

The Economics of Medical Procedure Innovation

David Dranove¹, Craig Garthwaite¹, Christopher Heard¹, Bingxiao Wu^{2*}

1 Northwestern University; 2 Rutgers University. (* Corresponding Author)

MOTIVATION

Rich literature on pharmaceutical innovation

- Development times, attrition rates, costs, patent, the FDA approval process and the timelines involved.

Sparse literature on medical procedure innovation

Why are medical procedures important?

- In 2018, the US spends \$3.6 trillion (18% of GDP) on health care—32% on hospital care, 20% on physician and clinical services, and 10% on prescription drugs.

Key Differences between drug innovation and procedure innovation

- Timing of Reimbursement: Role of the American Medical Association in granting reimbursable billing codes
- Appropriability of Investment: Enforceability of intellectual property rights.

RESEARCH QUESTIONS

Aim 1: Document the extent and pace of medical procedure innovation and contrast them with those of pharmaceutical innovation.

Aim 2: What are the impediments of procedure innovation incentives? .

- Mechanism 1: Timing of Reimbursement
 - The administrative hurdle of securing reimbursable billing codes substantially delays the diffusion of innovation.
 - Medicare Utilization increases 9-fold after the procedure code was promoted from provisional (non-reimbursable) to permanent (reimbursable) codes.
- Mechanism 2: Appropriability of investments
 - Since procedure patenting is not feasible, how does the medical profession solve the commons problem?
 - Role of medical societies in leading code applications when the procedure does not involve exclusive patented device

CONTRIBUTIONS TO THE LITERATURE

- First study to explore the economic incentives of medical procedure innovation.
- The ad hoc system that oversees medical procedure innovation v.s. the more deliberate process that oversees pharmaceutical innovation.

BACKGROUND

Rules and Regulations for Medical Procedure Innovation

- No regulatory oversight except for FDA regulation of medical device
- No patent system to protect intellectual property rights.
- Role of AMA in granting reimbursable billing codes.
 - Category III CPT codes for emerging procedures - temporary, nonreimbursable
 - Category I CPT codes for permanent procedures - permanent, reimbursable

EMPIRICAL ESTIMATION

Model 1: DID

$$Y_{it} = \beta_0 + \beta_1 PostCPTI_{it} + ACharacteristics_{it} + \Gamma Tenure_{it} \times LnTimeTrend_t + YProcedure_i + \Theta Year_t$$

Model 2: Event Study

$$Y_{it} = \beta_0 + \Phi \sum_d CPTI_Event_{id(t)} + ACharacteristics_{it} + \Gamma Tenure_{it} \times LnTimeTrend_t + YProcedure_i + \Theta Year_t$$

For procedure i in year t , Y_{it} is $\ln(\text{utilization})$. $PostCPTI_{it}$ is whether time t is after the promotion to reimbursable billing codes (Category I CPT codes) from provisional codes (Category III CPT codes).

Data

- CPT code application documentation between 2008 and 2017
 - Once a new code (e.g., CPT III code) becomes available, reporting is accurate.
- Utilization Data: CMS Medicare Provider Utilization and Payment Data in 2012-2017.

Sample

- 801 procedure-year observations (184 procedures with active CPT III codes between 2012 and 2017)

MECHANISM

Mechanism: Certification Effect vs. Financial Effect

- Certification mechanism: approval can certify the quality of the procedure.
- Financial incentive mechanism: promotion of CPT codes from temporary status (Category III) to permanent status (Category I) allows for payer reimbursement.

RESULTS

DID

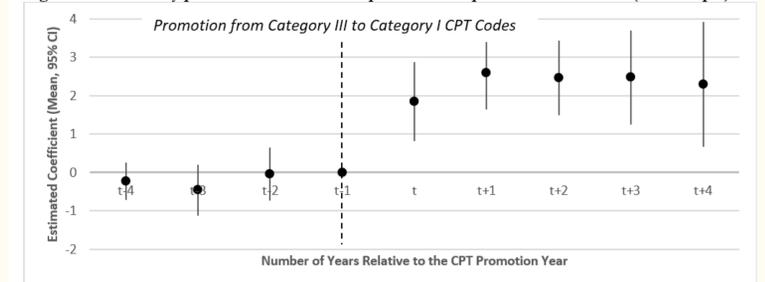
Table 6. Main Results—Effect of CPT Code Promotion on Procedure Utilization

Dependent Variable = $\ln(Utilization_{it})$	Sample 1	Sample 2	Sample 3
$PostCPTI_{it}$	(1) 2.287*** (0.519)	(2) 2.574*** (0.580)	(3) 1.023*** (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. *** $p < 0.01$.

Event Study

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



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

Role of Medical Society in Solving the Commons Problem

Table 8. Association between Procedure (Device) Patent and Applicant Type.

DV = $1(Industry_Applicant)$	(1)	(2)
Exclusive Patented Device	0.544** (0.150)	0.610*** (0.110)
Non-Exclusive Device	-0.504 (0.160)	0.029 (0.187)
Specialty Fixed Effects	N	Y
N	128	128
R-squared	0.42	0.48

Notes: Sample includes 128 CPT III procedures approved between 2008 and 2017. The dependent variable is an indicator variable for industry applicant. 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. Standard errors in parentheses are clustered by procedure. *** $p < 0.01$.

CONCLUSIONS AND IMPLICATIONS

The administrative hurdle of securing reimbursable billing codes delays the diffusion of innovative medical procedures.

Medical societies leads the billing code application when the procedure does not involve exclusive patented devices.

Future policies should find a better balance among safety, access, and innovation incentives of medical procedure innovations.