Impact of Coverage Gap Reform on Adherence to Diabetes Medications

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Disclosure

"Feng Zeng declares no conflict of interest or financial interests in any product or service mentioned in this presentation, including grants, employment, gifts, stock holdings, or honoraria."

Learning Objectives

- Identify Part D coverage gap reform stipulated in Affordable Care Act (ACA)

- Understand the impacts of coverage gap reform in 2011 on adherence to diabetes medications

Introduction of Part D Coverage Gap (Donut Hole)

- Unique benefit design feature in Part D

- Difference between the initial coverage limit and catastrophic coverage limit

- Beneficiaries usually pay 100% copay in the donut hole

# An Illustration of Donut Hole in 2010
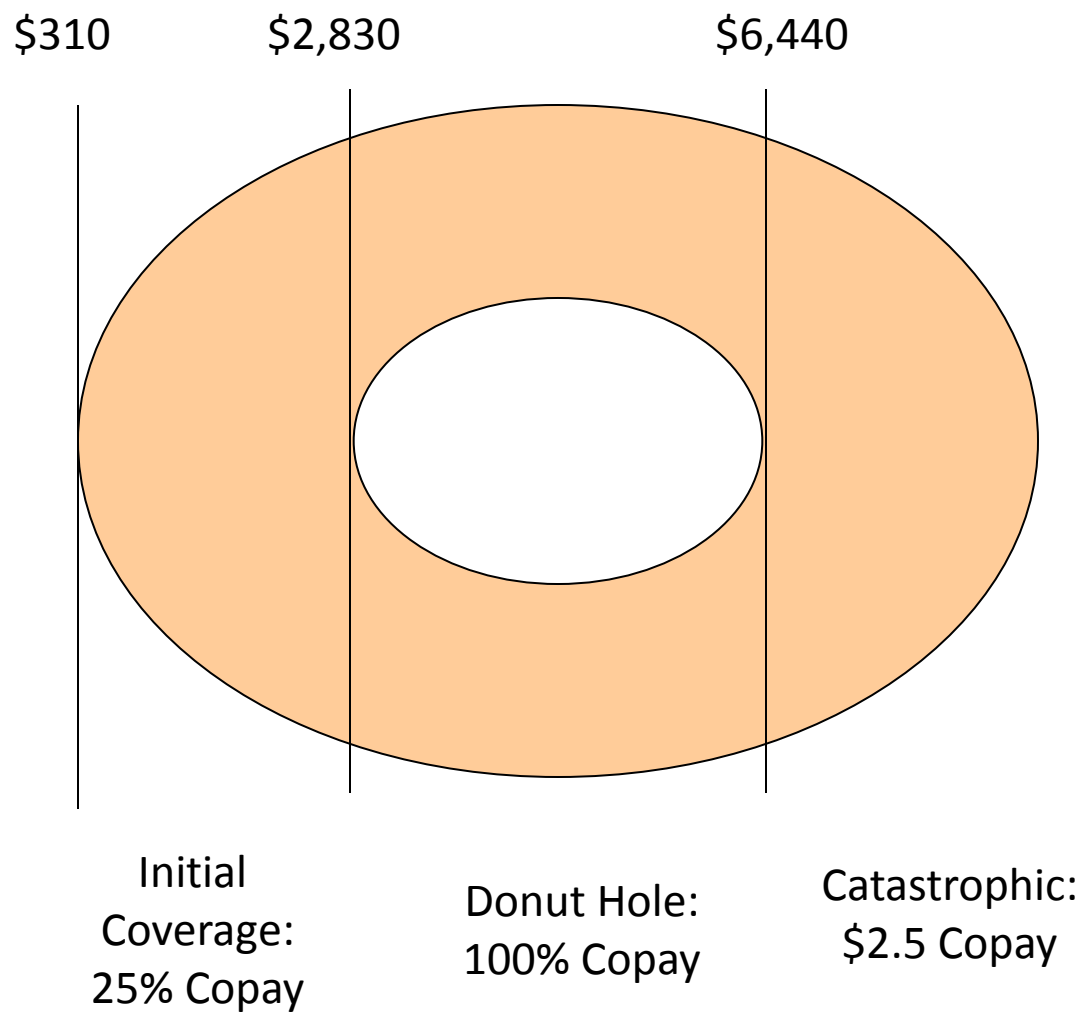
Problems of Part D Donut Hole

- Decreased drug spending in coverage gap (Zhang et al, 2009, *Health Affairs*)

- Lower adherence to diabetes medications (Zeng et al, 2010, *AJMC*)

- Lower adherence to 3 chronic illness drugs: oral diabetes, hypertension and lipid (Fung et al, 2010, *Health Services Research*)

- Delayed cardiovascular medications (Hales et al, 2010, *Managed Care*)

Coverage Gap Reform in 2011 by ACA

- 50% discount for brand drugs for patients in coverage gap

- 7% discount for generic drugs for patients in coverage gap

- Entire drug cost will be counted as out-of-pocket spending

- Patients with coverage in coverage gap will get discount in copayment

Donut Hole Reform Timeline
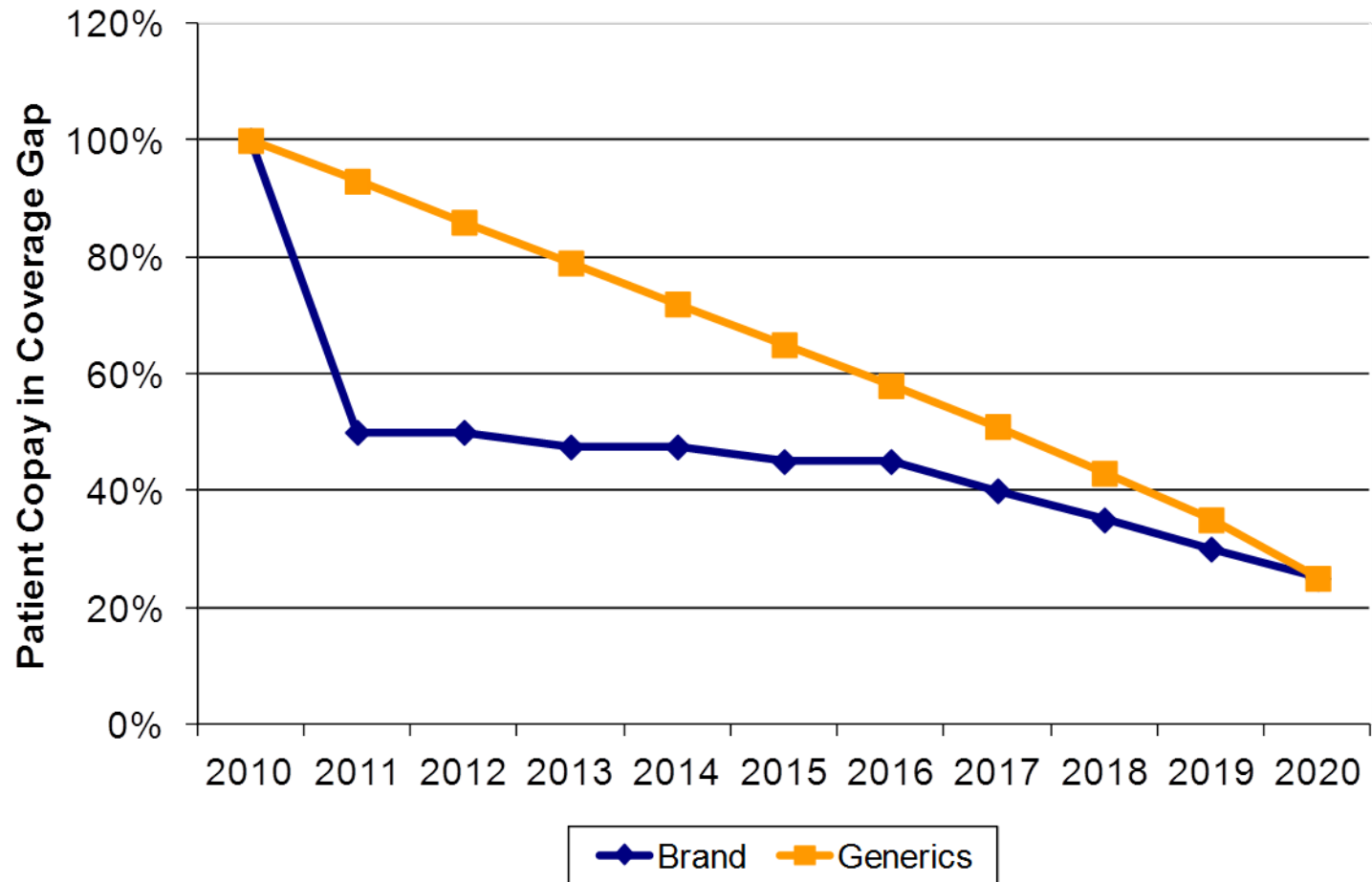
Source: Kaiser Family Foundation. Explaining Health Care Reform: Key Changes to the Medicare Part D Drug Benefit Coverage Gap. Kaiser Family Foundation Publication #8059, March 2010

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What is the Impact of Coverage Gap Reform on Adherence to Diabetes Medications?

Why Focus on Diabetes?

Diabetes Is Highly Prevalent within Medicare Population
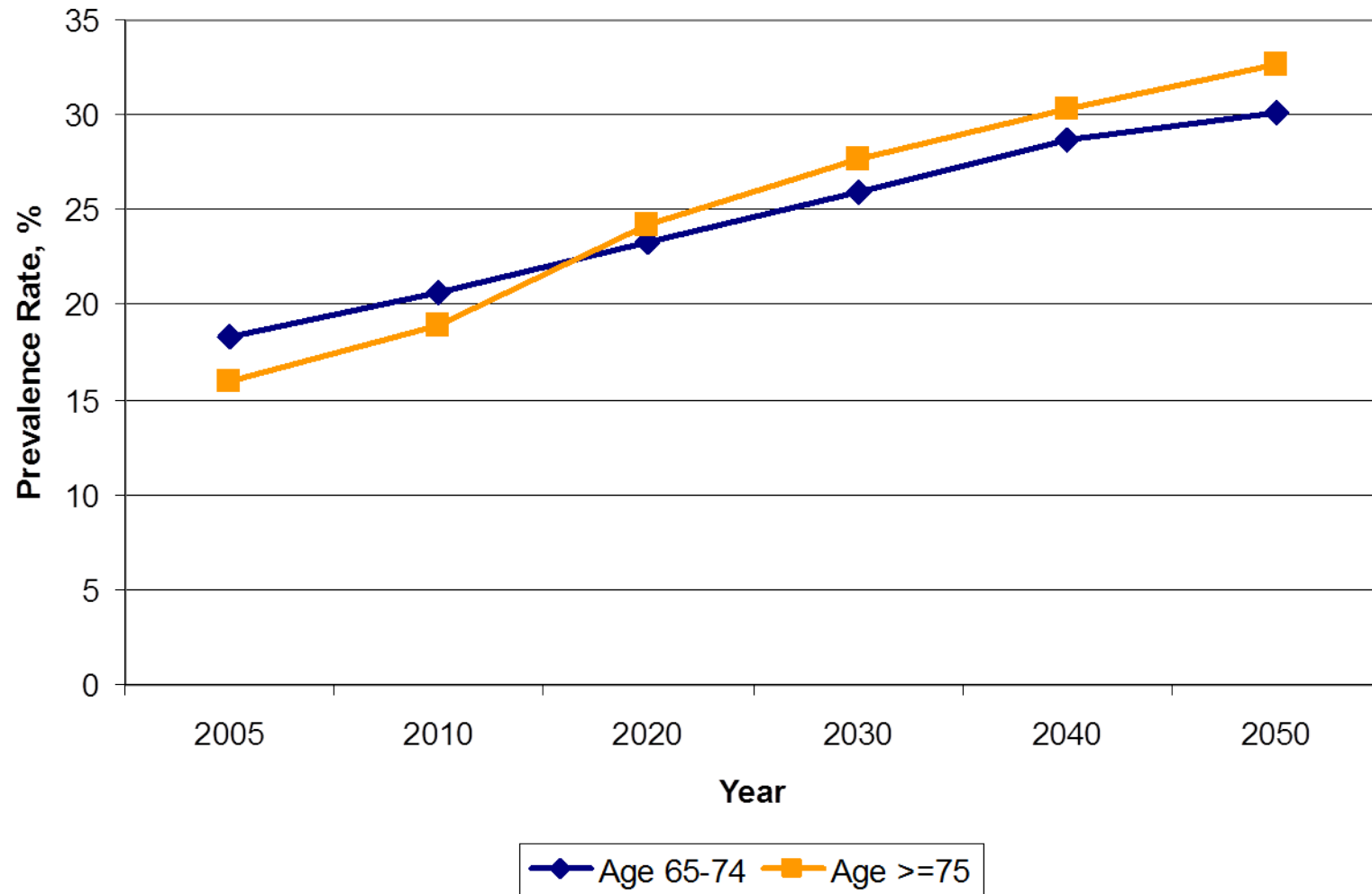
Source: Narayan KM, Boyle JP, Geiss LS, Saaddine JB, Thompson TJ. Impact of recent increase in incidence on future diabetes burden: U.S., 2005-2050. *Diabetes Care*. 2006;29(9):2114-2116.

Adherence Is Critical

- Poor adherence is a major contributor of poor glycemic control (1-4)

- Poor adherence can increase the risk of adverse events associated with diabetes (5-7)

1. **Pladevall M, Williams LK, Potts LA, Divine G, Xi H, Lafata JE.** Clinical outcomes and adherence to medications measured by claims data in patients with diabetes. *Diabetes Care*. 2004;27(12):2800-2805.
2. **Krapek K, King K, Warren SS, et al.** Medication adherence and associated hemoglobin A1c in type 2 diabetes. *Ann Pharmacother*. 2004; 38(9):1357-1362.
3. **Schectman JM, Nadkarni MM, Voss JD.** The association between diabetes metabolic control and drug adherence in an indigent population. *Diabetes Care*. 2002;25(6):1015-1021.
4. **Dalewitz J, Khan N, Hershey CO.** Barriers to control blood glucose in diabetes mellitus. *Am J Med Qual*. 2000;15(1):16-25.
5. **Hepke KL, Martus MT, Share DA.** Costs and utilization associated with pharmaceutical adherence in a diabetic population. *Am J Manag Care*. 2004;10(2 pt 2):144-151.
6. **Ho PM, Rumsfeld JS, Masoudi FA, et al.** Effect of medication nonadherence on hospitalization and mortality among patients with diabetes mellitus. *Arch Intern Med*. 2006;166(17):1836-1841.
7. **Lau DT, Nau DP.** Oral antihyperglycemic medication nonadherence and subsequent hospitalization among individuals with type 2 diabetes. *Diabetes Care*. 2004;27(9):2149-2153.

Research Method

- Retrospective data analysis based on MedImpact's pharmacy claim data

- Two data cohorts:
    - 2010 cohort: last year before ACA reform
    - 2011 cohort: first year after ACA reform

Coverage Gap and Catastrophic Limits Change Little from 2010 to 2011

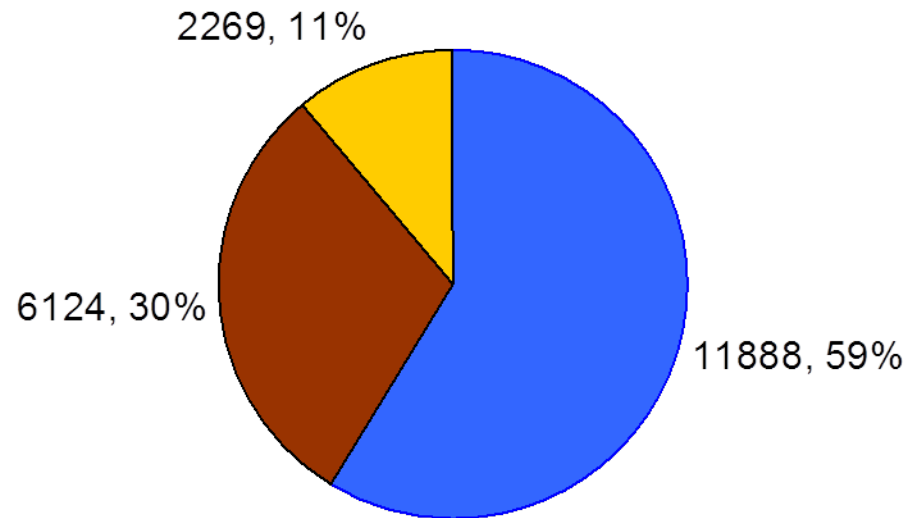| Coverage Gap Limits	2010	2011
Deductible	$310	$310
Initial Coverage Limit	$2,830	$2,840
End of Coverage Gap (Catastrophic Starting Point)	$6,440.00	$6,447.50
Out-of-Pocket Limit	$4,550	$4,550

Data Inclusion/Exclusion Criteria

- Age 65 and older

- Continuously enrolled in a Medicare Part D plan for two years (1 year before the cohort year and the cohort year)

- Not eligible for LIS (low income subsidy)

- Had at least 2 diabetes medication claims in both years
  - Different from CMS star rating (not limited to oral medications, includes insulin)
  - Robustness Check

- 20,281 patients identified in 2011 cohort and 20,709 patients identified in 2010

Selected Patients Reaching Donut Hole But Not Catastrophic

Final Sample Contains 6,828 patients for 2010 cohort and 6,124 patients for 2011 cohort

Patient Spending Distribution for Cohort 2011

2269, 11%

6124, 30%

11888, 59%

Legend:
- ■ Did not reach coverage gap
- ■ Coverage gap but not catastrophic
- ■ Both coverage gap and catastrophic

Outcome Variables: Adherence to Diabetes Medications

- Measured by PDC (Proportions of days covered)
  - Calculated based on drug fill date and days of supply
  - Shift filled date for overlapping claims in the same diabetes class

- Adherence defined as PDC>=80%

Type of Coverage within Coverage Gap

- No coverage
  - Defined standard benefits (DSB)
  - Basic alternatives (BA)
  - Actuarially equivalent (AE)
  - Enhanced alternatives (EA)

- Partial: Generics only but no brand-name drugs
  - Enhanced alternatives (EA)

- Full: Both generics and brand-name drugs
  - Enhanced alternatives (EA)

Model Specifications

$$Y = X\beta + DH * \beta_1 + NoCov * \beta_2 + GenCov * \beta_3 + Y2011 * \beta_4 + DH * NoCov * \beta_5$$

$$+ DH * GenCov * \beta_6 + DH * Y2011 * \beta_7 + DH * NoCov * Y2011 * \beta_8$$

$$+ DH * GenCov * Y2011 * \beta_9 + \varepsilon$$

DH: Donut Hole

NoCov: No Coverage in Coverage Gap

GenCov: Generic Coverage only in Coverage Gap

Y2011: Dummy Variable for the year 2011

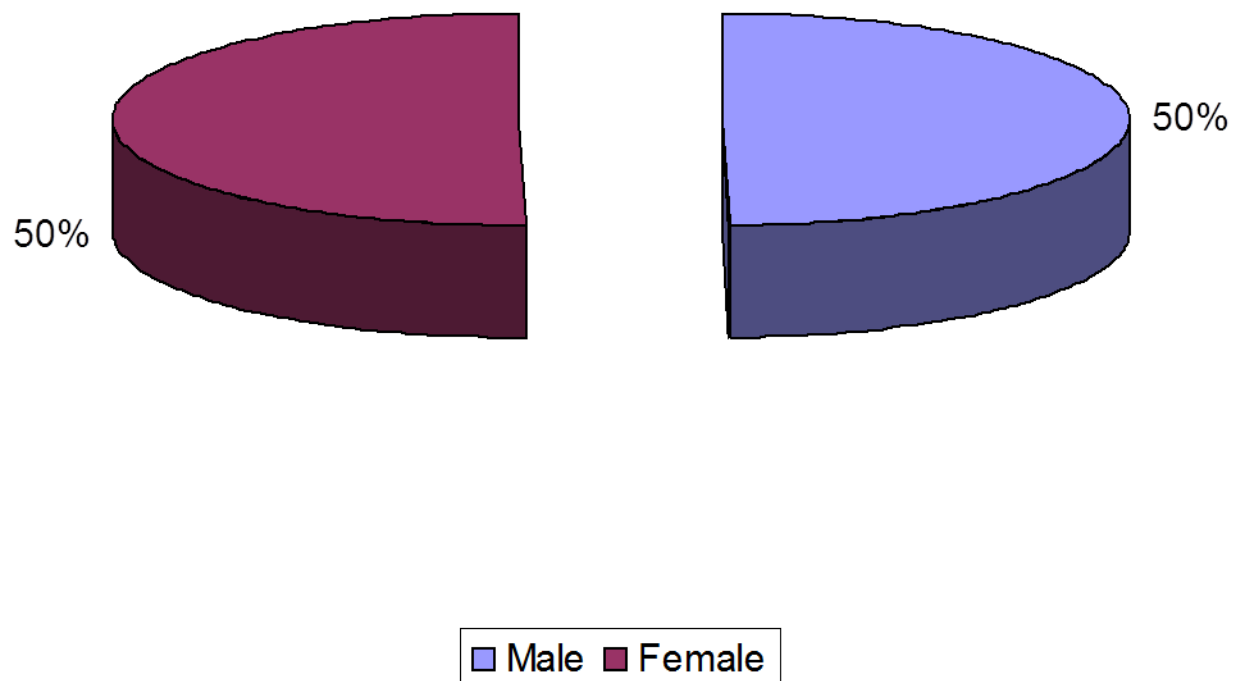Key Variables of Interest: $\beta_5, \beta_6, \beta_7, \beta_8, \beta_9$

Estimated by Proc GENMOD, adjusted by individual clustering effect
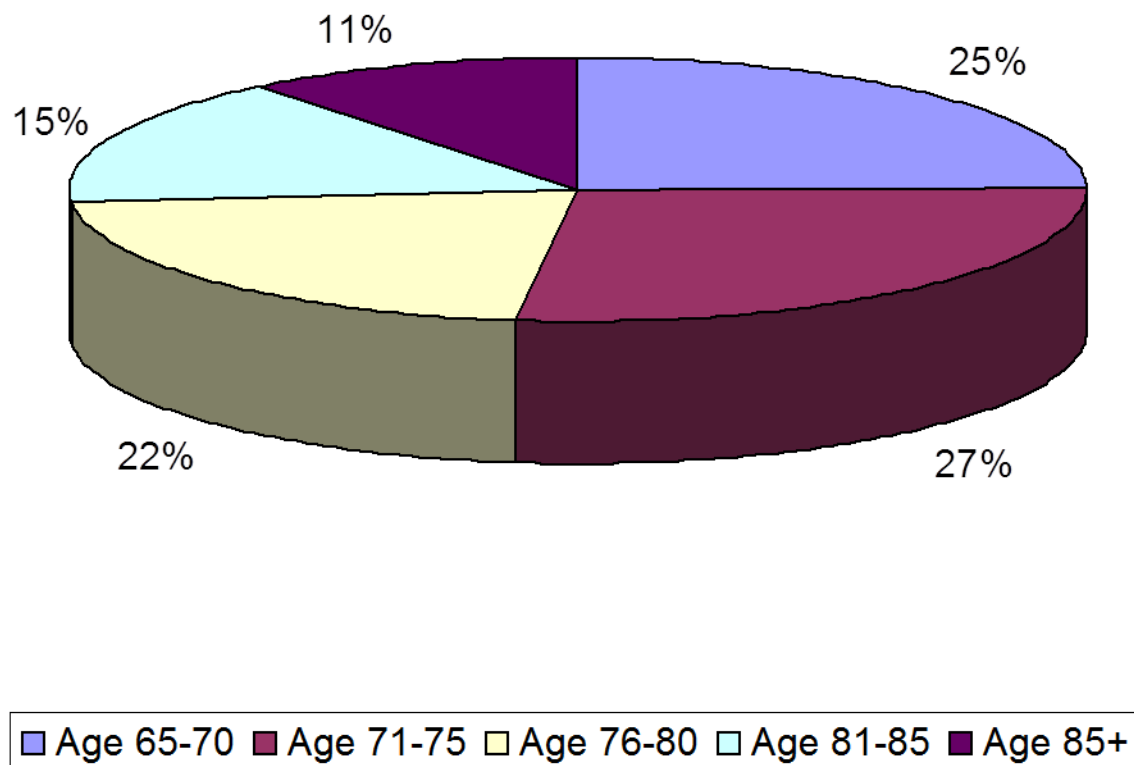
Control Variables

- Age

- Gender

- History of insulin use in the last year

- Geographical locations

- Comorbidities, measured by RxRisk (measured by drug use in the past year)

Descriptive Statistics
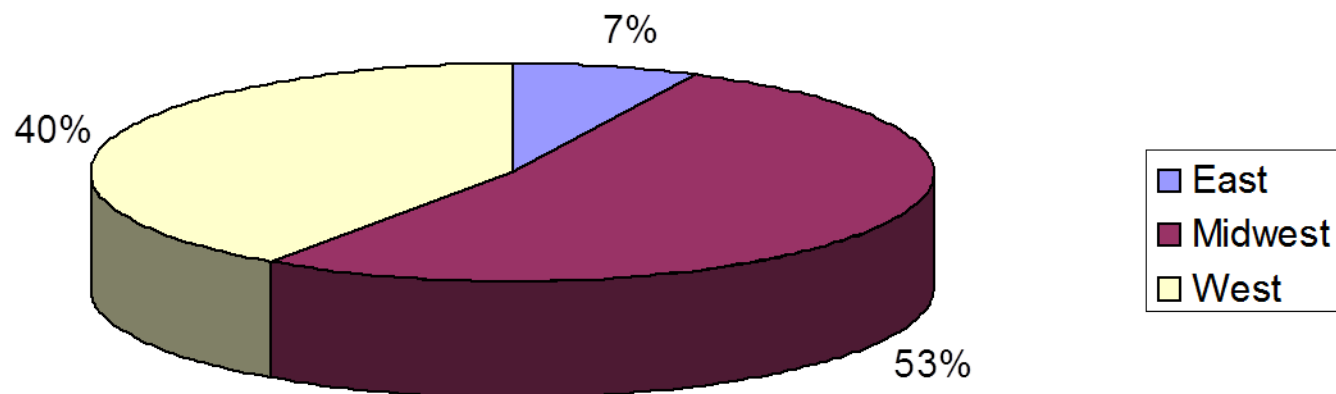
Roughly Equal Gender Distribution

50%   50%

☐ Male ☐ Female

Half Patients Under 75
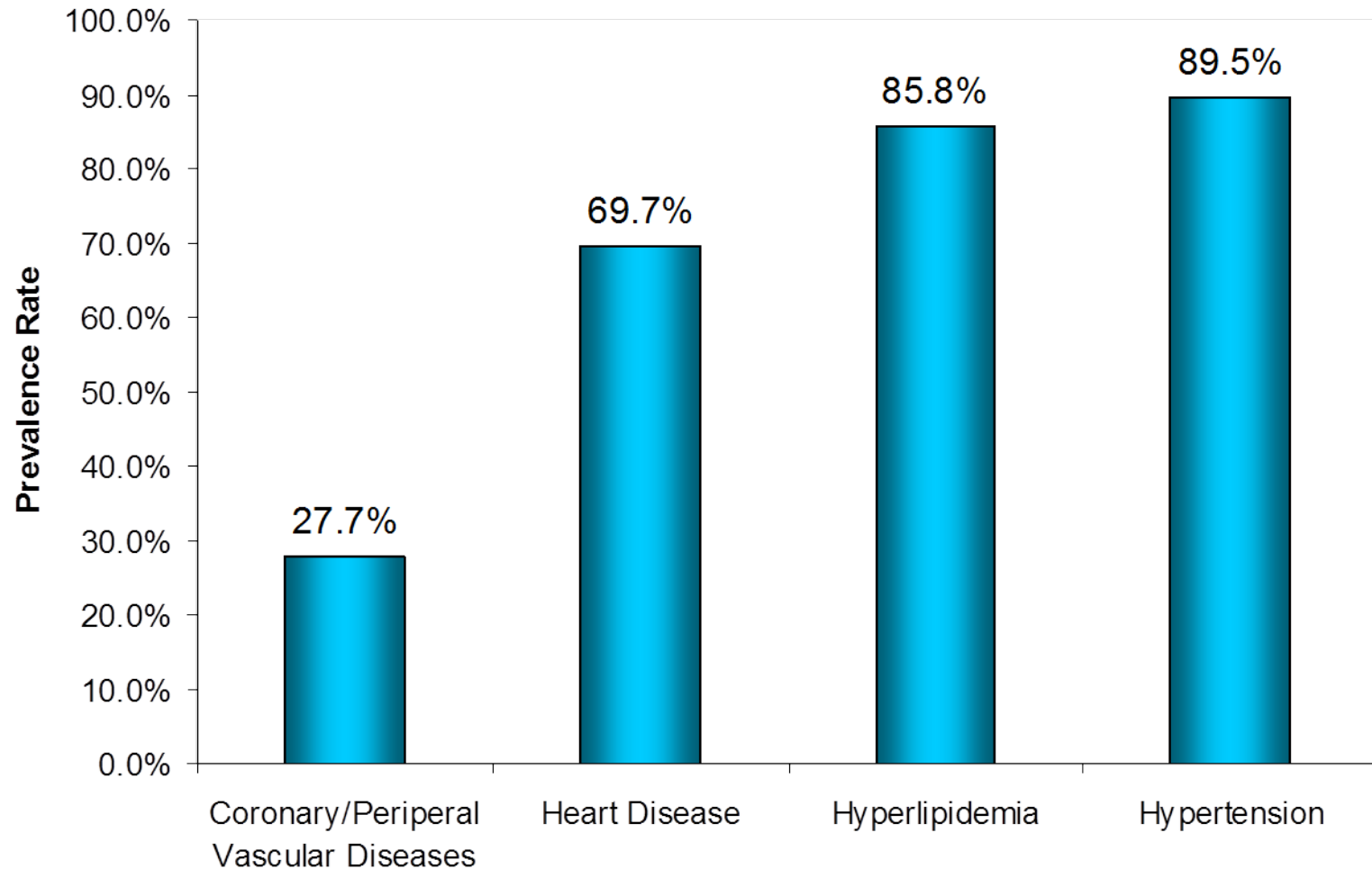

11%
25%
15%
22%
27%

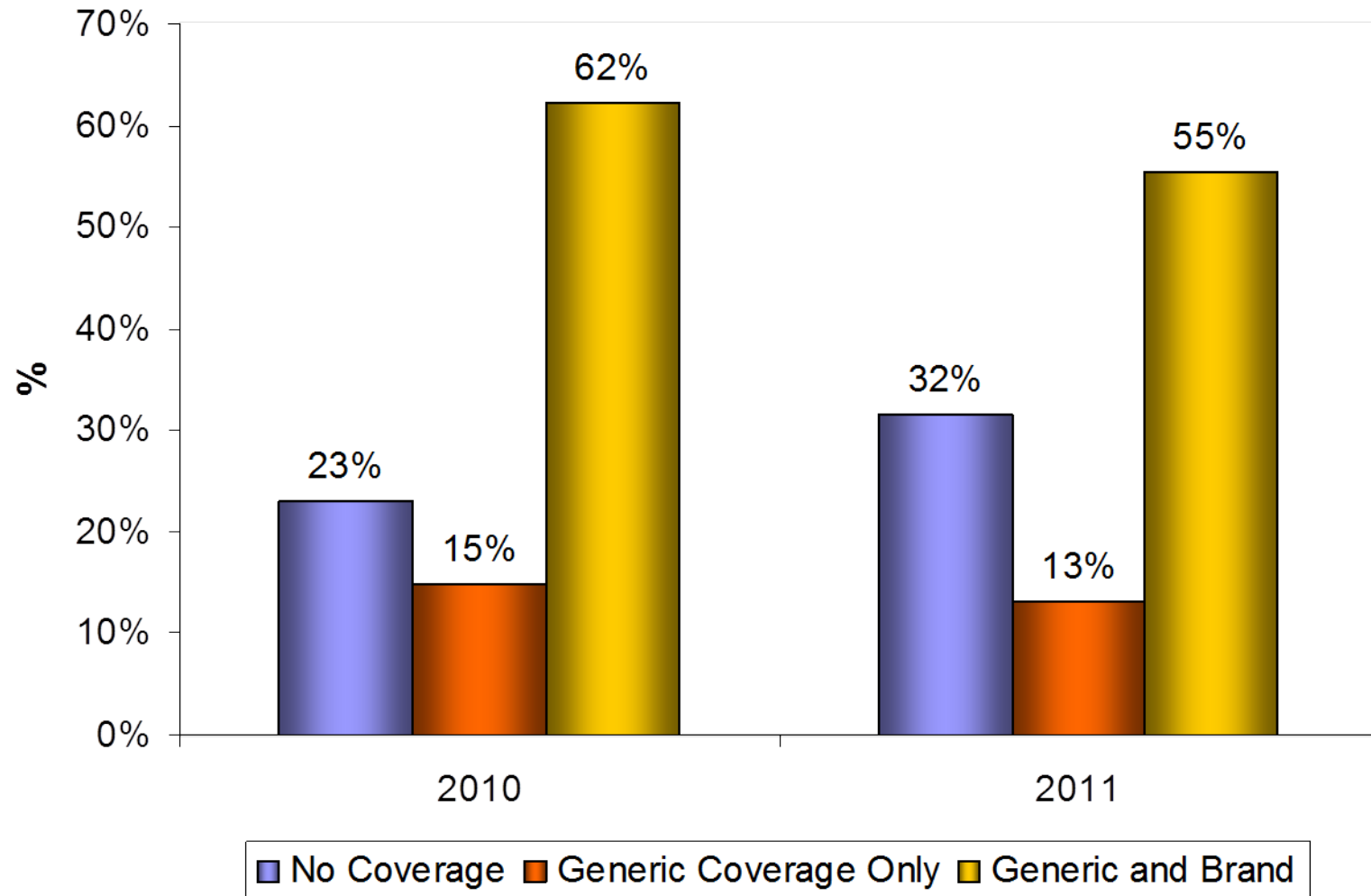Legend: □ Age 65-70 ■ Age 71-75 □ Age 76-80 □ Age 81-85 ■ Age 85+

Most Patients in Midwest and West

High Prevalence of Diabetes-Related Comorbidities
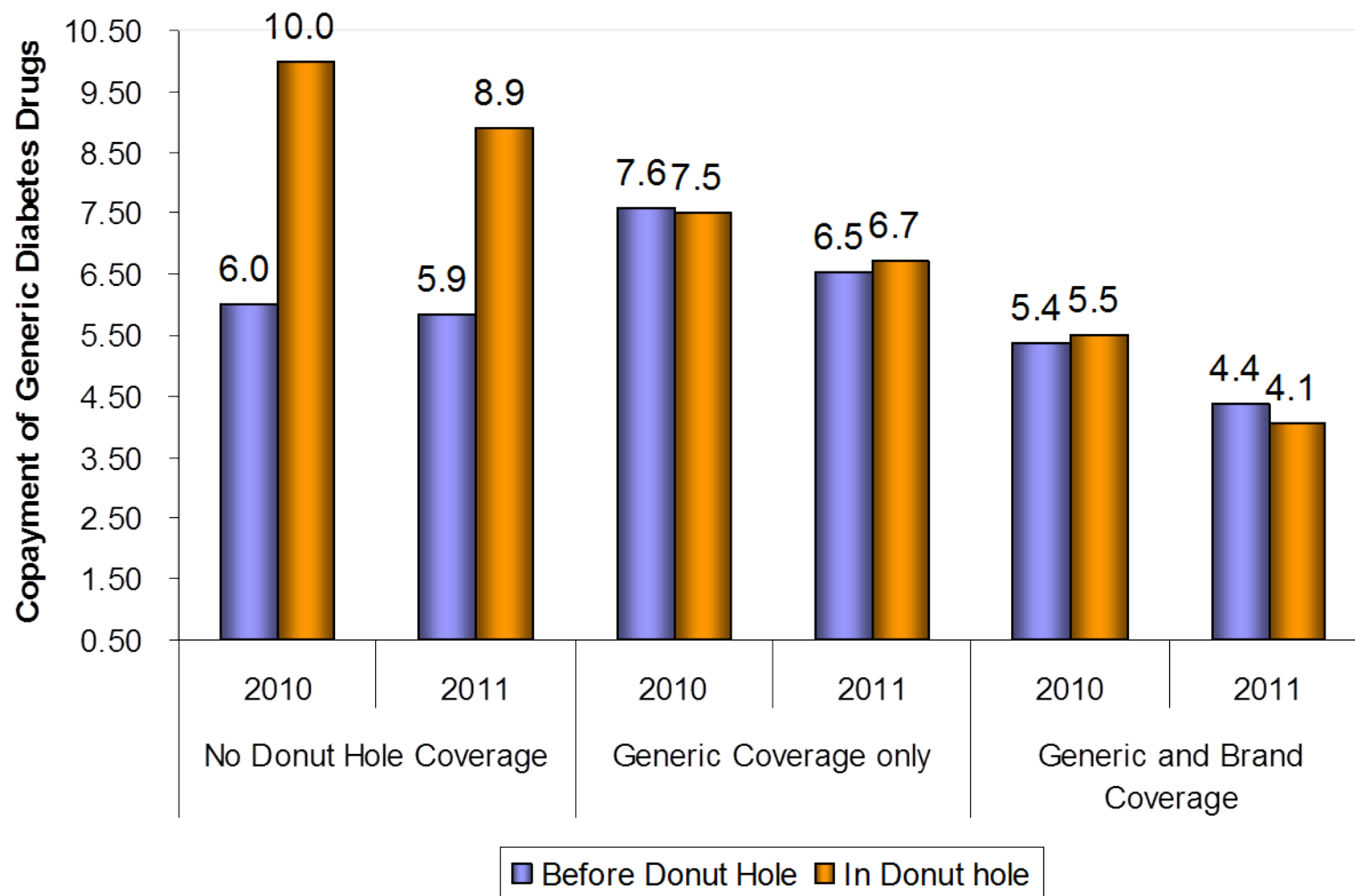
Most Patients Had Full Coverage in Donut Hole

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No Clear Trend of Patient Characteristics Across Groups

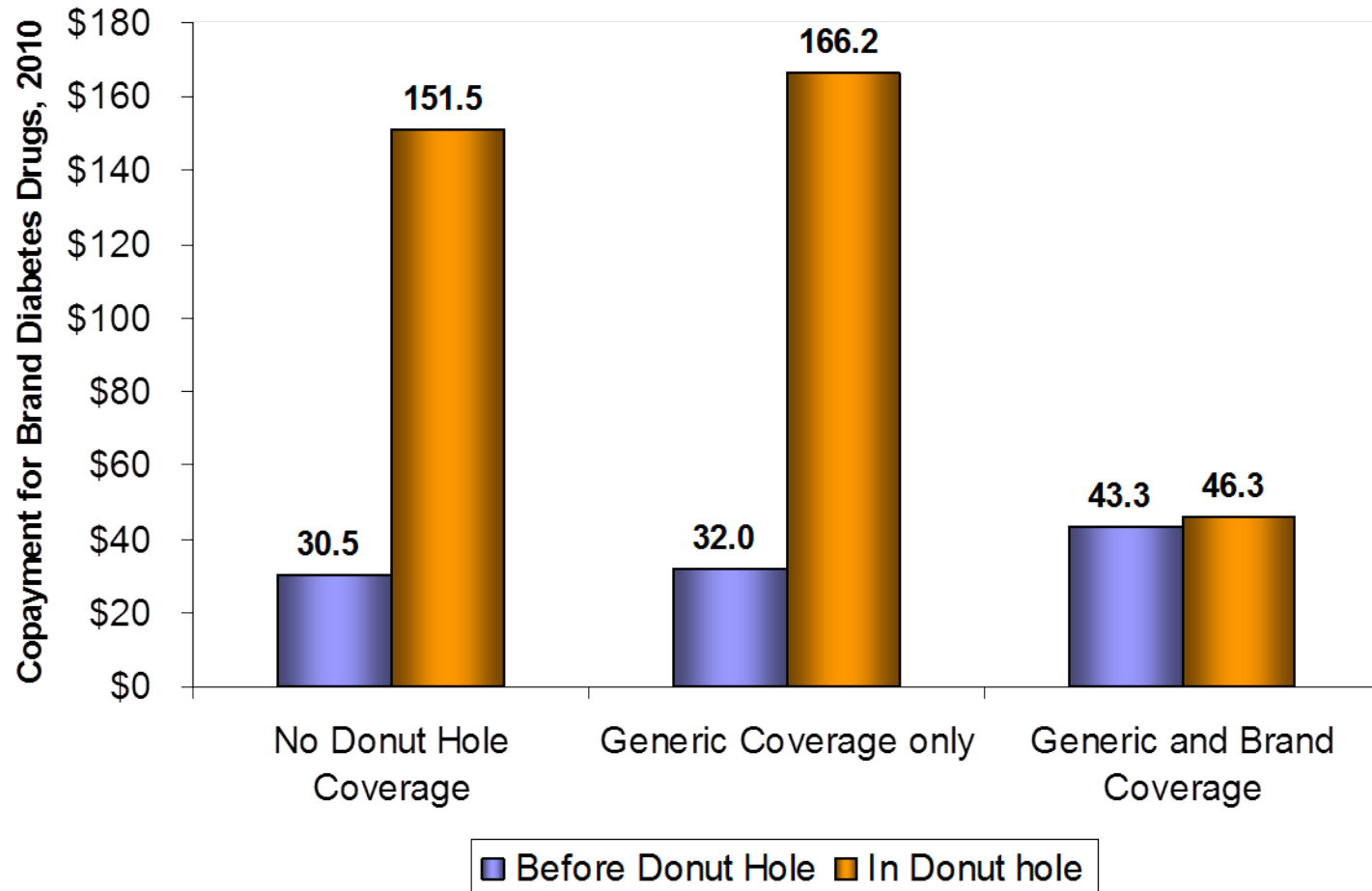| Characteristics	All Patients (N=6,124)	No Donut Hole Coverage (N=1,931)	Generic Drug Coverage Only (N=802)	Generic and Brand Drug Coverage (N=3,391)
Age, Years (SD)	74.13 (6.70)	74.28 (7.14)	73.48 (6.52)	74.21 (6.47)
Days in Donut Hole (SD)	114.52 (62.90)	106.49 (65.03)	137.52 (62.37)	113.65 (60.46)
Male, %	49	48	51	50
Ever Used Insulin in 2010,%	44	50	52	39

Impact of Donut Hole on Generic Diabetes Drugs, 2010
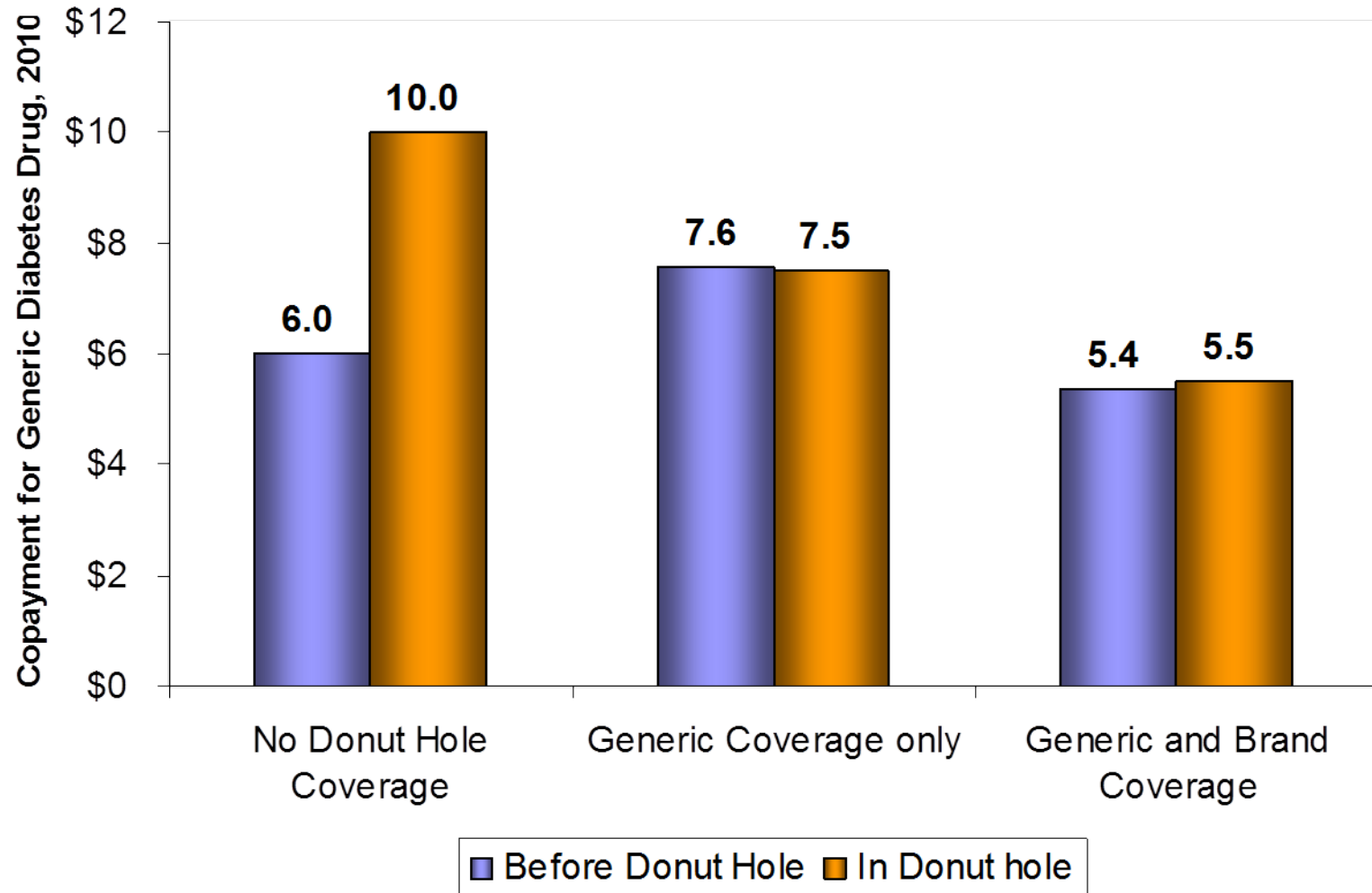
Generic Drug Cost Sharing Decreases for Patients Without Coverage in Donut Hole

Chart: Copayment of Generic Diabetes Drugs comparing "Before Donut Hole" (purple) and "In Donut hole" (orange)

No Donut Hole Coverage
- 2010: Before Donut Hole 6.0, In Donut hole 10.0
- 2011: Before Donut Hole 5.9, In Donut hole 8.9

Generic Coverage only
- 2010: Before Donut Hole 7.6, In Donut hole 7.5
- 2011: Before Donut Hole 6.5, In Donut hole 6.7

Generic and Brand Coverage
- 2010: Before Donut Hole 5.4, In Donut hole 5.5
- 2011: Before Donut Hole 4.4, In Donut hole 4.1

Legend: ■ Before Donut Hole ■ In Donut hole

Comparison of Brand Drug Cost Sharing Before and In Coverage Gap, 2010

Bar chart — Copayment for Brand Diabetes Drugs, 2010 (y-axis $0 to $180):

Category	Before Donut Hole	In Donut hole
No Donut Hole Coverage	30.5	151.5
Generic Coverage only	32.0	166.2
Generic and Brand Coverage	43.3	46.3

Legend: ■ Before Donut Hole ■ In Donut hole

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Substantial Cost Sharing Decrease for Brand-Name Diabetes Drugs in 2011 in Coverage Gap

Chart: Copayment of Brand Diabetes Drug

- No Donut Hole Coverage
  - 2010: Before Donut Hole 30.5; In Donut hole 151.5
  - 2011: Before Donut Hole 32.3; In Donut hole 93.8
- Generic Coverage only
  - 2010: Before Donut Hole 32.0; In Donut hole 166.2
  - 2011: Before Donut Hole 21.3; In Donut hole 71.7
- Generic and Brand Coverage
  - 2010: Before Donut Hole 43.3; In Donut hole 46.3
  - 2011: Before Donut Hole 50.8; In Donut hole 33.4

Legend: ■ Before Donut Hole ■ In Donut hole

Donut Hole Had a Large Impact on Adherence in 2010
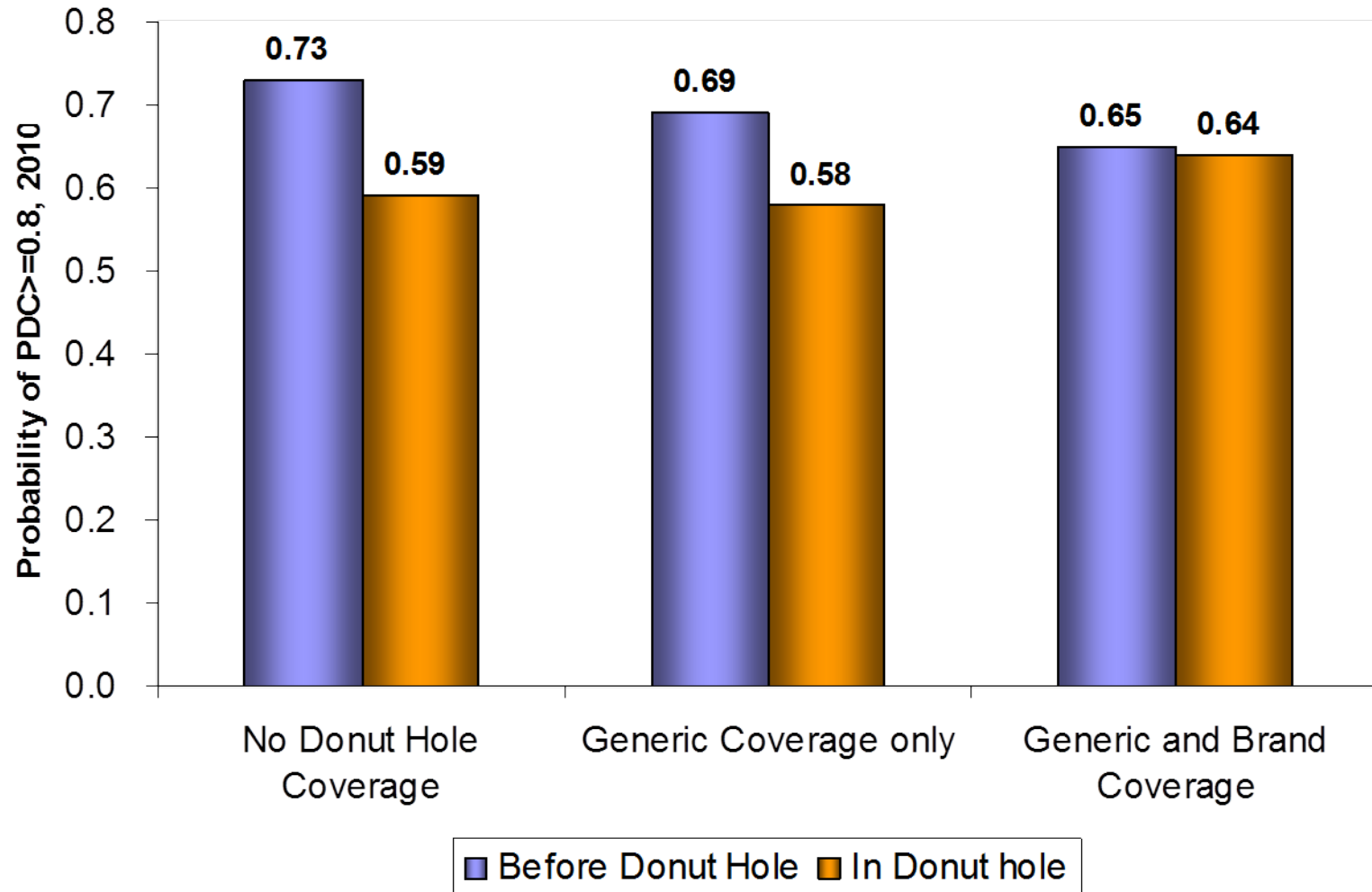
Noticeable Increase in Adherence Donut Hole in 2011
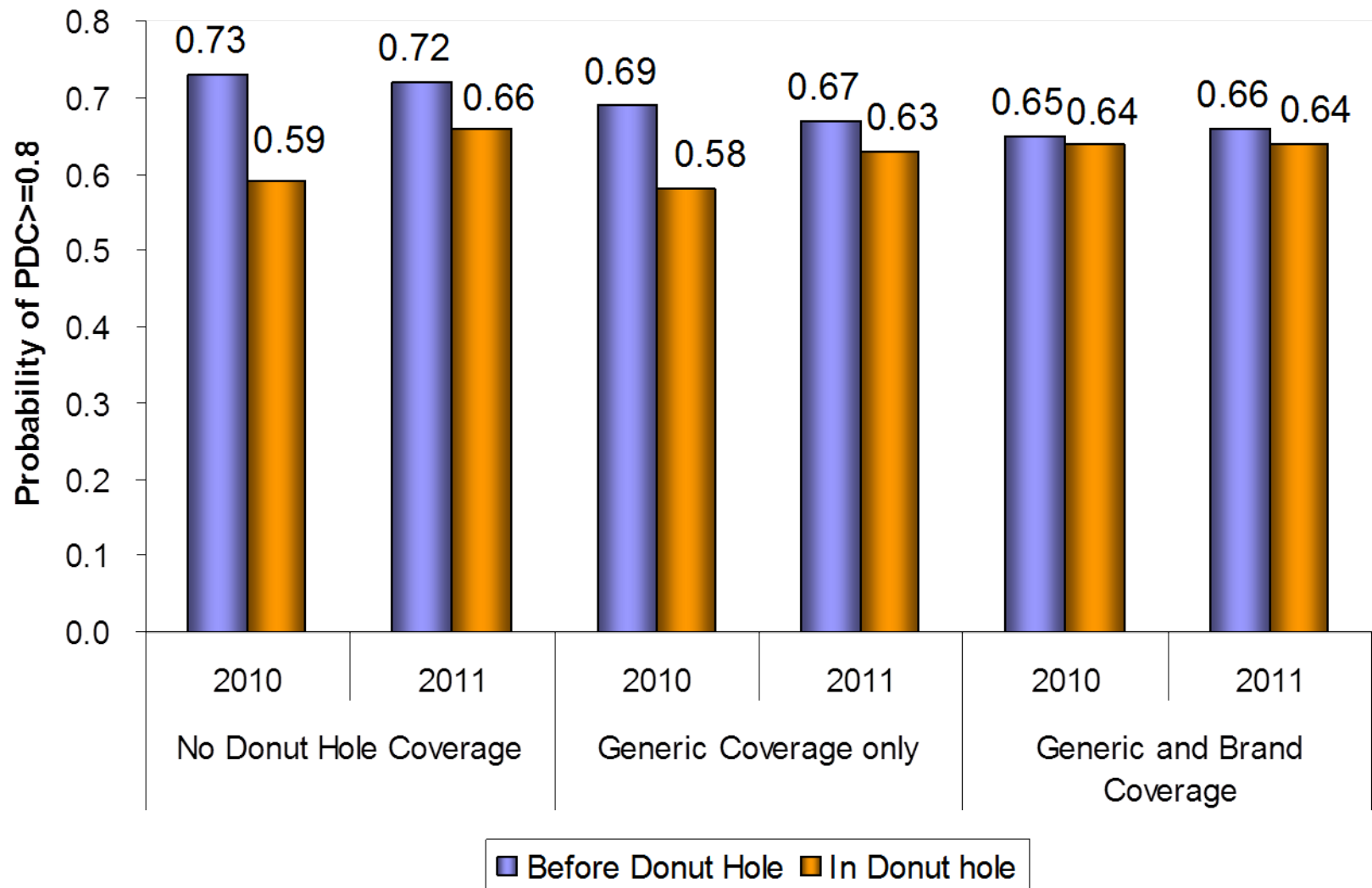
Multivariate Model Results

Donut Hole Had A Negative Impact on Adherence

Regression on Probability Adherence >=0.8

	Odds Ratio	95% Confidence Interval		P Value
		Lower Bound	Upper Bound	
No Coverage Group in Coverage Gap (β_5)	0.58	0.51	0.66	<.0001
Generic Coverage Group in Coverage Gap (β_6)	0.68	0.58	0.80	<.0001

Reform in 2011 Increased Adherence in Donut Hole Significantly

Regression on Probability Adherence >=0.8

	Odds Ratio	95% Confidence Interval		P Value
		Lower Bound	Upper Bound	
Coverage Gap Effect in 2011 (β_7)	1.01	0.91	1.11	0.9099
No Coverage Group in Coverage Gap in 2011 (β_8)	1.30	1.14	1.49	<.0001
Generic Coverage Group in Coverage Gap in 2011 (β_9)	1.24	1.03	1.50	0.0231

Robustness Analysis: Patients Without Using Insulin

	Outcome Variable: PDC>=0.8	
	Odds Ratio	P Value
No Coverage Group in Coverage Gap	0.58	<.0001
Generic Coverage Group in Coverage Gap	0.70	0.0012
Coverage Gap in 2011	0.98	0.7704
No Coverage Group in Coverage Gap in 2011	1.44	0.0005
Generic Coverage Group in Coverage Gap in 2011	1.36	0.031

Improvement in Whole Year Adherence to Diabetes
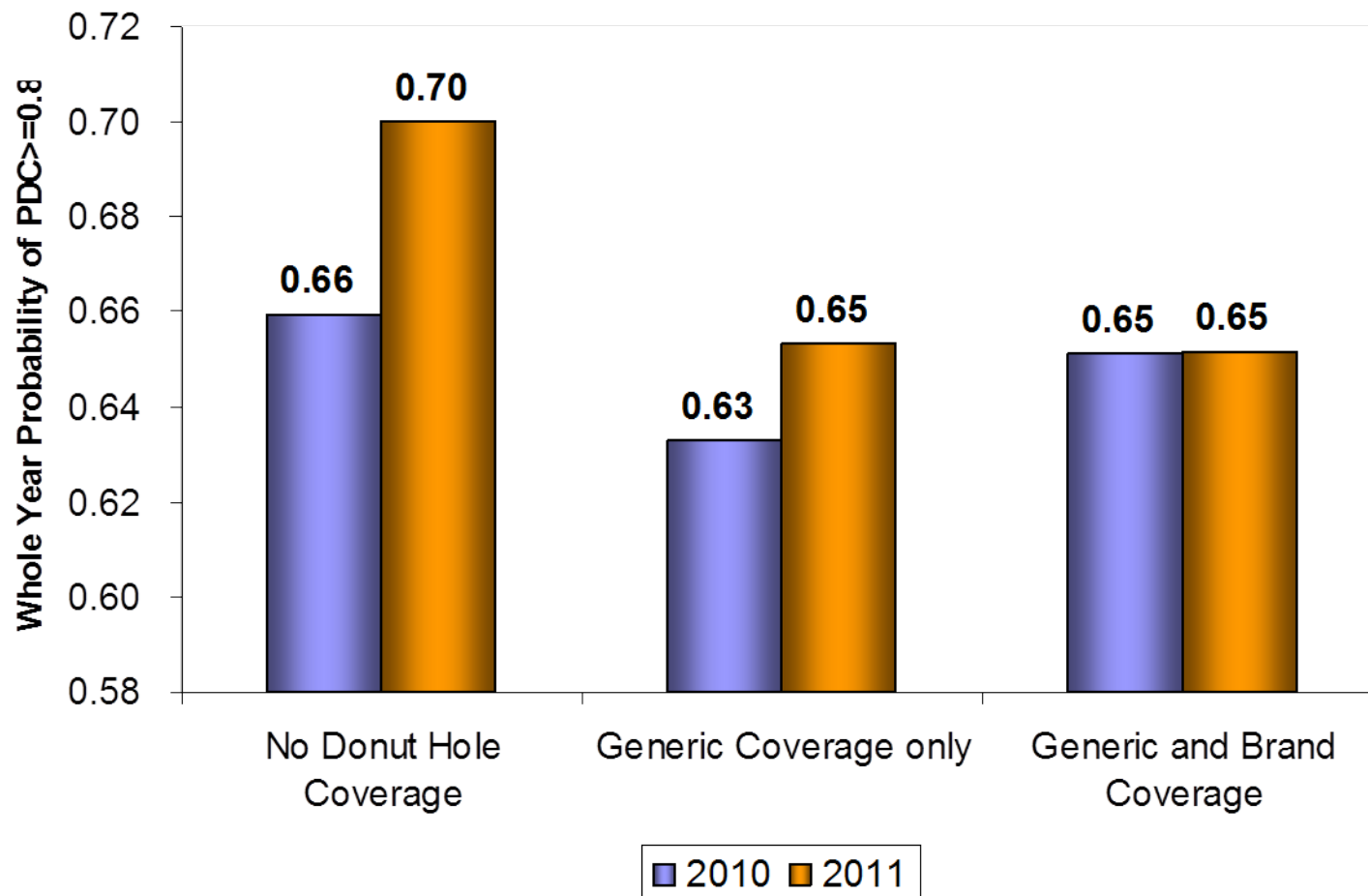
Conclusion

- Coverage gap has negative impact on adherence to diabetes drugs

- Brand-name drug coverage is important for patients with diabetes

- Coverage gap reform in 2011 decreases copayments for patients with diabetes dramatically

- Coverage gap reform improved adherence to diabetes drugs for no coverage and generic coverage patients substantially

Assessments

Assessment Question 1

What is the percentage of discount for brand name medications in coverage gap in 2011?

1/A 20%

2/B 40%

3/C 50%

4/D 70%

Assessment Question 2

In the presented research, which group of patients had improved adherence to diabetes medications in the coverage gap in 2011?

1/A Both patients with no coverage and patients with generic drug coverage

2/B Patients with no coverage only

3/C Patients with generic drug coverage only

4/D Neither group

Questions?

Contact Information

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