Plan Benefit Generosity, Adherence to Statins and Hospitalizations under Medicare Part D

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(ARS Response Card: Channel 41)

Disclosure

"I, Tami Swenson, declare no conflicts of interest or financial interests in any product or service mentioned in this presentation, including grants, employment, gifts, stock holdings, or honoraria."

Learning Objectives

(1) Identify the data elements needed from the prescription drug event (PDE) data and plan characteristics file for purposes of creating a measure of Part D plan generosity.

(2) Assess the impact of Part D plan benefit generosity on adherence to statin drug therapy and the likelihood of subsequent hospitalizations.

Presentation Outline

- Policy and Project Background
- Research Objectives
- Adherence Model
- Hospitalization Model
- ACA Policy Findings Application
- Future Research and Analysis

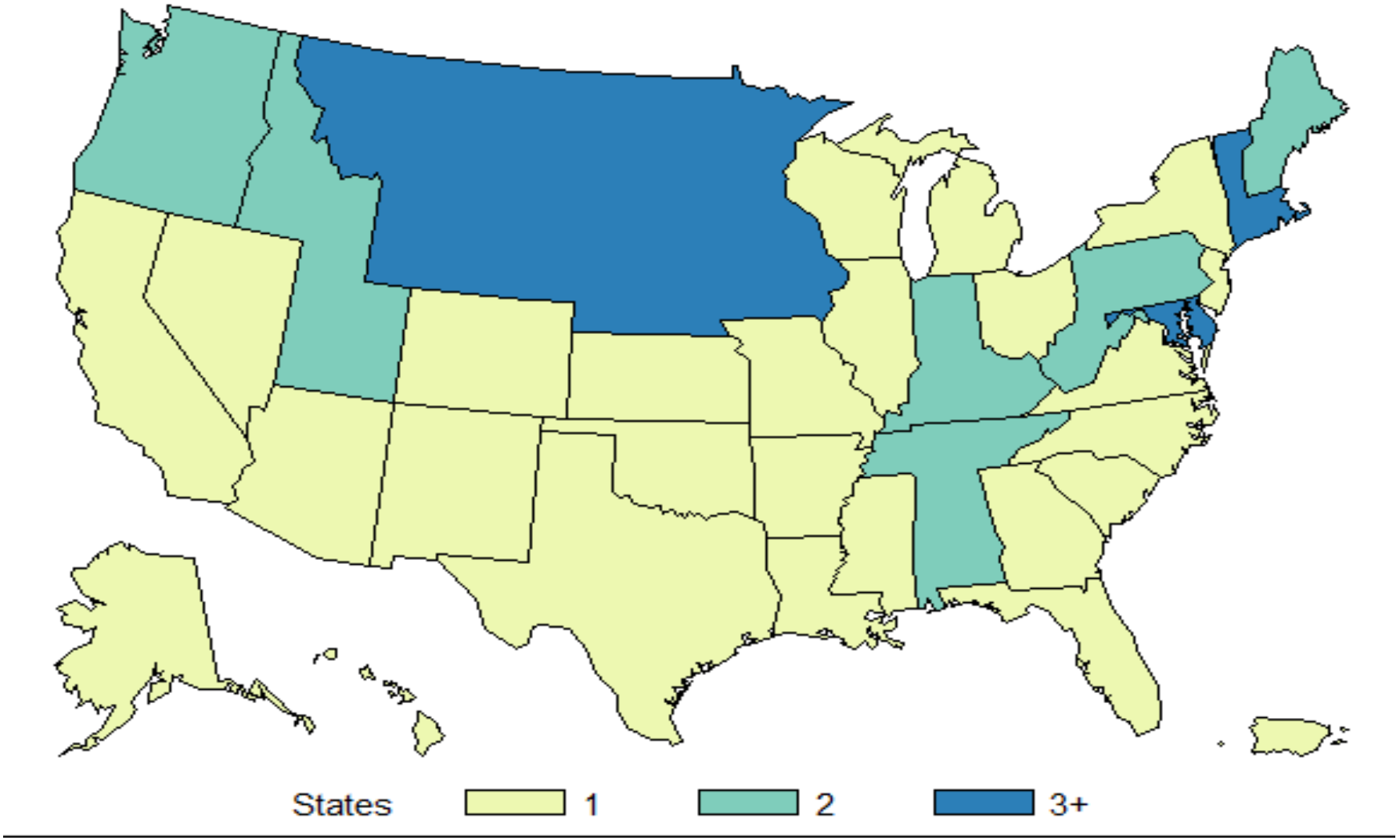
Policy Background

- Medicare Part D, outpatient prescription drug coverage, started January, 2006
- Initial enrollment was open through mid-May, 2006. Participation is optional
- Approximately 50% of the Medicare population is enrolled in the Part D program
- Beneficiaries have the option of enrolling in stand-alone prescription drug plans (PDPs) or in Medicare Advantage prescription drug plans (MA-PDs)

Policy Background, continued

- Phased benefit coverage
  - Deductible
  - Pre-Initial Coverage Limit (ICL)
  - ICL (also known as benefit gap or donut hole)
  - Catastrophic Coverage
- Beneficiaries' out of pocket (OOP) spending and total drug costs during the calendar year move them through the phases
- Plans have many options for structuring coverage

Stand-Alone Prescription Drug Plan (PDP) Regions



Policy Background, continued

- Low Income Subsidy (LIS) program offers different levels of premium subsidies and cost sharing amounts to beneficiaries based on income and asset level qualification
  - Medicare/Medicaid duals are a large majority of the LIS program enrollees
  - LIS beneficiaries do not encounter a coverage gap phase

Policy Background, continued

- Both PDPs and MA-PDs are required to submit administrative prescription drug event (PDE) data to the Centers for Medicare and Medicaid (CMS) for reconciliation purposes
- The federal legislation that allows the PDE data to be released for research purposes does not allow the release of commercially sensitive data
  - Utilization formulary only option, therefore

Project Background

- “Understanding Geographic Variation in Medicare Part D: Effects of Plan Design on Utilization and Expenditures”
- Pinar Karaca-Mandic, PI; Jean Abraham, Co-Investigator
- Funding from University of Minnesota Academic Health Center Faculty Development Grant

Project Background, continued

- Purpose is to examine regional variations in benefit design and formulary characteristics and how they affect Part D drug utilization and spending
- Focus on 3 therapeutic drug classes:
  - Anti-hyperlipidemics
  - Gastrointestinal agents and proton pump inhibitors
  - Oral anti-diabetic agents
- Today's presentation is first article from project on statin adherence that is co-authored by Pinar Karaca-Mandic, Tami Swenson, Jean Abraham, and Bob Kane at the University of Minnesota

Research Objectives

To estimate the role of plan benefit generosity towards statins on adherence with cholesterol-lowering medications and the subsequent cardiovascular hospitalizations

- H(1): Beneficiaries with less generous benefit design will have lower statin adherence
- H(2): Beneficiaries with less generous benefit design will be more likely to have a cardiovascular hospitalization

Background Academic Literature

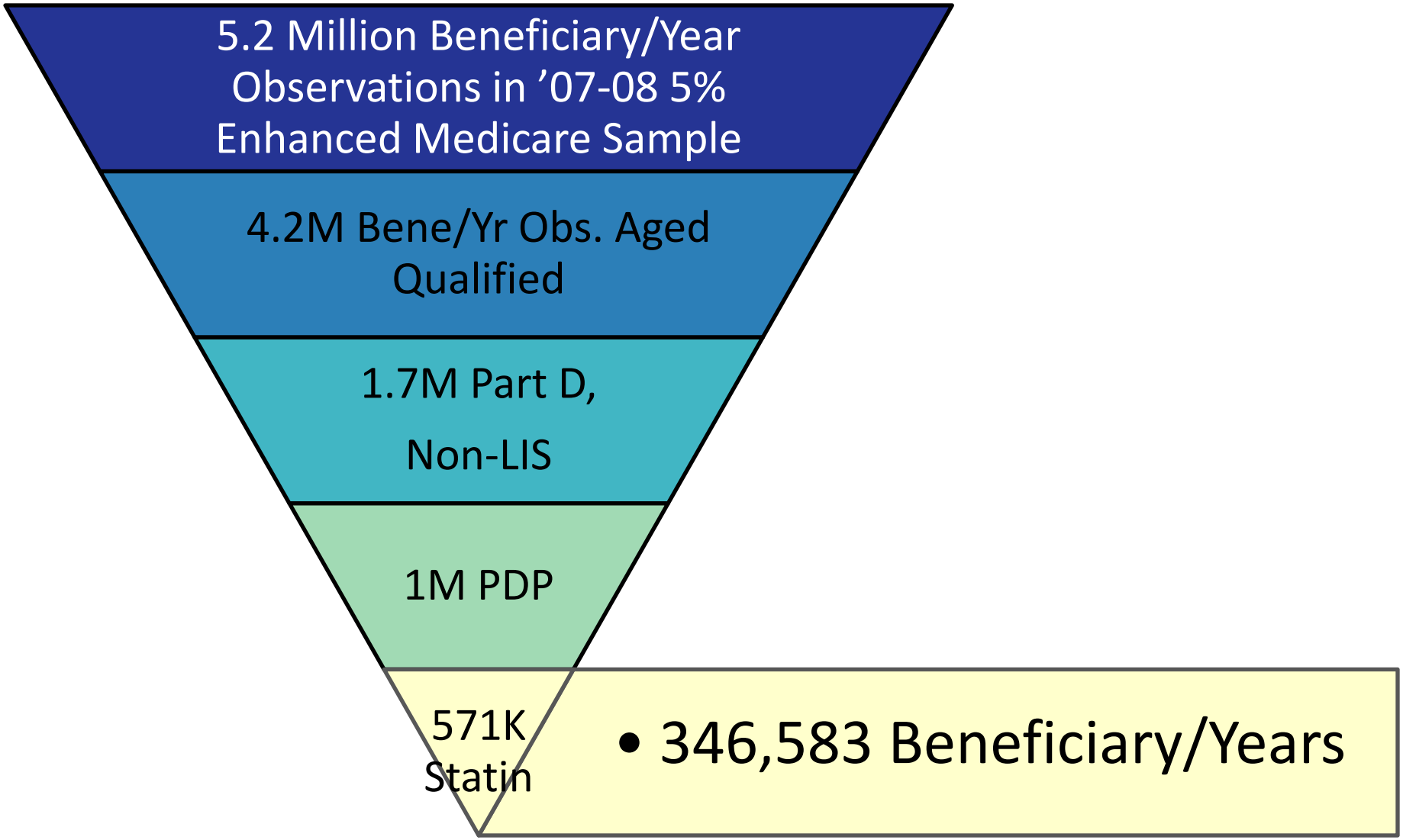
- Cardiovascular disease remains the single largest cause of death in the US (Mensah & Brown 2007)
- Statin medications accounted for close to 10% of all Part D expenditures in 2007 (MedPAC 2010)
- Goldman, Joyce, and Karaca-Mandic (2006) found that full compliance with cholesterol-lowering therapy reduces the use of hospital services by 25% among high risk patients
- The relationship between plan benefit generosity and adherence within the Medicare Part D population has not been studied nor its relation with other medical service utilization

Data

- Administrative claims for the 5% enhanced Medicare sample
  - 2006-08 prescription drug event (PDE) data
  - 2007-08 plan characteristics file
  - 2006-08 denominator file
  - 2007-2008 MedPAR

- Medispan Drug Database

Analytical Sample



Adherence Model

$$Adherence_{it} = f(Plan\ design_{it}, Demographic\ Characteristics_{it}, Risk\ Adjusters_{it}, Time\ Fixed\ Effect_{t}, Regional\ Fixed\ Effects_{it})$$

- Estimate model using logistic regression for adherent/non-adherent behavior
- Clustered standard errors by beneficiary

Adherence Measure

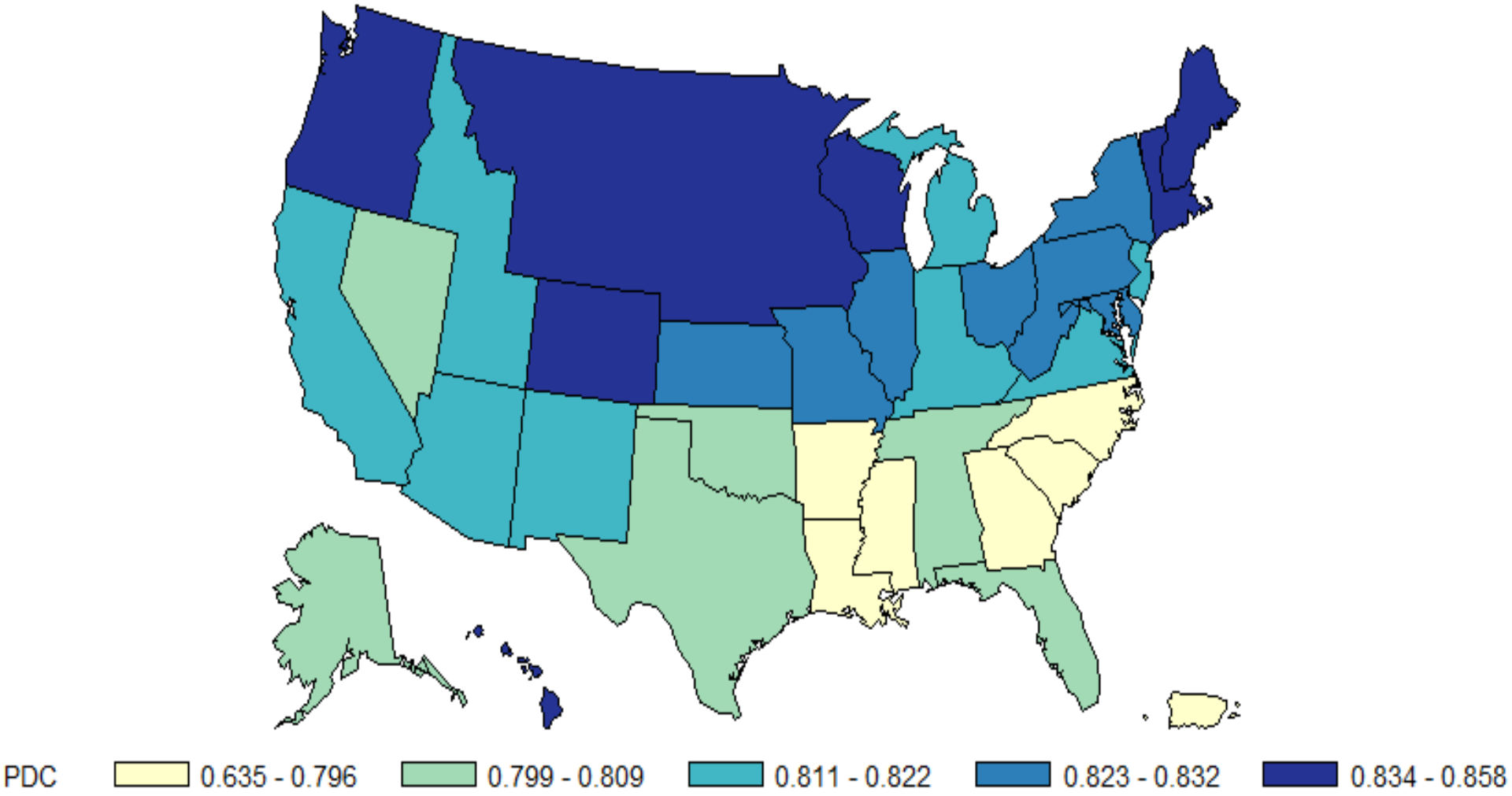
- Proportion of days (PDC) covered during calendar year (CY)
  - January 1 index start with stock coverage from previous CY or date of first fill of CY as start index date
  - December 31 ends PDC period
  - Diary method arrays covered days during CY
  - Index adjusted for hospitalizations
  - Accumulation limited to max 30 days
- $0 < PDC \leq 1$
- $PDC \geq 0.80$ are adherent levels

Adherence Measure, continued

- PDC Summary Statistics for ‘07 and ‘08 cohorts
  - Average 0.821
  - STD 0.224

- PDC distribution
  - 3.6% Non-compliers (<0.20 PDC)
  - 29.4% Moderate compliers (0.20 – 0.80 PDC)
  - 67.0% Adherent (≥ 0.80 PDC)

Adherence by PDP Regions



Plan Design Characteristics

- Plan deductible indicator
  - 76% have zero deductible
- Plan deductible amount
  - Overall Average $63.67 (STD 113.88)
  - Non-zero Avg. $264.20 (STD 28.85) Min $20 Max $275
- Any gap coverage
  - 16% have some gap coverage
- Plan expected out-of-pocket (OOP) for a representative basket of statins (Basket OOP)

Basket OOP

- Construct average OOP cost of a representative market basket of statins for each plan
  - OOP for each statin for each plan
  - Weighted by the overall distribution for each statin in the Part D population
- Example for two drugs
  - Basket $OOP_P = OOP_{1P}*share_1 + OOP_{2P}*share_2$
  - The major challenge is when we don't observe a fill for every drug in each plan (i.e.,OOP_{1P}, OOP_{2P})

Basket OOP, continued

Constructing a Statin Plan Utilization Formulary

1. Plan Characteristics File
    - Tier ID
    - Pre-Initial Coverage Limit (ICL) Tier Type
        - For example in 2007: generic, preferred generic, non-preferred generic, brand, non-preferred brand, preferred brand, and any combination of these
    - Pre-ICL coinsurance rate for in-network pharmacy
    - Pre-ICL co-pay for in-network pharmacy

Basket OOP, continued

Constructing a Statin Plan Utilization Formulary, cont.

2. PDE file
    - Tier ID
    - Active Ingredient (merged from Medispan information)
    - Days supplied
    - OOP
- Using all of the PDE data for all beneficiaries, create a summary file by statin active ingredient by plan file and a statin active ingredient file
- Use the summarized PDE files and plan file to create the basket OOP measure

Basket OOP, continued

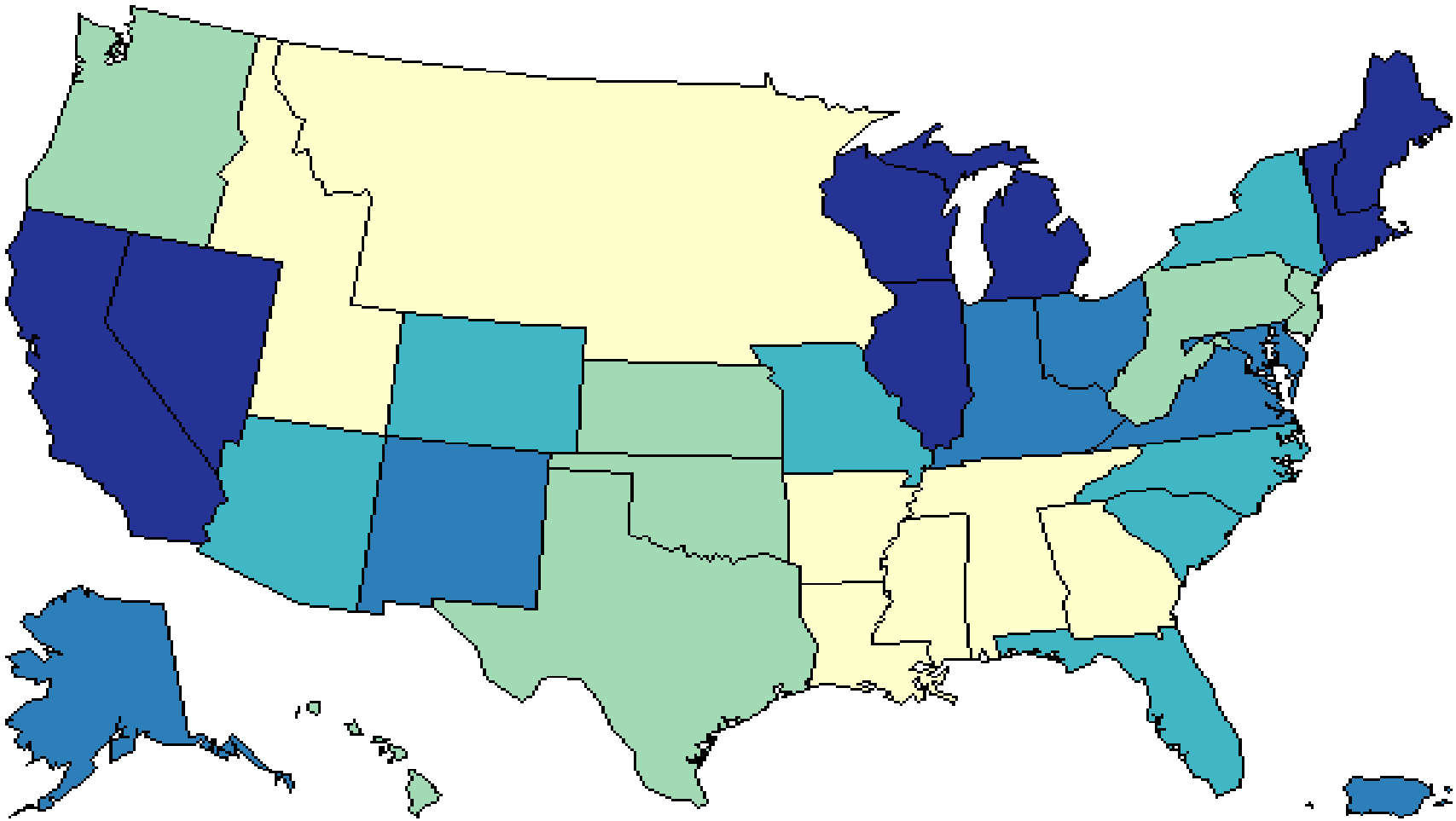
- Step 1 - If plan has a fill for $statin_j$, then we know the Pre-ICL co-pay/coinsurance
- Step 2 - If plan does not have a fill for $statin_j$, then we impute OOP_{jP} by assigning pre-ICL co-pay/coinsurance using information on:
  - Type of tier $statin_j$ is covered for all other users
    - Example: Atorvastatin Calcium (Lipitor) is covered under following tier types for all users – 87% preferred brand, 7% brand, 6% non-preferred brand
  - Universe of tiers and tier types from plan characteristics for each plan
    - Example: Plan has tier for preferred and non-preferred brand. Imputed pre-ICL copay is weighted average of pre-ICL copay of (0.94,0.06) the two tiers

Basket OOP, continued

- Pre-ICL Basket OOP Summary Statistics for ‘07 and ‘08 Cohorts
  - $15.32 Average Basket OOP
  - 3.65 STD, $6.08 Min, $37.66 Max
- Pre-ICL Basket OOP distribution
  - 25.7% $6.03 – $12.35
  - 59.6% $12.35 – $18.67
  - 14.3% $18.67 – $24.99
  - 0.4% $24.99 – $37.66

Basket OOP, continued

Pre-ICL Basket OOP by PDP Region



Basket OOP, continued

- Pre-ICL basket process was repeated to construct gap-phase OOP basket
- Plans without any gap coverage were assigned the total cost of the active ingredient as the monthly OOP gap basket

	Mean	Standard Deviation
One-month gap OOP for statin basket ($)	$41	$14
For beneficiaries in a plan with gap coverage	$9	$4
For beneficiaries in a plan without gap coverage	$47	$1

Basket OOP, continued

- The final plan generosity measure of OOP associated with a standard market basket of statin drugs was constructed using individual weights for expected time spent in each benefit phase for the pre-ICL and gap phase baskets
  - The average PDP statin user spent 9.5 months in the pre-ICL phase and 1.5 months in the gap phase (first month deductible phase)
  - Plan generosity = weighted annual OOP for the pre-ICL and gap phases combined

Basket OOP, continued

	Mean	Standard Deviation
Annual OOP for statin basket – pre-ICL & gap combined ($)	$200	$40
For beneficiaries in a plan with gap coverage	$169	$39
For beneficiaries in a plan w/o gap coverage	$210	$36
For low medication use intensity beneficiaries	$162	$41
In a plan with gap coverage	$180	$40
In a plan without gap coverage	$159	$41
For high medication use intensity beneficiaries	$274	$59
In a plan with gap coverage	$161	$41
In a plan without gap coverage	$296	$29

Demographic, Socioeconomic, Geographic Characteristics

- Age on January 1
  - Mean 75.2 years
  - SD 6.96
- Female Indicator
  - 63.8% Female
  - 36.2% Male
- Zip-Code Level Socioeconomic measures from Census
- Rural Indicator
- PDP region/HRR

- RTI race/ethnicity

Non-Hispanic White	92.7%
African American	3.34
Hispanic	2.23
Asian/Pacific Islander	1.03
American Indian	0.16
Other	0.43
Unknown	0.10

Risk Adjusters

- Medispan Therapeutic Class Groups
  - Concurrent adjuster
  - 17 groups:
    - anti-infective agents
    - biologicals
    - anti-neoplastic agents
    - endocrine and metabolic drugs
    - cardiovascular agents
    - respiratory agents
    - gastrointestinal agents
    - genitourinary agents
    - central nervous system drugs
    - ADHD/Anti-narcotic/Anti-obesity/anorexic agents
    - psychotherapeutic/neurological agents
    - analgesics and anesthetics
    - neuromuscular drugs
    - nutritional products
    - hematological agents
    - topical products
    - miscellaneous products

Adherence Model Findings

	All			High Cardiovascular Risk			Low Cardiovascular Risk		
Plan Benefit Variable	OR	(95% CI)	P>|z|	OR	(95% CI)	P>|z|	OR	(95% CI)	P>|z|
Annual OOP for statin basket - pre-ICL & gap combined (in $100)	0.92	(0.91, 0.95)	< 0.001	0.93	(0.91, 0.96)	< 0.001	0.91	(0.87, 0.95)	< 0.001
Any deductible (1/0)	1.05	(0.92, 1.21)	0.46	0.98	(0.84, 1.15)	0.85	1.31	(0.99, 1.72)	0.06
Deductible amount conditional on positive deductible (in $100)	0.99	(0.94, 1.04)	0.63	1.02	(0.96, 1.08)	0.49	0.89	(0.80, 0.99)	0.03
Number of observations	346,583			246,048			100,535		

Adherence Model Findings, continued

	High Medication Use Intensity			Low Medication Use Intensity		
Plan Benefit Variable	OR	(95% CI)	P>|z|	OR	(95% CI)	P>|z|
Annual OOP for statin basket - pre-ICL & gap combined (in $100)	0.88	(0.87, 0.90)	< 0.001	1.00	(0.97, 1.03)	0.80
Any deductible (1/0)	0.96	(0.79, 1.17)	0.67	1.13	(0.94, 1.37)	0.20
Deductible amount conditional on positive deductible (in $100)	1.09	(1.02, 1.18)	0.02	0.94	(0.88, 1.01)	0.10
Number of observations	138,027			208,556		

Cardiovascular Hospitalization models

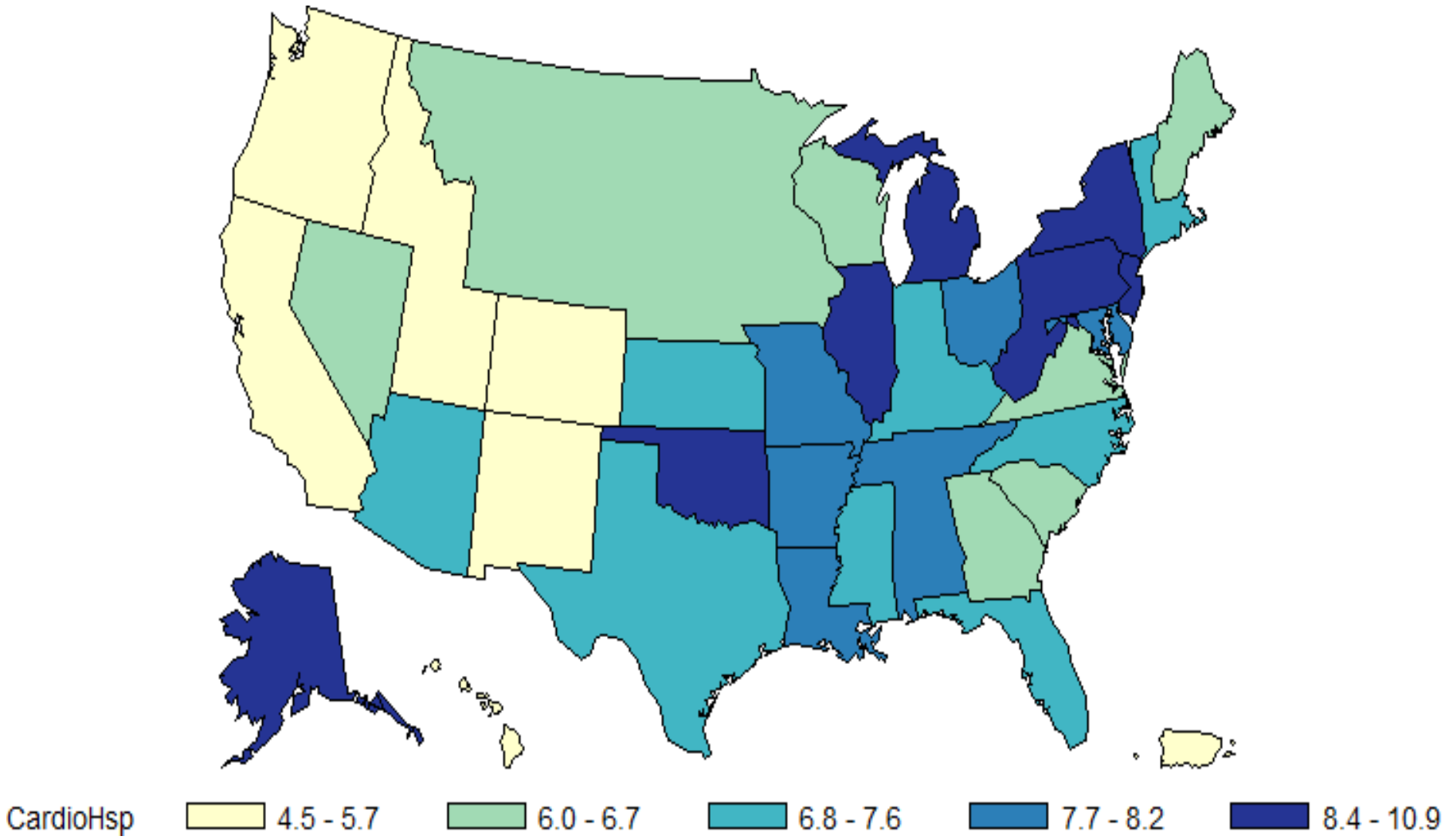
$$Cardiovascular\ Hospitalization_{it} = f(Plan\ design_i, Demographic\ Characteristics_i, Risk\ Adjusters_i, Regional\ Fixed\ Effects_i)_{t-1}$$

- Estimate model using logistic regression
- Examined any cardiovascular hospitalizations during calendar year as binary outcome
- Expenditures conditional on any hospitalization will be studied in future analysis

Cardiovascular Hospitalization Definitions

- "Any hospitalization" is an indicator for a hospital admission in the 2008 MedPAR
  - 21.5% 2007 cohort have hospitalization in 2008
- Cardiovascular hospitalizations are a subset of "any hospitalizations" and defined by the major disease classification (MDC) of the diagnostic related group (DRG) for the hospital stay
  - 7.4% have cardiovascular hospitalization

Cardiovascular Hospitalizations by PDP Regions



Cardiovascular Hospitalization Model Findings

	All			High Cardiovascular Risk			Low Cardiovascular Risk		
Plan Benefit Variable	OR	(95% CI)	P>|z|	OR	(95% CI)	P>|z|	OR	(95% CI)	P>|z|
Annual OOP for statin basket - pre-ICL & gap combined (in $100)	1.10	(1.06, 1.15)	< 0.001	1.09	(1.04, 1.14)	< 0.001	1.19	(1.06, 1.32)	0.002
Any deductible (1/0)	0.88	(0.66, 1.18)	0.41	0.93	(0.68,1.27)	0.63	0.62	(0.24, 1.59)	0.32
Deductible amount conditional on positive deductible (in $100)	1.07	(0.95,1.19)	0.25	1.05	(0.93,1.18)	0.41	1.20	(0.84, 1.70)	0.32
Number of observations	346,583			246,048			100,535		

Cardiovascular Hospitalization Model Findings, continued

	High Medication Use Intensity			Low Medication Use Intensity		
Plan Benefit Variable	OR	(95% CI)	P>|z|	OR	(95% CI)	P>|z|
Annual OOP for statin basket - pre-ICL & gap combined (in $100)	1.11	(1.08, 1.15)	< 0.001	1.04	(0.97, 1.12)	0.22
Any deductible (1/0)	0.93	(0.65, 1.33)	0.68	0.83	(0.49, 1.39)	0.48
Deductible amount conditional on positive deductible (in $100)	1.00	(0.88, 1.15)	0.96	1.13	(0.93, 1.37)	0.22
Number of observations	138,027			208,556		

Implications of Findings for ACA Policy Context

- The Affordable Care Act (ACA) provides beneficiaries additional OOP financial support during the coverage gap phase by discounting brand and generic drugs
  - In 2012, beneficiary OOP in coverage gap phase is:
    - 50% for brand-name drug purchases
    - 86% for generic drug purchases
- Estimation of the annual OOP cost for a representative basket of statins under the ACA discount rates for beneficiaries with high medication use intensity shows:
  - Adjusted adherence rates increase from 70.6% to 73.0%
  - Adjusted risk of cardiovascular hospitalization rates decrease from 8.9% to 8.2%

Conclusions

- Less generous plan benefits for coinsurance and co-payments are associated with lower statin adherence rates
  - Overall, the plan deductible does not have a statistically significant effect on statin adherence
- Less generous plan benefits are associated with increases in the likelihood of cardiovascular hospitalizations; the plan deductible does not have a statistically significant effect

Future Research from Project

- Apply similar framework as statin paper to diabetic analytical cohort
  - Note: This paper has been accepted for presentation at 2012 ASHE conference in June
- Followed by analysis of the final cohort of gastrointestinal agents
- Examine regional variation in adherence levels for Low Income Subsidy enrollees for three clinical cohorts, which is part of my dissertation research objectives
- Compare the regional variations in the PDP and MA-PD populations for the three clinical cohorts

Assessments

Assessment Question 1

Which of the following variables are NOT used in the construction of the market basket measuring Part D plan generosity:

Drug tier identifier

Beneficiary out-of-pocket (OOP) amount

Beneficiary date of birth

Drug tier type (e.g., generic, brand, preferred brand, etc…)

Assessment Question 2

The study findings suggest that less generous Part D plan benefits (i.e., higher out-of-pocket expenses) are associated with the following effects of statin adherence levels and the risk of cardiovascular hospitalizations:

Lower adherence levels and increased risk of hospitalizations

Higher adherence levels and no statistically significant effect on hospitalizations

No statistically significant effect on adherence and decreased risk of hospitalization

No statistically significant effect on either

Questions?

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