# THE ECONOMICS OF MEDICAL PROCEDURE INNOVATION

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# THE ECONOMICS OF MEDICAL PROCEDURE INNOVATION

**Abstract**

This paper explores the economic incentives of medical procedure innovation. Using a novel, proprietary dataset on billing code applications of emerging medical procedures, we highlight two mechanisms that could hinder innovation. First, the administrative hurdle of securing permanent, reimbursable billing codes substantially delays innovation diffusion. We find that Medicare utilization of innovative procedures increases nine-fold after the billing codes are promoted to permanent (reimbursable) from provisional (non-reimbursable). However, only 29 percent of the provisional codes are promoted within the five-year probation period. Second, medical procedures lack intellectual property rights, especially those involving no patented devices. When appropriability is limited, specialty medical societies lead the applications of billing codes. Our work indicates that the *ad hoc* process that oversees procedure innovations creates uncertainty over both the development process and the allocation and enforceability of property rights; this stands in stark contrast to the more deliberate regulatory oversight for pharmaceutical innovations.

Key Words: Medical Procedure Innovation, CPT Codes, Property Rights

JEL: I11, O33, I18

## 1. Introduction

Improvements in medical technology have been a primary driver of increased life expectancy and medical spending (Cutler, 2004; Newhouse, 1992). These improvements have taken many forms. Society now enjoys access to pharmaceuticals that treat a wide range of both common and rare conditions. For example, medications exist to help lower blood pressure and cholesterol levels, cures have been developed for hepatitis C, HIV has been transformed from a horrific plague into a largely manageable condition, and a variety of gene therapy products are promising cures for rare illnesses that previously served as death sentences. Technological progress has also been made in medical procedures. Surgical improvements now allow medical providers to address a wide range of medical conditions including, but certainly not limited to, relatively non-invasive surgeries for heart attacks, improvements in the diagnosis and treatment of strokes, surgical solutions for various types of cancer, and a variety of effective mental health treatments.

A rich economics literature has evolved examining how firms decide to invest in developing medical innovations. This literature, however, has primarily focused on both investments in *pharmaceutical* innovations and how the resulting drugs diffuse into clinical practice.[1] This focus is likely driven by the fact that the economic model and the regulatory process governing drug development are more clearly understood and data about each stage of the production process are more widely available.

In contrast, economists have devoted much less attention to the development of new medical procedures.[2] As a result, little is known about the process by which such novel procedures are developed let alone whether this process is optimal. In this paper, we attempt to fill this gap in the existing literature by examining the underlying economics, rules, and regulations governing the innovative process for medical procedures. Whereas every step of pharmaceutical development is planned and regulated, medical process improvement comes about in a far more *ad hoc* manner. This includes both the regulatory structures and the ways in which products eventually diffuse throughout the medical community.

[1] See, e.g., Acemolgu and Linn, (2004), Finkelstein, (2004), Blume-Kohut and Sood, (2013), Dubois *et al.* (2015), Agha and Molitor, (2018), Dranove *et al.* (2020), and Garthwaite *et al.* (2020).
[2] There is a small literature on medical devices, as we describe below. However, many new value creating procedures are not directly connected to new devices.

The broad economic decision is the same for both products and procedures. In both categories, potential innovators must make large, fixed, and sunk investments in research and development. Such investments can take the form of explicit financial investments as well as the opportunity cost of medical research teams. Despite this fundamental economic similarity, and the potentially large welfare gains afforded by both types of technologies, the regulatory and legal frameworks governing the development of these two types of innovation are vastly different. Such differences can influence both the amount and scope of resulting innovation.

The development of pharmaceuticals is heavily regulated by both the Food and Drug Administration (FDA) and the patent system. This accomplishes two goals. First, the FDA approval process assures a measure of safety and efficacy. Second, firms are granted clear and well-understood protections over the intellectual property resulting from their successful investments. In addition, a variety of other regulations and competitive forces cause payers to cover nearly all FDA-approved pharmaceutical products. The combination of these factors means that innovative firms have some certainty they will maintain pricing power resulting from their market exclusivity for the novel pharmaceutical products. Policymakers and economists alike believe that without the market power created by this market exclusivity, firms would underinvest in the development of new technologies (Nordhaus, 1969). A robust empirical literature supports this belief by demonstrating that increased market opportunities drive investments in research and development.[3] Fundamentally, these policies represent a tradeoff of accepting decreased welfare from reduced access to products today in order to provide the incentives for firms to make the investments necessary to develop goods and services in the future.

There are at least two primary differences between the development process for drugs and procedures that should directly affect appropriability and therefore the firm's optimal investment decision. The first is a question of property rights. The development of novel pharmaceuticals involves well-defined property rights that are enshrined in the patent system. As a result, firms making large and sunk investments

[3] For example, see Ward and Dranove (1995), Acemoglu and Linn (2004), Finkelstein (2004), Blume-Kohout and Sood (2013), and Dranove *et al.* (2020).

in developing new drugs have a reasonable assurance they will capture a meaningful portion of the value created by successful products. The same cannot be said for the firms and individuals who develop new procedures, for several reasons. First, procedures are difficult to successfully patent.[4] Second, many new procedures involve devices that no longer have exclusive patent protection, either because the patent has expired or competing devices have reached the market. Even when patent-protected devices are involved, the financial returns of a new procedure are diffused across both the device maker and a large number of providers of the procedure. For example, while stents can cost anywhere from a few hundred to a few thousand dollars, the median facility fee for stent placement is $21,000.[5] Even after provider discounts, the facility payment dwarfs the payment to the stent manufacturer. Much of this payment represents incremental profits above variable costs. Surgeons' fees are also in the thousands of dollars. This stands in contrast with new drugs, whose prices, and the resulting profits enjoyed by their patent holders, often vastly exceed the fees paid to providers who prescribe them.

A second important difference is that novel pharmaceutical products approved by the FDA receive almost immediate acceptance and reimbursement by payers. In contrast, the developers of new procedures have far less certainty about whether, when, and how much they will be reimbursed. As we explain below, reimbursement critically depends on whether and when the American Medical Association (AMA) grants a Current Procedural Terminology (CPT) billing code, an administrative process that has heretofore been relatively obscure to most researchers.

We begin by focusing on the former of these two differences using a novel dataset from the AMA that contains the universe of CPT applications. These novel data allow us to identify the entirety of the development process for new procedures, including the first benchmark research, the FDA approval of related devices, the AMA approval of "temporary" CPT III codes (for which insurers generally do not reimburse), and the subsequent promotion to "permanent" CPT I codes (for which insurers nearly always do

[4] See Section 5.3 for details.
[5] See https://www.epainassist.com/test-and-procedures/cost-of-stent-placement-procedure. Accessed 8/12/2020.

reimburse). Given that most new medical procedures involve medical devices, this descriptive information complements and extends the existing evidence in this area (e.g., Stern 2017).[6]

Among our key findings, we demonstrate that the timeline for discovering, developing, and commercializing novel procedures is far longer than previously reported. This difference primarily results from the fact that previous efforts focused on only specific stages of the development process and/or could not observe the administrative process determining reimbursement.[7] We document an average lag of more than six years between initial research publications about procedures involving new devices (i.e., those that have not previously been used in another medical procedure and have been approved less than two years before CPT III application) and filing of the FDA application. We then document an additional one year before FDA approval.

If this were a pharmaceutical process, then this seven-year-long development period would largely describe the time period before innovative firms could expect to earn revenue from a successful innovation. It would also support the common belief that procedures and devices could be developed more quickly than pharmaceuticals, with the latter taking nearly eight years on average from the initial clinical testing to marketing approval (DiMasi et al. 2016), even longer if we start the clock with the granting of patents. However, procedures face additional hurdles before they are widely reimbursed and diffused throughout the medical community. After FDA approval of the device, we estimate there are an additional nine months until the awarding of CPT III status of the procedure codes, and even these provisional codes are rarely reimbursed. Furthermore, only a small fraction of procedures subsequently advance from CPT III to fully reimbursed CPT I status—among all CPT III procedures approved between 2008 and 2014, only 29 percent are promoted after the five-year temporary period.[8]

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[6] We offer one important caveat. While there have been significant welfare gains from incremental improvements to existing procedures – consider for example the tremendous improvements in outcomes for CABG surgery patients since the first procedures were performed 60 years ago (Goetz et al. 1961)– our focus is on new procedures. We will return to this distinction in our conclusions.

[7] For example, Stern (2017) documents that the FDA requires less than two years after submission, on average, to review and approve new Class III ("High Risk") medical devices, while Makower *et al.* (2010) report that the average time between first communication and FDA approval is 54 months. A high risk device "supports or sustains human life, is of substantial importance in preventing impairment of human health, or presents a potential, unreasonable risk of illness or injury." Source: https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma. Accessed on 8/23/2020.

[8] For procedures involving new devices, only 17 percent are promoted within five years, and the average lag for promoted codes is 34 months.

Combining all stages of development together, we find a total average time from initial research to CPT I status for procedures involving new devices is about ten years, as long or longer than the timeline for new drugs.[9] In addition, this process contains additional forms of uncertainty about whether even successful innovations will be reimbursed by payers and/or implemented by providers.[10]

We also document that many new procedures involve devices that had previously been approved for other procedures. While these devices no longer require FDA approval, the associated new procedures may require new CPT codes, depending on whether they are substantially different and/or require substantially different effort by providers. We find that the CPT approval process for these "old device procedures" is even longer and less certain than for new devices. The same is true for new procedures that do not involve devices. While providers may be able to bill for the new procedure using an existing CPT code, this is far from certain. Even if insurers do reimburse under an old code, the payment may not fully compensate for the effort required to perform the new procedure.

A primary contribution of our results is demonstrating that the importance of the under-discussed administrative hurdle of securing a billing code to the development process for new medical procedures – a process, we note, that is largely absent from the calculations of firms investing in the development of new drugs.[11] We demonstrate that these codes are not simply the administrative formality that their absence from the literature suggested. We estimate that the AMA's decision to promote a code from CPT III to CPT I causes a statistically and economically significant increase in the use of these procedures by Medicare patients. This stands in stark contrast to new drugs, where no third party "seal of approval" beyond the FDA is required for firms to begin earning revenue. Therefore, the considerable lag between FDA approval and promotion from CPT III to CPT I codes represents a meaningful economic cost for innovators. To the

[9] The innovation time is much longer for procedures involving no device or old devices. See Section 3 for details.
[10] As we explain below, some of the delay may reflect the fact that providers may be able to bill for these procedures using existing CPT I codes, so there is less urgency in seeking new codes. In fact, given the limited reimbursement for CPT III codes and the lack of certainty about moving to CPT I, in expectation it may be more profitable to remain being reimbursed under the original code.
[11] Drug makers are not guaranteed reimbursement after FDA approval. Normally, they must negotiate with Pharmacy Benefits Managers (PBMs) for inclusion in formularies. PBMs are increasingly moving to closed formularies that do restrict coverage. See, e.g., Agha et al. (2020).

extent that the procedure requires a patented medical device, this delay likely affects particularly valuable periods of market exclusivity.

We next use our novel CPT application data to shed light on the potential role of property rights in the development process of medical procedures. For pharmaceutical products, firms that bring a product to market receive patent protection and are the firms that apply to the FDA for regulatory approval. For medical procedures, however, the firms or individuals that develop the procedure only receive defensible property rights to the extent that the procedure involves a patentable medical device. Even in that case, the property rights only pertain to the device which represents a fraction of the spending on many new procedures. This limits the appropriability of investments in new medical procedures.

At the margin, this limited appropriability could decrease the level of investment in procedures compared to pharmaceuticals that generate similar societal value. There could conceivably be rational reasons to prefer one category of innovation over another. That said, allowing less appropriability for procedures compared to pharmaceuticals does not appear to be a well thought out policy decision. Nor, does it necessarily reflect that these two product categories generate inherently different levels of economic value. In fact, many procedures have meaningfully affected the provision of medical services. Consider the transcatheter aortic valve replacement (TAVR), which was a revolutionary and lifesaving treatment for many patients with diseased aortic valves. Similarly, Applied Behavior Analysis (ABA), which is a set of related assessments and treatments for producing "clinically significant and lasting improvements in the functioning of people with autism."[12] Both procedures are extremely popular, provide substantial benefits to patients, and generate economically meaningful medical spending. For example, Medicare beneficiaries received over 50,000 TAVR procedures in 2016, and the adoption of TAVR has been described as a "tsunami" (Leon *et al.* 2018). ABA is sufficiently widespread to have its own board that has certified over 33,000 behavior analysts.[13] Even beyond these well-identified cases, a casual perusal of the practice of medicine in hospitals over the last 30 years would demonstrate that procedural innovation has had a meaningful effect on this sector.

[12] We purposely avoid calling these "process innovations," a term often used to describe an innovation that allows one to produce an existing product at a lower cost or higher quality.
[13] Source: Behavior Analyst Certification Board (BACB) 2019. *BACB Certification Data*. BACB. https://www.bacb.com/bacb-certificant-data/ Retrieved on 1/12/2020.

We examine the potential role of appropriability in the development of new procedures by examining the sponsors of applications for new CPT billing codes. Broadly speaking, applicants in our data are either firms or professional medical societies. We document meaningful differences in the types of procedures supported by these two types of applicants. For industry participants, 92 percent of CPT III applications are for procedures that involve an exclusive patented device.[14] In contrast, only 36 percent of medical society applications involve such a device. Furthermore, those remaining procedures supported by industry applicants that involved generic devices were promoted by consulting firms that are in the business of assisting physician groups with reimbursement. While not dispositive, the clear pattern in the data suggests that private firms are less likely to support devices without a clear path to appropriability. This could mean that process improvements unrelated to devices are underprovided to the market.

## 2. Background

### *2.1. The Procedure Innovation Process*

At a broad level, the scientific process leading to medical procedure innovation resembles the more often discussed process for discovering and developing new drugs.[15] For pharmaceuticals, target molecules are identified and refined over time through a combination of theoretical and laboratory research with limited clinical applications. Innovators often publish their findings throughout this process, both to help establish precedence and to provide information to the medical community. At some point, usually early in the discovery process, innovators almost always seek patent protection which provides clear intellectual property protection against other firms commercializing the target molecule.

In order to bring a drug to market, firms must then apply for permission to participate in the multi-stage drug development process, overseen in the United States by the FDA. Following FDA approval, insurers nearly always pay for the drug, although the exact amount is sometimes subject to negotiation.

[14] We define such a procedure as one that a) involves a medical device, b) the medical device is made by only one firm (i.e., no competing firms) based on the referenced studies in the CPT III application, and c) the medical device company has an unexpired patent claiming the device at the time of CPT III application.

[15] Several studies document drug development times, success rates, costs, the FDA approval process and the timelines involved. See, e.g., Dranove & Meltzer (1994), DiMasi *et al.* (2003), Keyhani *et al.* (2006), Hay *et al.* (2014), DiMasi *et al.* (2016), and Wong *et al.* (2019).

Finally, providers and patients decide whether to use the new drug based on the available evidence and the relevant reimbursement decisions.

This patent and approval process is highly standardized. The state of patent law for new drugs is mature and the FDA provides clear guidelines about acceptable evidence and criteria for approval. Firms still face scientific risk. After all, clinical trial outcomes are unpredictable and failure to successfully progress through all phases is relatively common (Wong *et al.* 2019). However, the FDA has a long history of systematic decision making and drug makers have established relationships with the FDA. Therefore, conditional on generating sufficient scientific evidence of safety and efficacy, firms have general predictability concerning the lengthy regulatory review process. Reimbursement of new drugs is common, typically follows shortly after FDA approval, and is largely based on market prices (Newhouse 2004).

The regulatory process for procedures exhibits far more variation. The closest match is for procedures involving new medical devices. In these cases, the FDA plays an important regulatory role, which has been described by Stern (2017) so we will only present the essentials necessary for understanding the economic issues discussed in this paper. The FDA review of devices varies according to the type of device.[16] Class I and Class II devices are both considered low risk, although Class II devices require special standards of care to assure patient safety. Approval of both Class I and Class II devices requires relatively little scrutiny. Makower *et al.* (2010) report that the average time between a low-risk device maker's first communication with the FDA and approval was just 31 months.

Firms that wish to market high-risk devices (i.e., Class III devices) must file for premarket approval (PMA). The PMA must provide evidence of safety and effectiveness, normally derived from clinical trials. Stern (2017) provides a systematic review of the PMA review process and documents that conditional on the submission of FDA applications, the approval rate is very high. Makower *et al.* (2010) report that the average time between first communication and FDA approval is 54 months. Stern (2017) finds that the average FDA review time is 18 months, suggesting that the clinical trials require three to four years.

[16] See Goldman & Lakdawalla (2011).

Some innovations represent applications of existing devices to new indications, exactly analogous to drugs. Unlike drugs, however, FDA approval for each new indication of an existing device is more rapid, often a matter of months.

Finally, there are some new procedures that do not involve any medical devices. For these procedures, the FDA plays no regulatory role in the development, testing, or marketing. In principle, there is no direct regulation of new procedures of this type. Innovative providers can experiment in their development and other providers can simply adopt them at their discretion (Darrow 2017). Adoption and diffusion are highly dependent on education within the medical community, such as through presentations at meetings of professional societies (McKinlay 1981). Beyond education, adoption also depends on reimbursement – a process we detail below.

*2.2. Administrative Coding and Reimbursement of Medical Procedures*

Medical procedures are complex and heterogeneous products, so payers have adopted standardized coding systems for different procedures as the administrative basis of reimbursement. Each service is reported to payers using the most appropriate code and reimbursed accordingly. Unlike drug treatments that are standardized by regulatory bodies (one dose must be chemically identical to any other), medical procedure coding inevitably groups slightly different services together under a single code. Furthermore, insurers often base payments for medical procedures on estimated costs, unlike drugs where prices are largely market-based.[17] Specifically, Medicare uses a "prospective payment system" for both inpatient and outpatient procedures, where payments are based on a standardized measure of costs per procedure. A large percentage of private payers follow Medicare, paying providers a multiple of Medicare's rates.

The willingness of providers to adopt new procedures relies on a procedure being sufficiently profitable or the provider being willing to undertake the procedure at a loss in order to satisfy some other part of their personal objective function. This means that, within the medical coding framework, one of three situations must apply. In some cases, a new procedure is sufficiently similar to existing procedures that

[17] Public payers use explicit cost-based payment structures, such as Diagnosis Related Groups (DRGs) and Relative Value Units (RVUs). Private payers often a multiple of DRG case weights and RVUs. Thus, even in a market setting, payments are tied to costs.

providers may bill under an existing code. This will persist as long as the new procedure is profitable at the rates payers are willing to pay for that code. In the second situation, the new procedure has a new code, with a corresponding new reimbursement rate. This is likely to arise when the new procedure is sufficiently different from existing procedures to make it impossible to bill under an existing code and/or the new procedure is not profitable at rates paid for the old procedure. Finally, providers can bypass the standard medical coding system and request *ad hoc* reimbursement from payers. This may occur for one of two reasons. First, there may be no similar procedure with a CPT I code. Second, there may be a similar procedure, but providers believe they can receive higher reimbursement if they request *ad hoc* payment. Either way, billing outside of the standard system can be administratively onerous and risky for providers because there is generally no guarantee of reimbursement before treatment and payers can be reluctant to accept *ad hoc* claims.

Adding further complexity is the fact that different coding systems are used in different situations. Two of the most important are the Current Procedural Terminology (CPT) code set maintained by the AMA, and the Medicare Severity-Diagnosis Related Group (MS-DRG) codes maintained by the Centers for Medicare and Medicaid Services (CMS).[18] The same treatment might be reported using multiple code sets because there are multiple providers to be paid. The situation under Medicare is informative. In outpatient settings, Medicare (and most private payers) uses CPT codes as the basis for fee schedules. In inpatient settings, Medicare uses both CPT and DRG codes.[19] Private payers use a wider variety of codes, including but not limited to CPT and DRG codes.

There are two important implications of this discussion of medical coding for the adoption and diffusion of innovative medical procedures. The first is that some utilization of innovative procedures may not be clearly reflected in administrative data. Unlike new drugs that must be reimbursed under their (new) names and are easily tracked, procedure innovations that are claimed and reimbursed under existing procedure codes (before the new codes get approved) will be difficult to detect in claims data. We explain below how we address this issue by taking advantage of the availability of the *provisional* (Category III) CPT

[18] The CPT and MS-DRG codes are the bases for other code sets. For example, the CPT code set is the core of the Healthcare Common Procedure Coding System (HCPCS) used by Medicare.
[19] CPT codes are used for physician reimbursement. DRG codes are used for hospital reimbursement.

codes in our data. The second is that for procedures that do require new codes, the new code assignment may be an important part of the innovation process that has not previously been studied and has no analogy to drugs. In Section 2.4, we provide more details about this process.

*2.3. The CPT Code Approval Process*

The AMA maintains and holds the copyright to the CPT code set described above. The AMA holds several meetings each year to consider changes to the code set, including adding new codes, removing old codes, reallocating or consolidating existing codes, and refining code descriptions. Understanding the process by which new codes are assigned requires an understanding of the structure of CPT codes.

There are three types of CPT codes. Category I (CPT I) codes form the bulk of the 10,000 CPT codes representing virtually all procedures that medical science has to offer. A CPT I code contains five digits organized by specialty or type of service. For example, codes 00100-01999 pertain to anesthesia while 99201-99499 are for evaluation and management services. CPT I codes are effectively permanent.[20] Category II (CPT II) codes are optional 'add-on' codes that providers can report alongside other procedure codes and are used for execution and performance measurement. They are not relevant to our study. Starting in 2001, the AMA introduced Category III (CPT III) codes, which contain four digits followed by a "T", such as 0099T (implant corneal ring). CPT III codes are temporarily assigned to procedures that do not meet the criteria for CPT I codes. They are designed to track the use of emerging procedures while evidence accumulates about whether a CPT I code should be assigned.

Finally, a class of CPT codes is reserved for procedures that do not appear elsewhere in the code set. These codes typically end with "999" or "99". For example, code 33999 covers unlisted cardiac surgery procedures A provider using these codes typically submits a request for reimbursement, describing the procedure, the medical justification, and the requested payment.[21] Each payer determines whether and how much to reimburse the provider for each code. For a common new procedure that is awaiting AMA approval, such as TAVR, providers may systematize the process of requesting reimbursement, and payers may routinely

[20] On occasion, the AMA will merge, delete, or introduce CPT I codes. However, the consistent structure of CPT I codes means that the mapping of a procedure to a group of related codes is generally stable.
[21] For an example of typical reporting requirements, see Chapter 4 of the CMS *Medicare Claims Processing Manual* (CMS Title 100-04).

approve these requests. For rarer procedures, the process of requesting reimbursement may be costly and payers may be slower to approve the payment. Importantly, providers can only report these unlisted codes when the relevant procedures are not covered by a specific existing CPT code. For example, CMS instructs Medicare contractors to verify that procedures cannot be covered by specific codes and to change submitted claims accordingly. This implies that once a specific code is available, reporting is accurate—every provider that reports the procedure must do so through the specific code. This is true even if it would be financially advantageous to use a different existing code for the procedure, e.g., a provider cannot use an existing CPT I code (reimbursable) to report when a newly issued CPT III code (oftentimes non-reimbursable) is available.[22]

Any stakeholder – the individuals who developed the new procedure, a medical society, or a device manufacturer – may apply for a new CPT code.[23] For example, the Society for Cardiovascular Angiography and Interventions, along with three other provider organizations, jointly applied for a set of CPT III codes for TAVR in November 2009.[24] An *ad hoc* review committee consisting of clinical and research specialists meets two or three times every year to consider all applications. In considering whether to grant a new CPT III code, the AMA committee considers the extent to which the new procedure differs from existing procedures, the extent to which it is already in use, and any clinical evidence of effectiveness. In this process, extra weight is given to peer-reviewed research supporting clinical efficacy. After approval, it can take one to two years before the CPT code is available for use. In the case of TAVR, the set of approved CPT III codes was not available until May 2012. After five years in CPT III status, the committee automatically sunsets codes, unless there is an application for extension or promotion to CPT I. An applicant may request an early promotion from CPT III to CPT I. For example, TAVR was promoted to CPT I status in January 2013.

### *2.4. CPT Codes and Procedure Utilization*

One of the central questions in this paper is whether and how AMA coding decisions affect procedure utilization, which is an important input to the investment decision of innovative firms. A few case

[22] See Section 2.4 for detailed discussion on reimbursement for CPT I and CPT III codes.
[23] If an applicant requests a CPT I code, the AMA may instead grant a CPT III code.
[24] The set includes four codes pertaining to variations in the approach to the procedure and whether there was cardiopulmonary bypass.

studies show that promotions do lead to increased utilization for specific medical services, but there has been no systematic analysis.[25] To appreciate why the answer to this question is not obvious, it is important to be clear about the implications of CPT I and CPT III codes. Neither code type implies explicit endorsement of a procedure by the AMA and neither code type assures reimbursement by payers.[26] Treatment and reimbursement decisions remain the independent responsibility of providers and payers. Furthermore, a CPT III code does not imply that the AMA believes a procedure should eventually be assigned a CPT I code. On the other hand, a CPT III code also does not imply that the AMA believes a procedure is 'experimental'. As a practical matter, all procedures must spend some time at CPT III before promotion to CPT I.

If physicians believe that a procedure is efficacious, the actual coding status could be theoretically irrelevant. In practice, coding matters for several reasons related to both reimbursement and information about treatment efficacy. First, most payers are reluctant to reimburse for CPT III codes. Indeed, many maintain blanket denials of reimbursement of all new CPT III codes. This is typically on the grounds that they represent 'experimental' or 'medically unnecessary' procedures, despite the AMA's agnosticism on this point. Second, while CPT codes are not AMA endorsements, a successful AMA review, as reflected in the granting of a CPT I code, could be a positive signal of the procedure's efficacy. In other words, although the AMA is clear that CPT code assignments do not represent medical judgments (endorsements or otherwise), it is possible that some providers or payers interpret them this way.

## 3. Basic Facts about CPT Applications and Approvals

### *3.1 Extent of Medical Procedure Innovation*

Our first goal is to document the extent of medical procedure innovation using a unique dataset on all CPT code applications filed with the AMA between 2008 and 2017.[27] Applications follow a fairly standard format and contain: (1) the identity of the applicant; (2) whether there is an associated device and whether the

[25] See, e.g., Duszak et al. (2010) and Cox et al. (2016), for case studies.
[26] As of 2019, each release of new CPT III codes contains the following text: "As with CPT I codes, inclusion of a descriptor and its associated code number does not represent endorsement by the AMA of any particular diagnostic or therapeutic procedure or service. Inclusion or exclusion of a procedure or service does not imply any health insurance coverage or reimbursement policy."
[27] We only observe the total count of applications filed in 2018 and 2019; no detailed information about these applications are provided to us. Applications filed before 2008 are only available in hard copy and were not produced for this study.

device has FDA approval; (3) published research findings pertaining to the procedure; (4) estimates of the frequency of use and how many different providers use it; (5) identity of any medical societies that support the application; (6) details about the procedure; and (7) how providers currently report the procedure for reimbursement purposes.

Unfortunately, we do not have information about procedures that were developed or attempted to be developed, but not ultimately proposed for AMA review. This could include procedures that failed early in the process and those that could be sufficiently profitable under an existing code. Thus, unlike drugs, where we have good early-stage research data and can estimate attrition rates from early in the process, we are unable to do the same for procedures.

Table 1 summarizes information about CPT III applications between 2008 and 2019. Columns (1)-(3) report numbers of applications, acceptances, and rejections by year. Columns (4)-(6) report the fate of each accepted application, i.e., whether they are promoted to CPT I codes, sunsetted, or remain as CPT III codes. The annual number of CPT III applications varies from 11 to 26, with a twelve-year total of 187. Of these, 162 were approved. Of the 86 applications approved between 2008 and 2014, only 28 were promoted to CPT I by 2019, while 32 remained as CPT III and 26 were sunsetted.[28] Among the 28 promoted procedures, 25 were promoted within five years after the CPT III approval, which indicates the 5-year promotion rate is 29% (25/86).

Table 2 reports the statistics by procedure type. Panel 1 breaks down the statistics by whether the application involves medical devices, and whether that medical device has been previously used for a different procedure or approved more than two years prior to the CPT III application ("old" versus "new" device).[29] Panel 2 reports results by type of applicant. There are slightly more industry applicants than medical society/physician applicants. Industry applicants have a slightly lower approval rate and a much lower conditional rate of promotion to CPT I codes.

[28] We focus on the promotion and sunset of CPT III applications approved between 2008 and 2014 because the CPT III codes are valid for a maximum of five years if not extended.
[29] We observe procedure characteristics such as device type, applicant type, and the innovation timeline for the 128 CPT III procedures approved between 2008 and 2017.

*3.2 Development and Administrative Approval Times of Medical Procedures*

Numerous studies estimate and discuss the average innovation timeline for pharmaceuticals. In this section, we aim to develop a roughly comparable timeline for medical procedures that accounts for the unique features of innovation in this area. We show that a meaningful portion of the development time for medical procedures is the time period between the FDA's approval of the associated device and the AMA's awarding of a permanent reimbursable billing code (CPT I code). Accounting for this administrative process, we estimate that these procedures can face a longer development process than pharmaceutical products.

Measuring the innovation timeline is not straightforward, as it requires defining and identifying beginning and endpoints. Studies of drug development use a variety of starting points, such as the first clinical trials, and usually choose the date of FDA approval as the endpoint.[30] For example, DiMasi et al. (2016) report that in 1990-2010, clinical trials for drugs require 95.2 months, on average. It takes another 16 months for FDA approval, for an average total development time of 9.2 years. They also report that the average time from the synthesis of a new drug to clinical trials is 31.2 months, giving a total time from the synthesis of a new drug to its approval of nearly 12 years. In contrast, Stern (2017) finds that the total development time for Class III medical devices is 54 months, on average, using the onset of clinical trials as the starting point and FDA approval as the endpoint.

With our unique access to CPT application data, we are able to extend the Stern (2017) time window in both directions, as well as measure development times for procedures that do not involve newly patented devices. As mentioned previously, there is no universally accepted definition of the starting point of innovation, which makes it difficult to compare development times across products and processes. With this in mind, we define the beginning of procedure innovation to be the first utilization of the procedure among humans, as reported in the first published research and/or the AMA applications.[31] Although some procedures benefit from earlier animal model studies or lab studies, we use the first in-human utilization

[30] See, e.g., Dranove & Meltzer (1994), Keyhani *et al.* (2006), DiMasi & Grabowski (2007), and DiMasi *et al.* (2016).
[31] For example, the initial TAVR procedures started in 1985 but were unsuccessful due to the limitation of the available devices (Cribier *et al.* 1986). In 1999, Edward Lifesciences invented a new bioprosthetic heart valve sutured onto a balloon expandable stent. Using this device, the first in-human percutaneous aortic valve implantation was successfully performed in April 2002 as a "last resort" treatment for a patient in France (Cribier *et al.* 2002). Phase I pilot trial started in August 2003 (Cribier et al. 2006). In this case, we use the first in-human utilization of the procedure (i.e., April 2002) as the starting point when calculating the time span.

when calculating the time span because it is reported in the vast majority of CPT III applications. This is roughly comparable to the start of phase I in drug trials. For procedures that involve FDA-approved/cleared devices, the second milestone is the FDA approval or clearance of the device.[32] The third milestone is the CPT III approval by the AMA. Some of the CPT III procedures are eventually promoted to CPT I, while others are sunsetted or temporarily extended by the AMA after five years from the initial CPT III code publication.[33]

Table 3 presents summary evidence on the innovation timeline up through the effective date of the CPT III approval. We report these estimates separately for innovations involving new devices, old devices, and no devices. The first two rows include information available for all CPT III applications. The last three rows contain information for the 75 CPT III applications involving devices for which we have information about the associated FDA application.

The development time of new procedures is quite long – 134 months (11.2 years) on average between the initial research study and CPT III approval. Most of this time occurs prior to the CPT III application. The average lag between the CPT III application and the effective date for the new CPT III code is only 14 months. This shows a relatively swift administrative process. That said, stakeholders of innovative medical procedures including the device companies face a long step, 52 months (4.3 years), after FDA approval before the associated procedure gets a provisional billing code (the CPT III code) with no guarantee for reimbursement. By comparison, innovative pharmaceutical firms generally do not face such a long lag after FDA approval before they can be reimbursed for their new product. In addition, there is considerable variation in the time to CPT III approval across procedure types. The longest development times are for old devices, perhaps because providers can usually bill for the new procedures using old codes and are therefore in no rush to secure new codes. Figure 1 shows the distribution of the development time for all observed CPT III approvals, ranging from 1 to more than 20 years.

[32] We use the approval time of the 510K containing the intended use of the device as described in the CPT III procedure, rather than that of the first 510K clearance of the device.
[33] The average regulatory review period from the submission of a new CPT III application (or an application for promotion from CPT III to CPT I code) to the effective date is about one year. For example, applications submitted in July 2017 are discussed in September 2017 meeting, and, if approved, become effective on July 1, 2018.

Table 4 repeats the analysis but restricts the sample to the 30 procedures promoted to CPT I by 2019. It takes an average of 194 months (16.1 years) from the first research study until the effective date of the CPT I code. This puts the development time for procedures on a par with, or even longer than, new drugs. Nearly half of this time is spent before the FDA submission. There are another 48 months (4 years) between FDA submission and CPT III application, although this is largely for procedures involving old devices, i.e., those that had previously been approved for another use. Finally, a full 38 months (3.2 years) is spent between CPT III approval and the effective CPT I date. There is considerable variation in innovation time: Appendix Figure A1 shows the distribution of promotion time from CPT III approval to CPT I promotion and Appendix Figure A2 shows the distribution of overall time from first research to CPT I code approval.

## 4. Effect of CPT Promotion on Utilization

### *4.1. Empirical Strategy*

When developing innovative medical procedures or products, it is important to understand how the procedure or product will be adopted and paid for in the marketplace. In this section, we show the promotion of procedure billing codes from CPT III (provisional, non-reimbursable) to CPT I (provisional, reimbursable) has a significant impact on utilization, which indicates that it must be considered in any analysis of the appropriability of investments in procedural innovation.

Ideally, in order to study the effect of administrative coding decision on utilization, we would have data on every time a medical provider uses the procedure regardless of the coding. Recall that providers are required to use appropriate CPT III codes once they are available, which means that procedures should not be occurring under other codes after the issuing of a CPT III code. Using AMA documentation, we are able to match CPT III to CPT I codes for new procedures.[34] This allows us to examine the effect on use from

[34] The other possible approach is to find overlapping claims using different procedure code sets. There is one candidate for this in the International Statistical Classification of Diseases and Related Health Problems (ICD) code set. Unfortunately, ICD procedure codes are typically reported in inpatient settings so do not track use of outpatient procedures. In addition, during the period covered by our data the relevant version of the ICD code set was the ICD-9 set. The ICD-9 code set is generally less detailed than the CPT code set,

granting a CPT I code. Unfortunately, we cannot identify procedure use prior to the assignment of the CPT III code and therefore cannot empirically estimate the effect of being granted a CPT III code.

The second empirical challenge is identification. First, since prior utilization is a criterion for procedure promotion and is also relevant when providers make decisions about use, we are concerned that promoted procedures are systematically different from non-promoted procedures. Therefore, we rely on "own case control" (i.e., procedure-specific fixed effects) to measure the bump in utilization for each promoted procedure. Also, to address the concern that the increase in procedure utilization after promotion may reflect a continuation of the increasing trend in the pre-promotion period, it is crucial to examine whether the utilization increased discontinuously at the time when CPT codes are promoted. We do so using an event study approach.

Specifically, we employ the following two specifications to estimate the effect of CPT code promotion on procedure utilization.

$$Y_{it} = \beta_0 + \beta_1 PostCPTI_{it} + \theta X_{it} + \Upsilon Procedure_i + \Theta Year_t \quad (1)$$

$$Y_{it} = \beta_0 + \Phi \sum_d CPTI\_Event_{id(t)} + \theta X_{it} + \Upsilon Procedure_i + \Theta Year_t \quad (2)$$

The first specification, Equation (1), is a time-varying difference-in-differences (DID) estimation. The dependent variable $Y_{it}$ takes two forms: a continuous variable representing the utilization (i.e., the natural log of the number of Medicare services) of procedure $i$ in year $t$, and an indicator variable for whether procedure $i$ records any Medicare utilization in year $t$. $PostCPTI_{it}$ is an indicator variable which equals 1 if procedure $i$ has been assigned a CPT I code in year $t$. $X_{it}$ represents time-varying procedure characteristics—we include a categorical variable for whether procedure $i$ involves device and whether the associated device has been approved by the FDA by year $t$. In a robustness test, we also control for the interaction between the number of years the procedure code has been effective since its initial CPT III approval, $Tenure_{it}$, and the log time trend $LnTimeTrend_t$ to allow procedures in different tenure stages to have different trajectories of

so new procedures that receive new CPT codes may not receive new ICD-9 codes. The recent adoption of the more detailed ICD-10 code set means that this approach might be more feasible in the future.

utilization growth. The coefficient of interest is $\beta_1$. If promotion from CPT III to CPT I has a positive impact on utilization, we expect $\beta_1$ to be positive.

A key assumption of validating the DID estimation is the parallel trend assumption, i.e., promoted procedures have similar utilization trends as non-promoted procedures in the pre-promotion period. To better assess this assumption and also to examine the dynamic effects, we estimate an event study model, Equation 2. Specifically, we replace the post-time dummy $PostCPTI_{it}$ with a set of dummy variables $\sum_d CPTI\_Event_{id(t)}$, indicating both leads and lags from year $t$ relative to the year of code promotion.

*4.2 Data*

The main data source for procedure utilization is the CMS Medicare Provider Utilization and Payment Data in 2012-2017. The data provides annual CPT code-level procedure utilization. It covers all procedures provided to Medicare beneficiaries enrolled in Medicare part B and includes both inpatient and outpatient procedures. The utilization of a procedure in a certain year is measured by the number of Medicare services reported in this data. We supplement the utilization data with information on procedure promotion date and procedure characteristics obtained from the AMA CPT code documentation. We also use the AMA documentation to aggregate related CPT codes that represent the same procedure and to match CPT III and CPT I codes for promoted procedures.[35] We extract utilization data for all CPT III codes created since 2001 that remained active in 2012-2017, as well as those that were promoted to CPT I codes.

We identify a total of 801 procedure-year observations, representing 184 procedures with active CPT III codes between 2012 and 2017 (Sample 1). Of the 184 procedures, only 72 recorded Medicare utilization in some years between 2012 and 2017, representing a subsample of 319 procedure-year observations (Sample 2). Furthermore, among the 319 procedure-year observations, only 240 observations record Medicare utilization in the given year (Sample 3). This relatively low rate of Medicare utilization record likely reflects the fact that

[35] CPT codes are primarily administrative, so a single procedure may be assigned to a range of codes. This allows providers to report common procedure variations which might involve different costs. Since the underlying technology and techniques are the same across these codes, it is more appropriate to group them as a single procedure for our analysis. There is also often not a one-to-one mapping from CPT III codes to CPT I codes after promotion.

procedures with utilization of fewer than 11 cases are unreported in the CMS data. Also, not all new procedures are relevant for the patient population covered by Medicare (i.e. the elderly and disabled). Among the 72 CPT III procedures with Medicare utilization, 24 percent (17 procedures) were promoted to CPT I between 2012 and 2017; none of the 112 CPT III procedures with unreported Medicare utilization were promoted during the study period.

Since it is unclear whether the unreported utilization indicates zero utilization or missing positive values, we use several alternative ways to handle the unreported utilization in the CMS data. First, our preferred method is to fill the unreported value in Samples 1 and 2 with 10, which leads to a lower bound estimate of the billing code promotion effect due to the fact that pre-promotion observations are more likely to have unreported utilization. Second, for robustness, we also consider filling the unreported values with 1, 0, and a randomly drawn integer between 1 and 10. Finally, in Sample 3, we drop the unreported values. Table 5 presents the summary statistics of the three samples.[36]

*4.3 Results*

The main results of DID estimation from Equation (1) are shown in Table 6. Our most preferred specification is based on the full sample with unreported utilization replaced by 10, which generates a lower bound estimate of the administrative coding effect. We find that CPT code promotion from Category III to Category I is associated with a 9-fold increase in utilization (Table 6, Column 1).[37] As expected, the effect becomes even larger when we focus on the subsample of procedures with recorded Medicare utilization (Table 6, Column 4), or fill the unreported utilization with 1 instead of 10 (Table 6, Columns 2 and 5). Next, when treating the unreported value as no utilization, we find that CPT code promotion is associated with a 31.9% higher odds of any utilization (Table 6, Column 3), and this effect again becomes larger when restricting to the subsample of procedures with recorded Medicare utilization (Table 6, Column 6). Finally,

[36] Note that the number of observations with procedure characteristics (i.e., whether involving exclusive or nonexclusive devices or applied by medical societies) is less than the total because we only observe procedure characteristics for those approved after 2007.
[37] $e^{2.328} - 1 = 9.26$

the result remains highly robust when we drop all observations with unreported utilization (Table 6, Column 7).

To validate the parallel assumption of the DID estimation and examine the dynamic effect, we present in Figure 2 the estimated coefficients from Equation (2).[38] Utilization increased discontinuously starting from the promotion year and it stays relatively stable throughout the post-promotion period. There is no anticipatory effect in the years prior to promotion. This finding suggests that there is a one-time increase in utilization upon promotion to Category I codes, but no significant change in the diffusion rate afterward. These estimates demonstrate that the administrative coding decision plays an important role in the ultimate use and diffusion of that procedure.

We offer one caveat to this analysis. An important limitation of this analysis is that there may be innovative procedures for which providers are content to bill under existing codes. Our data do not allow us to identify these procedures. Thus, we are likely overstating the extent to which obtaining a new CPT I code impedes utilization of all new procedures. In Section 5.4, we discuss in detail the new procedures reported in old codes and explain why the overstatement of our analysis is likely to be small. For those procedures that are not well-accommodated by existing codes, however, it is clear that coding matters.

### *4.4 Extensions—Heterogeneity and Robustness*

In this section, we first test the heterogeneity of the main effect by procedure type, i.e., whether the procedure involves exclusive patented devices, nonexclusive devices, or is applied by medical societies as opposed to industry firms (Appendix Table A1). Appendix Table A1, Column 2, suggests that the increase in utilization due to CPT code promotion is stronger among procedures that involve medical devices (both exclusive and nonexclusive devices). There could be several explanations: device manufacturers might invest more in promoting their devices when the relevant procedures are reimbursed; procedures involving devices

[38] Figure 2 is based on the full sample with unreported utilization replaced by 10. Results remain highly robust when using the subsample of procedures with recorded Medicare utilization (Appendix Figure A3).

might be difficult to claim under existing codes and procedures without devices might allow more flexibility in claiming.

Next, we perform a number of tests to show our main findings are robust to the selection of model specification and sample. First, as mentioned above, the CMS data does not report utilization for procedures with 10 or fewer cases in the year. In our baseline tests, we assigned the value of 10, 1, and 0 to unreported utilization. However, the missing value for these procedures could be any number between 1 and 10. Therefore, we re-run the analysis (Equation 1) 10,000 times with different random draws for the missing values of utilization from a discrete uniform {1, 10} distribution. Appendix Figure A4 shows the results of the estimated coefficients and standard errors of the post-CPT I dummy variable in Equation 1. Appendix Figure A2, Panel (a) shows the results when using the full sample, and panel (b) shows the results using the subsample of procedures with recorded Medicare utilization. The results are highly robust and remain statistically significant.

The second robustness test re-estimates Equation (1) by including the interaction term between the tenure of the procedure (i.e., number of years since gaining a unique CPT III code) and the log time trend. This specification captures potential differential trends in diffusion rates across procedures in different tenure stages. The third robustness test aims to exclude the potential effect of FDA device approval on utilization. Although we controlled for the time-varying variable in the main specification on whether the procedure involves a device that hasn't been approved by the FDA at the time of gaining a unique CPT III code, we conduct a robustness test by re-estimating Equation (1) using a subsample that excludes all procedures that involve unapproved devices at the time of CPT III approval. The results from these two tests are shown in Appendix Table A2 and A3, respectively. The results remain highly robust and quantitatively similar to the main results shown in Table 6. Last, since we use code publication date as the date of promotion in the main analysis, yet the promotion decision is normally made during the year prior to the year in which the code is published, we perform a robustness test by setting the promotion year based on the year prior to the publication year. We re-estimate Equation (1) and show the robust results in Appendix Table A4. Compared with the main analysis shown in Table 6, the effects become smaller but remain highly significant.

*4.5 Does CPT III Status Affect Utilization?*

While we have documented that promotion to CPT I status has a profound impact on utilization, we cannot readily quantify the effect of the AMA granting of CPT III status, as there is no consistent documentation of utilization for procedures that do not have their own CPT codes. Several qualitative factors suggest that insurers generally do not reimburse for procedures with CPT III status, which in turn suggests that utilization may be limited. Perhaps most importantly, CMS does not assign RVUs to CPT III codes, which means that they cannot be billed like other procedures.[39] Indeed, insurer contracts with providers often include a blanket denial of reimbursement for Category III procedures, making a small number of exceptions for specific treatments. For example, the March 2019 Policy Guideline for UnitedHealthcare's Medicare Advantage program, notes that, except under specific circumstances, "UnitedHealthcare considers all services and procedures listed in the current and future CPT III code list as not proven effective and will deny submitted claims as not medically necessary."[40] In the accompanying list of CPT III codes, more than 85 percent are listed as noncovered, and all but one of the covered codes are covered with restrictions.[41]

Documents from medical device manufacturers provide additional evidence that reimbursement of CPT III codes can be difficult. Respiri (formerly iSonea) develops asthma monitoring devices. Its 2011 Annual Report describes receiving a Category III code for one of its products as a key achievement of the preceding year.[42] However, it also notes that upgrading the code to CPT I is necessary for securing reimbursement in the US market: "Achievement of a Category I CPT code will enable the company's products to become reimbursed by CMS and the majority of US health insurance payers." To take another example, Si-Bone develops minimally invasive surgical treatments for sacroiliac joint disorders. It completed

[39] Source: AMA CPT Category III Codes Long Descriptors https://www.ama-assn.org/system/files/2020-07/cpt-category3-codes-long-descriptors.pdf Retrieved on 8/23/ 2020.
[40] Source: UnitedHealthCare Medicare Advantage Policy Guideline Category III CPT Codes. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-guidelines/c/category-iii-cpt-codes.pdf Retrieved on 8/23/2020.
[41] For example, coverage is only granted for certain indications, e.g., meeting the FDA-approved protocols for IDE clinical trials, or performed under coverage with evidence development (CED) when a clinical study meets certain criteria.
[42] Source: iSonea Annual Financial Report. https://www.asx.com.au/asxpdf/20111019/pdf/421vl9t3rc2xfq.pdf Retrieved on 8/23/2020.

an initial public offering (IPO) in 2018 and included a detailed discussion of the relationship between CPT codes and reimbursement in its prospectus.[43] According to this document, the creation of a new CPT III code for the procedure involving their product in 2013 may have slowed adoption. The reason is that the minimally invasive procedure was previously claimed under the CPT I codes for the invasive version of the procedure. The new CPT III code threatened reimbursement because, as the prospectus notes, CPT III codes are reimbursed "sporadically". Positive coverage decisions by payers were delayed until after a new CPT I code became effective in 2015.

## 5. Contrasting Drug and Procedure Innovation

### *5.1 The Pace of Innovation*

In documenting the CPT approval process, one may be struck by the relatively small numbers of new procedures. Over the past ten years, the AMA has approved an average of fewer than 14 procedures for CPT III status, and only about 4.3 per year for CPT I promotion. In contrast, the FDA has approved an average of 44 new chemical entities and therapeutic biological products each year during the most recent five years.

We show Medicare utilization of the top 5 utilized *new* medical procedures and *new* drugs in Appendix Tables A5 and A6, respectively, where new procedures and drugs are defined as those approved within five years of the corresponding year. The comparison between the two tables suggests that utilization is higher for top-utilized new drugs than top-utilized new procedures. Looking at the data another way, Appendix Table A7 shows that total Medicare spending on new procedures during 2013-17 was only 21 percent of spending on new drugs.[44] This results from both the small number of identifiable new procedures compared to new drugs and differential pricing across the two categories.

Next, we show in Appendix Tables A8 and A9 the year of introduction of the top 15 utilized medical procedures and top 15 utilized drugs by Medicare beneficiaries in 2017. Examining these data, one may be tempted to conclude that the pace of drug innovation has outstripped the pace of procedure innovation.

[43] Source: SiBone IPO Report. https://investor.si-bone.com/static-files/83477437-1762-4a30-be4a-43a8c88968eb Retrieved on 8/23/2020.
[44] Because we no longer count TAVR as a new procedure in 2016, there is sharp drop in new procedure payments that year.

However, we caution against such a stark interpretation. This pattern could also reflect the relatively unmonitored development process for procedures. Each stage of every new drug (even those involving incremental improvements to an existing product such as a change in the delivery mechanism) is meticulously tracked by the FDA. Therefore, even small changes to pharmaceutical products are readily apparent in the data. In contrast, many (if not most) procedures are continually improved without any formal review and therefore are unobservable in any systematic fashion. As a result, the data on incremental advancements in new procedures is almost certainly under-reported in the data.

That said, there are also reasons to be concerned that the observed differences in the rate of innovation across the two categories are real, i.e. that we are experiencing more product than procedural innovation. These concerns stem from the institutions surrounding the innovative process. In particular, the lack of comparable property rights across the two categories could create differences in the pace of innovation for procedures compared to drugs.

As we discuss below, the deliberative process of regulatory oversight for drugs has created well-established rules for product development as well as clear and strong property rights. These rules represent a considered tradeoff among three factors: safety, innovative incentives, and monopoly pricing.

In contrast, the *ad hoc* process for oversight regarding innovation for medical procedures creates uncertainty over both the development process and the allocation and enforceability of property rights. There is little evidence of a considered tradeoff in policies that address the ways in which a lack of appropriability could cause potential underinvestment in value-creating procedures. As a result, the existing pace of process innovation could only be optimal by chance.

### *5.2 Contrasting Rules and Regulations Regarding Innovation*

The Federal Food, Drug, and Cosmetic Act of 1938 gave the FDA authority to oversee drug safety. After concerns about the safety of approved medications, notably thalidomide, the FDA Amendments of 1962 codified the testing requirements for drugs. The resulting structure for developing drugs – from preclinical trials through three phases of Investigational New Drug trials and final FDA review, all supervised

by the FDA – remains essentially unchanged. Once the FDA approves a drug, insurers nearly always agree to pay for it, although the price may be subject to negotiation. Over time, the FDA has taken steps to accelerate approval of "important drugs".[45] The FDA continues to modify the review process, as witnessed by recent efforts to accelerate the review of COVID-19 treatments and vaccines. Through the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) of 1984, Congress increased the effective patent lives of drugs that required lengthy reviews, while facilitating entry by generics once patents expired. These changes suggest that regulators are carefully weighing safety, development times, and protection of property rights. While stakeholders debate whether patent lives should be extended and whether testing is too rigorous, few take meaningful issue with the general structure of the drug approval process.[46]

In contrast, there is minimal regulatory oversight of medical procedures. Any medical provider can perform any medical procedure that they deem necessary and appropriate, even a procedure that no one has previously performed. There are two legal obstacles. The first is the malpractice risk. The second arises with procedures involving new medical devices. The FDA must approve a device for systematic clinical use in a specific procedure, a process that requires much less formal testing and development time than the process for drugs.[47] Once the FDA approves a device for one procedure, providers may use it for other procedures without additional approval. That said, the FDA does not ban inventive activities of physicians that lead to new medical devices, or oftentimes, new patents. In fact, physician-generated patents play a more important role in subsequent R&D activities by device manufacturers than non-physician patents (Chatterji *et al.* 2008; Smith & Sfekas 2013).

Without AMA approval of a CPT I code, however, providers cannot be assured of reimbursement, even if the procedure involves an FDA-approved device. The centrality of CPT coding and the central role played by the AMA seems almost accidental. The AMA initially classified diseases in the 1872 *Nomenclature of*

[45] See Dranove and Meltzer (1994).
[46] For details about the Federal Food, Drug, and Cosmetic Act of 1938, see https://www.fda.gov/about-fda/fdas-evolving-regulatory-powers/part-ii-1938-food-drug-cosmetic-act. For details about the FDA Amendments of 1962, see https://www.fda.gov/consumers/consumer-updates/kefauver-harris-amendments-revolutionized-drug-development. For details about the Drug Price Competition and Patent Term Restoration Act of 1984, see https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters.
[47] See Stern (2017).

*Diseases*. In the 1942 edition of the *Nomenclature*, the AMA added a list of commonly performed operations. By the 1960s, the AMA was expanding this list to include diagnostic tests and a range of medical treatments, and in 1966 it published a copyrighted report entitled *Current Procedural Terminology*. CPT coding did not become central to reimbursement until 1983 when CMS sought to better codify Medicare payments. With no better alternative, CMS adopted CPT codes, and private insurers quickly followed suit. In this way, a coding system developed to facilitate the exchange of clinical information became the foundation for billing of medical procedures.

Whereas the FDA spells out testing requirements in great detail, the AMA offers little specific guidance for innovators. The CPT III/CPT I promotion ladder resembles, at least superficially, the Investigational New Drug (IND) development process for drugs. In addition, innovators that wish to fast track approval may seek promotion to CPT I status prior to the expiration of the 5 year probation period. There, the similarities end. There are no distinctions among stages comparable to the safety/small scale trials, large trials distinctions of IND I, II, and III. The AMA does not specify sample sizes, type I, and type II error criteria. Instead, applicants for Category III CPT codes must meet at least one of the three criteria: a) support by at least one CPT/HCPAC advisor representing practitioners who would use the procedure, b) support by peer-reviewed literature, and c) an IRB approved protocol of the clinical study, an ongoing U.S. clinical trial, or other evidence of evolving clinical utilization.[48] As a result, there is a wide range of research methods used to assess the efficacy of new procedures. Among the 128 procedures approved by the AMA for Category III CPT codes between 2008 and 2017, only 20 percent are supported by completed Randomized Controlled Trials (RCTs). In contrast, Hatswell et al. (2016) document that 94 percent of the 774 drug approvals issued by the FDA between 1999 and 2014 are based on RCTs. Instead, 65 percent of procedure applications are supported by non-Randomized Controlled Trials (RCT), and 15 percent are supported by ongoing RCTs of which results are still pending at the time of the CPT III application.

[48] Source: Criteria for CPT® Category I and Category III codes, https://www.ama-assn.org/practice-management/cpt/criteria-cpt-category-i-and-category-iii-codes Accessed on 8/23/2020.

Admittedly, it may be difficult to perform RCTs with many procedures, but the heterogeneity of evidence presented in support of CPT applications is striking.

*5.3 Property Rights*

Perhaps the biggest difference between drug and procedure development that could contribute to the pace of innovation involves property rights. While device makers hold patents, these patents seem to be easy to invent around.[49] For procedures, there are significant obstacles to obtaining and enforcing patents. In 1994, the AMA House of Delegates voted to condemn patenting of medical procedures. In 1998, the AMA Council on Ethical and Judicial Affairs appealed to "the open exchange of information without the expectation of financial reward for advancing medical science" (American Medical Association 1998). The AMA still subscribes to this view and has pushed for legislation banning procedure patents (Anderson 1999). It is also unclear whether courts will uphold procedure patents independent of the patent for the associated medical device (Meier 1997). Perhaps for this reason, procedure patents are rarely enforced (Anderson 1999).

Another key consideration is reimbursement. Consider that the price of any product or procedure is a function of the value that it creates. When a physician prescribes a patented drug, most of the value captured by the producer goes to the drug company. In contrast, providers receive a substantial share of the value created by a medical procedure. Thus, the financial benefits of a new procedure are diffused across both the device maker (if there is a device) and potentially thousands of independent stakeholders. Facing a commons problem, organized medicine has responded by initiating the CPT coding applications for new procedures that lack property rights protection.

To shed some light on the role of property rights in the development process of medical procedures, we examine heterogeneity in the applicants across procedures based on whether the procedure involves a device and whether the device has non-expired patents. As previously noted, medical societies and physicians represent nearly half of all applicants for new CPT III codes, and 84 percent of the applicants for successful CPT I promotions. However, the data reveals systematic patterns in these applications. Table 7 reports the

[49] As Goldman and Lakdawalla (2011) noted, the innovation process for medical devices is typically much faster than that for drugs.

type of CPT III applicant (industry versus medical society) based on whether the procedure involves an exclusive patented device, nonexclusive device (e.g., off-patent device), or no device. Consistent with the aforementioned role of medical societies in solving the commons problem when there is a lack of property rights protection, we find that the vast majority (37 out of 42) of CPT III procedures with no device or off-patent devices are applied by medical societies, with the rest applied by consulting firms that are in the business of assisting physician groups with reimbursement issues (Table 7, Col 3 and 4). In contrast, only 21 out of 86 (24%) of CPT III procedures involving exclusive patented devices are applied by medical societies (Table 7, Col 2).

*5.4 New Procedures in Old Codes*

The scope of our study focuses on new medical procedures that have entered the CPT system and gained unique CPT codes. Admittedly, there are also "new procedures in old codes (NPOCs)" i.e., new procedures that are well-accommodated by existing codes and thus never assigned a unique CPT code. Our data do not allow us to separately identify NPOCs from old procedures sharing the same codes.[50] Therefore, our analysis, which focuses on new CPT codes, likely understates the extent of new procedure innovation. In this section, we conceptualize why some new procedures can be well-accommodated by old codes. We then offer some reasons why, with a few caveats, any understatement of novel procedure innovation is likely to be small.

As described in Section 2.2, there are two broad categories of new procedures based on the degree of innovation.[51] The first category is *radically* new procedures that are discontinuous from existing procedures (Type I). Since these procedures share few common features with existing offerings, they can only be billed under "unlisted" CPT codes with no assigned RVUs before gaining unique CPT codes. Therefore, in order to get reimbursement, providers who perform these procedures have incentives to obtain new CPT codes. The second category is *incrementally* new procedures that are adapted from existing procedures and offer limited

[50] The volume of old procedures may dwarf that of many NPOCs, making it difficult to detect any meaningful increase in the use of the shared codes.
[51] See Schumpeter (1934) for definitions of radical and incremental innovations.

changes; without unique CPT codes, they may be billed under existing codes. Within this second category, there are two different types: *cost-increasing incrementally* new procedures, i.e., those cost more than the existing alternatives (Type II), and *cost-decreasing incrementally* new procedures, i.e., those cost less than the existing ones (Type III). Similar to Type I procedures, billing Type II procedures under existing codes that were designed for low-cost alternatives reduces providers' profits; therefore, providers have incentives to obtain new CPT codes with higher assigned RVUs. This does not apply to Type III procedures, however, because billing Type III procedures under existing codes is profitable, and thus providers have little incentive to apply for new codes. This means Type III new procedures are the NPOCs that are well-accommodated under existing codes and are unobservable to researchers.

Next, we compare the relative prevalence of these three types of new procedures based on our data and explain why Type III procedures are unlikely to be widespread, which reduces our concern about the overstatement of the CPT I effect on the utilization of new procedures. First, recall that providers are required to bill under the most appropriate codes when available, which means a procedure cannot be reported under existing codes once a new CPT code is issued. This indicates that we observe the correct utilization of Type I and Type II procedures conditional on new codes being issued. In our data, among the 128 procedures that have been issued new CPT III codes during the study period, 79 were reported under unlisted codes with no assigned RVUs before obtaining new codes—the fact that there are no appropriate existing codes for these procedures indicates that they are Type I procedures; 49 were reported under existing codes with assigned RVUs, and they can be deemed as Type II procedures. This finding suggests that Type II procedures are less prevalent than Type I procedures.

What about Type III procedures, which have the potential to reduce costs? Weisbrod (1991) persuasively argued that the healthcare system historically favored *cost-increasing* (and *quality-enhancing*) technologies rather than *cost-decreasing* technologies (Weisbrod 1991). If this still holds true, then Type III procedures may be even less prevalent than Type II procedures.

A glaring exception to our taxonomy of procedures involves new technologies that had the potential to improve outcomes at a higher cost but have failed to deliver. This is exemplified by robotic-assisted

surgery, in which a physician-guided robot is a substitute in production for a laparoscopic surgeon. Since the initial FDA approval of the da Vinci robot for clinical use in 2000, robotic-assisted procedures have been increasingly adopted for gynecologic, prostate, head and neck, and other surgeries. Accounting for both fixed and variable costs, including the costs of the robot and the costs of the surgeon's time, robotic surgery is probably, but not definitively, more costly than hands-on surgery.[52] There is also no clear evidence that it offers meaningfully superior outcomes (Wilensky 2016; Wright 2017). As a result, the AMA has determined that it is unnecessary to issue unique CPT codes for robotic-assisted procedures.[53] Instead, the use of a robot is considered integral to the performance of laparoscopic procedures and should be billed under existing codes.[54] The da Vinci robot is the culmination of large investments in procedure innovation, and the use of robotic surgery continues to grow despite the mixed evidence on outcomes. Even so, a taxonomy of procedure innovation based on CPT coding must inevitably miss investments like these, even if they translate into commercially successful products.

We finally note that we do observe incremental innovations to existing procedures. These include drugs that complement procedures (e.g., immunosuppressants for transplant surgery), diagnostics that facilitate procedure improvements (e.g., 3T MRIs used in conjunction with prostate biopsies), better prosthetics, and changes in the way that procedures are performed (e.g., off-pump open heart surgery). Continuing improvements in outcomes for patients undergoing a wide range of procedures suggest that these incremental innovations may be equally or more important than the development of new medical procedures.

## 6. Conclusion

In this paper, we seek to explore inside the black box of the economics of medical procedure innovation and contrast it with the previously well-documented innovation process of pharmaceutical

[52] The fixed cost of purchasing a da Vinci robot is about 2 million USD; the incremental cost ranges from 3,000 to 6,000 USD per patient (Wilensky 2016).
[53] Source: Kaiser Permanente Clinical Review Criteria—Robotic Assisted Surgeries. https://provider.ghc.org/all-sites/clinical/criteria/pdf/robotic_assist_surgeries.pdf Accessed on 8/16/2020.
[54] Note that physicians can report their use of robotic-assistant procedures by attaching an add-on HCPCS code (S2900) to the primary laparoscopic procedure; however, this add-on code is not reported in administrative databases such as the Medicare Provider Utilization and Payment Data used in our study. For inpatient facilities, there has been no unique DRG codes for providers to bill robotic surgery, although providers can use ICD-9 codes to report their utilization.

products. Using a novel and proprietary dataset on CPT applications of emerging medical procedures, we unveiled, for the first time in the literature, the extent and overall timeline of an important subset of medical procedure innovations - those receiving consideration for new billing codes. The ten-year estimate from initial research to obtaining unique procedure codes is much longer than previously reported for the innovation process of medical devices, and is as long or longer than that of new drugs; there are also meaningful variations in innovation times across procedures, depending on whether the procedure involves medical devices and the type of devices.

Compared with pharmaceutical innovations, we highlight two striking features of medical procedure innovations were highlighted. First, many new procedures, especially those that do not involve recently developed devices, lack property rights. This creates a potential appropriability issue and suboptimal innovation incentives. In many cases, physicians address this problem through their specialty medical societies, which are responsible for the majority of applications for billing codes. Second, administrative coding decisions can be crucial to the success of procedure innovations; we found that promotion to a CPT I code from a CPT III code has a large, positive effect on new procedure use. This finding is consistent with qualitative evidence from payers and medical device manufacturers and stands in stark contrast with drugs, where FDA approval is, with rare exceptions, sufficient to trigger reimbursements from payers.

There are several limitations to this study that may point ways to future research. First, as mentioned in Section 5.4, the scope of this study focuses on new medical procedures that have obtained unique administrative procedure codes; therefore, our findings do not speak to new procedures in old codes or incremental innovations to existing procedures. Future work is needed to assess the full picture of economic incentives behind all levels of inventive activities by firms and physicians that lead to new medical procedures. Second, a better understanding of the clinical and economic value of procedure innovation is essential to evaluate the welfare consequences of current and alternative regulatory environments, as well as the coding and billing systems, regarding medical procedures. In particular, economists had long made a distinction between breakthrough and "me-too" drugs, and research effort has been devoted to examine their distinct values (see, e.g., Kessler et al. 1994; Lu and Comanor 1998; Towse and Leighton 1999; Werthheimer et al.

2001; Lee 2004; DiMasi and Paquette 2012); comparatively little is known about new medical procedures. Finally, successful invention and adoption of innovative medical procedures involve many stakeholders, including patients, healthcare providers, professional medical societies, medical device companies, payers, as well as regulatory agencies and agencies that establish and maintain the billing and coding systems. Future work is needed to investigate the role of each stakeholder, the interplay among them, and the overall ecosystem surrounding procedure innovation.

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# Tables and Figures

**Table 1: Number of CPT III Applications, Approvals, and Rejections by Year**

| Year* | (1) CPT III Applications | (2) CPT III Approvals | (3) CPT III Rejections | (4) Approvals promoted to CPT I by 2019 | (5) Approvals Sunsetted by 2019 | (6) Approvals Remaining as CPT III by 2019 |
|---|---|---|---|---|---|---|
| 2008 | 11 | 9 | 2 | 2 | 4 | 3 |
| 2009 | 19 | 17 | 2 | 8 | 4 | 5 |
| 2010 | 14 | 12 | 2 | 5 | 3 | 4 |
| 2011 | 12 | 10 | 2 | 3 | 5 | 2 |
| 2012 | 11 | 10 | 1 | 3 | 2 | 5 |
| 2013 | 15 | 15 | 0 | 3 | 5 | 7 |
| 2014 | 13 | 13 | 0 | 4 | 3 | 6 |
| 2015 | 15 | 15 | 0 | 1 | 0 | 14 |
| 2016 | 16 | 14 | 2 | 1 | 0 | 13 |
| 2017 | 18 | 13 | 5 | 0 | 0 | 13 |
| 2018 | 17 | 10 | 7 | 0 | 0 | 10 |
| 2019 | 26 | 24 | 2 | 0 | 0 | 24 |
| Total | 187 | 162 | 25 | 30 | 26 | 106 |

Note: The sample contains 187 CPT III applications discussed in the AMA meetings between 2008 and 2019.
* Applications are classified by submission year.

**Table 2. Number of CPT III Applications by Procedure Type**

| | CPT III Applications | CPT III Approvals | Promoted to CPT I by 2019 | Sunsetted by 2019 | Remaining as CPT III by 2019 |
|---|---|---|---|---|---|
| *Panel 1: By Device Type* | | | | | |
| New Device* | 74 | 65 | 11 | 11 | 43 |
| Old Device | 52 | 50 | 17 | 11 | 22 |
| No Device | 18 | 13 | 2 | 4 | 7 |
| *Panel 2: By Applicant Type* | | | | | |
| Industry Applicant | 77 | 65 | 5 | 12 | 48 |
| Medical Applicant | 67 | 63 | 25 | 14 | 24 |

Notes: Sample includes 128 CPT III procedures approved between 2008 and 2017.
*New devices refer to those that have not previously been used in another medical procedure and have been approved less than two years prior to CPT III application.

**Table 3: Innovation Time of CPT III Procedures, in Months**
(Number of observations in parentheses)

| | All | By Procedure Type | | |
|---|---|---|---|---|
| | | New Device* | Old Device | No Device |
| Total: First Research to CPT III Approval | 134 (N=128) | 98 (N=65) | 173 (N=50) | 164 (N=13) |
| CPT III Submission to CPT III Approval | 14 (N=128) | 14 (N=65) | 14 (N=50) | 14 (N=13) |
| FDA Approval to CPT III Approval | 52 (N=75) | 8 (N=28) | 79 (N=47) | N/A |
| First Research to FDA Submission | 82 (N=75) | 82 (N=28) | 83 (N=47) | N/A |
| FDA Submission to FDA Approval | 10 (N=75) | 14 (N=28) | 7 (N=47) | N/A |

Notes: *New devices refer to those that have not previously been used in another medical procedure and have been approved less than two years prior to CPT III application

**Table 4. Innovation Time of Procedures with CPT I Status, in Months**

(Number of observations in parentheses)

| | All | By Procedure Type | | |
|---|---|---|---|---|
| | | New Device* | Old Device | No Device |
| First Research to FDA Submission | 80 (N=23) | 57 (N=6) | 88 (N=17) | N/A |
| FDA Submission to FDA Approval | 7 (N=23) | 13 (N=6) | 5 (N=17) | N/A |
| FDA Approval to CPT III Application Submission | 48 (N=23) | 9 (N=6) | 62 (N=17) | N/A |
| CPT III Application Submission to CPT III Effective | 14 (N=30) | 13 (N=11) | 15 (N=17) | 15 (N=2) |
| Subtotal (i.e., First Research to CPT III Effective) | 156 (N=30) | 95 (N=11) | 170 (N=17) | 370 (N=2) |
| CPT III Effective to CPT I Effective | 38 (N=30) | 34 (N=11) | 41 (N=17) | 30 (N=2) |
| Total: First Research to CPT I Effective | 194 (N=30) | 130 (N=11) | 212 (N=17) | 400 (N=2) |

Notes: The sample contains 30 CPT III applications that have been approved between 2008 and 2017 and promoted by September 2019. 23 of these 30 applications involve devices that have been approved by the FDA at the time of CPT III application.

*New devices refer to those that have not previously been used in another medical procedure and have been approved less than two years prior to CPT III application.

**Table 5. Summary Statistics of Active CPT III Procedures between 2012 and 2017**

| Variable | Mean | SD | Min | Max | No. of Procedure-Year Observations |
|---|---|---|---|---|---|
| *Sample 1: Full Sample (No. of procedures=184, No. of procedure-year observations=801)* | | | | | |
| No. of Medicare Services (filling unreported utilization with 10) | 2462 | 13950 | 10 | 251502 | 801 |
| No. of Medicare Services (filling unreported utilization with 1) | 2455 | 13951 | 1 | 251502 | 801 |
| No. of Medicare Services (filling unreported utilization with 0) | 2455 | 13951 | 0 | 251502 | 801 |
| Any Medicare utilization (filling unreported utilization with 0) | 0.30 | 0.46 | 0 | 1 | 801 |
| Post-Promotion (Promoted to CPT I) | 0.08 | 0.27 | 0 | 1 | 801 |
| Tenure (No. of years since CPT III approval) | 5.67 | 3.36 | 1 | 15 | 801 |
| No Device | 0.24 | 0.43 | 0 | 1 | 391 |
| Device Approved by the year (time-variant) | 0.60 | 0.49 | 0 | 1 | 391 |
| Device Unapproved by the year (time-variant) | 0.16 | 0.37 | 0 | 1 | 391 |
| Procedure involving exclusive patented medical devices (time-invariant) | 0.53 | 0.50 | 0 | 1 | 391 |
| Procedure involving nonexclusive patented medical devices (time-invariant) | 0.23 | 0.42 | 0 | 1 | 391 |
| *Sample 2: Observations for which the procedure records Medicare utilization in some years between 2012 and 2017 (No. of procedures=72, No. of procedure-year observations=319)* | | | | | |
| No. of Medicare Services (filling unreported utilization with 10) | 6166 | 21603 | 10 | 251502 | 319 |
| No. of Medicare Services (filling unreported utilization with 1) | 6164 | 21604 | 1 | 251502 | 319 |
| No. of Medicare Services (filling unreported utilization with 0) | 6163 | 21604 | 0 | 251502 | 319 |
| Any Medicare utilization (filling unreported utilization with 0) | 0.75 | 0.43 | 0 | 1 | 319 |
| Post-Promotion (Promoted to CPT I) | 0.18 | 0.38 | 0 | 1 | 319 |
| Tenure (No. of years since CPT III approval) | 5.60 | 3.24 | 1 | 15 | 319 |
| No Device | 0.15 | 0.36 | 0 | 1 | 167 |
| Device Approved by the year (time-variant) | 0.79 | 0.41 | 0 | 1 | 167 |
| Device Unapproved by the year (time-variant) | 0.06 | 0.24 | 0 | 1 | 167 |
| Procedure involving exclusive patented medical devices (time-invariant) | 0.49 | 0.50 | 0 | 1 | 167 |
| Procedure involving nonexclusive patented medical devices (time-invariant) | 0.37 | 0.48 | 0 | 1 | 167 |

| | | | | | |
|---|---|---|---|---|---|
| *Sample 3: Observations with recorded Medicare utilization (No. of procedures=72, No. of procedure-year observations=240)* | | | | | |
| No. of Medicare Services | 8192 | 24583 | 11 | 251502 | 240 |
| Post-Promotion (Promoted to CPT I) | 0.24 | 0.43 | 0 | 1 | 240 |
| Tenure (No. of years since CPT III approval) | 5.67 | 3.29 | 1 | 15 | 240 |
| No Device | 0.17 | 0.37 | 0 | 1 | 134 |
| Device Approved by the year (time-variant) | 0.79 | 0.41 | 0 | 1 | 134 |
| Device Unapproved by the year (time-variant) | 0.04 | 0.21 | 0 | 1 | 134 |
| Procedure involving exclusive patented medical devices (time-invariant) | 0.51 | 0.50 | 0 | 1 | 134 |
| Procedure involving nonexclusive patented medical devices (time-invariant) | 0.33 | 0.47 | 0 | 1 | 134 |

Notes: Number of observations with procedure characteristics (i.e., whether involving exclusive patented medical devices, nonexclusive devices, or applied by medical societies) is less than the total because we only observe procedure characteristics for those approved after 2007.

**Table 6. Main Results: Effect of CPT code promotion on Procedure Utilization**

| | Sample 1 | | | Sample 2 | | | Sample 3 |
|---|---|---|---|---|---|---|---|
| | Replacing unreported utilization with 10 | Replacing unreported utilization with 1 | Replacing unreported utilization with 0 | Replacing unreported utilization with 10 | Replacing unreported utilization with 1 | Replacing unreported utilization with 0 | Excluding observations with unreported utilization |
| Dependent Variable | $ln(Utilization_{it})$ | $ln(Utilization_{it})$ | $Dummy\_Use_{it}$ | $ln(Utilization_{it})$ | $ln(Utilization_{it})$ | $Dummy\_Use_{it}$ | $ln(Utilization_{it})$ |
| | (1) | (2) | □3□ | (4) | (5) | □6□ | (7) |
| $PostCPTI_{it}$ | 2.328*** | 3.061*** | 0.319*** | 2.705*** | 3.640*** | 0.406*** | 1.272*** |
| | (0.522) | (0.743) | (0.113) | (0.602) | (0.868) | (0.136) | (0.427) |
| No. of Procedures | 184 | 184 | 184 | 72 | 72 | 72 | 72 |
| No. of Observations | 801 | 801 | 801 | 319 | 319 | 319 | 240 |
| R-squared | 0.21 | 0.19 | 0.10 | 0.26 | 0.23 | 0.12 | 0.22 |

Notes: $ln(Utilization_{it})$ represents the natural logarithm of Medicare utilization of procedure *i* in year *t*.

$Dummy\_Use_{it}$ represents the indicator variable for whether the procedure *i* records any utilization in year *t*.

All regressions control for device approval status, procedure fixed effects, and year fixed effects.

Sample 1 is the full sample. Sample 2 restricts to observations for which the procedure records Medicare utilization in some years between 2012 and 2017. Sample 3 restricts to observations with recorded Medicare utilization.

Standard errors in parentheses are clustered by procedure. *** p<0.01, ** p<0.05, * p<0.1.

**Table 7: CPT III procedures by Device Patent Type**

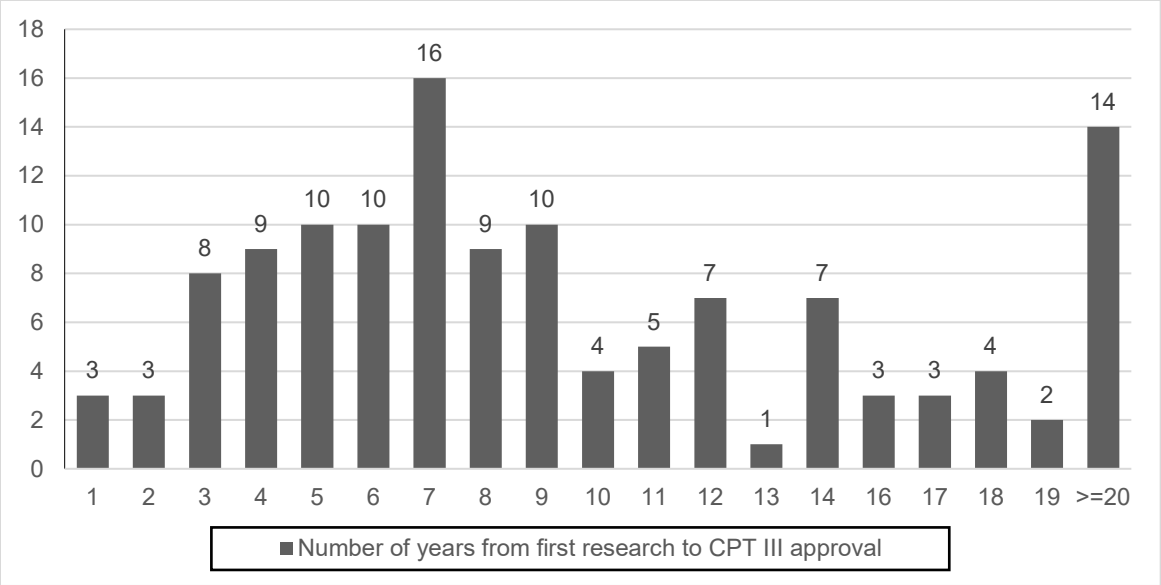
| | | CPT III approvals (1) | Exclusive Patented Device* (2) | Nonexclusive Device (3) | No Device (4) |
|---|---|---|---|---|---|
| Industry Applicants | | 65 | 60 | 3 | 2 |
| Medical Applicants | Medical Society | 58 | 21 | 26 | 11 |
| | Physician (with COI)** | 5 | 5 | 0 | 0 |
| Total | | 128 | 86 | 29 | 13 |

Notes: Sample includes 128 CPT III procedures approved between 2008 and 2017.

* A procedure is defined to involve a patented device if it a) involves a medical device; b) the medical device is made by only one firm (i.e., no competing firms) based on the referenced studies in the CPT III application; and c) the medical device company has an unexpired patent claiming the device at the time of CPT III application.

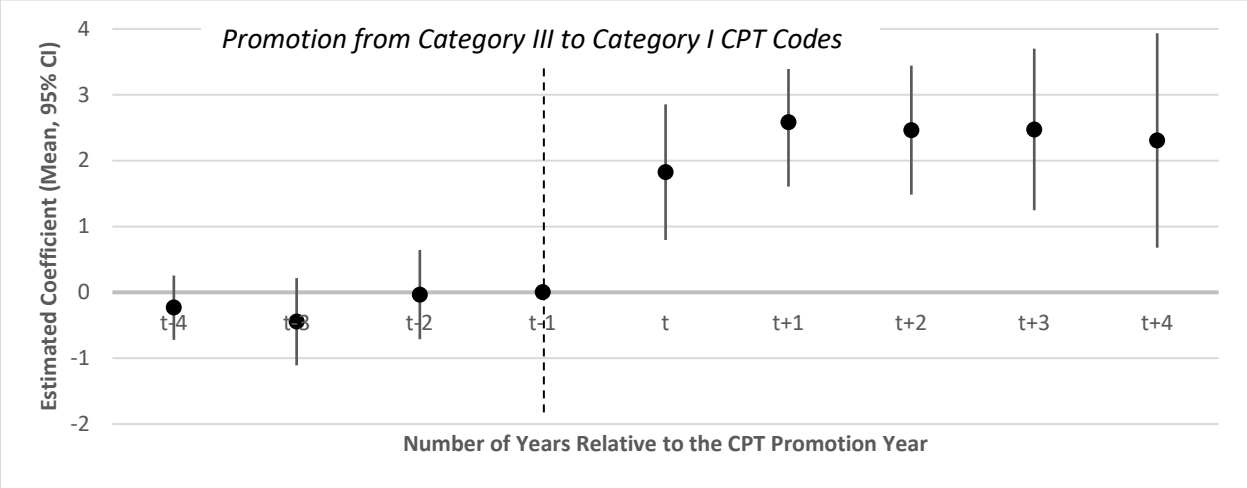
** All five physician applicants in this category disclosed Conflict of Interest (COI) and are paid consultants of medical device companies.

**Figure 1: Distribution of *New Medical Procedure Development* Time**




Notes: Sample includes 128 CPT III procedures approved between 2008 and 2017.

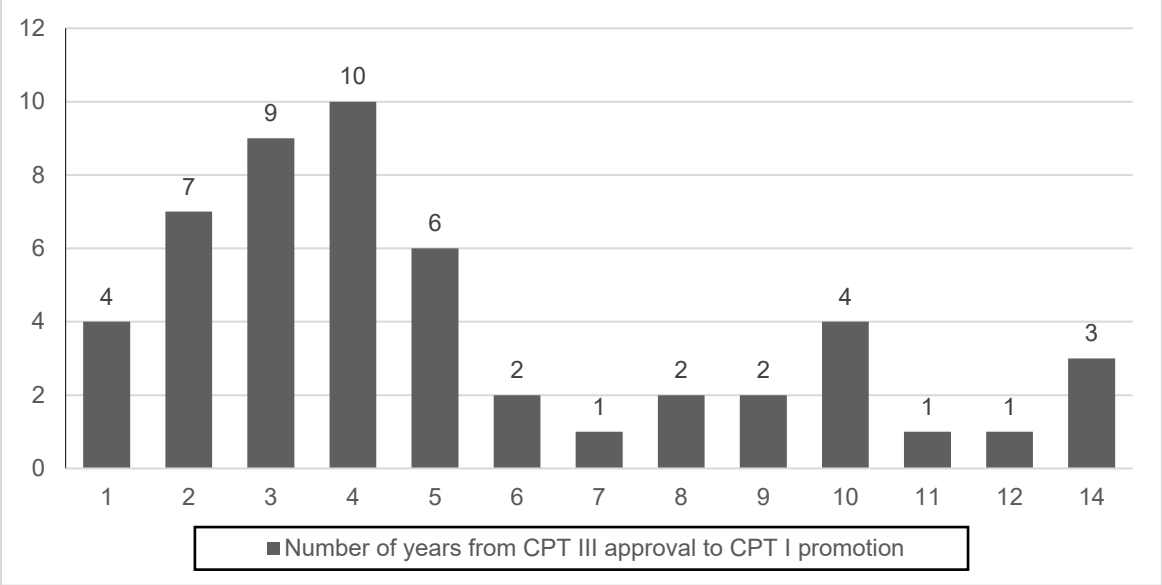
**Figure 2: Event study plot for the effect of CPT promotion on procedure utilization. (Full Sample)**




Note: This figure presents the estimated coefficient (mean and 95% CI) of $CPTI\_Event_{id(t)}$ from Equation (2). The x-axis represents the time leads or lags from the year of CPT code promotion. The dashed line represents the time when CPT code is promoted from Category III to Category I. N=801.

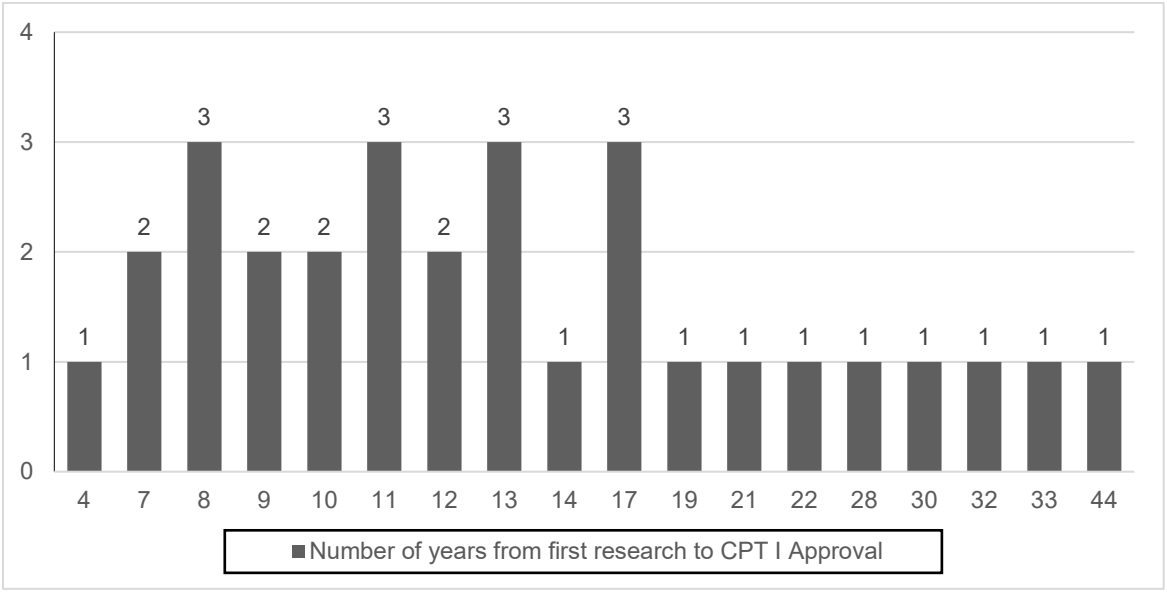
# Appendices

**Appendix Figure A1: Distribution of Promotion Time**



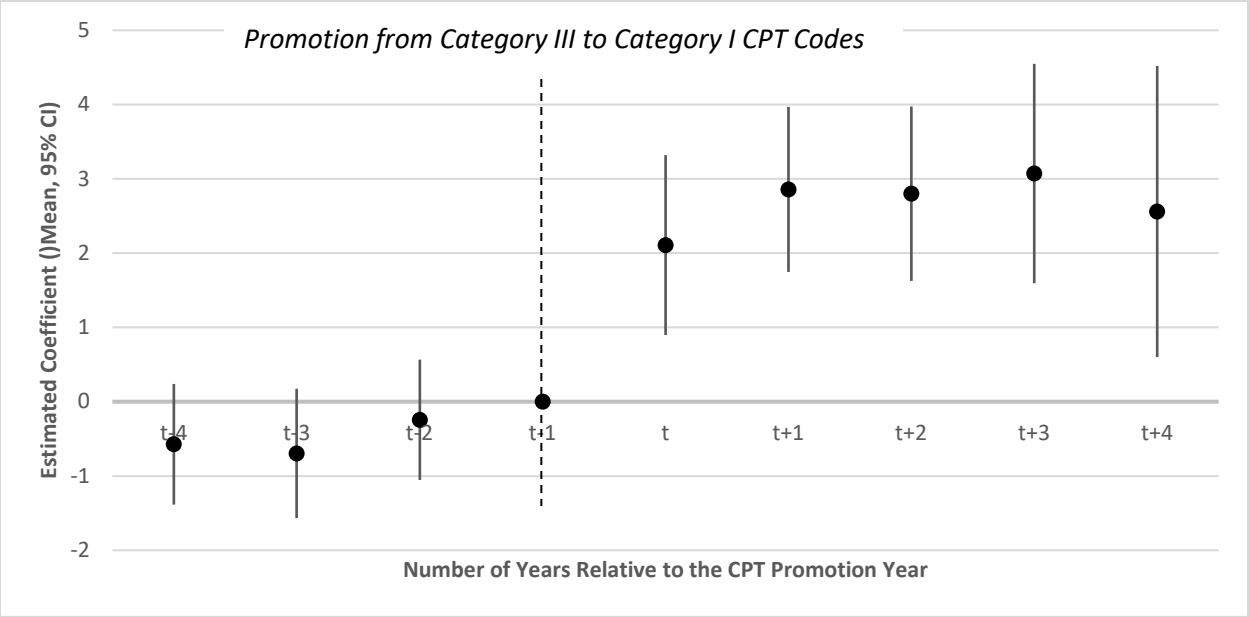

Note: The sample contains 52 procedures promoted to CPT I status during our time frame (i.e., between 2002 and 2019). It includes 22 procedures that are excluded from the calculation in Table 5 because they were approved as CPT III before 2008 and we do not observe their application/promotion details other than the CPT III approval date and the date of promotion to CPT I.

**Appendix Figure A2: Distribution of *CPT I Development* Time**



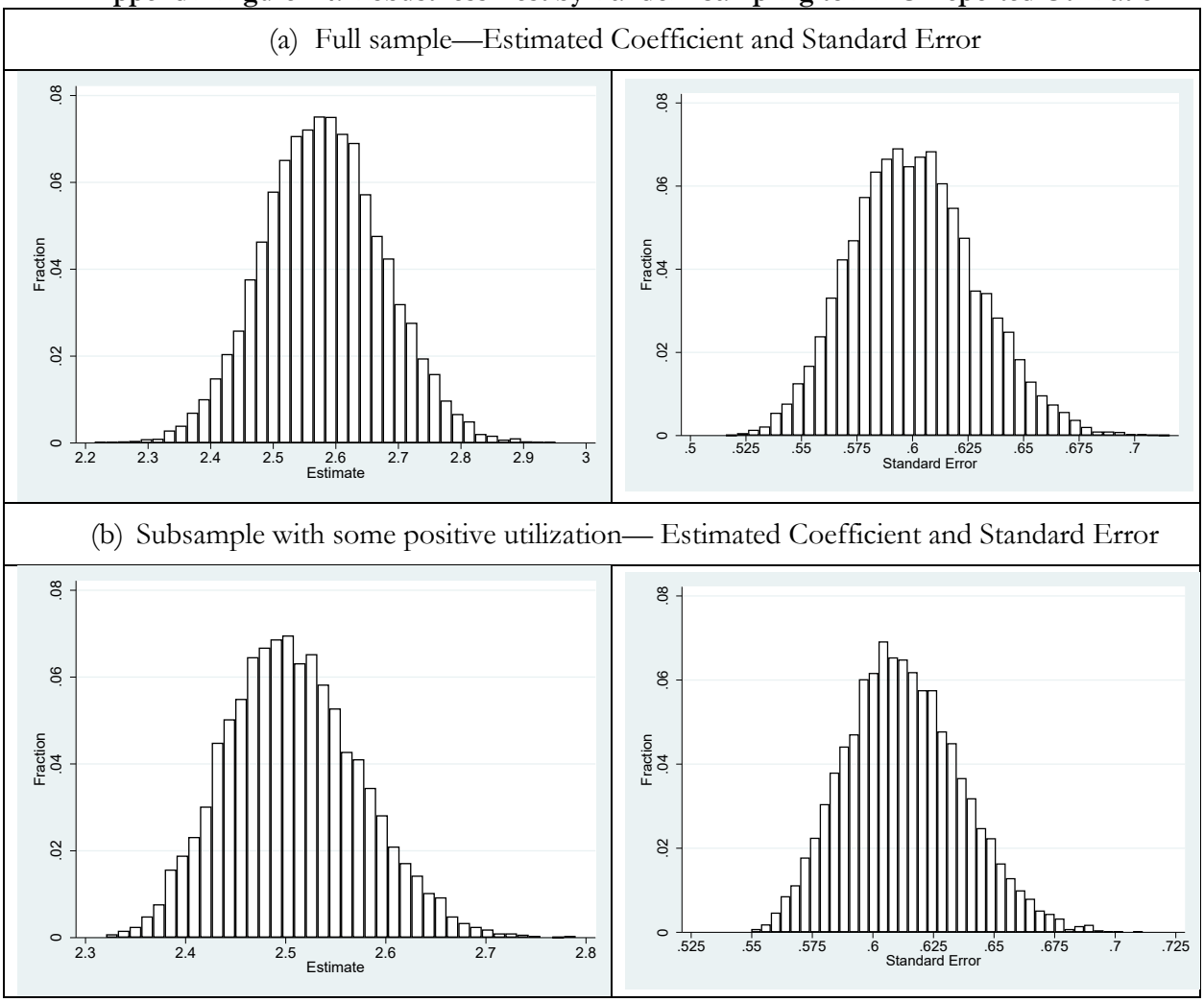

Note: The sample contains 30 CPT III applications that have been approved between 2008 and 2017 and promoted by September 2019.

**Appendix Figure A3. Robustnest Test: Event study plot for the effect of CPT promotion on procedure utilization (Subsample of procedures with positive utilization)**




Note: This figure presents the estimated coefficient (mean and 95% CI) of $CPTI\_Event_{id(t)}$ from Equation (2). The x-axis represents the time leads or lags from the year of CPT code promotion. The dashed line represents the time when CPT code is promoted from Category III to Category I. The estimation uses the subsample of CPT III procedures with positive utilization in the Medicare utilization data. N=319.

**Appendix Figure A4. Robustness Test by Random Sampling to Fill Unreported Utilization**




Note: This figure presents the distribution of the estimated coefficients and standard errors for $PostCPTI_{it}$ in Equation 1. Standard errors in parentheses are clustered by procedure.

**Appendix Table A1: Heterogeneity Analysis by Procedure Device Type**

| | Sample 1 | | Sample 2 | | Sample 3 | |
|---|---|---|---|---|---|---|
| | (1) | (2) | (3) | (4) | (5) | (6) |
| $PostCPTI_{it}$ | 2.416*** | 0.285* | 2.887*** | 0.560 | 1.350*** | 0.081 |
| | (0.534) | (0.164) | (0.669) | (0.360) | (0.428) | (0.308) |
| $PostCPTI_{it}$* $ExclusiveDevice_i$ | | 1.920*** | | 1.949*** | | 1.602*** |
| | | (0.468) | | (0.514) | | (0.542) |
| $PostCPTI_{it}$* $NonExclusiveDevice_i$ | | 3.493*** | | 3.413*** | | 1.108 |
| | | (1.034) | | (1.042) | | (0.688) |
| Number of Procedures | 104 | 104 | 41 | 41 | 41 | 41 |
| Number of Observations | 391 | 391 | 167 | 167 | 134 | 134 |
| R-squared | 0.33 | 0.41 | 0.41 | 0.46 | 0.34 | 0.37 |

Notes: The dependent variable is the natural log of the number of Medicare services, replacing the unreported utilization with 10. All regressions control for device approval status, procedure fixed effects, and year fixed effects.
Sample 1 is the full sample. Sample 2 restricts to observations for which the procedure records Medicare utilization in some years between 2012 and 2017. Sample 3 restricts to observations with recorded Medicare utilization.
Standard errors in parentheses are clustered by procedure. *** p<0.01, ** p<0.05, * p<0.1.

**Appendix Table A2. Robustness Test—Adding Interaction between Tenure and Log Time Trend**

| | Sample 1 | | | Sample 2 | | | Sample 3 |
|---|---|---|---|---|---|---|---|
| | Replacing unreported utilization with 10 | Replacing unreported utilization with 1 | Replacing unreported utilization with 0 | Replacing unreported utilization with 10 | Replacing unreported utilization with 1 | Replacing unreported utilization with 0 | Excluding observations with unreported utilization |
| Dependent Variable | $ln(Utilization_{it})$ | $ln(Utilization_{it})$ | $Dummy\_Use_{it}$ | $ln(Utilization_{it})$ | $ln(Utilization_{it})$ | $Dummy\_Use_{it}$ | $ln(Utilization_{it})$ |
| | (1) | (2) | □3□ | (4) | (5) | □6□ | (7) |
| $PostCPTI_{it}$ | 2.343*** | 3.040*** | 0.302*** | 2.630*** | 3.437*** | 0.351** | 1.271*** |
| | (0.527) | (0.753) | (0.115) | (0.610) | (0.899) | (0.145) | (0.433) |
| No. of Procedures | 184 | 184 | 184 | 72 | 72 | 72 | 72 |
| No. of Observations | 801 | 801 | 801 | 319 | 319 | 319 | 240 |
| R-squared | 0.26 | 0.24 | 0.14 | 0.35 | 0.33 | 0.22 | 0.38 |

Notes: $ln(Utilization_{it})$ represents the natural logarithm of Medicare utilization of procedure *i* in year *t*.
$Dummy\_Use_{it}$ represents the indicator variable for whether the procedure *i* records any utilization in year *t*.
All regressions control for device approval status, procedure fixed effects, and year fixed effects.
Sample 1 is the full sample. Sample 2 restricts to observations for which the procedure records Medicare utilization in some years between 2012 and 2017. Sample 3 restricts to observations with recorded Medicare utilization.
Standard errors in parentheses are clustered by procedure. *** p<0.01, ** p<0.05, * p<0.1.

**Appendix Table A3. Robustness Test—Excluding Procedures with Unapproved Devices at the Time of CPT III Approval**

| | Sample 1 | | | Sample 2 | | | Sample 3 |
|---|---|---|---|---|---|---|---|
| | Replacing unreported utilization with 10 | Replacing unreported utilization with 1 | Replacing unreported utilization with 0 | Replacing unreported utilization with 10 | Replacing unreported utilization with 1 | Replacing unreported utilization with 0 | Excluding observations with unreported utilization |
| Dependent Variable | $ln(Utilization_{it})$ | $ln(Utilization_{it})$ | $Dummy\_Use_{it}$ | $ln(Utilization_{it})$ | $ln(Utilization_{it})$ | $Dummy\_Use_{it}$ | $ln(Utilization_{it})$ |
| | (1) | (2) | □3□ | (4) | (5) | □6□ | (7) |
| $PostCPTI_{it}$ | 2.266*** | 3.056*** | 0.343** | 2.856*** | 3.887*** | 0.447*** | 1.040** |
| | (0.660) | (0.952) | (0.138) | (0.742) | (1.084) | (0.165) | (0.495) |
| No. of Procedures | 148 | 148 | 148 | 61 | 61 | 61 | 61 |
| No. of Observations | 687 | 687 | 687 | 281 | 281 | 281 | 209 |
| R-squared | 0.16 | 0.15 | 0.10 | 0.21 | 0.21 | 0.13 | 0.10 |

Notes: $ln(Utilization_{it})$ represents the natural logarithm of Medicare utilization of procedure *i* in year *t*.

$Dummy\_Use_{it}$ represents the indicator variable for whether the procedure *i* records any utilization in year *t*.

All regressions control for device approval status, procedure fixed effects, and year fixed effects.

Sample 1 is the full sample. Sample 2 restricts to observations for which the procedure records Medicare utilization in some years between 2012 and 2017. Sample 3 restricts to observations with recorded Medicare utilization.

Standard errors in parentheses are clustered by procedure. *** p<0.01, ** p<0.05, * p<0.1.

**Appendix Table A4. Robustness Test—Effect of CPT code promotion on Procedure Utilization Using the Year before CPT I publication year as the promotion year.**

| | Sample 1 | | | Sample 2 | | | Sample 3 |
|---|---|---|---|---|---|---|---|
| | Replacing unreported utilization with 10 | Replacing unreported utilization with 1 | Replacing unreported utilization with 0 | Replacing unreported utilization with 10 | Replacing unreported utilization with 1 | Replacing unreported utilization with 0 | Excluding observations with unreported utilization |
| Dependent Variable | $ln(Utilization_{it})$ | $ln(Utilization_{it})$ | $Dummy\_Use_{it}$ | $ln(Utilization_{it})$ | $ln(Utilization_{it})$ | $Dummy\_Use_{it}$ | $ln(Utilization_{it})$ |
| | (1) | (2) | □ 3□ | (4) | (5) | □ 6□ | (7) |
| $PostCPTI_{it}$ | 1.555*** | 2.225*** | 0.291** | 1.917*** | 2.849*** | 0.405** | 0.655* |
| | (0.470) | (0.687) | (0.133) | (0.573) | (0.827) | (0.162) | (0.343) |
| No. of Procedures | 184 | 184 | 184 | 72 | 72 | 72 | 72 |
| No. of Observations | 801 | 801 | 801 | 319 | 319 | 319 | 240 |
| R-squared | 0.08 | 0.05 | 0.11 | 0.13 | 0.12 | 0.09 | 0.16 |

Notes: $ln(Utilization_{it})$ represents the natural logarithm of Medicare utilization of procedure *i* in year *t*.
$Dummy\_Use_{it}$ represents the indicator variable for whether the procedure *i* records any utilization in year *t*.
All regressions control for device approval status, procedure fixed effects, and year fixed effects.
Sample 1 is the full sample. Sample 2 restricts to observations for which the procedure records Medicare utilization in some years between 2012 and 2017. Sample 3 restricts to observations with recorded Medicare utilization.
Standard errors in parentheses are clustered by procedure. *** p<0.01, ** p<0.05, * p<0.1.

**Appendix Table A5: Medicare Utilization (Measured by Number of Services) of Top 5 Utilized New Medical Procedures#**

| Procedure Name | AMA Approval Year (Category III CPT Code)[a] | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|---|
| External ECG Monitoring | 2012 | **28,161** | **56,291** | **108,442** | **176,264** | **251,502** |
| Surface Electronic High Dose Rate Brachytherapy | 2015 | - | - | - | **26,452** | **36,247** |
| Visual Field Assessment with Real Time Data Analysis | 2014 | - | - | 415 | **14,651** | **33,752** |
| Subcutaneous Implantable Defibrillator | 2013 | 122 | **1,712** | **4,109*** | **5,810*** | **6,328*** |
| Sacroiliac Joint Stabilization | 2013 | - | 175 | **1,910*** | **2,810*** | **3,704*** |
| Left Atrial Appendage Closure | 2011 | 151 | 71 | 288 | 3,223 | 8,801* |
| TAVR | 2011 | **15,823*** | **26,472*** | **37,882*** | 54,449* | 67,783* |
| Circulating Tumor Cells (CTC) Enumeration | 2011 | **6,541*** | **4,031*** | **2,115*** | 1,743* | 546* |
| Ultrasound Guided Facet Injection | 2010 | 6048 | **3,398** | N/A | N/A | N/A |
| Unattended Sleep Study | 2009 | **9,003*** | 11,490* | 13,115* | 16,145* | 19,174* |
| Intrafraction Target Tracking | 2009 | **24,377** | 23,466 | N/A | N/A | N/A |

Notes: Cells show Medicare utilization of each procedure in each year, measured by the number of unique Medicare beneficiary/provider interactions. Utilization data are from Medicare Provider Utilization and Payment Data: Physician and Other Supplier.

# New medical procedures are defined as those approved as Category III CPT codes within 5 years of the corresponding year. Procedures are selected so that the top 5 new procedures by total utilization are included for each year.

Numbers in **Bold** are the top5-utilized procedures in the corresponding year.

Shaded cells correspond to procedures that were introduced more than 5 years before the corresponding year (so are not considered 'new').

* The procedure has been promoted to Category I CPT status in the corresponding year.

[a] CPT codes are normally available to use in the following year of the approval year.

**Appendix Table A6: Medicare Utilization (Measured by Number of Medicare Beneficiaries) of Top 5 Utilized New Drugs#**

| Drug Name | FDA Approval Year | 2013 | 2014 | 2015 | 2016 | 2017 |
|---|---|---|---|---|---|---|
| ELIQUIS | 2012 | 46,920 | **204,210** | **481,422** | **826,969** | **1,142,004** |
| BREO ELLIPTA | 2013 | 632 | 44,744 | 133,609 | **293,833** | **533,708** |
| MYRBETRIQ | 2012 | 66,432 | **147,553** | **213,641** | **296,934** | **394,967** |
| LINZESS | 2012 | 53,657 | 144,002 | **204,280** | **268,598** | **321,437** |
| INVOKANA | 2013 | 18,624 | 91,499 | 194,566 | **233,132** | **231,835** |
| XARELTO | 2011 | **416,543** | **650,370** | **727,624** | 807,820 | 951,753 |
| TRADJENTA | 2011 | 105,342 | **155,144** | **227,831** | 276,586 | 301,919 |
| PRADAXA | 2010 | **250,767** | **238,057** | 221,745 | 229,987 | 231,294 |
| DEXILANT | 2009 | **310,989** | 305,373 | 312,967 | 313,985 | 299,688 |
| COLCRYS | 2009 | **431,070** | 465,482 | 238,512 | 144,750 | 185,601 |
| BYSTOLIC | 2009 | **401,397** | 399,956 | 366,945 | 346,811 | 338,263 |

Notes: Cells show Medicare utilization of each drug in each year, measured by the number of Medicare beneficiaries. Utilization data are from Medicare Provider Utilization and Payment Data: Part D Prescriber.

# New drugs are defined as those approved within 5 years of the corresponding year. Drug are selected so that the top 5 new drugs by total utilization are included for each year.

Numbers in **Bold** are the top5-utilized drugs in the corresponding year.

Shaded cells correspond to drugs that were introduced more than 5 years before the corresponding year (so are not considered 'new').

**Appendix Table A7: Payments for New Procedures versus New Drugs**

| | Payments ($ million) | |
|---|---|---|
| | Top 5-Utilized New Procedures* | Top 5-Utilized New Drugs** |
| 2013 | 679 | 1,848 |
| 2014 | 1,150 | 2,432 |
| 2015 | 1,668 | 3,550 |
| 2016 | 120 | 3,838 |
| 2017 | 151 | 5,977 |
| 5-yr Total | 3,768 | 17,645 |

*Payments for new procedures are from Medicare Provider Utilization and Payment Data: Physician and Other Supplier.

** Payments for new drugs are from Medicare Utilization and Payment Data: Part D Prescriber.

**Appendix Table A8: Year of Introduction of Top 15 Utilized Medical Procedures by Medicare Beneficiaries in 2017**

| Procedure | Medicare Beneficiary/Provider Interactions (Million) | Medicare Spending ($ Million) | Year of Introduction* |
|---|---|---|---|
| X-ray | 53 | 629 | 1896 |
| Collection of Venous Blood by Venipuncture | 24 | 70 | N/A |
| CT Scan | 22 | 1,320 | 1972 |
| Removal of Skin Lesions (Benign and Malignant) | 11.73 | 571 | 1938 |
| Ultrasound | 11 | 484 | 1956 |
| Cataract Removal and Lens Insertion | 9.5 | 6,315 | 1967 |
| Biopsy | 9.0 | 1,057 | 1875 |
| Endoscopic Diagnostic Examination | 3.0 | 399 | 1853 |
| Removal of Ear Wax | 1.4 | 41 | N/A |
| Complex Wound Repair | 0.72 | 157 | N/A |
| Knee Repair (incl. Replacement) | 0.56 | 6,750 | Early 1970s |
| Drainage of Abscess/Pilonidal Cyst | 0.49 | 47 | N/A |
| Dialysis (Outpatient)** | 0.40 (approx.) | 11,400 (approx.) | 1943 |
| Prosthetic Hip Replacement | 0.28 | 4,089 | 1940 |
| Endotracheal Intubation | 0.28 | 32 | 1878 |

Notes: Utilization and spending data are from Medicare Provider Utilization and Payment Data: Physician and Other Supplier, and Medicare Provider Utilization and Payment Data: Outpatient.
* See Appendix B for sources for year of introduction.
** Dialysis estimates are based on Medicare Payment Advisory Commission (2019).

**Appendix Table A9: Year of Introduction of Top 15 Utilized Drugs by Medicare Beneficiaries in 2017**

| Drug (Active Ingredient) | Typical Use | Medicare Part D Beneficiaries (Million) | Medicare Spending ($ Million) | Year of Initial FDA Approval* (Brand) |
|---|---|---|---|---|
| ATORVASTATIN CALCIUM | Hypercholesterolemia | 10.7 | 878 | 1996 (LIPITOR) |
| LEVOTHYROXINE SODIUM | Hypothyroidism | 8.4 | 1,120 | 2002 (LEVO-T) |
| AMLODIPINE BESYLATE | Hypertension, Angina | 8.3 | 288 | 1987 (NORVASC) |
| LISINOPRIL | Hypertension, Heart Failure, Kidney Disease | 8.2 | 263 | 1988 (ZESTRIL) |
| HYDROCODONE/ACETAMINOPHEN | Pain | 6.9 | 508 | 1997 (NORCO) |
| OMEPRAZOLE | Gastroesophageal Reflux Disease | 6.9 | 395 | 1989 (PRILOSEC) |
| METFORMIN HCL | Diabetes | 6.8 | 677 | 1995 (GLUCOPHAGE) |
| AZITHROMYCIN | Bacterial Infections | 6.1 | 73 | 1995 (ZITHROMAX) |
| SIMVASTATIN | Heart Disease | 5.9 | 223 | 1991 (ZOCOR) |
| PREDNISONE | Arthritis, Blood Disorders, Breathing problems, etc. | 5.8 | 119 | 1955 (RAYOS) |
| GABAPENTIN | Seizures | 5.8 | 549 | 1993 (NEURONTIN) |
| ALBUTEROL SULFATE | Asthma | 5.6 | 915 | 1981 (PROAIR) |
| FUROSEMIDE | Edema (Caused by Heart, Kidney and Liver Disease) | 5.5 | 141 | 1968 (LASIX) |
| AMOXICILLIN | Bacterial Infections | 5.1 | 32 | 1974 (AMOXIL) |
| LOSARTAN POTASSIUM | Hypertension, Heart Failure, Kidney Disease | 4.9 | 226 | 1995 (COZAAR) |

Notes: Utilization and spending data are from Medicare Provider Utilization and Payment data: Part D Prescriber, and year of FDA approval is from the Drugs@FDA database.
* Year of FDA Approval gives the earliest date of FDA approval for a product containing the active ingredient.

**Appendix B: Year of Introduction of Top-utilized Medical Procedures shown in Appendix Table A6.**

X-ray: https://www.nde-ed.org/EducationResources/CommunityCollege/Radiography/Introduction/history.htm#:~:text=In%20June%201896%2C%20only%206,pictures%20of%20metals%20were%20produced

CT Scan: https://www.imaginis.com/ct-scan/brief-history-of-ct#:~:text=Tomography%20is%20from%20the%20Greek,Cormack%20of%20Tufts%20University%2C%20Massachusetts

Removal of Malignant Lesions: https://en.wikipedia.org/wiki/Mohs_surgery

Ultrasound: https://www.livescience.com/32071-history-of-fetal-ultrasound.html#:~:text=When%20it%20was%20invented%3F,detect%20industrial%20flaws%20in%20ships

Cataract Removal and Lens Insertion: https://eyewiki.aao.org/History_of_Cataract_Surgery

Biopsy: https://pubmed.ncbi.nlm.nih.gov/7975522/#:~:text=The%20term%20%22biopsy%22%20was%20introduced,in%201875%20by%20M.%20M.%20Rudnev

Endoscopic Diagnostic Examination: https://www.olympus-global.com/technology/museum/endo/?page=technology_museum

Knee Repair (incl. Replacement): https://www.intechopen.com/books/arthroplasty-update/the-evolution-of-modern-total-knee-prostheses

Dialysis (Outpatient): https://www.dpcedcenter.org/news-events/news/a-brief-history-of-dialysis/#:~:text=The%20history%20of%20dialysis%20dates,patient%20suffer%20from%20kidney%20failure

Prosthetic Hip Replacement: https://en.wikipedia.org/wiki/Hip_replacement#:~:text=On%20September%2028%2C%201940%20at,the%20cobalt%2Dchrome%20alloy%20Vitallium

Endotracheal Intubation: https://pubmed.ncbi.nlm.nih.gov/16400793/#:~:text=In%20the%20early%201870's%2C%20Trendelenburg,elective%20endotracheal%20intubation%20for%20anesthesia.&text=In%201913%20the%20first%20anesthetic,the%20Magill%2C%20Miller%20and%20Macintosh