

# Provider Payments and the Direction of Innovation: The Case of the Wearable Artificial Kidney

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# Motivation

- Big picture question: what drives innovation?
- Why innovation in particular areas and not others?
- Today:
  - Effect of provider payments on the direction of innovation
  - End Stage Renal Disease

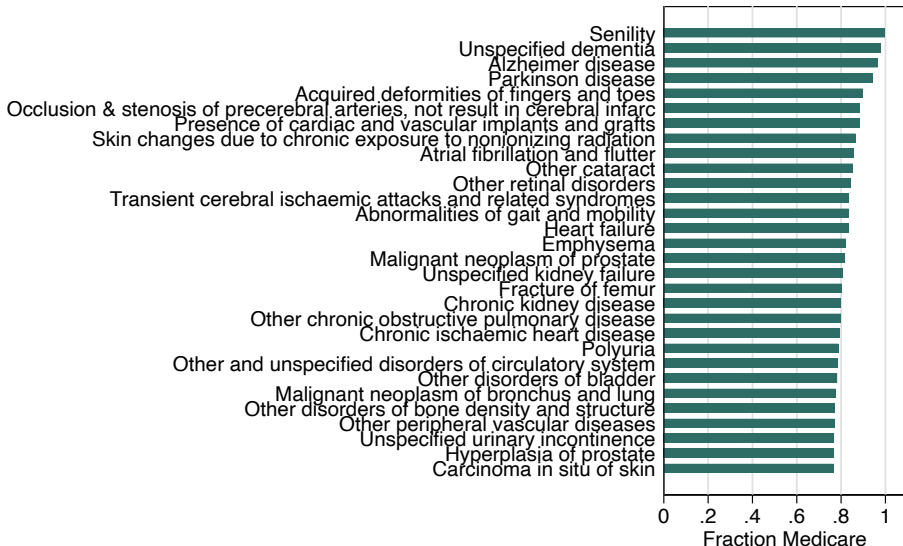
# Motivation

- Large literature on the effects of prices on physician decisions, treatment choice, health outcomes (in ESRD: Eliason et al., 2022, Erickson et al., 2016)
- Idea that innovation responds to market size/demand for innovation not new (Kremer 2002; Acemoglu 2004; Reiffen and Ward 2004; Lichtenberg and Walfogel 2003; Finkelstein 2004; Clemens and Rogers 2022)
- We consider potential effects of provider payments on innovation
  - Common in health care settings for prices to be administratively set
- Getting incentives right important for optimal patient care today, and also in the future through innovation

## ESRD and dialysis background

- End-Stage Renal Disease (ESRD): kidneys cease functioning on a permanent basis
  - Kidney transplant
  - Dialysis (maintenance therapy): process of removing excess water, solutes, and toxins from the blood in people whose kidneys can no longer perform these functions naturally
- Social Security Act includes ESRD as disabled (1972), universal Medicare coverage expanded to ESRD (1973)
  - Medicare: public insurance program for the elderly
  - Nice setting: all ESRD eligible for Medicare

# ESRD not only condition with high Medicare coverage



Note: ICD-10 codes with highest share Medicare coverage from MEPS (2019).

# Two broad categories of dialysis therapy

## ① In center

- Hemodialysis: circulation of blood through a machine that cleans blood of toxins
  - Large machines, lots of sterile water/session, needles
  - Very disruptive; most patients visit facility 3-4 hours, 3x/week

# Two broad categories of dialysis therapy

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## ② At home

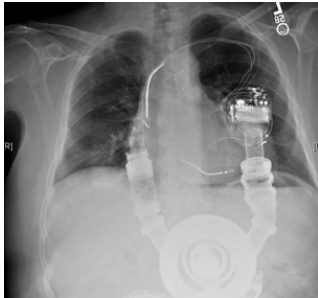
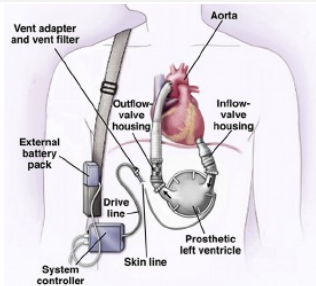
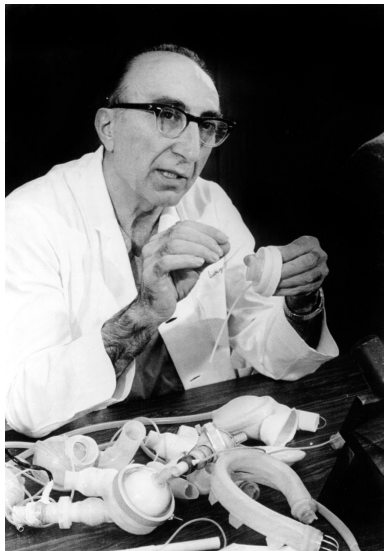
- Peritoneal: uses body's peritoneal membrane as the filter; smaller, more home-friendly
  - Greater lifestyle flexibility and independence, can keep working
  - Nocturnal and administered at home, uses fewer iv drugs
- Home hemodialysis: an option, rare
- Most dialysis in-center hemodialysis, fraction varies over time

## Dialysis technology

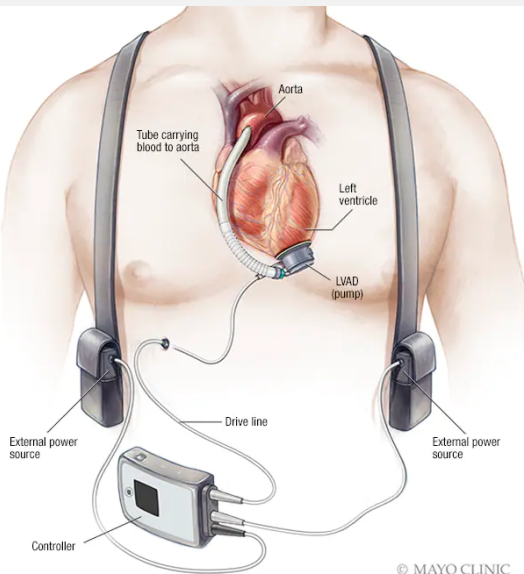
- Dialysis has remained a predominantly in-center therapy
- Other chronic conditions in the 1970s that require treatment while awaiting a transplant have witnessed equipment miniaturizations
  - Pacemaker, LVAD (“artificial heart”), closed loop insulin pump (“artificial pancreas”)
- Very little innovation in the miniaturization of dialysis equipment, esp hemodialysis
- Why do we not see this in dialysis? Where is the “artificial kidney”?
  - Related, why such low utilization of home treatments?



# Left ventricular assist device (LVAD): early

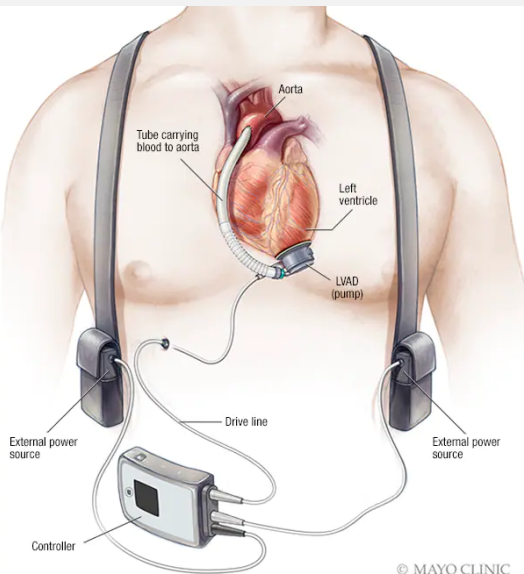


# Left ventricular assist device (LVAD): present day



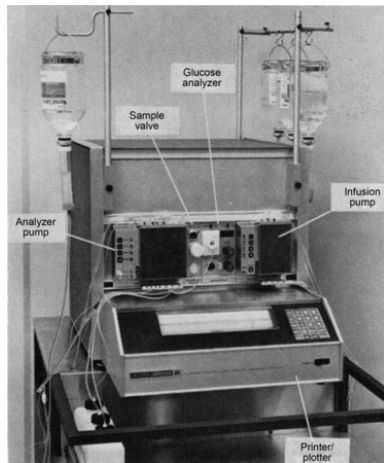
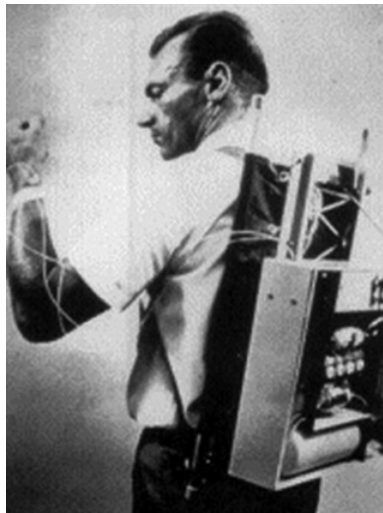
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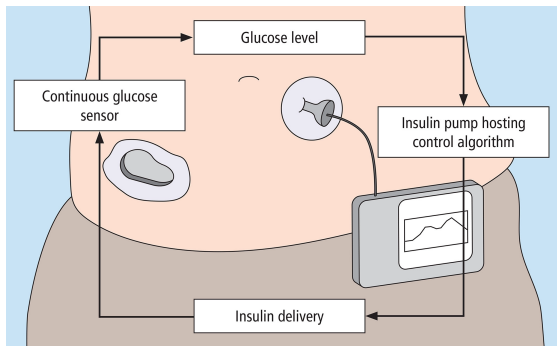


- 600,000 living with advanced heart failure in US

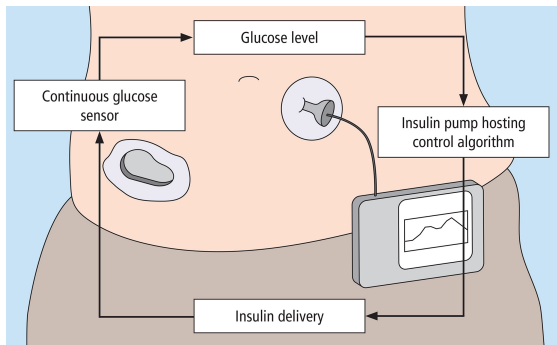
## Early insulin pumps



# Closed loop insulin pump



# Closed loop insulin pump



- Population using closed loop insulin pump in US: 1.15 million

# Hemodialysis over time



1983: 2008C



1988: A2008 Online HDF



1998: 4008H ONLINEplus



2005: 5008 CorDiax  
Therapy System



2012: 5008 CorDiax & 5008S  
CorDiax



NxStage One (FDA cleared for  
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2020: Quanta

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- 800,000 in US living with End Stage Renal Disease
- Is dialysis technology fundamentally different?
- ...or have financial incentives favoring in-center treatment hindered innovation?

Effect of provider payment structure on innovation in ESRD

### Effect of provider payment structure on innovation in ESRD

- 1 Payment structure affects relative profitability of treatments
  - First favored home treatment, then in-center, then home again

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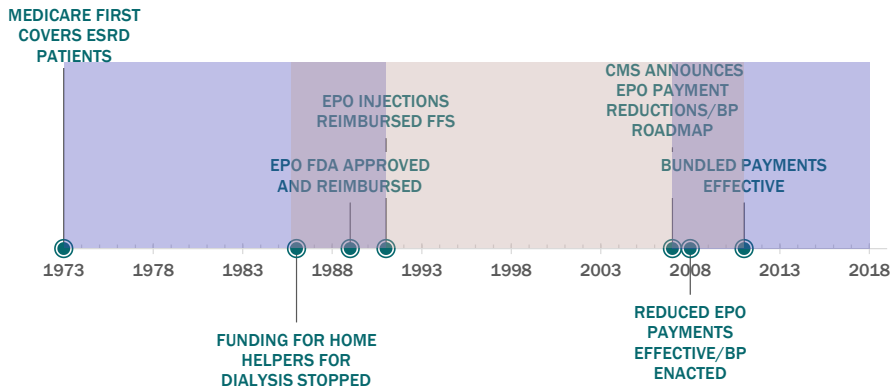
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  - Data: US Renal Data System; ESRD Medicare claims
  - Strategy: timing of fee change

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- 3 Changes in relative profitability (through type of treatment by providers) affects investment in technology/innovation
  - Data: patents (text analysis)
  - Strategy: timing + placebo tech

# Payment structure: three regimes

- Changes in relative profitability of treatments over time



details

## Epoetin Alfa (EPO) big part of the story

- ESRD patients need erythropoietin (EPO) supplementation to correct anemia (healthy kidneys produce it)
- Epoetin Alfa first synthetic EPO; changes in its reimbursement help define period favoring in center dialysis
  - FFS reimbursement (1991) encourages high dosing of EPO
  - FFS EPO revenue made up 50% of dialysis facility revenue in years before put in bundle
  - Frequent (daily) dialysis decreases the need for EPO (Locatelli & Del Vecchio, 2003; Movilli et al 2001; Ifudu et al 1996)
- Medicare's decision(s) to stop paying for excessive EPO use ends the era favoring in center

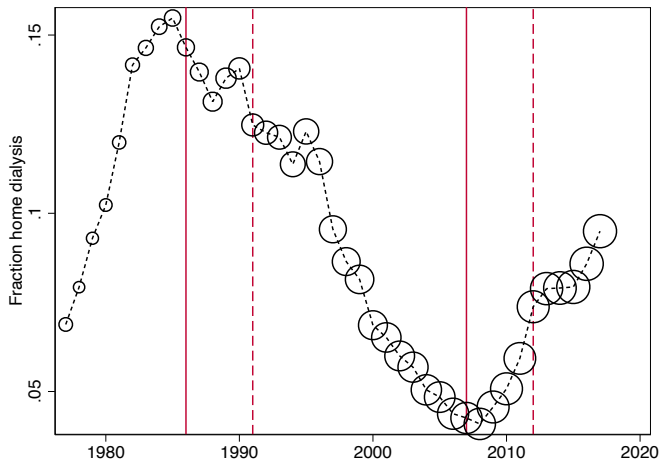
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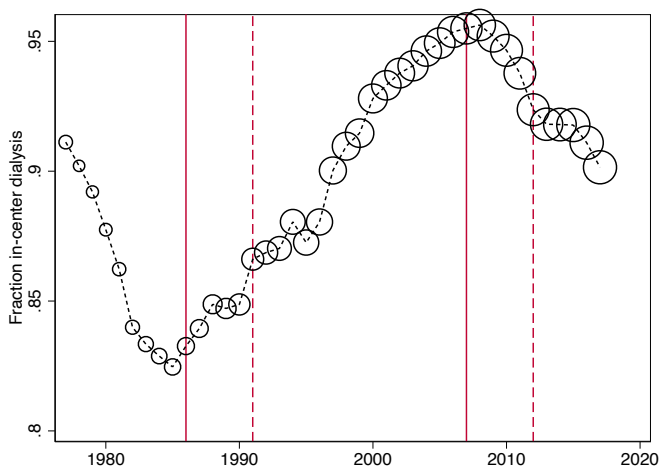
## Relative profitability affects treatment choices

- Share first dialysis is home



# Relative profitability affects treatment choices

- Share first dialysis is in-center



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- **Portability and ease-of-use**
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  - Technology that makes it easier to perform dialysis yourself, outside a clinic
- Ideal data: set of patents relevant for dialysis, categorized by whether the innovation is related to portability
  - In spirit of Clemens and Rogers (2022), who use text analysis to study effect of government procurement policy on traits of patents

## Do payments affect direction of innovation: data

- 1 Scrape kidney dialysis patents, using keywords in title, abstract, claims first 1000 words, description first 1000 words keywords



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- 4 Find control technologies that face similar challenges in their development, and repeat 1-3

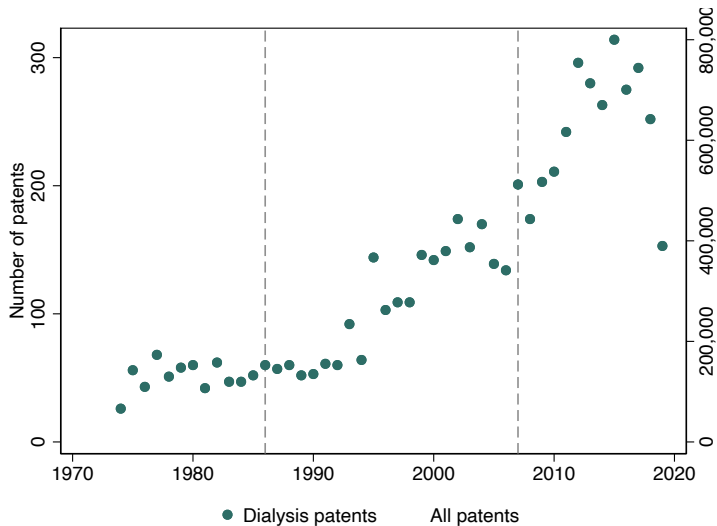
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- 5 Plot fraction of patents by trait over time for dialysis and control technologies  
(+ estimate discontinuity with interrupted time series)

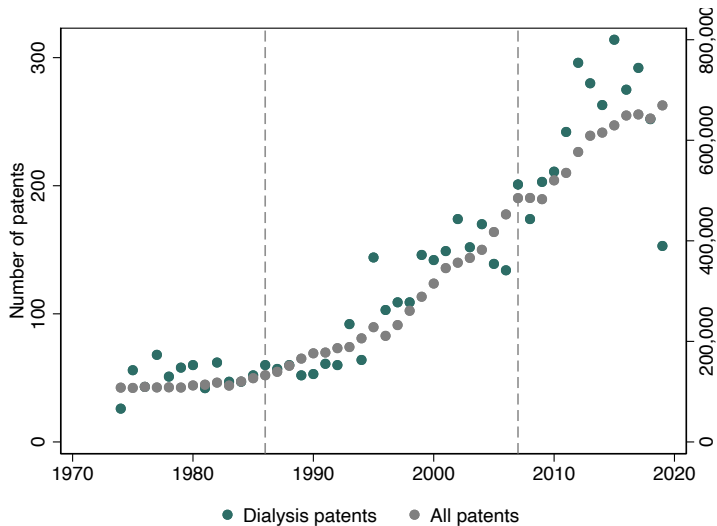
## Control groups: comparison technologies

- Goal: “placebo” technologies—are patterns in traits unique to dialysis (driven by changes in payments)
- Want technologies with similar challenges in their development
  - ① Left ventricular assist device (“artificial heart”)
    - Patients rely instead on the LVAD for circulatory support in absence of heart transplant
    - Initially large and bulky and used for short-term in the hospital, now fully wearable
  - ② Closed loop insulin pump (“artificial pancreas”)
    - Combines continuous monitoring and delivery of insulin
    - Over 30 years went from size of large microwave to pack of cards

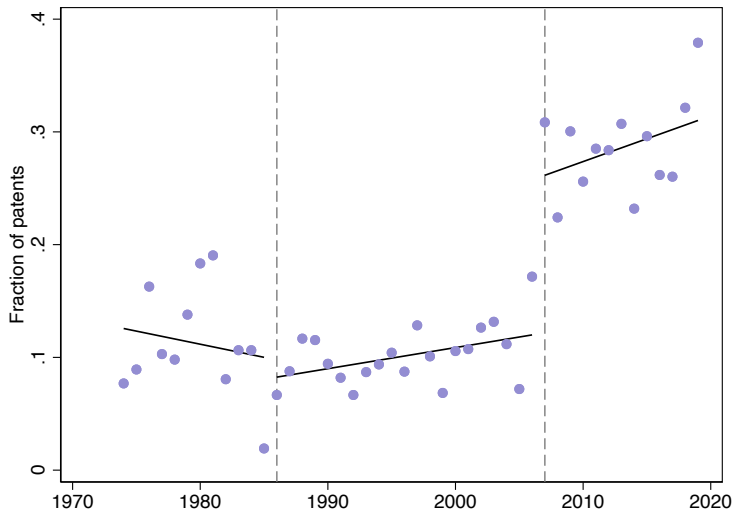
# Dialysis-relevant patents over time



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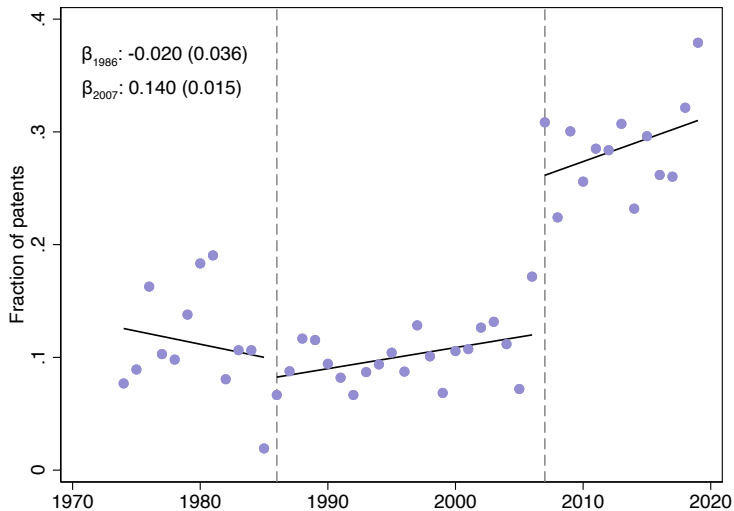


## Dialysis patent traits: portability and ease of use



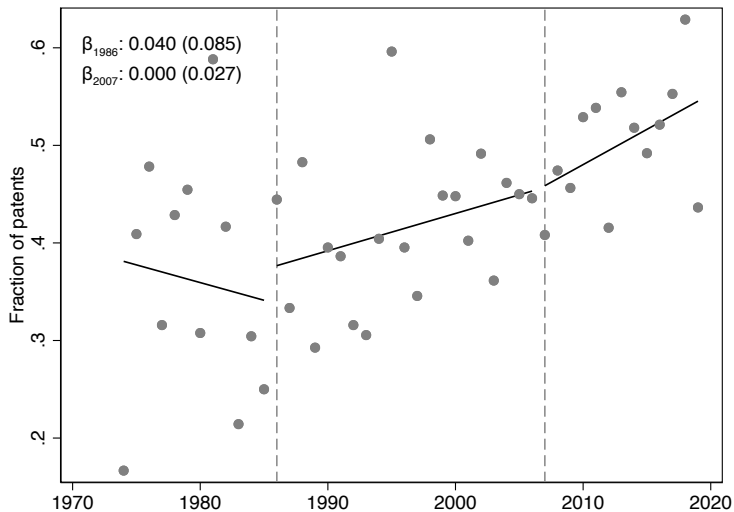


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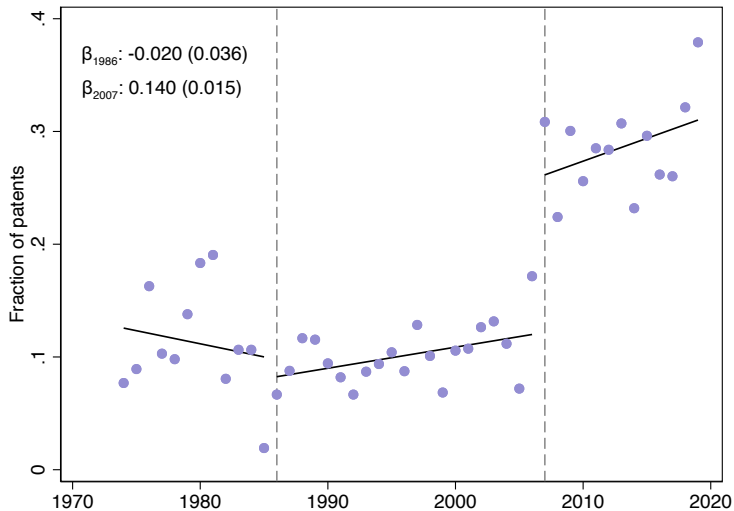


# Patent traits for comparison technologies

LVAD patent traits: portability



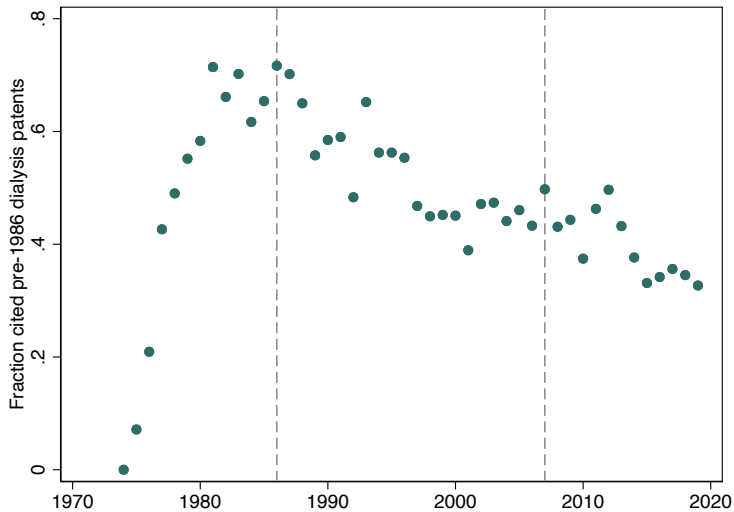
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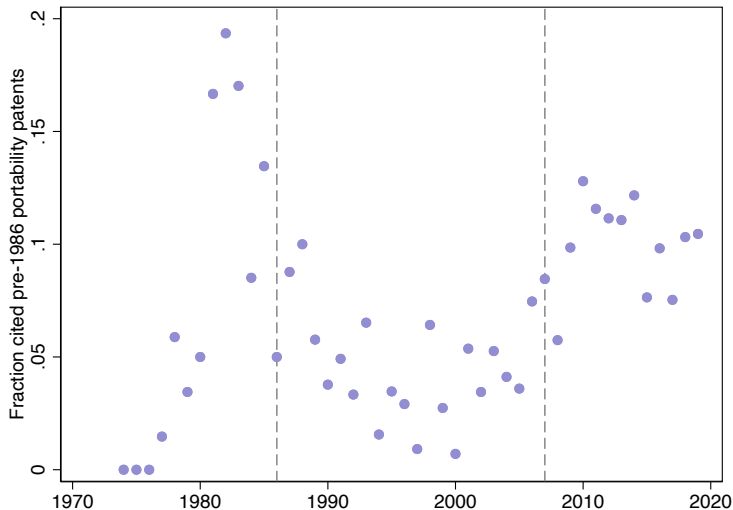
## Patent citations

- Are the pre-1986 and post-2007 patents that we are labelling “portability patents” meaningfully related?
- One way to investigate: patent citations
  - Citations received by a patent from future patents mark the technological descendants of the patented invention (Trajtenberg, 1990; Lanjouw and Schankerman, 2004)
- Examine patent citation patterns in dialysis and control technologies
- Early portability patents rarely cited during in center dialysis era, see a sudden jump in citations after 2007
- Pattern is atypical; not present in control technologies or non-portability dialysis patents

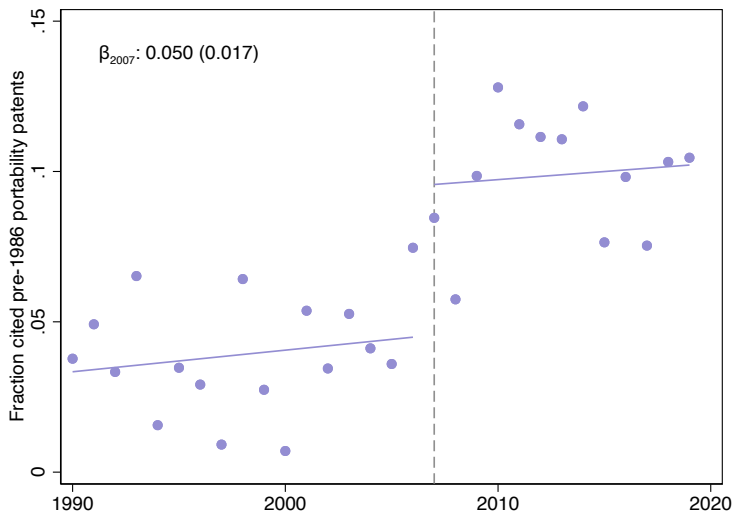
# Dialysis patents: frac. citing pre-1986 dialysis patents



# Dialysis patents: frac. citing pre-1986 portability patents



# Zooming in: frac. citing pre-1986 portability patents

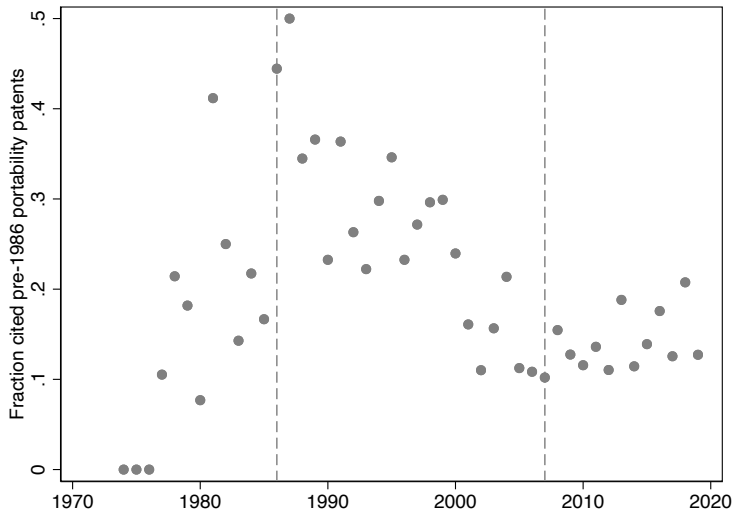


Forward cites (portability)

Forward cites (All dialysis)

# Patent traits for comparison technologies

LVAD patent traits: portability and ease of use

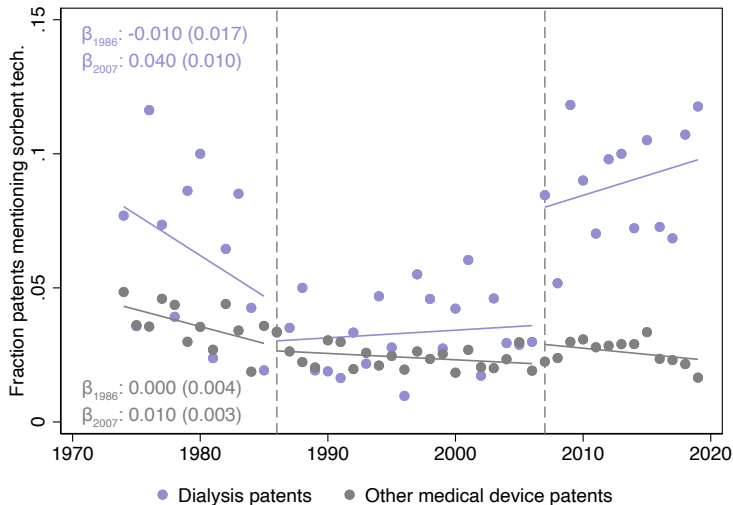




## Other evidence: sorbent technology use

- Are innovations in key components of dialysis tech being applied to dialysis machines similarly to other devices?
- Sorbents (adsorbents): material that can bind another substance or compound by adsorption to or absorption into its structure; used in kidney and liver dialysis, also for hypothermia treatments
- Key component of dialysis mobility—search for smaller, portable, water-sparing, low maintenance, user-friendly machines leads to sorbent technology
- Compare the use of a technology (sorbents) in dialysis versus other medical devices

# Sorbent technology in dialysis versus other medical devices



# Conclusion

- Distortion of innovation in health care from price setting
- When payment system favors certain treatments, ramifications not just for procedure use/costs/health today, also tomorrow through innovation
- Still to do:
  - Does the value of dialysis patents (the “innovativeness”) decrease over time during center-favored regime? Do portability patents get more valuable after switch?
  - Look for similar patterns in PMA and 510K filings for new medical devices (especially physical description, size/weight)

# Portability by patent assignee



# Patent classification

- ESRD sample:
  - Search in claims, SPEC, title, abstract for: dialysis, hemodialysis, kidney disease, dialysate, peritoneal dialysis, renal replacement, artificial kidney, wearable kidney, dialyzer, kidney implant, Hemodiafiltration, Hemofilter, implantable kidney, artificial replacement kidney, Recirculating Dialysate System, REDY, extracorporeal & dialysis [return](#)

## Home dialysis favored: the beginning of coverage

- 1973
  - Reimbursement for center/hospital dialysis limited by payment screen of \$138 per treatment
  - Home dialysis paid for separately, facilities managing home patients reimbursed on a reasonable-cost basis
  - Home dialysis more profitable: lower overhead, no payment cap
- 1983–1986
  - Dialysis goes to PPS along with Medicare
  - \$123 for home and center dialysis per patient per week
  - Home dialysis also gets additional training payments of \$20 for each self-dialysis/home dialysis training session, up to 3x/week; \$12 for each continuous ambulatory peritoneal dialysis training session per day, up to max 15 sessions

## Payments change to favoring in-center treatment

- 1986
  - Medicare stops payments for home dialysis aides; providers of aides must cover costs with payments received for home dialysis supplies and equipment
  - At the time, Medicare let patients get supplies and equipment directly from a supplier on reasonable-charge basis, which differed from the bundled payment rate (known as Method I)
  - Shortly after, OBRA 1989 limited the payment for home dialysis equipment and supplies under Method II to that authorized under the bundled rate (Method I). This policy reduced the incentive for an organization to establish a supply company for the purpose of receiving payment under Method II

## In-center treatment gets even better

- 1989
  - FDA approves recombinant human erythropoietin (EPO) for the treatment of anemia in dialysis patients
  - Medicare covers EPO for a \$40 per week fixed fee for a dosage less than 10k units or \$70 per week for 10k units or more
- 1991
  - CMS will reimburse EPO \$10 per unit FFS scheme rather than a \$70 bundled pay, supposedly cheaper for Medicare
- 2004
  - Physician pay for in-center hemodialysis to tiered model
    - \$308 for in-center if see patients 4+ times/month
    - \$256 for in-center if see patients 3 times or less/month
    - \$256 for home dialysis no matter how many visits



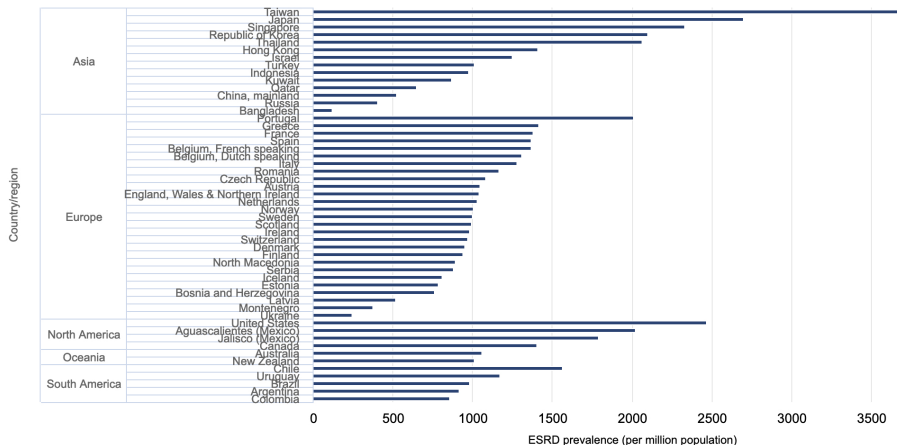
## Pendulum swings back the other way

- 2007
  - CMS report outlines intentions to bundle ancillary IV injections in ESRD and eliminate FFS payments for EPO
- 2008
  - Proposal enacted: Medicare Improvements for Patients and Providers Act of 2008
  - American Nephrology Nurses' Association: the most significant reform to the Medicare ESRD program since its inception
  - Effective in 2011, items and services drugs and laboratory tests that were previously paid for separately are to be included in the bundled payment. In 2010, under the previous bundled payment system, the base composite rate per treatment was \$135.15, in 2011, the new bundled payment was revised to \$229.63

## A brief history of dialysis payments: EPO

- Erythropoietin (EPO): injectable drug used to treat anemia in patients on kidney dialysis
- Administering EPO extremely lucrative for providers
  - 25% of DaVita's revenue, up to 40% of its accounting profits
  - When large chains acquired independent facilities, EPO doses doubled (Eliason, 2019)
- Several studies linked excessive doses to increased risk of mortality and cardiovascular events

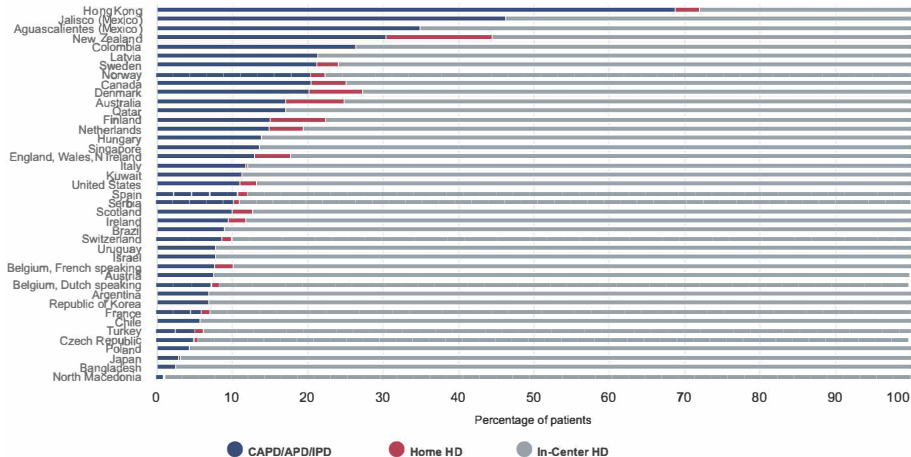
# Prevalence of treated ESRD internationally, 2019



Data Source: 2021 United States Renal Data System Annual Data Report

# Home dialysis treatment low internationally

- Dialysis modality in prevalent patients with ESRD, 2019



Data Source: 2021 United States Renal Data System Annual Data Report

# Hemodialysis dialysis reimbursed higher internationally

	Belgium	Germany	The Netherlands	UK	France	USA	Ontario, Canada
Reimbursement per week for dialysis services	HD > PD	Variable	HD > PD	HD > PD	HD > PD	HD = PD	HD > PD
Inclusive reimbursement package	No	No	Yes	No	No	Yes	No
Includes nephrologist fees	Yes	No	Yes	No	Yes <sup>a</sup>	No	No
Includes most oral medications	No	No	No	No	No	No	No
Three sessions per week	Yes <sup>a</sup>	Yes <sup>a</sup>	No	Yes	Yes <sup>b</sup>	Yes <sup>c</sup>	Yes
Case mix differential reimbursement							
Chronic viral infection	No	Yes	No	Yes	No	No	No
Vascular access	No	No	No	Yes	No	No	No
Quality metric scores linked to reimbursement	No	Yes	No	No	No	Yes	No

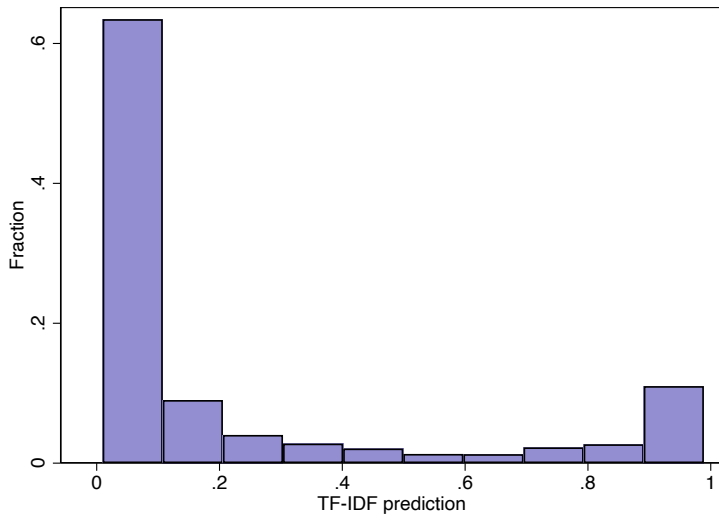
<sup>a</sup>Refers to in-hospital hemodialysis only

<sup>b</sup>Four sessions are allowed

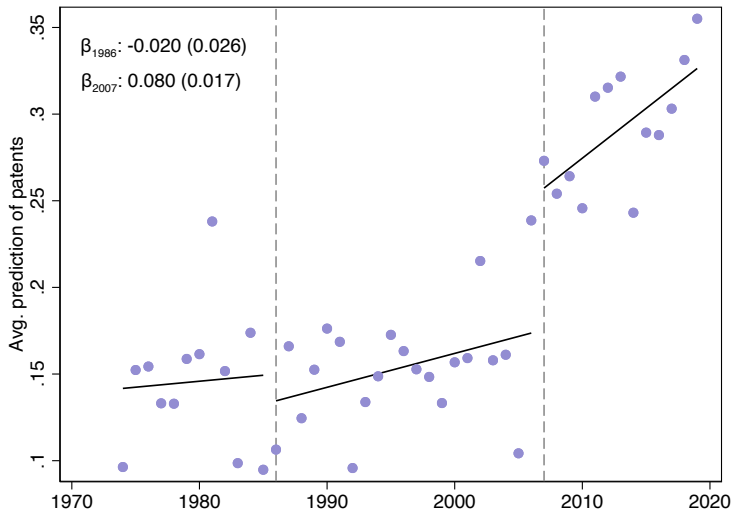
<sup>c</sup>Requires medical justification

Leonberg-Yoo, A., Weiner, D. (2016). Epidemiology of End-Stage Renal Disease. In: Magee, C., Tucker, J., Singh, A. (eds) Core Concepts in Dialysis and Continuous Therapies. Springer, Boston, MA.

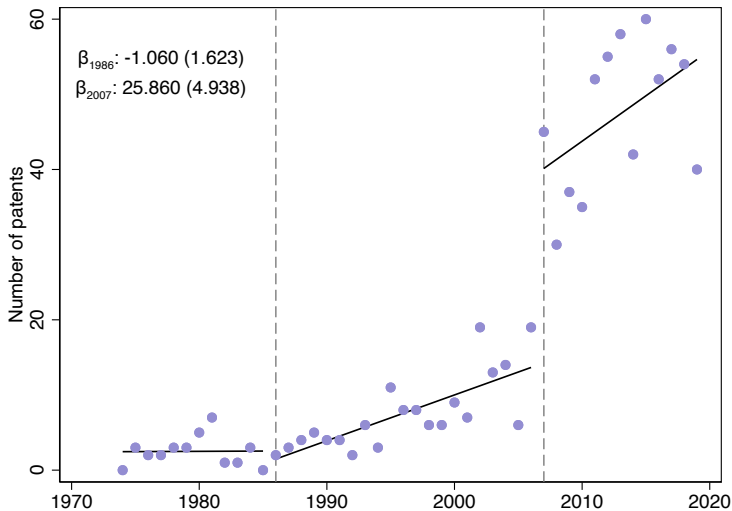
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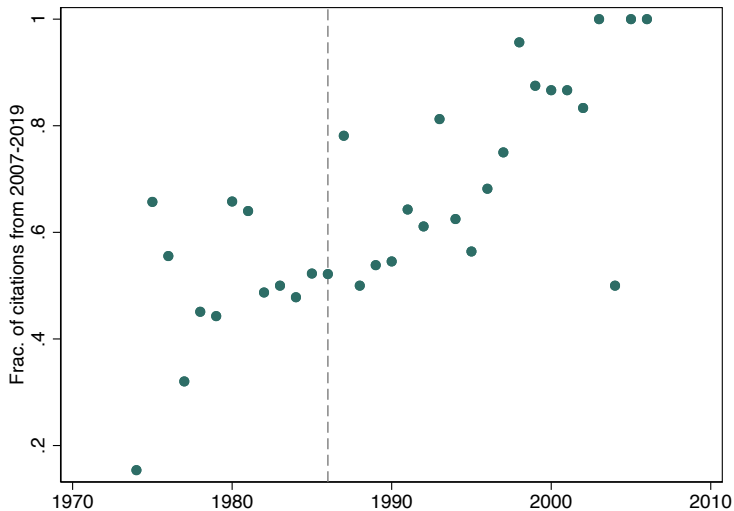


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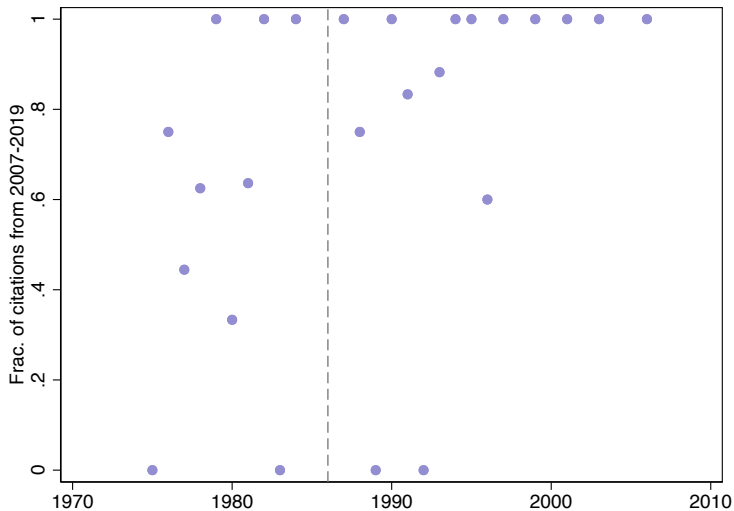




# All dialysis: frac. of forward citations from 2007-2019



# Portability: frac. of forward citations from 2007-2019



## Do payments affect direction of innovation

- Talk to experts, read technology roadmaps, etc. to figure out what traits are most helpful for in-center and at home dialysis
- ① **Portability and ease-of-use:** important for at-home dialysis
  - Technology that makes it easier to perform dialysis yourself, outside a clinic
- ② **Monitoring and safety:** important for in-center dialysis
  - Dialysis centers want to provide dialysis as quickly as possible to as many people as possible
  - Technology that makes it safer to perform dialysis faster, monitoring technology that lets one provider perform dialysis on many people at same time

## Interrupted time series analysis

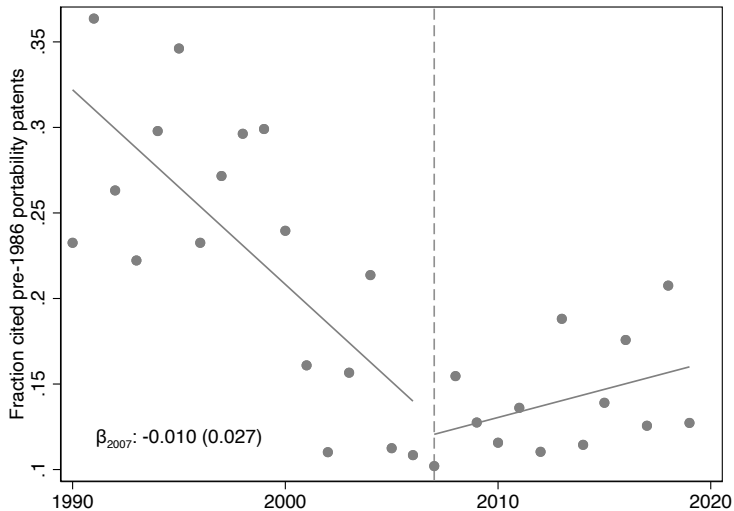
$$y_t = \beta_0 + \beta_1 t + \beta_2 \mathbb{1}[1986]_t + \beta_3 t * \mathbb{1}[1986]_t + \\ \beta_4 \mathbb{1}[2007]_t + \beta_5 t * \mathbb{1}[2007]_t + \epsilon_t$$

where:

- $t$  is time
- $\mathbb{1}[1986]_t$  and  $\mathbb{1}[2007]_t$  are indicator variables for time period after payment changes
- Newey-west standard errors with lag(1)
- Can reject presence of autocorrelation at greater lags

# Patent traits for comparison technologies

LVAD patents: frac. citing pre-1986 portability patents



## A brief history of Medicare dialysis payments

- 1973: reimbursement for center/hospital dialysis is \$138 per treatment, home reimbursed on reasonable-cost basis ●
- 1983: dialysis to PPS: \$123 for home and center dialysis per patient per week, home also gets training/aide payments ●

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- 1986: payments for home dialysis aides cut ●
- 1989: FDA approves EPO; Medicare covers at \$40/\$70 per week depending on dosage ● EPO
- 1991: EPO reimbursed \$10 per unit FFS rather than bundled ●

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- 1986: payments for home dialysis aides cut ●
- 1989: FDA approves EPO; Medicare covers at \$40/\$70 per week depending on dosage ● EPO
- 1991: EPO reimbursed \$10 per unit FFS rather than bundled ●
- 2007: CMS announces EPO payment reductions & roadmap to put EPO/IV injections in bundle ●
- 2008: Reduced EPO payments effective, Medicare Improvements for Patients and Providers Act of 2008 passed (effective 2011/12) ●