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The economics of medical procedure innovation

David Dranove[a], Craig Garthwaite[a], Christopher Heard[b], Bingxiao Wu[c,*]

[a] Kellogg School of Management, Northwestern University, 2211 Campus Drive, Evanston, IL 60208, USA
[b] Department of Economics, Northwestern University, 2211 Campus Drive, Evanston, IL 60208, USA
[c] Department of Economics, Rutgers University, 75 Hamilton St, New Brunswick, NJ 08901, USA

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ABSTRACT

This paper explores the economic incentives for medical procedure innovation. Using a proprietary dataset on billing code applications for 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 nearly 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 without patented devices. When appropriability is limited, specialty medical societies lead the applications for billing codes. We indicate that the *ad hoc* process for securing billing codes for procedure innovations creates uncertainty about 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.

1. Introduction

Improvements in medical technology have been a primary driver of increased life expectancy and medical spending (Newhouse 1992; Cutler 2004). Society now enjoys access to pharmaceuticals that treat a wide range of both common and rare conditions. For example, there are medications to help lower blood pressure and cholesterol levels, as well as cures for hepatitis C; HIV has been transformed into a largely manageable condition, and a variety of gene therapy products promise cures for rare illnesses that previously served as death sentences. Technological progress has also been made in medical procedures, including, but certainly not limited to, relatively noninvasive 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. Some new procedures involve new medical devices but, as we will show, the majority do not.

A rich economics literature examines firm investments in medical innovations. This literature has primarily focused on investments in *pharmaceutical* innovations and how the resulting drugs diffuse into clinical practice.[1] Most of these studies examine the development of new molecular entities (NMEs), which are the most innovative forms of new drugs (in contrast with generics and reformulations/combinations of existing drugs). This focus likely reflects the fact that both the economic model and the regulatory process governing the development of NMEs are more clearly understood. Further, data about each stage of NME development are more widely available, and NMEs usually generate the highest welfare gains.

* Corresponding author.
E-mail addresses: d-dranove@kellogg.northwestern.edu (D. Dranove), c-garthwaite@kellogg.northwestern.edu (C. Garthwaite), christopherheard2022@u.northwestern.edu (C. Heard), bwu@econ.rutgers.edu (B. Wu).

[1] See, e.g., Acemoglu & Linn (2004); Finkelstein (2004); Blume-Kohout & Sood (2013); Dranove *et al.* (2014); Dubois *et al.* (2015); Agha & Molitor (2018); Dranove *et al.* (2020).

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Economists have devoted far less attention to the development of new medical procedures. Extant studies focus on the approval process for new devices. We show that such innovation represents a minority of new procedures and only a small portion of the overall development process. As a result, little is known about how novel procedures are developed, let alone whether this process is optimal. We fill this gap in the existing literature by examining the underlying economics, rules, and regulations governing the innovative process for medical procedures. As has been done for drugs, we focus on the most innovative forms of new procedures – those that cannot be described by existing Current Procedural Terminology, or CPT codes. These codes are used by virtually all providers and payers for medical record keeping and billing.

The broad economic decisions facing innovators are the same for both products and procedures. Potential innovators must make large, sunk investments in research and development, with uncertain prospects about whether these investments will translate into successful treatments. 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 new medical products and procedures are vastly different in ways that can influence both the amount and scope of innovation. Section 2 of this paper contrasts the rules and regulations governing innovative drugs and procedures, including key differences in property rights. One key difference is the important role played by the American Medical Association (AMA), which owns the copyright to the CPT codes and solely manages the assignment process for new codes.[2] Section 3 introduces the novel data set, provided by the AMA, that we use to examine procedure innovation and presents basic facts about the approval process for new procedures. Section 4 shows how the granting of new CPT codes by the AMA has a profound impact on the diffusion of new procedures. Section 5 presents additional evidence on the innovative process for procedures, including evidence on the pace of innovation and the ways that innovators overcome limited property rights. Section 6 concludes.

Among our key findings, we demonstrate that the timeline for discovering, developing, and (perhaps most importantly) commercializing novel procedures is far longer than that suggested by prior research on the regulatory process for medical devices (Makower et al., 2010; Stern 2017). This difference results primarily from the fact that previous studies focused on specific stages of the development process and/or could not observe the administrative process determining reimbursement. Looking at the entirety of the development process, we document an average lag of over ten years, comparable to the timeline for new drugs. In addition, we find that this process contains additional uncertainty about whether even successful innovations will be reimbursed by payers and/or implemented by providers. Specifically, only a small fraction of procedures advance from provisional status (Category III CPT codes) to fully reimbursed status (Category I CPT Codes)—among all procedures approved for Category III CPT codes between 2008 and 2014, only 29 percent were promoted after the five-year temporary period.

A second contribution of our paper is demonstrating the importance of securing a CPT code to the pace of diffusion of new medical procedures. 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.[3] We estimate that the AMA's decision to promote a CPT code from Category III to Category I causes a statistically significant, nearly nine-fold, increase in the use of these procedures by Medicare patients. The considerable lag between the promotion from Category III to Category I CPT codes represents a meaningful economic cost for innovators. To the extent that the procedure requires a patented medical device, this delay likely affects particularly valuable periods of market exclusivity. This is even more important in the medical device space, since patents for such devices are in general less binding than those for drugs (Halm and Gelijns 1991). As a result, leading device companies can usually obtain profits within only the first two years after product launch – a time period that is much shorter than for pharmaceuticals (Chatterji et al., 2008). The significant delay in reimbursement could sharply reduce the expected profits from medical device innovations.

Finally, we explore how innovators deal with limited property rights by examining the sponsors of applications for new CPT billing codes. Broadly speaking, applicants in our data are either firms, such as medical device manufacturers, or professional medical societies. We find that firms are more likely to apply for CPT codes representing new procedures that involve exclusive patented devices, while medical societies are more likely to apply for CPT codes for procedures that involve non-exclusive devices or no device. These findings suggest that when there is no clear path to appropriability, private firms are less likely to support the procedure and medical societies help resolve the commons problem.

2. Contrasting rules and regulations regarding innovation

2.1. Drug versus procedure "Approval" processes

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 broad resulting structure for developing drugs – from preclinical trials through three phases of Investigational New Drug (IND) trials and final FDA review, all supervised by the FDA – remains essentially unchanged.[4] That said, the FDA continues to modify the review

[2] The CPT® Editorial Panel, authorized by the AMA, has the sole editorial authority over the CPT code set. It is responsible for maintaining the CPT code set. The panel is authorized by the AMA Board of Trustees to revise, update, or modify CPT codes, descriptors, rules, and guidelines. Source: https://www.ama-assn.org/about/cpt-editorial-panel/cpt-code-process (Accessed on 6/24/2021.)

[3] 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). According to Stuart *et al.* (2018), Medicare Part D formulary placements take 2-14 months post FDA approval.

[4] Over time, the FDA has taken steps to accelerate approval of "important drugs. This includes changes to the regulatory procedure as well as the development of novel pathways such as "orphan drugs" (Dranove & Meltzer 1994; Bagley *et al.* 2019).

process to achieve societal goals. 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. Very recently, the FDA accelerated the review of COVID-19 treatments and vaccines. This continual evolution of the approval and patent process suggests that regulators are carefully weighing safety, development times, and protection of property rights.[5]

These efforts have resulted in a well-understood system of patents and regulatory review. The FDA has a long history of systematic decision making and drug makers have established relationships with the FDA. Firms still face scientific risk resulting from the unpredictable nature of clinical trial outcomes. As a result, failure to successfully progress through all phases is relatively common (Wong et al., 2019). However, conditional on generating sufficient scientific evidence of safety and efficacy, firms can reasonably predict the length of the regulatory review process. This has limited the degree of regulatory uncertainty for pharmaceuticals. Reimbursement of new drugs typically follows shortly after FDA approval and is largely based on market prices. This relatively swift and standard process of pharmaceutical reimbursement limits some of the commercial risk that potential innovators face. While stakeholders debate whether patent lives should be extended, whether testing is too rigorous, and whether prices are too high, few take meaningful issues with the general structure of the drug approval process.

In contrast, the regulatory process for procedures exhibits far more variation. The closest match to the pharmaceutical process is for procedures involving new medical devices. In these cases, the FDA plays an important role that has been described by Stern (2017), so we will only present the essentials necessary for understanding the economic issues central to our paper. The FDA review of devices varies according to the type of device. 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 approximately three years.

As sometimes occurs with drugs, some procedure innovations represent applications of existing devices to new indications. Unlike drugs, where the innovator must engage in a new round of clinical trials, FDA approval for each new indication of an existing device is more rapid, often taking only a matter of months. Some procedure innovations do not involve any medical devices. For these procedures, the FDA plays no regulatory role in 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).

The current "review" process for procedures occurs during the application process for a CPT code. The Category III/Category I CPT code promotion ladder somewhat resembles the IND development process for drugs. In addition, innovators that wish to fast-track approval may seek promotion to Category I status prior to the expiration of the five-year probation period. Despite these similarities, unlike the FDA, the AMA offers little specific guidance for innovators of new procedures that are seeking new CPT codes. There are no distinctions among stages comparable to Stage I, II, and III for clinical trials of drugs. The AMA does not specify sample sizes or 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 a clinical study, an ongoing U.S. clinical trial, or other evidence of evolving clinical utilization.[6]

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 were supported by completed Randomized Controlled Trials (RCTs), 15 percent were supported by ongoing RCTs, and 65 percent were not supported by RCTs. In contrast, Hatswell et al. (2016) document that 94 percent of the 774 drug approvals issued by the FDA between 1999 and 2014 were based on RCTs. Admittedly, it may be difficult to perform RCTs with many procedures, but the heterogeneity of evidence presented in support of CPT applications is striking. This is especially true in comparison to the highly regimented processes of the FDA.

2.2. Administrative coding and reimbursement of medical procedures

Given the complexity and heterogeneity of medical procedures, payers use standardized coding systems as the administrative basis for reimbursement. Providers report each service to payers using the most appropriate code and they are reimbursed accordingly. Unlike drug treatments that are standardized by regulatory bodies (i.e., each dose must be chemically identical to any other of the same name), medical procedure coding inevitably groups slightly different services together under a single code. An additional difference between procedures and pharmaceuticals is that many payers attempt to base payments for medical procedures on estimated costs, unlike drugs where prices are largely market-based (i.e., they are the result of bilateral negotiations between manufacturers and payers). For example, Medicare uses a "prospective payment system" for both inpatient and outpatient procedures, where payments

[5] 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. (Accessed on 6/24/2021.)

[6] Source: https://www.ama-assn.org/practice-management/cpt/criteria-cpt-category-i-and-category-iii-codes (Accessed on 6/24/2021).

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 (Clemens and Gottlieb 2017; Clemens et al., 2017; Chan and Dickstein 2019).

In order to receive reimbursement for a medical procedure, providers must nearly always bill using a procedure code. In some cases, a new procedure is sufficiently similar to existing procedures that providers are able to bill under an existing code. This can persist for as long as the new procedure is sufficiently profitable at the rates paid for that code such that no party attempts to secure a new code. In other cases, the new procedure has a new CPT code, with a corresponding new reimbursement rate. Finally, providers can bypass the standard medical coding system and request *ad hoc* reimbursement from payers. This may occur either because there is no similar procedure with a CPT code, or because there is 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.[7]

There are two important economic implications of this coding process for the adoption and diffusion of innovative procedures. The first is that some utilization of innovative procedures may not be 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 (i.e., before new codes are approved) are 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 codes in our data. The second is that the assignment of a new CPT billing code may be an important determinant of the diffusion of a procedure, a feature for which there is no analogy to drugs and may affect a variety of incentives for innovation.

2.3. The CPT code approval process

Given the importance of CPT codes to the reimbursement and diffusion of new procedures, it is important to understand the details of the approval process of these codes. The AMA generally holds three CPT Editorial Panel meetings each year to consider changes to the CPT code set, including adding and removing codes, reallocating or consolidating existing codes, and refining code descriptions.[8] 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 currently in medical practice. A CPT I code contains five digits organized by specialty or type of service. For example, codes 00,100–01,999 pertain to anesthesia while 99,201–99,499 are for evaluation and management services. CPT I codes are effectively permanent.[9] Most CPT I codes are reimbursable under the Medicare Physician Fee Schedule and have an assigned relative value unit (RVU), with the exception of unlisted CPT I codes that end with a "99."[10] 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 for emerging procedures that do not meet the criteria for CPT I codes.[11] CPT III codes are temporarily assigned and contain four digits followed by a "T", such as 0099T (implant corneal ring). They are designed to track the use of emerging procedures while evidence accumulates about whether a CPT I code should eventually be assigned. CPT III codes do not have assigned RVUs.

A class of CPT I codes is reserved for procedures that do not appear elsewhere in the code set. These "unlisted" codes typically end with "999″ or "99″. For example, code 33,999 covers unlisted cardiac surgery procedures. A provider using an unlisted code may submit a request for *ad hoc* reimbursement, describing the procedure, the medical justification, and the requested payment.[12] Each payer determines whether and how much to reimburse for unlisted codes. For some new procedures awaiting AMA approval, providers may systematize the process of requesting reimbursement, and some payers may routinely approve these requests. For rarer procedures, the process of requesting reimbursement using these codes may be costly and payers may be slower to approve

[7] Adding further complexity is the fact that different coding systems are used in different situations. Two of the most important are the 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). 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. Private payers use a wider variety of codes, including but not limited to CPT and DRG codes.

[8] In addition to the three CPT Editorial Meetings in which the CPT Editorial panel revises the CPT code set, the AMA also holds three Specialty Society Relative Value Scale Update Committee (RUC) meetings each year to determine the relative value unit (RVU) for relative resource costs of medical procedures. For example, the 2023 CPT code set is updated at the three AMA CPT Editorial Meetings held in February, May, and October 2021; the RVUs for 2023 Medicare Payment Schedule is determined at the three AMA/Specialty Society RUC meetings held in April 2021, October 2021, and January 2022. Source: https://www.ama-assn.org/system/files/2020-10/cpt-ruc-calendar.pdf (Accessed on 6/24/2021). The context of this study is the CPT Editorial Panel meetings. For more information about the Specialty Society RUC meetings, see Chan & Dickstein (2019).

[9] 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.

[10] As mentioned in Section 2.2., Medicare fee for each physician service depends on the RVU of the procedure CPT code. If a CPT code does not have an RVU, the procedure is not reimbursable based on regular fee schedule. For more information on Medicare Physician Fee Schedule, see https://www.cms.gov/medicare/physician-fee-schedule/search/overview (Accessed on 6/24/2021).

[11] One key requirement for CPT I codes is that if the procedure involves medical devices, the device must be approved by the FDA; this is not required for CPT III codes. Detailed criteria for Category I and Category III CPT codes can be found at https://www.ama-assn.org/practice-management/cpt/criteria-cpt-category-i-and-category-iii-codes (Accessed on 6/24/2021).

[12] For an example of typical reporting requirements, see Chapter 4 of the CMS *Medicare Claims Processing Manual* (CMS Title 100-04).

the payment. Importantly, providers can only report these unlisted codes when the relevant procedures are *not covered* by a specific existing CPT code. CMS instructs Medicare contractors to verify that procedures are not covered by existing codes and to change submitted claims accordingly if they can. Thus, once a specific code is available, every provider that reports the procedure must do so through that code. This is true even if it would be financially advantageous to use a different existing code for the procedure.

Any stakeholder, such as the innovating scientists, a medical society, or a device manufacturer, may apply for a new CPT code. For example, four provider organizations, including the Society for Cardiovascular Angiography and Interventions, jointly applied for CPT III codes for transcatheter aortic valve replacement (TAVR) in November 2009.[13] At the CPT Editorial Panel meetings, an *ad hoc* review committee consisting of clinical and research specialists considers all applications for code changes. For new CPT III code applications, the committee considers the extent to which the new procedure differs from existing procedures, whether it is already in use, and clinical evidence of effectiveness. Extra weight is given to peer-reviewed research supporting efficacy. However, unlike the IND process administered by the FDA, there is no requirement for the use of particular types of RCTs or other evidence-gathering standards. 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 February 2013, only two years after obtaining CPT III status.

To illustrate the mileposts in the development process of innovative medical procedures, including the CPT approval process and the property rights issues we have raised herein, Appendix B offers three detailed case studies of recent procedure innovations, which represent three types of innovation: a) innovative procedures with exclusive patented device (TAVR), b) innovative procedures with old device (Corneal Incisions using Laser), and c) innovative procedures with no device (Applied Behavior Analysis).[14] These procedures have meaningfully affected the provision of medical services, provided substantial benefits to patients, and generated economically meaningful medical spending.

2.4. Property rights

The development of novel pharmaceuticals involves well-defined property rights that are enshrined in the patent system and the FDA process of market exclusivity. 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.[15] The same cannot be said for the firms and individuals who develop new procedures.

Writing about the history of surgical innovations, Riskin et al. (2006) state that "Surgeons have historically been idea generators…(their) training requires frequent development of new processes." While well-positioned to innovate, physicians effectively lack property rights to their discoveries. In 1994, the AMA House of Delegates voted to condemn patenting of medical procedures (Yang 1995). 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" (AMA, 1998). The AMA has pushed for legislation banning procedure patents (Anderson 1999). In addition, courts may be reluctant to uphold procedure patents independent of the patent for the associated medical device. For these reasons, procedure patents are rarely enforced (Anderson 1999).

In the absence of property rights protection, what are the innovation incentives for medical procedures? At a broad level, the evolution of medical technologies reflects the underlying payment incentives. Under a fee-for-service system where reimbursement is based on provider costs, providers attempting to maximize profits should have cost-increasing, quality-improving technologies rather than cost-reducing ones (Ellis and McGuire, 1986; Weisbrod, 1991). This is not a mere theoretical hypothesis. Clemens and Rogers (2020) find that the fixed-priced procurement policy for artificial limbs during the Civil War led to cost-reducing innovations; while the less cost-conscious procurement during World War I did not.

While these broad incentives determine the nature of innovation, it tells us little about the development process. It is well believed that medical procedure innovations are user innovations, or innovation-by-practitioners (Von Hippel 1976, 2006). As the end-users of medical technology, physician inventors are skilled practitioners who innovate-by-doing (Clemens and Olsen 2021). Therefore, it is natural to consider physician motivations when attempting to understand the incentives for procedural innovation.

One clear possible motivation for innovating physicians is reputation and career concerns (Strandburg 2017). Such innovators are invited to speak at conferences worldwide, receive many prestigious honors, and gain opportunities to practice at the world's leading medical centers. Many of these opportunities are not just honorifics, but they also provide tangible financial benefits directly to the innovator. Consider the career of Willem Kolff, who invented the first artificial kidney during World War II. After the war, he donated artificial kidneys to other hospitals in Europe. In 1950, he joined the Cleveland Clinic and later moved on to Brigham and Women's Hospital in Boston, where he used funding from private investors to develop the first artificial kidney for mass production. He eventually became head of the University of Utah's Division of Artificial Organs, where he helped develop the first artificial heart. Along the way, Dr. Kolff received 12 honorary doctorates and over 120 awards and prizes, including the Japan Prize, the $500,000

[13] TAVR is a revolutionary and lifesaving treatment for many patients with diseased aortic valves. 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). The new set of codes for TAVR includes four codes pertaining to variations in the approach to the procedure and whether there was cardiopulmonary bypass.

[14] Applied Behavior Analysis (ABA) is a set of related assessments and treatments for producing "clinically significant and lasting improvements in the functioning of people with autism." It is sufficiently widespread to have its own board that has certified over 33,000 behavior analysts.

[15] See, e.g., Ward & Dranove (1995), Acemoglu & Linn (2004), Finkelstein (2004), Blume-Kohout & Sood (2013), and Dranove *et al.* (2020).

Russ Prize, and the Lasker Award, considered the highest honor in American medicine.[16] It is reasonable to assume that each of these moves across prestigious institutions provided tangible and intangible benefits. Many other physician innovators enjoyed similar, if not quite so illustrious, rewards from their achievements.[17]

That said, these benefits almost certainly pale in comparison to the financial rewards for physicians and academics that are able to develop successful pharmaceutical products. Consider the cases of Michael Jung and Charles Swayer who invented enzalutamide (Xtandi) for prostate cancer, Patrick Soon Shiong who invented paclitaxel (Abraxane), or Richard Silverman who invented pregabalin (Lyrica). Each of these individuals ended up earning billions of dollars in royalty payments both personally and for their universities.

The difference in returns for innovators across these two types of innovations is not simply about the amount of value created. Many medical procedures are widely used and generate substantial welfare gains. Instead, this is a question of appropriability. This distinction is important because the development of a new procedure requires several costly steps, from initial experimentation through navigating the CPT development process, a step that is necessary for a novel procedure to generate value. While these costs of developing and commercializing a procedure are primarily borne by the innovator, the benefits are diffused across countless physicians and patients. This leads to an obvious commons problem that could decrease the amount of innovation below the optimal level. Even if the procedure involves a patented device, the financial incentives for approval of CPT codes are often diffused across a variety of parties. Not only are device patents less binding than drug patents (Halm and Gelijns, 1991; Chatterji et al., 2008), providers often receive a substantial share of the value created by the device through their own billings.

The portion of this commons problem related to administrative coding could be addressed by larger groups of physicians acting together to bear the cost of navigating this process. As we demonstrate in Section 5, medical societies often initiate the CPT coding applications on behalf of their members for new procedures that lack property rights protection. This should help address a portion of the commons problem in procedure innovation related to the costly administrative process of developing codes. It is important to note that while this role of medical societies addresses this portion of the commons problem, concerns regarding the concentration of the direct costs of innovative activity remain.

3. Basic facts about CPT applications and approvals

3.1. Extent of medical procedure innovation

We document the extent of medical procedure innovation using data on all CPT code applications filed with the AMA between 2008 and 2017.[18] The data allow us to identify the entirety of the development process for new procedures, including the first benchmark research, FDA approval of related devices, 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 reimburse). Given that most new medical procedures involve medical devices, including devices already in use for other procedures, this descriptive information complements and extends the existing evidence in this area (Stern 2017).

Applications follow a fairly standard format and contain: (1) the identity of the applicant; (2) whether there is an associated device and whether the device has received FDA approval; (3) published research pertaining to the procedure; (4) identity of any medical societies that support the application; (5) details about the procedure; and (6) how providers currently report the procedure for reimbursement purposes. We lack information about procedures that were 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. 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.[19] 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 percent (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). Panel 2 reports result by type of applicant. There are slightly more industry

[16] Source: https://achievement.org/achiever/willem-j-kolff/ (Accessed on 6/24/2021).

[17] Here are two more examples. Harold Ridley, who pioneered cataract surgery, was rewarded by promotion to "full surgeon" at Moorsfield Eye Hospital. Among his many honors was election as a Fellow to the Royal Society of London (Apple & Sims 1996). Phillippe Mouret performed the first laparoscopic cholecystectomy in 1987. Within one year he had presented his technique at medical conferences worldwide. Dr. Mouret received numerous prizes for his innovation, including becoming only the third physician to receive the Honda Prize in Ecotechnoloy. In 2004, Dr. Mouret was named the first President of the French Society for Endoscopic Surgery. Source: http://www.philippemouret.com/index.php/about/ (Accessed on 6/24/2021).

[18] For applications filed after 2017, we only observe the total count; no detailed information about these applications is provided to us. Applications filed before 2008 are only recorded in hard copy and were not produced for this study.

[19] 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 and we observe promotions and sunsets up to year 2019.

Table 1
Number of Applications, Approvals, and Rejections for Category III CPT Codes.

Year*	CPT III Applications	CPT III Approvals	CPT III Rejections	Approvals promoted to CPT I by 2019	Approvals Sunsetted by 2019	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

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

Table 2
Number of Applications for Category III CPT Codes 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	2	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 device refers to those that have not previously been used in another medical procedure and have been approved less than two years prior to the CPT III application.
**Industry applicant refers to those applied by industry firms (e.g., medical device companies).
***Medical applicant refers to those applied by medical societies and physicians.

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.

3.2. Development and administrative approval times of medical procedures

While numerous studies examine the innovation timeline for pharmaceuticals, there is a lack of comparable data on the development process for procedures. In this section, we develop a broadly 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 period between the FDA's approval of the associated device and the AMA's awarding of a permanent reimbursable billing code (CPT I code) – a time period without a clear analogue in the development of pharmaceuticals. Accounting for this administrative process, we estimate that the development process for procedures is comparable in length, if not longer, than that for drugs.[20]

Measuring the innovation timeline requires defining and identifying beginning and endpoints. Studies of drug development use a variety of starting points, such as the first clinical trial, and usually choose the date of FDA approval as the endpoint.[21] 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 a 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, Makower et al. (2010) find 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.

We extend the Makower et al. (2010) 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

[20] Note that medical procedure innovators may cover some losses during the CPT promotion process if they can use prevailing CPT codes, while drug innovators cannot.
[21] See, e.g., Dranove & Meltzer (1994), DiMasi *et al.* (2003), Keyhani *et al.* (2006), DiMasi & Grabowski (2007), DiMasi *et al.* (2016).

Table 3
Innovation Time of Procedures Approved for Category III CPT Codes, 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: Sample includes 128 CPT III procedures approved between 2008 and 2017.
*New device refers to those that have not previously been used in another medical procedure and have been approved less than two years prior to the CPT III application.

Table 4
Innovation Time of Procedures Promoted from Category III to Category I CPT 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 to CPT I by September 2019. 23 of these 30 applications involve devices that have been approved by the FDA at the time of the CPT III application.
*New device refers to those that have not previously been used in another medical procedure and have been approved less than two years prior to the CPT III application.

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. Although some procedures benefit from earlier animal model studies or lab studies, we use the first-in-human utilization 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.[22] 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. We exhibit the timeline of the key events in procedure innovation in Appendix Fig. A1.[23]

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 data about the associated FDA application.

The first clear result is that the development time of new procedures is long. While the average lag between the CPT III application and the effective date for the new CPT III code is only 14 months, suggesting a relatively quick administrative process, it takes 134 months (11.2 years) on average from the initial research study to CPT III approval. We find that 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 CPT III billing code with no guarantee for reimbursements. 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. Developers may also spend considerable time experimenting with the new procedure prior to submitting the CPT application. This may partially be due to the uncertainty about the evidence that is required for CPT approval. There is also considerable variation in the time to CPT III approval across procedure types. The longest development times are for procedures involving 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. Fig. 1 shows the distribution of the development time for all observed CPT III approvals, ranging from 1 to more than 20 years.[24]

Table 4 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. Nearly half of this time is spent before the FDA submission. There

[22] 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.

[23] 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.

[24] Appendix Fig. A2 shows the distribution of development time for the subsample excluding procedures with old devices.

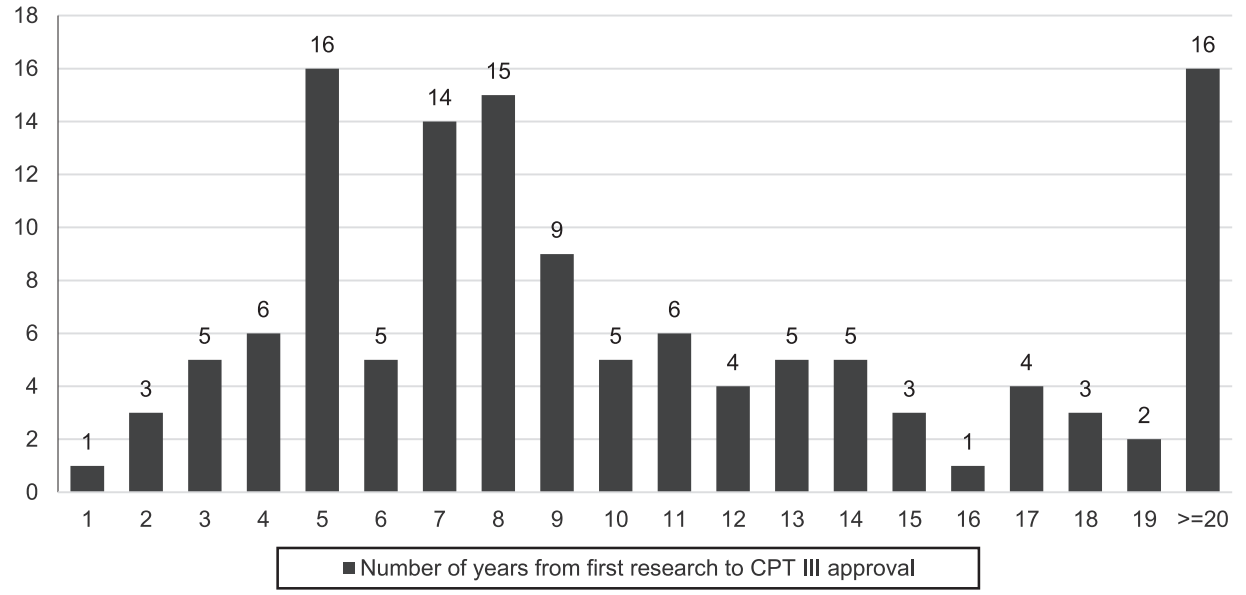


Fig. 1. Distribution of New Medical Procedure Development Time.
Notes: Sample includes 128 CPT III procedures approved between 2008 and 2017.

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 Fig. A3 shows the distribution of promotion time from CPT III approval to CPT I promotion and Appendix Fig. A4 shows the distribution of overall time from first research to CPT I code approval.

4. Effect of CPT promotion on diffusion of new procedures

One of the central questions in this paper is whether and how AMA coding decisions affect the adoption and diffusion of new procedures. Case studies, including Duszak et al. (2011) and Cox et al. (2016), show that CPT code promotions lead to increased utilization for specific medical services, but there is no existing systematic analysis. 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.[25] 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 is also not meant to imply the AMA believes a procedure is experimental.

If physicians believe a procedure is efficacious, the actual coding status could be theoretically irrelevant to their adoption decision. Indeed, education within the medical community, such as through presentations at meetings of professional societies, is a key determinant of utilization (McKinlay 1981). In practice, however, coding likely matters for at least two reasons. First, most payers are reluctant to reimburse for CPT III codes; 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. Berger et al. (2021) show that FDA approval of drugs serves as a signal of quality to consumers and enhances demand; a similar process may apply to AMA approval of procedure codes. 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.

4.1. Empirical strategy

Ideally, in order to study the effect of the administrative coding decision on utilization, we would have data on every time a medical provider uses the procedure regardless of its coding status. Recall that providers are required to use appropriate CPT III

[25] 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."

codes once they are available, which means that procedures should not be occurring under other codes after the issuing of such a code. Using AMA documentation, we are able to match CPT III to CPT I codes for new procedures.[26] This allows us to examine the effect on use from 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. Since prior utilization is a criterion for procedure promotion and is also relevant when providers make decisions about use, promoted procedures may be 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 precisely the time when CPT codes are promoted. We present estimates of such an effect using an event study approach that shows the change in use when the code is promoted.

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

$$Y_{it} = \alpha PostCPTI_{it} + X_{it}\mathrm{B} + Procedure_i\Gamma + Year_t\Delta + \varepsilon_{it} \tag{1}$$

$$Y_{it} = \sum_d CPTI\_Event_{id(t)}\mathrm{A} + X_{it}\mathrm{B} + Procedure_i\Gamma + Year_t\Delta + \varepsilon_{it} \tag{2}$$

In Eq. (1), 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 devices 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 utilization growth. The coefficient of interest is α. If promotion from CPT III to CPT I has a positive impact on utilization, we expect α 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. Our event study model (Eq. (2)) documents this effect. 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 for promoted procedures. We expect the estimated coefficients to increase discontinuously from the year of promotion.

4.2. Data

The main data source for procedure utilization is the CMS Medicare Provider Utilization and Payment Data in 2012–2018. 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's 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.[27] We extract utilization data for all CPT III codes created since 2001 that remained active in 2012–2018, including those that were promoted to CPT I codes.

We identify a total of 871 procedure-year observations, representing 167 procedures with active CPT III codes between 2012 and 2018 (Sample 1).[28] Of the 167 procedures, only 69 record Medicare utilization between 2012 and 2018, representing a subsample of 385 procedure-year observations (Sample 2). Among the 385 procedure-year observations, only 298 observations record Medicare utilization in the given year (Sample 3). This relatively low rate of Medicare utilization record likely reflects the fact that procedures with the 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. Among the 69 CPT III procedures with recorded Medicare utilization, 41 percent (28 procedures)

[26] 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, 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.

[27] 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.

[28] The sample is unbalanced because some CPT III procedures were introduced after 2012 and some procedures were sunsetted (i.e., expired after the probationary period and thus disappeared from the CPT system) before 2018.

Table 5
Summary Statistics of Procedures with Active Category III CPT codes between 2012 and 2018.

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)	3409	19,334	10	385,223	871
No. of Medicare Services (filling unreported utilization with 1)	3403	19,335	1	385,223	871
No. of Medicare Services (filling unreported utilization with 0)	3402	19,335	0	385,223	871
Any Medicare utilization (filling unreported utilization with 0)	0.34	0.47	0	1	871
Post-Promotion (Promoted to CPT I)	0.13	0.34	0	1	871
Tenure (No. of years since CPT III approval)	6	3.66	1	16	871
No Device	0.21	0.41	0	1	461
Device Approved by the year (time-variant)	0.62	0.49	0	1	461
Device Unapproved by the year (time-variant)	0.16	0.37	0	1	461
Procedure involving exclusive patented medical devices (time-invariant)	0.55	0.50	0	1	461
Procedure involving nonexclusive patented medical devices (time-invariant)	0.23	0.42	0	1	461
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)	7700	28,527	10	385,223	385
No. of Medicare Services (filling unreported utilization with 1)	7698	28,528	1	385,223	385
No. of Medicare Services (filling unreported utilization with 0)	7697	28,528	0	385,223	385
Any Medicare utilization (filling unreported utilization with 0)	0.77	0.42	0	1	385
Post-Promotion (Promoted to CPT I)	0.26	0.44	0	1	385
Tenure (No. of years since CPT III approval)	6.18	3.61	1	16	385
No Device	0.16	0.37	0	1	209
Device Approved by the year (time-variant)	0.78	0.41	0	1	209
Device Unapproved by the year (time-variant)	0.06	0.23	0	1	209
Procedure involving exclusive patented medical devices (time-invariant)	0.50	0.50	0	1	209
Procedure involving nonexclusive patented medical devices (time-invariant)	0.34	0.48	0	1	209
Sample 3: Observations with recorded Medicare utilization (No. of procedures=72, No. of procedure-year observations=240)					
No. of Medicare Services	9944	32,091	11	385,223	298
Post-Promotion (Promoted to CPT I)	0.34	0.48	0	1	298
Tenure (No. of years since CPT III approval)	6.35	3.70	1	16	298
No Device	0.17	0.38	0	1	166
Device Approved by the year (time-variant)	0.78	0.41	0	1	166
Device Unapproved by the year (time-variant)	0.04	0.20	0	1	166
Procedure involving exclusive patented medical devices (time-invariant)	0.53	0.50	0	1	166
Procedure involving nonexclusive patented medical devices (time-invariant)	0.30	0.46	0	1	166

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.

were promoted to CPT I between 2012 and 2017; none of the CPT III procedures with unreported Medicare utilization were promoted during the study period.

It is unclear whether the unreported utilization in the CMS data indicates zero utilization or missing values. To address this issue, we employ several alternative ways of coding unreported utilization. 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. For robustness, we consider filling the unreported values with 1, 0, and a randomly drawn integer between 1 and 10. Furthermore, we consider alternative samples by dropping the unreported values and show the robustness of the results using sample 2 and sample 3. Table 5 presents the summary statistics of the three samples.[29]

4.3. Main results

Table 6 presents estimates from Eq. (1). Our most preferred specification, in Column 1, is based on the full sample with unreported utilization replaced by 10, which generates a lower bound estimate of the effect. Despite this being a lower bound estimate, we find that CPT code promotion from Category III to Category I is associated with an economically meaningful 8.85-fold increase in

[29] 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.

Table 6
Main Results—Effect of CPT Code Promotion on Procedure Utilization.

Dependent Variable=$ln(Utilization_{it})$	Sample 1	Sample 2	Sample 3
$PostCPTI_{it}$	2.287***	2.574***	1.023***
	(0.519)	(0.580)	(0.392)
No. of Procedures	167	69	69
No. of Observations	871	385	298
R-squared	0.275	0.329	0.236

Notes: Sample 1 is the full sample, where we replaced the unreported utilization with 10. Since Medicare data does not report utilization when the annual utilization is equal to or less than 10, replacing the unreported utilization with 10 generates a lower bound estimate of the administrative coding effect. Sample 2 restricts to observations for which the procedure records Medicare utilization in some years between 2012 and 2018, where we replaced the unreported utilization with ten. Sample 3 excludes observations with unreported utilization. $ln(Utilization_{it})$ 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. Standard errors in parentheses are clustered by procedure and bootstrapped with 200 iterations. *** $p<0.01$.

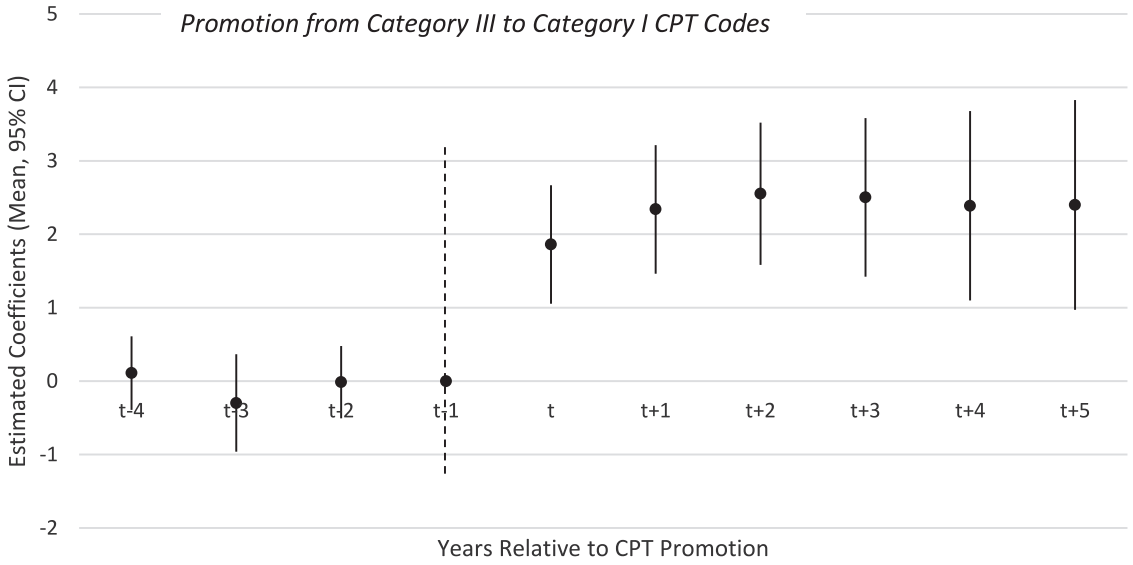


Fig. 2. Event Study Plot for the Effect of CPT Promotion on Procedure Utilization. (Full Sample).
Notes: This figure presents the estimated coefficient (mean and 95% CI) of $CPTI\_Event_{id(t)}$ from Eq. (2), with the dependent variable being the logged number of Medicare services (replacing unreported utilization with 10). The x-axis represents the time leads or lags from the year of CPT code promotion. The dashed line represents the time when the CPT code is promoted from Category III to Category I status. No. of Observations=871. No. of Procedures = 167.

utilization.[30] As expected, the effect becomes even larger when we focus on the subsample of procedures with recorded Medicare utilization (Table 6, Column 2). Finally, the result remains highly robust when we drop all observations with unreported utilization (Table 6, Column 3).

Figs. 2 and 3 show the estimated coefficients from the event-study model (Eq. (2)) with the logged number of Medicare services as the dependent variable, using the full sample and the subsample of procedures with recorded Medicare utilization, respectively. Utilization increased discontinuously starting from the promotion year and it stays relatively stable in the post-promotion period. There is no anticipatory effect in the years prior to promotion. This suggests that there is a one-time increase in utilization upon code promotion, 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.

To confirm that the main results are not driven by random events, we perform a placebo test by randomly assigning CPT I status across different procedures while keeping the promotion rate (i.e., the proportion of codes being promoted) the same as in the actual data. We perform 1000 iterations and show the distribution of the estimated coefficients and standard errors in Fig. 4. The results from this placebo test are insignificant. We also perform a number of tests to show our main findings are robust to the specification of the estimation model, treatment of missing values, and sample selection. The results of the robustness tests are shown in Appendix C.

[30] $e^{2.287} - 1 = 8.85\langle / END \rangle$

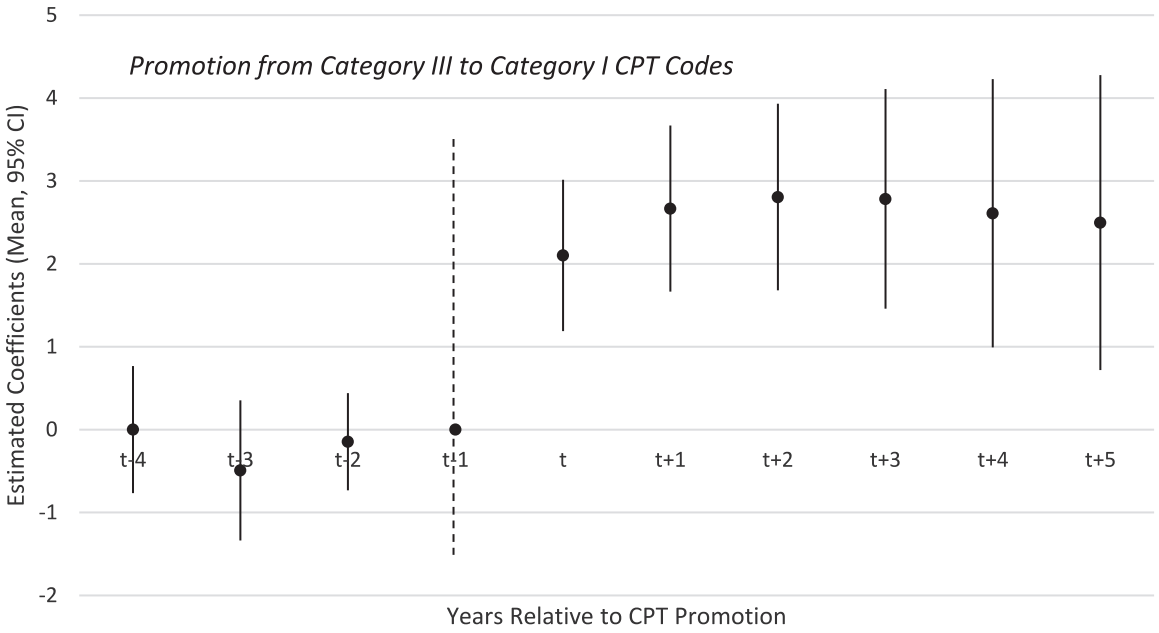


Fig. 3. Event study plot for the effect of CPT promotion on procedure utilization. (Subsample of procedures with positive utilization).
Notes: This figure presents the estimated coefficient (mean and 95% CI) of $CPTI\_Event_{id(t)}$ from Eq. (2), with the dependent variable being the logged number of Medicare services (replacing unreported utilization with 10). The x-axis represents the time leads or lags from the year of CPT code promotion. The dashed line represents the time when the CPT code is promoted from Category III to Category I status. The estimation uses the subsample of CPT III procedures with positive utilization in the Medicare utilization data. No. of Observations=385. No. of Procedures = 69.

Finally, we conduct a back-of-the-envelope calculation of the additional profits earned by the medical device companies associated with the utilization increase due to CPT code promotion. The results are shown in Appendix D.

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 the utilization of all new procedures. In Section 5.3, we discuss this in detail. For those procedures that are not well-accommodated by existing codes, however, it is clear that coding matters.

4.4. Heterogeneity and mechanisms

AMA approval of new CPT codes, including the promotion of CPT codes from Category III to Category I, can increase the diffusion of procedures in two distinct ways. First, approval can certify the quality of the procedure. We call this the *certification* mechanism. Second, the promotion of CPT codes from temporary status (Category III) to permanent status (Category I) allows for payer reimbursement. We call this the *financial incentive* mechanism. To catalyze diffusion through either mechanism, the AMA, medical specialties, and independent companies routinely publish articles informing their members of newly approved codes, and physicians can take online classes to learn when it is appropriate to use new codes.

We conduct a number of heterogeneity analyses to shed light on mechanisms. To test for the *certification* mechanism, we measure the amount of existing knowledge of a procedure at the time of CPT code promotion using the number of relevant peer-reviewed publications recorded in PubMed.[31] If the *certification* mechanism is important, we expect code promotion to have a larger impact on utilization for those procedures with fewer publications. We define procedures with less than the median number of existing publications to have "fewer publications."[32] We then conduct a heterogeneity analysis by the level of existing publications and present the results in Appendix Table A1. The results do not support the *certification* mechanism—utilization increases after CPT code promotion are similar across procedures with differential levels of existing knowledge. This provides indirect evidence of the importance of the *financial incentive* mechanism. Physicians may have information about a procedure, as evidenced by prior publications, but they do not adopt it until they can bill for it.

Second, we test for the heterogeneity of the main effect by whether the procedure involves exclusive patented devices, nonexclusive devices, or no devices. Appendix Table A2 suggests that the increase in utilization due to CPT code promotion is stronger among

[31] PubMed is a search engine for the MEDLINE database of references and abstracts on life sciences and biomedical topic. We thank the anonymous referee for this valuable suggestion. Link to PubMed: https://pubmed.ncbi.nlm.nih.gov/.

[32] There is sufficient variation in this measure of existing knowledge: among the 28 promoted procedures, the number of existing publications ranges from 2 to 681, with mean of 159, median of 83, and standard deviation of 186.

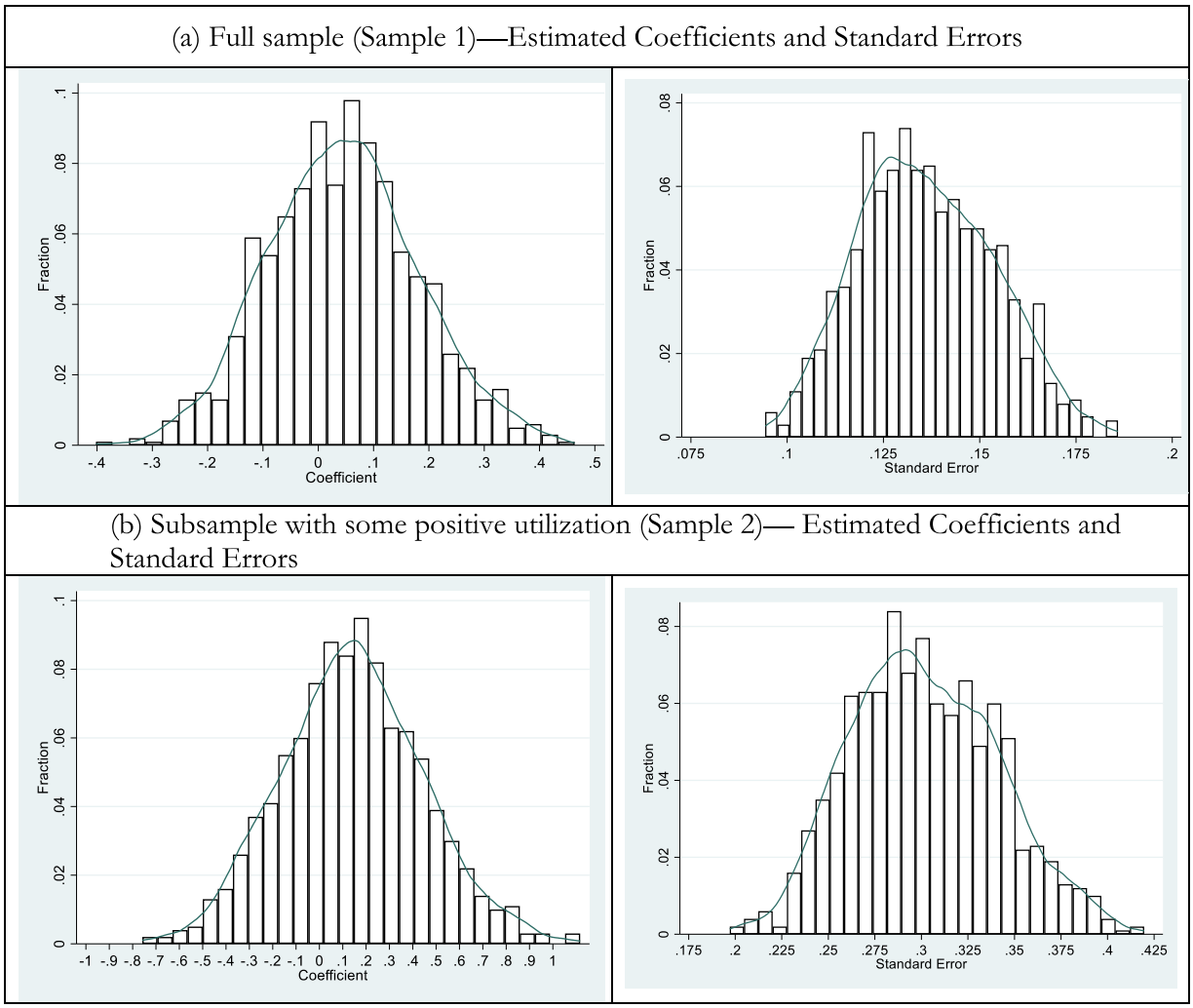


Fig. 4. Placebo Analysis—Distribution of Esitamted Coefficients and Standard Errors from Randomly Assigning CPT I Promotion Status.
Notes: This figure presents the distribution of the estimated coefficients and standard errors for $PostCPTI_{it}$ in Eq. (1), with randomly assigned CPT I promotion status. The dependent variable is the logged Medicare utilization. Sample 1 is the full sample, where we replaced the unreported utilization with 10. Since Medicare data does not report utilization when the annual utilization is equal to or less than 10, replacing the unreported utilization with 10 generates a lower bound estimate of the administrative coding effect. Sample 2 restricts to observations for which the procedure records Medicare utilization in some years between 2012 and 2018, where we replaced the unreported utilization with ten. Standard errors in parentheses are clustered by procedure and bootstrapped with 200 iterations. Number of iterations = 1000.

procedures that involve medical devices (both exclusive and nonexclusive devices). There could be several explanations. First, device manufacturers might invest more in promoting their devices when the relevant procedures are reimbursed. Second, procedures involving devices might be difficult to claim under existing codes, and procedures without devices might allow more flexibility in claiming.

4.5. Does CPT III status affect diffusion?

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 previously noted, providers may offer a procedure under an existing code or an "unlisted" code in the pre-CPT III period. We have no way to determine utilization from these codes. However, we believe that increase in utilization after granting of a CPT III code is likely to be very low. At a minimum, the nominal level of utilization of CPT III codes is quite small. This demonstrates that the *absolute* amount of diffusion cannot be large. Only 38% of procedures with active CPT III codes between 2012 and 2018 (65 out of 171) reported any Medicare utilization when retaining the CPT III status. This is consistent with the *financial incentive* mechanism, as insurers generally do not reimburse for procedures with CPT III status. Importantly, CMS does not

assign RVUs to CPT III codes, which means that they cannot be billed like other procedures.[33] 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."[34] 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.[35]

Documents from medical device manufacturers provide additional evidence that reimbursement of CPT III codes can be difficult. For example, 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.[36] However, it also notes that upgrading the code to CPT I is necessary for securing reimbursement in the US market. The granting of a CPT III code is not always a positive step for an innovator. Consider the case of Si-Bone, a firm that developed minimally invasive surgical treatments for sacroiliac joint disorders. It completed an initial public offering (IPO) in 2018 and included a detailed discussion of the relationship between CPT codes and reimbursement in its prospectus.[37] 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. Additional evidence on drug and procedure innovation

5.1. The overall 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 in Appendix E the utilization and spending are higher for top-utilized new drugs than those of top-utilized new procedures. We also compare the year of introduction for top-utilized drugs and procedures and find that top-utilized procedures were introduced earlier than top-utilized drugs. Examining these data, one may be tempted to conclude that the pace of drug innovation has outstripped the pace of procedure innovation. 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; 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.

5.2. Evidence on property rights and the commons problem

To shed light on how the medical profession addresses the commons problem, we examine who files applications for different types of procedures. Table 7 reports the type of CPT III applicant based on whether the procedure involves an exclusive patented device, nonexclusive device (e.g., off-patent device), or no device. Consistent with the 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, Columns 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, Column 2).

To further address the concern that unobserved factors might drive the application types among industry applicants and medical societies (e.g., differential types of R&D investments and thus focusing on different specialties), we regress whether the applicant is an industry firm on procedure type (i.e., whether the procedure involves exclusive patented devices or non-exclusive devices,

[33] Source: AMA CPT Category III Codes Long Descriptors https://www.ama-assn.org/system/files/cpt-category3-codes-long-descriptors.pdf (Accessed on 6/24/2021).

[34] 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 (Accessed on 6/24/2021).

[35] 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.

[36] Source: iSonea Annual Financial Report. https://www.asx.com.au/asxpdf/20111019/pdf/421vl9t3rc2xfq.pdf (Accessed on 6/24/2021).

[37] Source: SiBone IPO Report. https://investor.si-bone.com/static-files/83477437-1762-4a30-be4a-43a8c88968eb (Accessed on 6/24/2021)..

Table 7
Number of Procedures with Category III CPT Codes by Device Patent Type.

		Total CPT III Approvals	By Device Patent Type		
			Exclusive Patented Device*	Nonexclusive Device	No Device
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 procedures approved for CPT III codes 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.

Table 8
Association between Device Patent Type and Applicant Type.

DV=*1(Industry Applicant)*	(1)	(2)
Exclusive Patented Device	0.544**	0.610***
	(0.150)	(0.110)
Non-Exclusive Device	−0.504	0.029
	(0.160)	(0.187)
Specialty Fixed Effects	N	Y
No. of Observations	128	128
R-squared	0.42	0.48

Notes: Sample includes 128 procedures approved for CPT III codes between 2008 and 2017. The dependent variable is an indicator variable for industry applicants. A procedure is defined to involve an exclusive 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. *** $p<0.01$, ** $p<0.05$.

with the omitted category being procedures that do not involve devices), while controlling for procedure specialty fixed effects (i.e., ophthalmology, orthopedics, oncology, radiology, general surgery, cardiology and pulmonary, and the other specialties). Results shown in Table 8 suggest that medical societies and other non-industry applicants are more likely to seek CPT codes for new procedures that do not involve exclusive patented devices, whereas industry firms are more likely to seek CPT codes for procedures that do involve patented devices. This confirms the role of medical societies in attempting to address the commons problem.

5.3. 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. These procedures include radical innovations as well as incremental innovations that involve higher costs than the existing ones, which renders the necessity for providers, represented by the medical societies, to apply for new procedure codes and secure a higher payment. Admittedly, there are also "new procedures in old codes (NPOCs)," i.e., new procedures that are well-accommodated by existing codes and never assigned a unique CPT code. Our data do not allow us to separately identify NPOCs from old procedures sharing the same codes, and 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. Therefore, our analysis, which focuses on new CPT codes, likely understates the extent of new procedure innovation.

Another category of procedures not captured by our study 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.[38] There is also no clear evidence that it offers meaningfully superior outcomes (Wilensky 2016; Wright 2017). As a result, the AMA deemed it unnecessary to issue unique CPT codes for robotic-assisted procedures.[39] Instead, the

[38] 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).

[39] 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. Source: https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-Robotic-Assisted-Surgery-Policy.pdf (Accessed on 6/24/2021).

use of a robot is considered integral to the performance of laparoscopic procedures and should be billed under existing codes. 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 explore inside the black box of the economics of medical procedure innovation and contrast it with the previously well-documented innovation process of pharmaceutical products. Better understanding the underlying economics driving the process by which individuals and firms develop and adopt new medical procedures is important because such innovations can have large welfare gains.

Using a novel and proprietary dataset on CPT applications of emerging medical procedures, we document several important facts about the economics of procedural innovation. Such information can be used to inform policy development and future research in this area.

We begin by documenting, 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. Our 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. We also uncover meaningful variation in innovation times across procedures, depending on whether the procedure involves medical devices and the type of devices.

Second, we highlight two striking features of medical procedure innovation that are distinct from the process of developing new pharmaceuticals. First, many new procedures, especially those that do not involve recently developed devices, lack explicit or even implicit property rights. Second, administrative coding decisions can be crucial to the success of procedure innovations. For example, 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.

As we note above, these two facts create a potential appropriability issue and may provide suboptimal innovation incentives. This appropriability concern exists on two dimensions. The first relates to the investments necessary to develop the new procedure and the second involves the administrative and regulatory costs necessary to secure approval and reimbursement. Our results demonstrate that in many cases physicians address this second problem through their specialty medical societies. We find that these organizations are responsible for the majority of applications for billing codes. That said, this does little to address the limited appropriability of new procedures by the innovator compared to pharmaceuticals.

If the AMA should continue to have de facto control over the review of new procedures, it might consider adopting some of the practices used by CMS. These include special designations for “orphan” procedures and other innovations that address unmet needs. The AMA review board would work closely with the procedure developer to identify the kinds of evidence that would be required for approval, thereby accelerating the process. Alternatively, CMS could assume responsibility for procedure review, again drawing on the review process for procedures similar to that used by the FDA for drugs. This could reduce the wide variation in evidence produced during the development process and potentially speed approval.

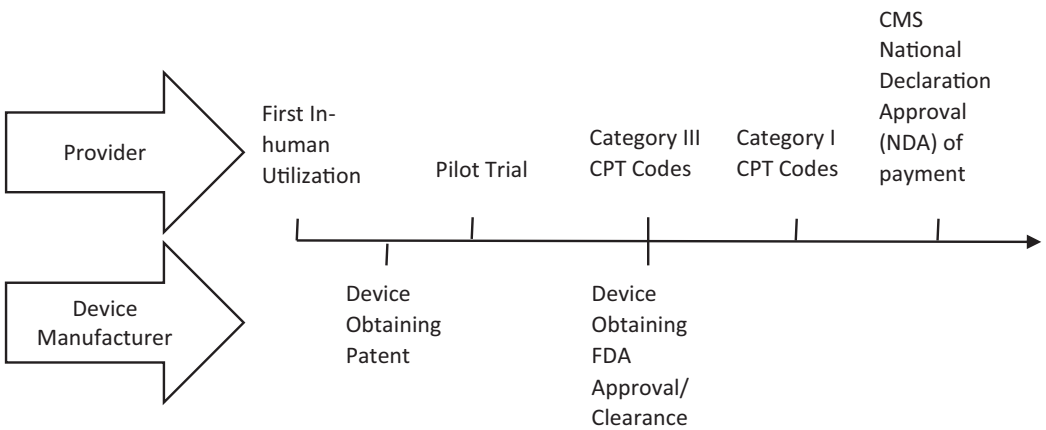
Even if the AMA were to adopt such procedures, there would still be a remaining concern regarding the appropriability of the investments necessary to develop a new procedure in the Our finding that medical societies are instrumental in gaining approval for many procedures demonstrates the importance of property rights in the development process. Over time, the medical profession may revisit its position against physicians patenting procedures. However, more research is required to determine whether additional financial incentives will encourage physicians to invest in developing new procedures. If so, then the benefits to patients may offset the higher prices associated with patents. This may raise additional questions about the role of the government in regulating procedure prices.

As policymakers and academics consider potential remedies to existing shortfalls in the system of developing an optimal amount of procedural innovation we note that there are several limitations to this study that may point that way to future research. First, as mentioned in Section 5.3, 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 examining their distinct values, 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.

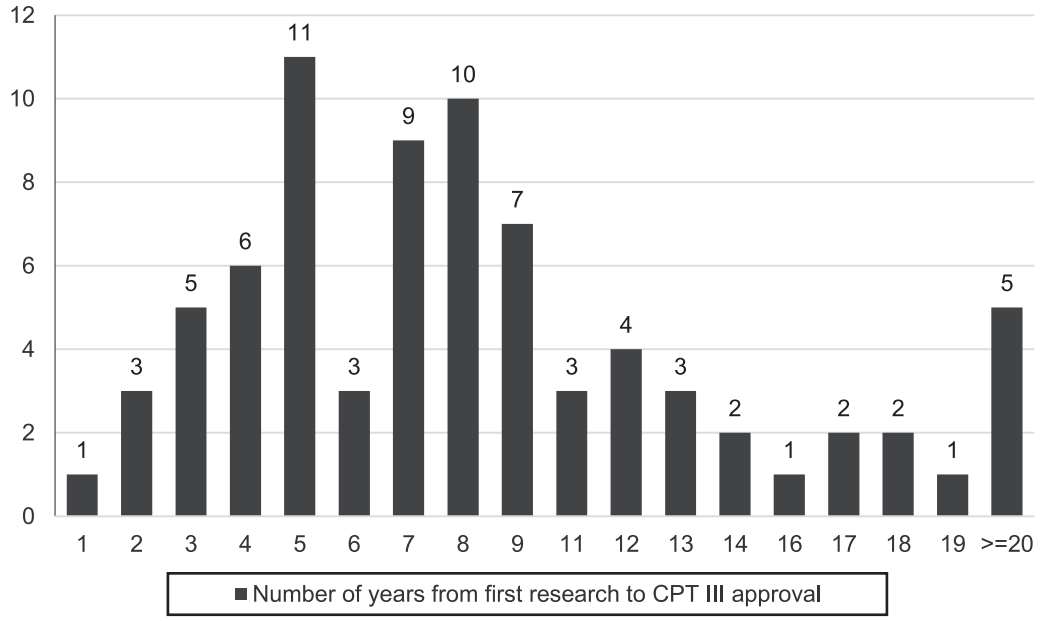
Acknowledgement

We are grateful to the editor and two anonymous referees for their valuable comments and suggestions. We are particularly thankful to the American Medical Association for sharing the data. We would like to thank participants at the 19th Annual International Industrial Organization Conference and the 2021 International Health Economics Association, and at the seminar series of Rutgers University. We declare no financial or personal relationship that could cause a conflict of interest regarding this article.We are grateful to the editor and two anonymous referees for their valuable comments and suggestions. We are particularly thankful to the American Medical Association for sharing the data. We would like to thank participants at the 19th Annual International Industrial Organization Conference and the 2021 International Health Economics Association, and at the seminar series of Rutgers University. We declare no financial or personal relationship that could cause a conflict of interest regarding this article.

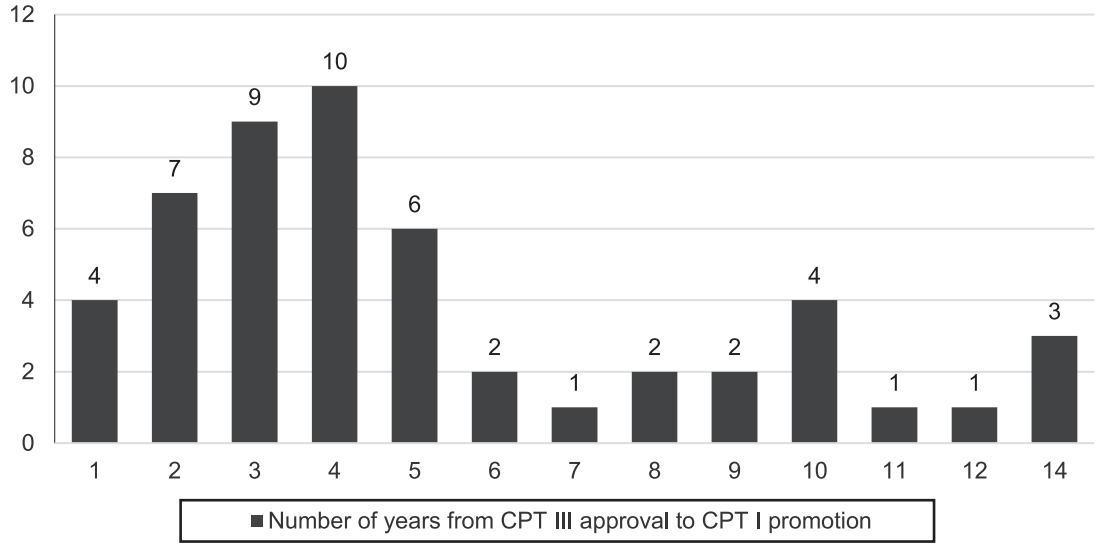
Appendix A. Additional Figures and Tables.



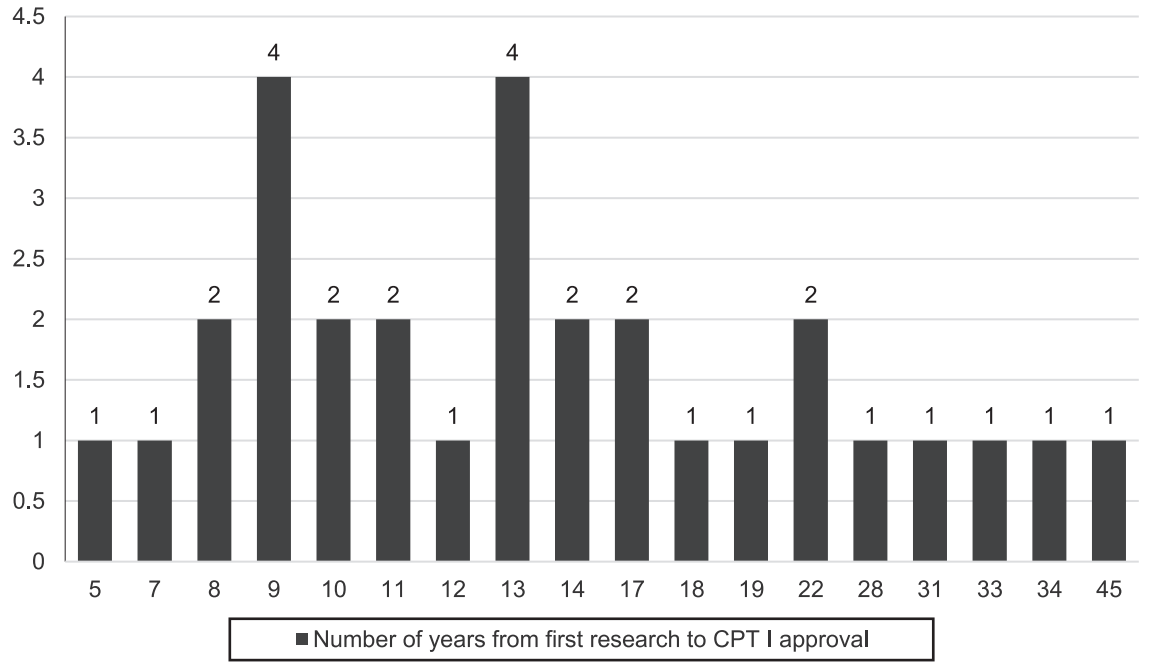
Appendix Fig. A1. Medical Procedure Innovation Timeline.
Notes: This figure shows the innovation timeline for medical procedures. It highlights the key events for both providers and device manufacturers.



Appendix Fig. A2. Distribution of Development Time Excluding Procedures with Old Devices.
Notes: Sample includes 78 CPT III procedures that involve either new devices or no devices (excluding procedures with old devices) and have been approved between 2008 and 2017.



Appendix Fig. A3. Distribution of Procedure 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 4 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 Fig. A4. Distribution of Overall Procedure Development Time.
Note: The sample contains 30 CPT III applications that have been approved between 2008 and 2017 and promoted by September 2019.

Appendix Table A1
Heterogeneity Analysis by Level of Existing Research.

DV= $ln(Utilization_{it})$	Sample 1	Sample 2	Sample 3
$PostCPTI_{it}$	2.241***	2.960***	1.027**
	(0.742)	(1.015)	(0.490)
$PostCPTI_{it} \times$	0.095	−0.709	−0.008
$FewerPublications_i$	(0.976)	(1.181)	(0.729)
No. of Procedures	167	69	69
No. of Observations	871	385	298
R-squared	0.275	0.334	0.236

Notes: $ln(Utilization_{it})$ represents the natural log of Medicare utilization of procedure *i* in year *t*. $FewerThanFivePublications_i$ is equal to one if the procedure has fewer than five peer-reviewed publications as recorded in the CPT code application file. Sample 1 is the full sample with non-missing research information. Sample 2 restricts to observations for which the procedure records Medicare utilization in some years between 2012 and 2018 with non-missing research information. Sample 3 restricts to observations with recorded Medicare utilization and non-missing research information. The number of existing publications for each procedure is obtained from searching on PubMed: https://pubmed.ncbi.nlm.nih.gov/. $FewerPublications_i$ is one if the number of existing publications for the procedure is less than the median number (i.e., 83). Standard errors in parentheses are clustered by procedure and bootstrapped with 200 iterations. *** $p<0.01$, ** $p<0.05$.

Appendix Table A2
Heterogeneity Analysis by Procedure Device Type.

DV= $ln(Utilization_{it})$	Sample 1	Sample 2	Sample3
$PostCPTI_{it}$	2.206***	2.504***	1.849***
	(0.545)	(0.567)	(0.570)
$PostCPTI_{it}$* $NoDevice_i$	−1.672***	−1.590***	−1.214*
	(0.550)	(0.552)	(0.629)
$PostCPTI_{it}$* $NonExclusiveDevice_i$	1.631	1.419	−0.484
	(1.117)	(1.221)	(1.156)
No. of Procedures	109	46	46
No. of Observations	515	238	182
R-squared	0.361	0.416	0.353

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 with non-missing device type. Sample 2 restricts to observations for which the procedure records Medicare utilization in some years between 2012 and 2018 with non-missing device type. Sample 3 restricts to observations with recorded Medicare utilization and non-missing device type. Standard errors in parentheses are clustered by procedure and bootstrapped with 200 iterations. *** $p<0.01$, ** $p<0.05$, * $p<0.1$.

Appendix B. Three Short Case Studies of Innovation Medical Procedures

In this appendix, we offer brief case studies of each of three types of medical procedure innovation: a) procedures with exclusive patented device, b) procedures with old device, and c) procedures with no device. We also present timelines for each innovation, in order to illustrate the information available from the CPT application and its paper trail.

Case 1: TAVR (Innovative procedure with exclusive patented device)

This is an example of the type of breakthrough innovations, defined as "new device" innovations, which involve newly approved/cleared devices (within two years) or unapproved/uncleared devices. These procedures do not have any prior reporting code other than the unlisted codes.

Appendix Table B1 presents the timeline for the development of TAVR. The earliest animal study using percutaneous catheter-based systems for the treatment of heart disease dated back to 1965 (Davies 1965). The initial in-human attempts of the procedure started in 1985 but were unsuccessful (could not last for more than one year) due to the limitation of the available devices (Cribier, et al. 1986). In 1999, Edward Lifesciences, Irvine, California, invented a new device, a bioprosthetic heart valve sutured onto a balloon-expandable stent. Using this new device, the first-in-human percutaneous aortic valve implantation was successfully performed in 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). As mentioned above, we use the first-in-human utilization of the procedure (i.e., April 2002) as the starting point when calculating the time span.

Several dates stand out in Appendix Table B1. First, while the patent was immediately granted after the first-in-human utilization, there is a considerable lag between patent granting and the FDA application. Second, there is a relatively short lag between FDA approval and AMA approval for Category III. Third, Medicare issues a national coverage determination (NCD) approving payment for TAVR, an approval that is not binding on commercial insurers. Compared to other new procedures, TAVR received a relatively broad NCD shortly after its introduction. Finally, there is an additional two-year lag before Category I approval. As we will show, this is an exceptionally short lag between Categories III and I. The overall time span from first-in-human utilization to CPT I approval is ten years.

Case 2: Corneal Incisions using Laser ("Old Device No Prior Code" Innovation)

The second case is an example of how new procedures evolve from existing devices that have been previously approved and used for other procedures. Although these procedures do not involve product innovation, they are innovative in the sense that there is no prior reporting code other than the "XXX99", unlisted code. We define these procedures as "old device no prior code" innovations.

Appendix Table B2 describes the timeline of Corneal Incisions using Laser for Donor and Recipient, a new surgical procedure using existing devices. In December 1999, the initial FDA clearance was granted to IntraLase Corp. (Irvine, CA)'s laser device, with the intended use for initial lamellar resection of the cornea. Since then, a series of FDA clearances were issued, allowing for other uses of the device. In December 2004, the first lab study was conducted using the laser device to perform keratoplasty (i.e., corneal transplantation). In 2006, the first-in-human keratoplasty procedure using the laser device was performed at the University of California, Irvine. In the same year, IntraLase Corp. received a new 510 K clearance to use the device for keratoplasty. In 2010, only four years after the first-in-human utilization, an ophthalmologist group submitted a CPT III application for the procedure to the AMA. The application was approved, and the CPT III codes took effect in 2012. Prior to its CPT III approval, the procedure was reported under an unlisted CPT I code.

Case 3: Applied Behavior Analysis ("No Device/Prior Code" Innovation)

This procedure is an example of emerging medical procedures that do not involve devices and/or have been previously reported under existing CPT codes, defined as "no device/prior code" innovations. Because these procedures do not involve devices, their

Appendix Table B1
Timeline of TAVR.

Time	Device Manufacturer	Physician/ Academic group	FDA/AMA/CMC
January 1965		First animal study	
August 1984		First (unsuccessful) in-human procedure using old devices	
June 1999	Patent application by Edwards Lifesciences		
April 2002		First successful in-human procedure using the new device	
May 2003	Patent granted to Edwards Lifesciences		
August 2003		First pilot trial	
November 2009		Category III CPT application submitted to the AMA.	
November 2010	FDA Class III PMA application		
January 2011			AMA grants Category III CPT codes
November 2011			FDA Class III PMA approval
February 2012			AMA grants Category I CPT codes contingent on FDA approval of the device
May 2012			Medicare issues national declaration approving payment for TAVR
February 2013			AMA reaffirms the Category I codes.

Appendix Table B2
Timeline of Corneal Incisions using Laser (Donor and Recipient).

Date	Event
December 1999	First FDA Class II 510 K clearance of IntraLase Corp. femtosecond laser for a different intended use—initial lamellar resection of the cornea.
December 2004	First lab study
February 2006	FDA Class II 510 K application
March 2006-December 2006	First-in-human utilization and pilot trial
August 2006	FDA Class II 510 K clearance
November 2010	Category III CPT application submitted to the AMA.
January 2012	AMA grants Category III CPT codes

Appendix Table B3
Timeline for Applied Behavior Analysis.

Date	Event
Mid-1960s	First-in-human utilization
1973, 1987, 2007, 2010	Surge in research
August 2013	Category III CPT application submitted to the AMA.
July 2014	AMA grants Category III CPT codes
January 2018	AMA grants Category I CPT codes

applicants are mostly academic institutions (i.e., medical specialty societies or universities). The innovation time for this type of procedure is normally longer compared with the other two types.

Mental health professionals had been performing the set of procedures for autism patients collectively called Applied Behavior Assessment since the mid-1960s, although the first two controlled trials were not published until 1973 and 1987, with an explosion of studies appearing between 2007 and 2010. There are no property rights associated with ABA procedures, and the procedure had been reported under various CPT I codes before the CPT III approval. Appendix Table B3 provides the timeline for ABA. It took almost 50 years for the procedure to obtain its own CPT I code since its first-in-human utilization.

Appendix C. Additional Robustness Tests

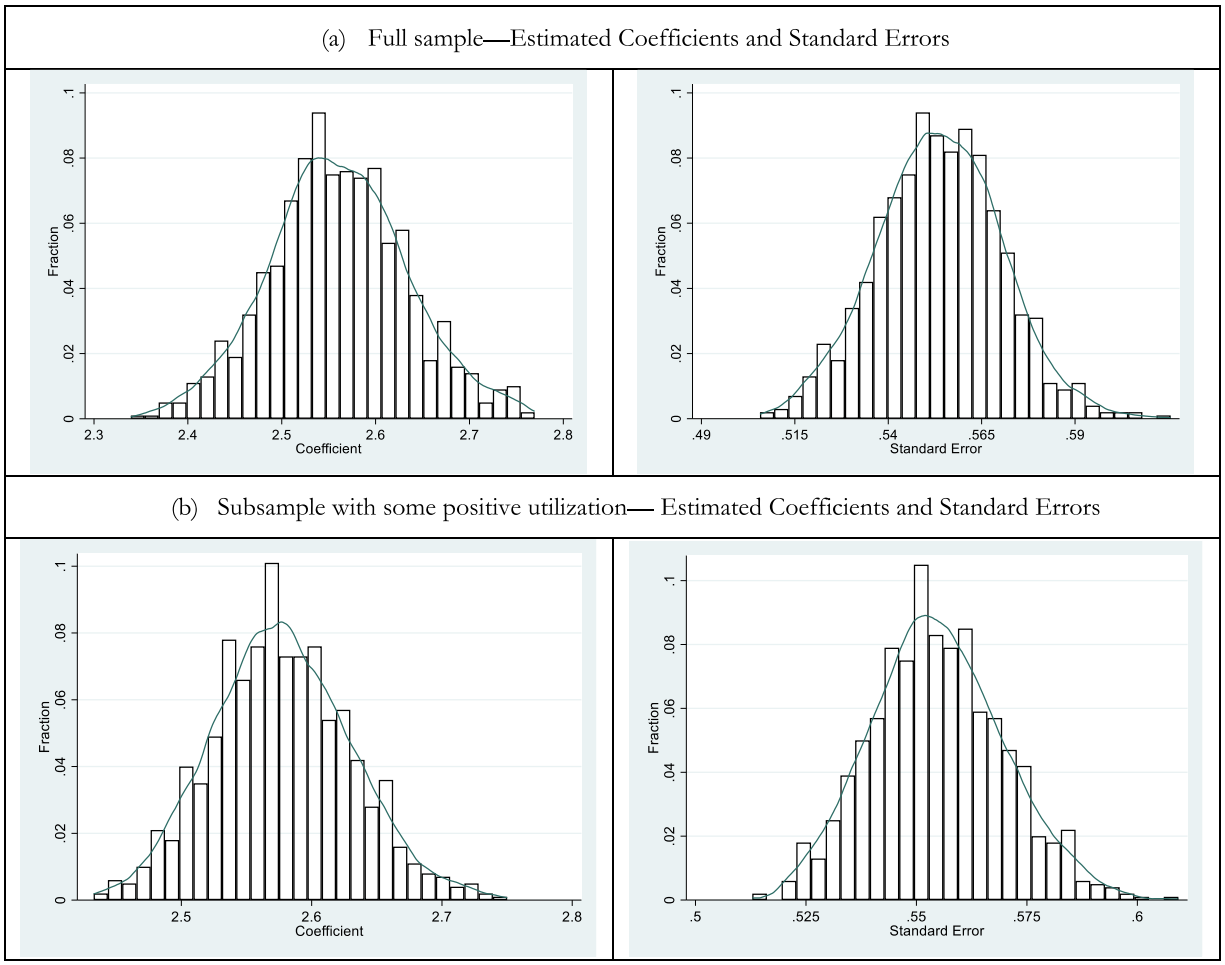
In this section, we perform a number of tests to show our main findings are robust to the selection of model specifications and samples.

First, we consider alternative treatments of the missing values. 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 to unreported utilization. Here, we show the robustness results of alternative specifications of missing values. We first replace the unreported utilization with 1 and report the robust results in Columns 1 and 3 of Appendix Table C1, using sample 1 and sample 2 respectively. As expected, the results become quantitatively larger than the main results. Next, when treating the unreported value as no utilization, we find that CPT code promotion is associated with a 34.4 percent higher odds of any utilization (Appendix Table C1, Column 2), and this effect becomes larger when restricting to the subsample of procedures with recorded Medicare utilization (Appendix Table C1, Column 4). Further, since the missing values could be any number between 1 and 10, we re-run the analysis 1000 times with different random draws for the missing values of utilization from a discrete uniform {1, 10} distribution. Appendix Fig. C1 shows the results of the estimated

Appendix Table C1
Robustness Test—Alternative Specifications of Unreported Utilization.

	Sample 1		Sample 2	
	Replacing unreported utilization with 1	Replacing unreported utilization with 0	Replacing unreported utilization with 1	Replacing unreported utilization with 0
Dependent Variable	$ln(Utilization_{it})$	$Dummy\_Use_{it}$	$ln(Utilization_{it})$	$Dummy\_Use_{it}$
$PostCPTI_{it}$	3.079***	0.344***	3.522***	0.412***
	(0.658)	(0.092)	(0.702)	(0.112)
No. of Procedures	167	167	69	69
No. of Observations	871	871	385	385
R-squared	0.266	0.141	0.329	0.175

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 2018. Standard errors in parentheses are clustered by procedure and bootstrapped with 200 iterations. *** $p<0.01$.



Appendix Fig. C1. Robustness Test by Random Sampling to Fill Unreported Utilization.
Notes: 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 the procedure. Number of iterations = 1000.

coefficients and standard errors of the post-CPT I dummy variable in Eq. (1), using the full sample (Panel a) and the subsample of procedures with recorded Medicare utilization (Panel b). The results remain highly robust. To further reduce the confounding effects of unreported utilization, we drop the 11 procedures with unreported pre-promotion Medicare utilization (among the total of 28 promoted procedures), and re-estimate Eq. (2) using this subsample. The event-study results as shown in Appendix Fig. C2 remain highly robust.

The second robustness test aims to exclude the potential effects 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 Eq. (1) using a subsample that excludes all procedures that involve unapproved devices at the time of CPT III approval. The results shown in Appendix Table C2 are highly robust and are quantitatively similar to the main results.

The third robustness test re-estimates Eq. (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 results are shown in Appendix Table C3.

Fourth, 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 Eq. (1) and show the robust results in Appendix Table C4. Compared with the main results shown in Table 6, the effects become smaller but remain highly significant.

Last, we consider alternative model specifications to better identify the code promotion effect on utilization. Since multiple procedures are promoted in different years, we account for potential heterogeneous treatment effects across time by adopting an alternative estimation model as proposed in De Chaisemartin and d'Haultfoeuille, 2020. The robust event-study results are shown

Appendix Table C2
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	$ln(Utilization_{it})$	$ln(Utilization_{it})$	$Dummy\_Use_{it}$	$ln(Utilization_{it})$	$ln(Utilization_{it})$	$Dummy\_Use_{it}$	$ln(Utilization_{it})$
$PostCPTI_{it}$	2.233***	3.073***	0.365***	2.649***	3.693***	0.453***	0.854**
	(0.610)	(0.739)	(0.107)	(0.647)	(0.945)	(0.133)	(0.380)
No. of Procedures	131	131	131	57	57	57	57
No. of Observations	726	726	726	334	334	334	256
R-squared	0.240	0.239	0.148	0.290	0.293	0.192	0.117

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 2018. Sample 3 restricts to observations with recorded Medicare utilization. Standard errors in parentheses are clustered by procedure and bootstrapped with 200 iterations. *** $p<0.01$, ** $p<0.05$.

Appendix Table C3
Robustness Test—Adding Interaction between Tenure and Log Time Trend.

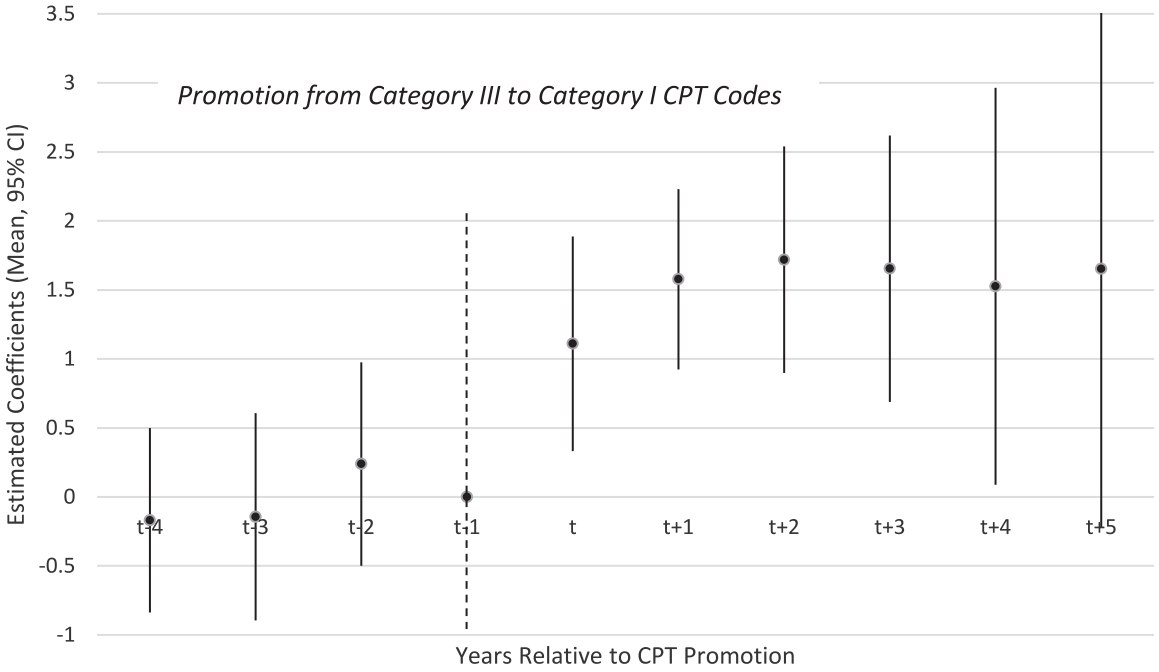
	Sample 1			Sample 2			Sample 3
	Replacing unreported utilization with 10	Replacing unreported utilization with 1	Replacing unreported utilization with 0	Replacing unreported utilization with 10	Replacing unreported utilization with 1	Replacing unreported utilization with 0	Excluding observations with unreported utilization
Dependent Variable	$ln(Utilization_{it})$	$ln(Utilization_{it})$	$Dummy\_Use_{it}$	$ln(Utilization_{it})$	$ln(Utilization_{it})$	$Dummy\_Use_{it}$	$ln(Utilization_{it})$
$PostCPTI_{it}$	2.297***	3.100***	0.349***	2.492***	3.400***	0.395***	1.068**
	(0.489)	(0.637)	(0.090)	(0.531)	(0.683)	(0.113)	−0.423
No. of Procedures	167	167	167	69	69	69	69
No. of Observations	871	871	871	385	385	385	298
R-squared	0.328	0.307	0.165	0.438	0.407	0.231	0.360

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 2018. Sample 3 restricts to observations with recorded Medicare utilization. Standard errors in parentheses are clustered by procedure and bootstrapped with 200 iterations. *** $p<0.01$, ** $p<0.05$.

Appendix Table C4
Robustness Test—Effect of CPT code promotion on Procedure Utilization Using the Year before CPT I publication year as the promotion year.

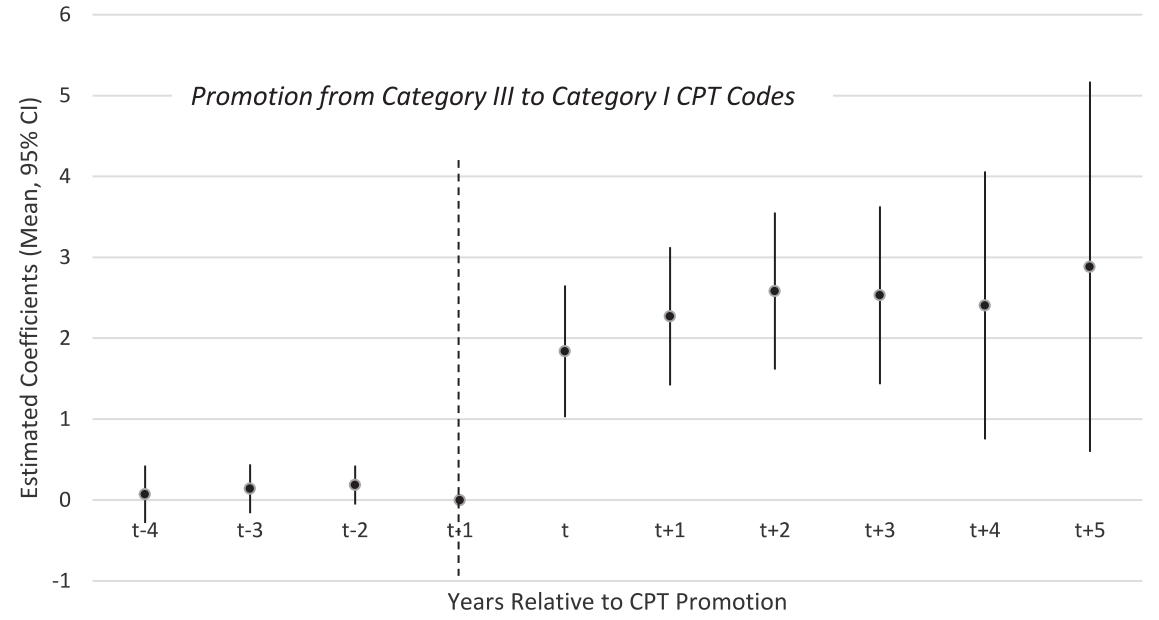
	Sample 1			Sample 2			Sample 3
	Replacing unreported utilization with 10	Replacing unreported utilization with 1	Replacing unreported utilization with 0	Replacing unreported utilization with 10	Replacing unreported utilization with 1	Replacing unreported utilization with 0	Excluding observations with unreported utilization
Dependent Variable	$ln(Utilization_{it})$	$ln(Utilization_{it})$	$Dummy\_Use_{it}$	$ln(Utilization_{it})$	$ln(Utilization_{it})$	$Dummy\_Use_{it}$	$ln(Utilization_{it})$
$PostCPTI_{it}$	1.433***	2.107***	0.293***	1.521***	2.350***	0.360***	0.179
	(0.424)	(0.560)	(0.083)	(0.510)	(0.713)	(0.099)	(0.330)
No. of Procedures	167	167	167	69	69	69	69
No. of Observations	871	871	871	385	385	385	298
R-squared	0.123	0.130	0.092	0.178	0.181	0.127	0.184

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 2018. Sample 3 restricts to observations with recorded Medicare utilization. Standard errors in parentheses are clustered by procedure and bootstrapped with 200 iterations. *** $p<0.01$.



Appendix Fig. C2. Event study plot for the effect of CPT promotion on procedure utilization excluding promoted procedures with missing values in the pre-promotion period.

Notes: This figure presents the estimated coefficient (mean and 95% CI) of $CPTI\_Event_{id(t)}$ from Equation (2), with the dependent variable being the logged number of Medicare services (replacing unreported utilization with 10). 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 sample excludes promoted procedures with missing values in pre-promotion period.



Appendix Fig. C3. Event study plot for the effect of CPT promotion on procedure utilization accounting for heterogeneous intertemporal treatment effects. (Full Sample).

Note: This figure presents the estimated coefficient (mean and 95% CI) of $CPTI\_Event_{id(t)}$ from Equation (2) with the dependent variable being the logged number of Medicare services (replacing unreported utilization with 10). We use the *did_multiplegt* command in STATA 16 developed by Clément de Chaisemartin and Xavier D'Haultfœuille (2020). 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.

Appendix Table C5
Robustness Test—Using Synthetic Controls.

	Sample 1			Sample 2		
	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
Dependent Variable	$ln(Utilization_{it})$	$ln(Utilization_{it})$	$Dummy\_Use_{it}$	$ln(Utilization_{it})$	$ln(Utilization_{it})$	$Dummy\_Use_{it}$
Post_OneYear	3.601***	5.149***	0.667***	3.210	4.284***	0.463***
Post_TwoYear	3.995***	5.495***	0.645***	3.851*	5.062***	0.523***
Post_ThreeYear	4.034***	5.545***	0.650***	3.958	5.196***	0.535***
No. of Procedures	74	74	74	38	38	38
No. of Observations	518	518	518	266	266	266

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*. Results are estimated using *synth_runner* command in STATA 16. Sample 1 is the full balanced sample. Sample 2 restricts to a balanced sample with observations for which the procedure records Medicare utilization in some years between 2012 and 2018. *** Standardized p-value<0.01, ** Standardized p-value<0.05, * Standardized p-value<0.1.

in Appendix Fig. C3. In addition, we adopted the synthetic control method to select controls to match baseline trends between the promoted procedures and unprompted procedures (Abadie et al., 2010). The robust results are shown in Appendix Table C5.[40]

Appendix D. Back-of-the-Envelope Calculation for Additional Profits Earned by Medical Device Companies associated with CPT Code Promotion

In this section, we aim to conduct a rough estimate of the additional profits earned by medical device companies associated with procedure utilization increase driven by CPT code promotion. To calculate additional profits, one needs the volume increase and the average price. The volume increase (i.e., increase in the number of Medicare services) due to CPT code promotion is readily available from our estimation; however, we are unable to get a consistent measure on the average price of medical devices. Therefore, we choose to show the estimates for only one procedure of which there is a credible source for the device price — the transcatheter aortic valve replacement (TAVR). Our data shows the pre-promotion (CPT III stage) utilization (number of Medicare services) of TAVR was 6968 per year. Based on our main estimate (i.e., 8.85-fold increase in utilization after CPT code is promoted from Category III to Category I), the additional number of TAVR utilization is 61,667 each year after CPT code promotion. The typical TAVR device costs $32,000.[41] This amounts to $1.9 billion additional sales each year for the device makers, which is about 1% of the total market value of the U.S. medical device industry in 2015.[42] Given the 20%−30% average profit margin of large medical device companies,[43] the additional profits is $380 million to $570 million. Although we note that this might be an extreme example as other medical devices may cost less than the TAVR device, the fact that device makers could benefit this much from the CPT code promotion for a single procedure confirms our statement about the importance of securing a reimbursable CPT I code for procedure innovators.

Appendix E. Evidence on the Overall Pace of Innovation

In this section, we aim to compare the pace of innovation between drugs and medical procedures. We first show Medicare utilization of the top 5 utilized *new* medical procedures and *new* drugs in Appendix Table E1 and Appendix Table E2, 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 E3 shows that total Medicare spending on new procedures during 2013–17 was only 21 percent of spending on new drugs. This finding could result 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 Table E4 and Appendix Table E5 the year of introduction of the top 15 highly-utilized medical procedures and 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. However, we caution against such a stark interpretation. This

[40] We estimate the model using the *synth_runner* command in STATA 16. We focus on the fully-balanced subsample of 74 procedures across 7 years; 19 out of the 74 procedures were promoted during the time period.

[41] This price is measured in 2014 dollars. Source: https://www.modernhealthcare.com/article/20140329/MAGAZINE/303299961/nonsurgical-heart-valve-procedure-spurs-cost-concerns#:~:text=TAVR%20devices%20typically%20cost%20about,of%20thoracic%20and%20cardiovascular%20surgery.

[42] The United States medical device market is valued at more than $140 billion in 2015. Source: https://legacy.trade.gov/topmarkets/pdf/Medical_Devices_Executive_Summary.pdf.

[43] Source: http://www.medpac.gov/docs/default-source/reports/jun17_ch7.pdf?sfvrsn=0#:~:text=Large%20medical%20device%20companies%20are,of%20delivering%20care%20to%20beneficiaries.

Appendix Table E1
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	**1712**	**4109***	**5810***	**6328***
Sacroiliac Joint Stabilization	2013	–	175	**1910***	**2810***	**3704***
Left Atrial Appendage Closure	2011	151	71	288	3223	8801*
TAVR	2011	**15,823***	**26,472***	**37,882***	54,449*	67,783*
Circulating Tumor Cells (CTC) Enumeration	2011	**6541***	**4031***	**2115***	1743*	546*
Ultrasound Guided Facet Injection	2010	6048	**3398**	N/A	N/A	N/A
Unattended Sleep Study	2009	**9003***	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 usually available to use in the following year of the approval year.

Appendix Table E2
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**	**1142,004**
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. Drugs 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 E3
Medicare Payments for New Procedures versus New Drugs.

	Medicare Payments ($ million) Top 5-Utilized New Procedures*	Top 5-Utilized New Drugs**
2013	679	1848
2014	1150	2432
2015	1668	3550
2016	120	3838
2017	151	5977
5-yr Total	3768	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 E4

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	1320	1972
Removal of Skin Lesions (Benign and Malignant)	11.73	571	1938
Ultrasound	11	484	1956
Cataract Removal and Lens Insertion	9.5	6315	1967
Biopsy	9.0	1057	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	6750	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	4089	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.

* Source for Year of Introduction of Top-utilized Medical Procedures:

X-ray: https://www.nde-ed.org/EducationResources/CommunityCollege/Radiography/Introduction/history.htm#:~:text=In%20June%201,896%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/32,071-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/7,975,522/#:~:text=The%20term%20%22biopsy%22%20was%20introduced,in%201,875%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%201,940%20at,the%20cobalt%2Dchrome%20alloy%20Vitallium.

Endotracheal Intubation: https://pubmed.ncbi.nlm.nih.gov/16,400,793/#:~:text=In%20the%20early%201,870's%2C%20Trendelenburg,elective%20endotracheal%20intubation%20for%20anesthesia.&text=In%201,913%20the%20first%20anesthetic,the%20Magill%2C%20Miller%20and%20Macintosh.

** Dialysis estimates are based on Medicare Payment Advisory Commission (2019).

Appendix Table E5
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	1120	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.

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.

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