation-weights for a large sample of devices and firms may not be currently feasible.

Conclusion

Millions of patients every year rely on the medical device industry to develop lifesaving innovations. Researchers interested in studying how firms develop those innovations need precise measures that clearly describe different dimensions of the value of innovation relevant to different stakeholders. Current measures of firm-level innovation such as R&D spending and FDA approvals can be used to describe the overall extent of innovation among medical device firms, while metrics describing venture capital funding and patent receipts can drill down into the scientific value and producer value of firms' innovations. However, more work is needed to define clear measures describing the iterative development of innovation that benefits patients both at the individual and population-level. Future research should consider how to incorporate cost-effectiveness measures and genealogical analyses of FDA documents to better describe the clinical value and population health value of iterative innovations in the medical device industry.

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