

Lessons for the Future from 25 Years of Health Insurance Policy Research: Diabetes as an Index Condition



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Outline

- The importance of unbiased studies of Natural Experiments in Health Insurance Policy Research
- Medicare Managed Care: Provision of a limited prescription benefit, influence of OOP costs on medication use behavior
- TRIAD: The Part D Study
- DHP – Influence of a Disease specific benefit design – is this the pathway to value based care?



Evaluating Diabetes Health Policies Using Natural Experiments

The Natural Experiments for Translation in Diabetes Study

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Table 1. Hierarchy of Natural Experimental Study Designs and their Capacity to Address Threats to Internal Validity

Study design	Strength of design	Key strengths and weaknesses in ability to control for threats to validity*
Randomized controlled trial (experiment) Treatment: Randomize O_1 X O_2 Comparison: Randomize $O_1 - O_2$	Strong ↑ ↓ Weak	<ul style="list-style-type: none"> • Gold standard of evidence • Controls for major validity threats* (history; maturation; selection; instrumentation) • Frequently not feasible to randomize individuals • Randomization of groups (e.g. clinics) is an option but can introduce bias; can lead to type 2 error (inadequate sample size); and requires statistical models for intercorrelation of data within groups • Often requires exclusion criteria that limits external generalizability
Interrupted time series with a comparison series [†] Treatment: O_1 O_2 O_3 O_{12} X O_{13} O_{14} O_{15} O_{24} Comparison: O_1 O_2 O_3 O_{12} - O_{13} O_{14} O_{15} O_{24}		<ul style="list-style-type: none"> • Multiple baseline observations allows control for major validity threats* (history; maturation; selection; instrumentation)
Single interrupted time series [‡] Treatment: O_1 O_2 O_3 O_{12} X O_{13} O_{14} O_{15} O_{24}		<ul style="list-style-type: none"> • Baseline trends allow visible effects/control for most biases*
Pre-post with comparison group Treatment: O_1 X O_2 Comparison: $O_1 - O_2$		<ul style="list-style-type: none"> • Comparability of baseline trend unknown • Strong risk of history, maturation, selection bias, regression to mean*
Pre-post without comparison Treatment: O_1 X O_2		<ul style="list-style-type: none"> • Single observation before and after with no baseline trends • Weak design for assessing effectiveness • Strong risk of history, maturation, instrumentation bias, regression to mean*
Cross-sectional designs Treatment: X O_1 Comparison: O_1	<ul style="list-style-type: none"> • Weak design for assessing effectiveness • Simple correlation, no baseline, no measure of change • Very strong risk for most major threats to validity* 	



Why Natural Experiments?

- Changes in insurance benefit design often times happen before there is an evidence base estimating benefits and harms
- Growing body of administrative, clinical data in electronic formats, and linkage to geocoded information provides a comprehensive platform for analyses of new insurance designs
- Emergence and refinement of statistical methods for longitudinal data that strengthen causal inference

Medicare Managed Care Drug Benefit: The Canary in the Coal Mine for Medicare Part D

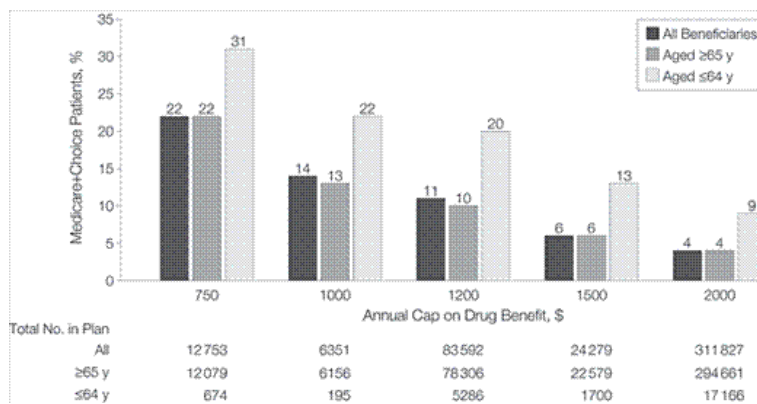


Impact of an Annual Dollar Limit or "Cap" on Prescription Drug Benefits for Medicare Patients

- Annual dollar limits, or "caps," on drug benefits were common in Medicare managed care and were part of several proposals for a national Medicare drug benefit.
- To determine how cap levels affect the percentage of patients exceeding the cap and their out-of-pocket drug costs.
- Cross-sectional analysis of 2001 pharmacy claims data from a large Medicare + Choice plan in a mature market with caps of \$750 to \$2000 per year applied to the plan's share of prescription costs.
- Participants were patients who filled at least 1 prescription in 2001 (n = 438 802).



Percentage of Medicare + Choice Patients Using Prescriptions in 2001 Who Exceeded Annual Drug Benefit Cap



Tseng et al. JAMA. 2003;290(2):222-227. doi:10.1001/jama.290.2.222

Cost-Lowering Strategies Used by Medicare Beneficiaries Who Exceed Drug Benefit Caps and Have a Gap in Drug Coverage

- To describe strategies adopted by beneficiaries exceeding annual drug benefit caps
- A survey in 2002 of Medicare + Choice beneficiaries aged 65 years and older with high medication costs and benefits capped on the plan's share of costs
- Study participants (n = 665) exceeded a \$750 or \$1200 yearly cap in 2001 and had coverage gaps of 75 to 180 days. Control participants (n = 643) had \$2000 caps, which they did not exceed. Study and control participants were matched by average total drug expenditures per month.



Adjusted Predicted Percentages of Participants Who Used Strategies to Lower Medication Costs

Table 3. Adjusted Predicted Percentages of Participants Who Used Strategies to Lower Medication Costs

	Sample Size*	Adjusted Predicted Percentages		P Value†
		Intervention Participants: Exceeded \$750 or \$1200 Cap (n = 665)	Control Participants: Did Not Exceed \$2000 Cap (n = 643)	
Medication strategies for decreasing cost that involve decreasing use				
Used less medication than was prescribed or less than desired (eg, skipped dose)	1244	16	10	<.001
Stopped a medication	1243	8	8	.86
Did not fill a prescription for a new medication (ie, did not start a new medication)	1240	6	5	.39
Adopted at least 1 strategy above that decreased medication use	1261	24	16	<.001
Strategies for decreasing cost that may or may not involve decreasing use				
Switched medications	1235	15	9	.002
Received free medication samples	1257	34	27	.006
Took someone else's medication	1256	2	1	.26
Called pharmacies to find the best price	1272	46	29	<.001
Received discount for being age ≥65 y	1272	12	7	.003
Received discount for being in Medicare	1272	10	7	.13
Received discount from a pharmaceutical company	1271	2	1	.11
Used mail order	1272	63	62	.84
Bought medications outside of the United States	1259	3	3	.92

*Varies because of missing values.
 †For the adjusted difference, based on multivariate logistic regression including age, sex, education, ethnicity, annual household income, general health status, functional limitations in instrumental activities of daily living, number of health problems, written vs telephone survey, and whether or not participants had income data as covariates.



Tseng et al. JAMA. 2004;292(8):952-960.
 doi:10.1001/jama.292.8.952



Bivariate Associations Between Exceeding the Cap and Financial Burden of Medication Costs

Table 5. Bivariate Associations Between Exceeding the Cap and Financial Burden of Medication Costs

	No./Total (%)*		P Value†
	Intervention Patients: Exceeded \$750 or \$1200 Cap (n = 665)	Control Patients: Did Not Exceed \$2000 Cap (n = 643)	
How easy or how difficult was it for you to pay for your prescriptions?			
Very easy	45/661 (7)	101/640 (16)	<.001
Somewhat easy	93/661 (14)	149/640 (23)	
Neither easy nor difficult	100/661 (15)	150/640 (23)	
Somewhat difficult	273/661 (41)	184/640 (29)	
Very difficult	142/661 (21)	50/640 (8)	
Financial impact of prescription costs			
Decide not to do enjoyable activities	301/656 (46)	214/629 (34)	<.001
Difficulty paying rent or other bills	155/659 (24)	116/633 (18)	.02
Decide not to get other medical care	101/658 (15)	81/631 (13)	.20
Have to borrow money or get help paying for medications	77/656 (12)	61/632 (10)	.23

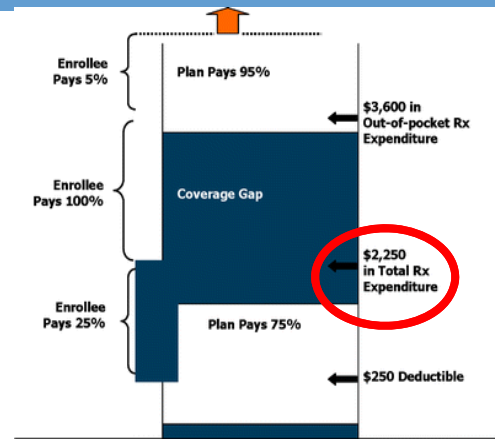
*Actual sample sizes vary due to missing values (intervention range, 656-661; control range, 629-640).
†Total sample size ranges from 1285-1301 due to missing values.



Tseng et al. JAMA. 2004;292(8):952-960. doi:10.1001/jama.292.8.952



Standard 2006 benefit for Medicare Part D*



*Entry into the coverage gap is triggered by \$2,250 in total (enrollee + Plan) expenditure but entry into the catastrophic coverage is triggered by \$3,600 in enrollee out-of-pocket expenditure (Federal Register and the Kaiser Family Foundation).



Ettner, S.L., et al. JGIM (2010) 25: 568.
<https://doi.org/10.1007/s11606-010-1300-6>



UCLA TRIAD Part D Study (2006-2011)

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Medicare Part D

- Medicare Part D program is a success.
- One-quarter of patients who lacked drug coverage in 2005 signed up for a Part D plan in 2006, implying that 3.4 million seniors acquired drug benefits as a result of the Part D program.
- Moreover, previously uninsured patients saved 60% of their drug costs due to the new benefit.
- However, concerns remain about equity and whether it affords adequate financial protection.

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Diabetes & the Part D Coverage Gap

- Diabetes treatment is associated with significant out-of-pocket medication costs
- Patients with diabetes may be at high risk of entering the coverage gap, leading to adverse consequences such as cost-related non-adherence
- Cost-related non-adherence leads to increased hospitalizations and mortality



Entering and Exiting the Medicare Part D Coverage Gap: Role of Comorbidities and Demographics

Ettner SL et al. Entering and Exiting the Medicare Part D Coverage Gap: Role of Comorbidities and Demographics. *J Gen Intern Med.* 2010 Mar 9



Data and Sample

- 2005-6 pharmacy, outpatient and inpatient claims from MAPD plan, linked to enrollment information
- Data were geocoded and linked to 2000 Census block data
- Main sample was patients who were continuously enrolled in the MAPD during 2005-6 and who did not have drug coverage in the gap
- 2005 data used to identify diagnoses
- 2006 data used to calculate gap entry and exit

Outcomes

- Whether the beneficiary entered the coverage gap during 2006
- Among beneficiaries entering the coverage gap in 2006, whether they exited again by the end of the year

Rates of Gap Entry and Exit

- 15.9% of the study population entered the coverage gap during 2006
- Of those who entered the gap, 6.7% exited again by the end of the year



Gap entry any time during 2006 (baseline probability = 15.9%)

	<i>Risk Diff (PP)</i>	<i>99% CI</i>
Diabetes	11.9%	11.2%, 12.6%
Coronary artery disease	7.6%	6.8%, 8.3%
Mental health condition	6.2%	5.2%, 7.2%
Dementia	17.1%	15.5%, 18.8%
Rheumatoid arthritis	5.2%	3.3%, 7.2%
Chronic obstructive pulmonary disease	7.3%	6.6%, 8.1%
Congestive heart failure	6.2%	5.2%, 7.2%
End-stage renal disease	9.7%	7.5%, 12.0%
Stroke	5.8%	4.9%, 6.6%

< 5%: HTN, hyperlipidemia, osteoarthritis, non-skin cancer, stroke, atrial fibrillation, and peripheral vascular disease



Conclusions

- Dementia was the single strongest clinical predictor of gap entry
- Diabetes was also as strong correlate
- Women were also more likely to enter gap, even controlling for age and clinical characteristics
- Consider therapeutic substitution with a lower cost choice when available
- Elimination of unnecessary or less effective medications for those at the greatest risk for gap entry.

Policy Implications

- Cost barriers such as the “doughnut hole” in Part D can reduce adherence to chronic medications
- Managed care claims data is a useful for examining the impact of Medicare policies such as the implementation of Part D for patients with chronic conditions



Does a Disease-Specific Health Insurance Plan Lead to Better Health Outcomes?



UCLA / UnitedHealthcare Evaluation of the Diabetes Health Plan (DHP)

- | | |
|---|--|
| <ul style="list-style-type: none">• Study Investigators (UCLA): | <ul style="list-style-type: none">Health Plan Partners (UHC): |
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Diabetes Health Plan (DHP)

- DHP is a disease-specific health plan for employees and covered dependents with diabetes or pre-diabetes
- Offered to employers for purchase from UHC since 2009
 - Employers = companies, cities, universities
- Enhanced benefit design which includes:
 - Decreased out-of-pocket costs for diabetes related medications and preventive care
 - Health promotion
 - Compliance features
 - Customization by the employer group



Cost-Sharing in DHP (example)

	Standard Plan In-network	DHP In-network
Office Visit Copays: PCP	\$20	Waived (\$0)
Office Visit Copays: Specialist	\$30	Waived (\$0)
Rx Copays: Retail (30d supply)	Tier 1 - \$5 Tier 2 - \$15	Tier 1 - \$0 Tier 2 - \$0
Rx Copays: Mail (90d supply)	Tier 1 - \$15 Tier 2 - \$30	Tier 1 - \$0 Tier 2 - \$0

Medications include all covered anti-glycemics, ACE inhibitors, ARBs, statins, and antidepressants



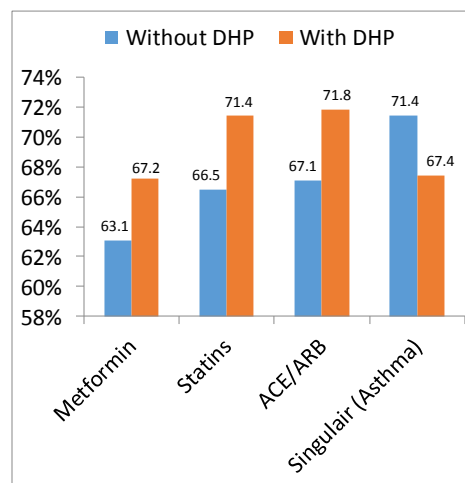
Specific Aims

- To determine whether eligibility for the DHP vs. standard health benefit is associated with:
 - Better adherence to meds and preventive services, for patients with diabetes
 - Lower total costs (patient + health plan) for patients with pre-diabetes and diabetes



Adherence to Metformin, Statins, and ACE/ARBs Within the DHP

- Claims-based measure to assess adherence, the Proportion of Days' Covered (PDC)
- Baseline adherence to metformin, statins, & ACE/ARBs varied from 64% to 69%



Duru et al, J Gen Intern Med. 2015

Change in adherence significant for ONLY the 3 DHP-covered medications (all $p < 0.02$)

The Association of the DHP with Emergency Room and Inpatient Hospital Utilization*

- Compared changes in any ER and inpatient hospital utilization over a 3-year period at the employer-level
- Lower rate of ER utilization 1-year and 2-year post-DHP

	Predicted ER Utilization without DHP Exposure	Predicted ER Utilization with DHP Exposure	Absolute Difference (percentage points)	Relative Difference	P value
1-year post-DHP	18.9%	16.5%	-2.4	13% Reduction	0.012
2-years post-DHP	18.9%	17.1%	-1.8	10% Reduction	0.046

- No significant association with inpatient hospital utilization

*Pre-publication, currently under review, do not re-produce or cite



Summary & Implications

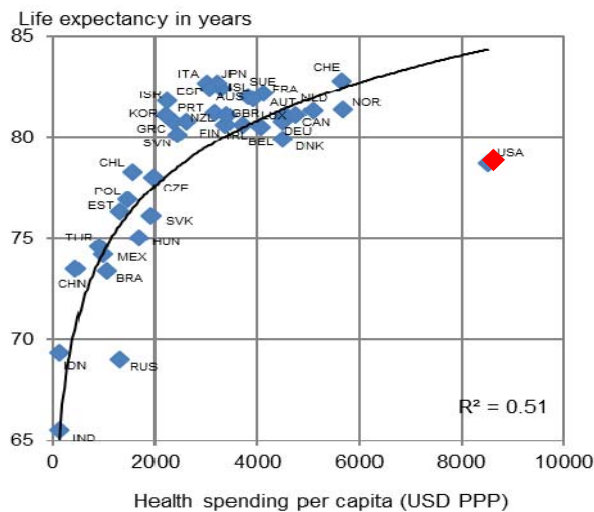
- The Diabetes Health Plan is associated with improvements in several outcomes
 - Patients with diabetes have better adherence to treatment, lower use of ER services, reduction in medical and Rx costs
- Condition-specific health plans may enable focused care delivery & better results for high-risk populations



Key Issues and Challenges for Health Insurance Policy for the Future



Life expectancy at birth and health spending per capita, 2011



Can we provide the evidence base to distinguish high value from low value care?

- Of the \$3.2 trillion the US spends each year on health care, between 10-30% consists of low value care.
- Low value care = patient care that provides no net benefit in specific clinical scenarios.
- Specifically, can we provide the evidence base to inform the design of health insurance that incentivizes high value care?
- Can these goals be accomplished in a equitable way that mitigates rather than exacerbating health disparities?
- What are the best strategies for getting results in front of policy makers in a time frame where we can make a difference?

Thank You and Happy Anniversary!

Questions?

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