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

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In Partnership with Sam Ho MD, Chief Medical Officer and Many Colleagues

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Disclaimer: The views and opinions expressed here are those of the investigators and do not necessarily reflect those of UHC or the funding agencies.
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. Menory of Natural Experimental Study Designs and their Capacity to Address Threats to Internal Validity

<table>
<thead>
<tr>
<th>Study design</th>
<th>Strength of design</th>
<th>Key strengths and weaknesses in ability to control for threats to validity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Matched paired retrospective</td>
<td>Strong</td>
<td>Good standard of evidence, controls for severe confounding, low variance, low selection bias</td>
</tr>
<tr>
<td>Randomized controlled trial</td>
<td>Strong</td>
<td>Controls for severe confounding, low variance, low selection bias, high external validity</td>
</tr>
<tr>
<td>Prospective cohort</td>
<td>Strong</td>
<td>Controls for severe confounding, low variance, low selection bias, high external validity</td>
</tr>
<tr>
<td>Case-control</td>
<td>Moderate</td>
<td>Controls for severe confounding, low variance, low selection bias</td>
</tr>
<tr>
<td>Cross-sectional</td>
<td>Weak</td>
<td>Single observation at time point, no control for confounding, no control for selection bias</td>
</tr>
</tbody>
</table>

Notes:
- **Threats to Internal Validity**
  - **Confounding:** Variables that affect both exposure and outcome.
  - **Selection bias:** Differences between groups that affect the study's results.
  - **Measurement error:** Errors in measuring exposure or outcome.

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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

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>
<thead>
<tr>
<th>Medication strategies for increasing cost that involved decreasing use</th>
<th>Sample Size</th>
<th>Intervention Participants Exceeded $750 or $1200 Cap (n = 665)</th>
<th>Control Participants Did Not Exceed $2000 Cap (n = 643)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not fill a prescription for a new medication as did not start a new medication</td>
<td>1246</td>
<td>8</td>
<td>5</td>
<td>.26</td>
</tr>
<tr>
<td>Did not fill a prescription for a new medication as did not start a new medication</td>
<td>1246</td>
<td>6</td>
<td>5</td>
<td>.39</td>
</tr>
</tbody>
</table>

Adjusted at least 1 strategy above their prescribed medication use

<table>
<thead>
<tr>
<th>Strategy for decreasing cost that may or may not involve decreasing use prescribed medications</th>
<th>Sample Size</th>
<th>Intervention Participants Exceeded $750 or $1200 Cap (n = 665)</th>
<th>Control Participants Did Not Exceed $2000 Cap (n = 643)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received drug samples</td>
<td>1239</td>
<td>15</td>
<td>9</td>
<td>.009</td>
</tr>
<tr>
<td>Took someone else's medication</td>
<td>1268</td>
<td>2</td>
<td>1</td>
<td>.26</td>
</tr>
<tr>
<td>Called pharmacies to find the best price</td>
<td>1272</td>
<td>46</td>
<td>29</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Received cash discount for being age eligible</td>
<td>1272</td>
<td>13</td>
<td>7</td>
<td>.03</td>
</tr>
<tr>
<td>Received discount for being in Medicare</td>
<td>1272</td>
<td>16</td>
<td>7</td>
<td>.39</td>
</tr>
<tr>
<td>Received discount from a pharmacy/insurance company</td>
<td>1272</td>
<td>2</td>
<td>1</td>
<td>.11</td>
</tr>
<tr>
<td>Used mail order</td>
<td>1272</td>
<td>62</td>
<td>62</td>
<td>.64</td>
</tr>
<tr>
<td>Bought medications outside of the United States</td>
<td>1259</td>
<td>3</td>
<td>3</td>
<td>.92</td>
</tr>
</tbody>
</table>

*Fisher's exact test used for cells with expected counts of less than 5. Numbers may not add to sample sizes as other strategies were used in combination.

doi:10.1001/jama.292.8.952
Bivariate Associations Between Exceeding the Cap and Financial Burden of Medication Costs

| No. Total (%) | Intervention Patients: Exceeded $750 or $1,000 Cap (n = 665) | Control Patients: Did Not Exceed $2,000 Cap (n = 643) | P Value
|---------------|---------------------------------------------------------------|------------------------------------------------------|------
| 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 | 30/661 (4) | 84/640 (13) | |
| Neither easy nor difficult | 14/661 (2) | 18/640 (3) | |
| Somewhat difficult | 23/661 (4) | 184/640 (29) | |
| Very difficult | 122/661 (18) | 50/640 (8) | |

Financial impact of prescription costs

| Did not finish college | 201/661 (30) | 214/640 (34) | < .001 |
| Did not finish college | 155/661 (24) | 116/640 (18) | .02 |
| Did not finish college | 101/661 (15) | 81/640 (13) | .20 |
| Did not finish college | 77/661 (12) | 81/640 (13) | .23 |

*Actual sample sizes vary due to missing values (intervention range, 236-661; control range, 239-643).
†Total sample sizes range from 1286-1301 due to missing values.

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Standard 2006 benefit for Medicare Part D*

*Employee coverage gap is $2,550 in total (employee + Plan) expenditure before (pre-

Enrollee Pays 95%

Enrollee Pays 100%

Enrollee Pays 25%

Plan Pays 5%

Coverage Gap

$3,600 in Total Rx Expenditure

$2,250 in Total Rx Expenditure

$230 Deductible

https://doi.org/10.1007/s11606-010-1300-6

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UCLA TRIAD Part D Study (2006-2011)

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.
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

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

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

< 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)

- Study Investigators (UCLA):
  - Carol M. Mangione, MD, MSPH
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  - Tannaz Moin, MD, MBA, MSHS
  - Susan Ettner, PhD
  - Norman Turk, MS
  - Neil Steers, PhD
  - Jinnan Li, MS
  - Carolina Vasquez
  - Lindsay Kimbro
  - Romain Neugebauer (Kaiser)

- Health Plan Partners (UHC):
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  - Abigail M. Keckhafer, MBA, MPH
  - Charles Chan, MS
  - Anya Kirvan, RN, MS
  - Karen Mtready
  - Craig Hankins, MBA
  - Sam Ho, MD
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)

<table>
<thead>
<tr>
<th></th>
<th>Standard Plan In-network</th>
<th>DHP In-network</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office Visit Copays: PCP</td>
<td>$20</td>
<td>Waived ($0)</td>
</tr>
<tr>
<td>Office Visit Copays: Specialist</td>
<td>$30</td>
<td>Waived ($0)</td>
</tr>
<tr>
<td>Rx Copays: Retail (30d supply)</td>
<td>Tier 1 - $5, Tier 2 - $15</td>
<td>Tier 1 - $0, Tier 2 - $0</td>
</tr>
<tr>
<td>Rx Copays: Mail (90d supply)</td>
<td>Tier 1 - $15, Tier 2 - $30</td>
<td>Tier 1 - $0, Tier 2 - $0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Predicted ER Utilization without DHP Exposure</th>
<th>Predicted ER Utilization with DHP Exposure</th>
<th>Absolute Difference (percentage points)</th>
<th>Relative Difference</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-year post-DHP</td>
<td>18.9%</td>
<td>16.5%</td>
<td>-2.4</td>
<td>13% Reduction</td>
<td>0.012</td>
</tr>
<tr>
<td>2-years post-DHP</td>
<td>18.9%</td>
<td>17.1%</td>
<td>-1.8</td>
<td>10% Reduction</td>
<td>0.046</td>
</tr>
</tbody>
</table>

- 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 an 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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