ORIGINAL ARTICLE

Effects of Medicare Part D Coverage Gap on Medication and Medical Treatment Among Elderly Beneficiaries With Depression

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Context: Maintenance antidepressant pharmacotherapy in late life prevents recurrent episodes of major depression. The coverage gap in Medicare Part D could increase the likelihood of reducing appropriate use of antidepressants, thereby exposing older adults to an increased risk for relapse of depressive episodes.

Objectives: To determine whether (1) beneficiaries reduce antidepressant use in the gap, (2) the reduction in antidepressant use is similar to the reduction in heart failure medications and antidiabetics, (3) the provision of generic coverage reduces the risk of reduction of medication use, and (4) medical spending increases in the gap.

Design: Observational before-after study with a comparison group design.

Setting and Patients: A 5% random sample of US Medicare beneficiaries 65 years or older with depression (n = 65 223) enrolled in stand-alone Part D plans in 2007.

Main Outcome Measures: Antidepressant pharmacotherapy, physician, outpatient, and inpatient spending.

Results: Being in the gap was associated with comparable reductions in the use of antidepressants, heart failure medications, and antidiabetics. Relative to the comparison group (those who had full coverage in the gap because of Medicare coverage or low-income subsidies), the no-coverage group reduced their monthly antidepressant prescriptions by 12.1% (95% CI, 9.9%-14.3%) from the pregap level, whereas they reduced use of heart failure drugs and antidiabetics by 12.9% and 13.4%, respectively. Those with generic drug coverage in the gap reduced their monthly antidepressant prescriptions by 6.9% (95% CI, 4.8%-9.1%); this decrease was entirely attributable to the reduction in the use of brand-name antidepressants. Medicare spending on medical care did not increase for either group relative to the comparison group.

Conclusions: The Medicare Part D coverage gap was associated with modest reductions in the use of antidepressants. Those with generic coverage reduced their use of brand-name drugs and did not switch from brand-name to generic drugs. The reduction in antidepressant use was not associated with an increase in nondrug medical spending.

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DEPRESSION AFFECTS 13% of Medicare beneficiaries 65 years or older, many of whom have coexisting chronic physical conditions.[1] Maintenance treatment of late-life depression with antidepressants has been shown to prevent recurrent episodes of major depression.[2] Thus, experts recommend 2 years of maintenance antidepressant pharmacotherapy to reduce recurrences, even for patients whose index episodes represent their first lifetime bout of major depression.[2,3] Because depression is highly prevalent and costly and because a large potential for quality improvement exists, the National Quality Forum has argued that the Centers for Medicare & Medicaid Services (CMS) should give improvement in the quality of depression care its highest priority.[4]

Medicare Part D, implemented in 2006, provides prescription drug coverage to Medicare beneficiaries. Since the implementation of Part D, medication treatment for beneficiaries with depression has improved.[5] However, the structure of the Part D benefit, particularly the coverage gap, imposes a serious risk for discontinuing maintenance antidepressant pharmacotherapy among senior beneficiaries.[6] For example, the standard Part D benefit in 2007 included an initial $265 deductible, an insured period during which the beneficiary paid 25% of drug spending from $265 and $2400, a coverage gap in which

the beneficiary paid 100% of spending until his or her total out-of-pocket spending reached a catastrophic limit of $3850, and a catastrophic coverage period in which the beneficiary paid 5%.[7]

A few recent studies have investigated the effects of the coverage gap on medication use, but these studies used pharmacy data from 1 local Medicare-Advantage Part D plan or focused on beneficiaries with diabetes.[8-11] No study has reported on how the coverage gap affects medication use among aged beneficiaries with depression nationally.

In this article, we examine how aged beneficiaries with major depression responded to the coverage gap and specifically whether they reduced antidepressant use more than their use of nonpsychotropic drugs, such as heart failure medications and oral antidiabetics. In addition, we examine whether the provision of some generic coverage in the gap protected them from the risks of reducing or discontinuing their antidepressant pharmacotherapy. Finally, we determine whether nondrug medical spending increased in the coverage gap if beneficiaries decreased their use of medications.

Under the current provisions of the Affordable Care Act, the coverage gap will not be closed until 2020; thus, it is very important to analyze the effect of the gap on medication use, especially on maintenance pharmacotherapy for those with major depression.

METHODS

DATA SOURCE

We obtained data for a 5% random sample of Medicare beneficiaries who were continuously enrolled in stand-alone Part D plans in 2007. These beneficiaries were all enrolled in fee-for-service plans. We identified our study population as those 65 years or older who were diagnosed as having depression in 2007. The study design was approved by the institutional review board at the University of Pittsburgh.

We identified beneficiaries with depression using the CMS Chronic Condition Data Warehouse definition as a single claim from January 1 through December 31, 2007, with a code of 296.2 through 296.6, 296.89, 298.0, 300.4, 309.1, or 311 from the *International Classification of Diseases, Ninth Revision*.[1] From this population, we then excluded those with a 2007 diagnosis of bipolar disorder or schizophrenia because the medication regimens for depression for these groups often differ from those for people living with nonbipolar, nonpsychotic major depression.[3]

SETTING AND STUDY POPULATION

Although the standard Part D benefit design has a coverage gap, some beneficiaries have some or full drug coverage in that gap.[12] First, companies can modify the benefit design if their plans offer actuarially equivalent or enhanced benefits compared with the standard benefit. For example, many plans eliminate deductibles, others cover some generic drugs or generic and brand-name drugs in the coverage gap, and a few offer slightly modified thresholds for entering the coverage gap or catastrophic coverage periods.[13] Second, some beneficiaries receive subsidies for their medication use from federal and state governments.[14] These beneficiaries have Medicaid coverage or Part D low-income subsidies (LIS) and therefore are not exposed to the coverage gap even when their pharmacy spending reaches the coverage-gap threshold.[14]

Thus, based on the types of coverage before and after the coverage gap threshold, we identified 2 study groups—a no-coverage group and a generic-only coverage group—and 1 comparison group. The no-coverage group included those who had no coverage in the coverage gap, whereas the generic-only group included those with plans covering the generic drugs in the coverage gap. The comparison group consisted of beneficiaries whose coverage did not change before or after the coverage-gap threshold because they had Medicaid coverage or LIS for 12 months. We used the LIS group as a comparison group because its drug coverage remained unchanged, whereas beneficiaries in the other 2 groups had a sudden decrease in drug coverage. We used the comparison group to control for underlying trends in use. A small number (n=559) of beneficiaries were enrolled in plans with generic and brand-name drug coverage, but there were too few to draw any meaningful conclusions. Thus, we did not include them in the analyses.

STUDY DESIGN

We used a before-after design with a comparison group to assess the effect of the coverage gap on use of medication and medical care. This design relies on a difference-in-difference estimate; that is, it compares the pregap and within-gap change for each study group, relative to the pregap and within-gap change in the comparison group. This design does not require that the study and comparison groups have the same baseline characteristics because it can adjust for unobserved factors if these factors did not change in the pregap and within-gap periods.[15] When different groups have similar baseline trends, the results can be unbiased.[15] We tested the baseline trends in antidepressant use and overall medication use across 3 groups and found no statistically significant difference between each group comparison (data not shown).

We did not hypothesize that beneficiaries who went through the coverage gap and entered the catastrophic coverage period would reduce their medication use in the gap.[6] We conducted a regression analysis to test this hypothesis, and the result indicated that beneficiaries entering the catastrophic period did not change their medication use in the gap. Thus, for this study, we focused on beneficiaries who entered the gap but did not go through it (this represented 79.4% of all beneficiaries with depression who entered the coverage gap and 34.4% of all beneficiaries with depression). Thus, each individual in our study sample had a pregap period and a within-gap period.

To define the pregap and within-gap periods, we identified the index date as the first day that the beneficiary's total drug spending reached the coverage-gap threshold. The pregap period was defined as January 1, 2007, to the index date. The within-gap period was defined as the duration from the first day after the index date until December 31, 2007. We then calculated each outcome separately for the pregap and within-gap periods.

We compared the change in each outcome in the pregap and within-gap periods between each study group and the comparison group as no coverage vs LIS and generic coverage only vs LIS. We then used the propensity score weighting mechanism to balance each study group with the comparison group.

OUTCOMES

We defined the following 3 main outcome variables to measure medication use in the pregap and within-gap periods:

Table 1. Characteristics of Elderly Beneficiaries With Depression Who Entered the Coverage Gap but Did Not Go Through It in 2007 After Propensity Score Weighting[a]

	Group Comparison					
	No Coverage vs LIS			Generic Only vs LIS		
Variable	No Coverage (n = 7650)	LIS (n = 11 537)	*P* Value	Generic Only (n = 2989)	LIS (n = 11 537)	*P* Value
Female sex	78.6	78.4	.57	79.7	79.7	>.99
Race[b]						
Non-Hispanic white	82.1	82.4	.43	78.9	78.5	.32
African American	6.7	6.6	.48	7.6	8.0	.17
Hispanic	8.0	8.3	.43	10.2	10.2	.94
Asian	1.7	1.7	.78	1.9	2.1	.26
Age						
65-74 y	35.8	36.6	.12	37.8	37.7	.82
75-84 y	37.6	37.5	.88	35.2	35.9	.19
≥85 y	26.6	25.9	.12	27.0	26.4	.24
Prescription drug risk score, mean (SE)	1.09 (0)	1.10 (0)	.17	1.10 (0.01)	1.10 (0)	.99
CMS-HCC risk, mean (SE)	1.49 (0.01)	1.51 (0.01)	.22	1.50 (0.02)	1.51 (0.01)	.67
No. of Elixhauser comorbidities, mean (SE)	4.49 (0.03)	4.56 (0.03)	.08	4.58 (0.05)	4.62 (0.03)	.53
Time spent in the coverage gap, d						
Mean (SE)	115 (0.7)	128 (0.6)	<.001	137 (1.3)	129 (0.6)	<.001
25th Percentile	61	77		80	79	
Median	115	132		140	132	
75th Percentile	165	178		192	178	
Diagnosed chronic conditions						
Hypertension	60.7	61.6	.06	59.8	61.9	<.001
Hyperlipidemia	35.8	27.6	<.001	34.0	27.7	<.001
AMI	2.0	1.7	.05	1.2	1.8	<.001
COPD	20.7	24.6	<.001	20.3	24.8	<.001
Heart failure	32.2	36.6	<.001	32.9	37.6	<.001
Diabetes mellitus	31.2	39.3	<.001	36.8	40.2	<.001
RA/OA	38.3	41.5	<.001	37.7	42.1	<.001

Abbreviations: AMI, acute myocardial infarction; CMS-HCC, Centers for Medicare & Medicaid Services Hierarchical Condition Category; COPD, chronic obstructive pulmonary disease; LIS, low-income subsidies; RA/OA, rheumatoid arthritis/osteoarthritis.

[a] All data were adjusted using inverse propensity score weights. Propensity scores were calculated using logistic regression models that predict the probability of being in a study group relative to the comparison group, controlling for age, sex, race, number of comorbidities (using the comorbidity measures of Elixhauser et al[16]), and prescription drug hierarchical condition. Unless otherwise indicated, data are expressed as percentage of patients.

[b] Race categories do not total 100% because we did not report Native Americans, other, or unknown races.

(1) the probability of using any medication (1 indicates use and 0, nonuse), (2) the mean number of monthly prescriptions filled per month, and (3) the mean monthly pharmacy spending. For the second outcome, we calculated the number of prescriptions filled, standardized by a 30-day supply (ie, a prescription with a 90-day supply would count as 3 monthly drugs), in the pregap and within-gap periods and then divided them by the number of months in each period to get the mean number of monthly prescriptions filled. We examined the use of antidepressants and the use of heart failure drugs and oral antidiabetics (drug classes are listed in the eTable; http://www.archgenpsychiatry.com).

We defined physician spending, outpatient spending, and inpatient spending to measure nondrug medical spending in the pregap and within-gap periods. We followed the formula provided by the Research Data Assistance Center contracted by CMS. Physician spending was calculated using the Medicare carrier file (claims data submitted by noninstitutional providers, including physicians, physician assistants, clinical social workers, nurse practitioners, independent clinical laboratories, ambulance providers, and free-standing ambulatory surgical centers). Outpatient spending was calculated using the outpatient claim file (claims data submitted by institutional outpatient providers, including hospital outpatient departments, rural health clinics, renal dialysis facilities, outpatient rehabilitation facilities, comprehensive outpatient rehabilitation facilities, and community mental health centers). Inpatient spending only included spending for inpatient hospital services in the Medicare Provider and Analysis Review file (algorithms are available from the authors on request).

STATISTICAL ANALYSIS

To implement propensity score weighting, we conducted a 2-stage analysis. In the first stage, we ran 2 logistic regression models to predict the probability of being in a study group relative to the comparison group, controlling for age, sex, race, number of comorbidities using the comorbidity measures of Elixhauser et al,[16] and prescription drug hierarchical condition category (measured by RxHCC software).[17] The RxHCC software is the beneficiary risk adjuster used by CMS to adjust payment to plans for expected pharmacy costs.

In the second stage, we conducted a difference-in-difference model with the inverse of the propensity score as a weight.[18] This method effectively assigned a higher weight to individuals in the comparison group with characteristics similar to those in the study group. In this model, the dependent variable was the difference between the within-gap and pregap periods for each previously defined outcome. Because

Table 2. Effect of the Coverage Gap on Antidepressant, Heart Failure Medication, and Oral Antidiabetic Use Among Elderly Beneficiaries Diagnosed as Having Depression in 2007

Drug Covered	Coverage Group	Unadjusted Data[a]		Coverage Gap Effect, Estimate (95% CI)[b]	Change, % (95% CI)[c]
		Pregap	Within-Gap		
Probability of Using an Antidepressant					
All	No coverage	0.81	0.63	−0.05 (−0.06 to −0.03)	−5.6 (−7.1 to −4.1)
	Generic only	0.83	0.72	−0.03 (−0.05 to −0.02)	−4.1 (−5.6 to −2.5)
	LIS	0.80	0.70	1.00 [Reference]	1.0 [Reference]
Brand-name	No coverage	0.40	0.27	−0.06 (−0.07 to −0.05)	−14.2 (−16.9 to −11.6)
	Generic only	0.37	0.27	−0.04 (−0.05 to −0.03)	−11.0 (−14.1 to −7.8)
	LIS	0.30	0.24	1.00 [Reference]	1.0 [Reference]
Generics	No coverage	0.56	0.43	0.00 (−0.02 to 0.01)	−0.9 (−3.0 to 1.3)
	Generic only	0.62	0.55	−0.01 (−0.02 to 0.01)	−1.3 (−3.4 to 0.8)
	LIS	0.62	0.53	1.00 [Reference]	1.0 [Reference]
No. of Monthly Prescriptions for Antidepressants					
All	No coverage	0.75	0.57	−0.09 (−0.11 to −0.07)	−12.1 (−14.3 to −9.9)
	Generic only	0.86	0.71	−0.06 (−0.08 to −0.04)	−6.9 (−9.1 to −4.8)
	LIS	0.78	0.70	1.00 [Reference]	1.0 [Reference]
Brand-name	No coverage	0.29	0.19	−0.07 (−0.08 to −0.06)	−23.6 (−26.9 to −20.3)
	Generic only	0.29	0.19	−0.06 (−0.07 to −0.05)	−20.3 (−24.0 to −16.7)
	LIS	0.22	0.19	1.00 [Reference]	1.0 [Reference]
Generics	No coverage	0.46	0.38	−0.02 (−0.04 to −0.01)	−4.9 (−8.0 to −1.8)
	Generic only	0.58	0.52	0.00 (−0.02 to 0.02)	−0.1 (−2.9 to 2.7)
	LIS	0.56	0.51	1.00 [Reference]	1.0 [Reference]
Monthly Pharmacy Spending for Antidepressants					
All	No coverage	40	26	−8.29 (−9.38 to −7.21)	−20.8 (−23.5 to −18.0)
	Generic only	44	31	−6.63 (−7.83 to −5.43)	−15.0 (−17.8 to −12.3)
	LIS	35	30	1.00 [Reference]	1.0 [Reference]
Brand-name	No coverage	30	19	−7.98 (−9.02 to −6.95)	−27.0 (−30.5 to −23.5)
	Generic only	30	19	−7.05 (−8.22 to −5.88)	−23.4 (−27.3 to −19.5)
	LIS	21	19	1.00 [Reference]	1.0 [Reference]
Generics	No coverage	10	7	−0.31 (−0.76 to 0.14)	−3.0 (−7.3 to 1.3)
	Generic only	14	11	0.42 (−0.15 to 0.99)	3.0 (−1.1 to 7.1)
	LIS	14	11	1.00 [Reference]	1.0 [Reference]
Probability of Using a Heart Failure Medication					
All	No coverage	0.88	0.72	−0.05 (−0.05 to −0.04)	−5.2 (−6.2 to −4.2)
	Generic only	0.91	0.80	−0.04 (−0.05 to −0.03)	−4.6 (−5.7 to −3.6)
	LIS	0.90	0.82	1.00 [Reference]	1.0 [Reference]
Brand-name	No coverage	0.65	0.40	−0.05 (−0.07 to −0.04)	−8.2 (−10.1 to −6.3)
	Generic only	0.66	0.45	−0.06 (−0.08 to −0.05)	−9.7 (−11.8 to −7.6)
	LIS	0.60	0.42	1.00 [Reference]	1.0 [Reference]
Generics	No coverage	0.75	0.64	−0.02 (−0.03 to −0.01)	−2.3 (−3.7 to −1.0)
	Generic only	0.79	0.73	−0.02 (−0.03 to −0.01)	−2.2 (−3.6 to −0.7)
	LIS	0.81	0.75	1.00 [Reference]	1.0 [Reference]
No. of Monthly Prescriptions for Heart Failure Medications					
All	No coverage	1.79	1.33	−0.23 (−0.26 to −0.20)	−12.9 (−14.7 to −11.2)
	Generic only	2.04	1.63	−0.18 (−0.21 to −0.14)	−8.7 (−10.4 to −7.0)
	LIS	1.90	1.66	1.00 [Reference]	1.0 [Reference]
Brand-name	No coverage	0.71	0.36	−0.15 (−0.17 to −0.13)	−21.1 (−23.4 to −18.7)
	Generic only	0.78	0.40	−0.14 (−0.16 to −0.13)	−18.6 (−21.1 to −16.2)
	LIS	0.61	0.39	1.00 [Reference]	1.0 [Reference]
Generics	No coverage	1.08	0.97	−0.08 (−0.11 to −0.06)	−7.6 (−10.0 to −5.1)
	Generic only	1.27	1.23	−0.03 (−0.06 to 0.00)	−2.6 (−4.9 to −0.2)
	LIS	1.29	1.27	1.00 [Reference]	1.0 [Reference]

(continued)

the pregap and within-gap measures were likely to be correlated, the advantage of this approach was, rather than using 2 interrelated outcomes, one could simply eliminate the correlated structure in the 2 outcomes. The key independent variable was the indicator for being in the study group relative to the comparison group. All the covariates used in calculating propensity scores were included in this model. In addition, we controlled for the duration of time spent in the coverage gap in the model because the longer the beneficiary stayed in the gap, the more likely he or she would change medication use.

We conducted a sensitivity analysis by excluding beneficiaries who had at least 1 nursing home stay funded by Medicare, and the results remained similar (data not shown). All analyses were conducted using commercially available statistical software (SAS, version 9.2 [SAS Institute, Inc] and R:

Table 2. Effect of the Coverage Gap on Antidepressant, Heart Failure Medication, and Oral Antidiabetic Use Among Elderly Beneficiaries Diagnosed as Having Depression in 2007 (continued)

Drug Covered	Coverage Group	Unadjusted Data[a]		Coverage Gap Effect, Estimate (95% CI)[b]	Change, % (95% CI)[c]
		Pregap	Within-Gap		
Monthly Pharmacy Spending for Heart Failure Medications					
All	No coverage	65	40	–12.10 (–13.38 to –10.82)	–18.7 (–20.7 to –16.7)
	Generic only	72	47	–11.39 (–12.86 to –9.92)	–15.8 (–17.8 to –13.7)
	LIS	62	49	1.00 [Reference]	1.0 [Reference]
Brand-name	No coverage	49	25	–10.44 (–11.64 to –9.25)	–21.5 (–24.0 to –19.1)
	Generic only	53	27	–10.26 (–11.64 to –8.88)	–19.5 (–22.1 to –16.9)
	LIS	43	28	1.00 [Reference]	1.0 [Reference]
Generics	No coverage	16	15	–1.66 (–2.23 to –1.08)	–10.3 (–13.9 to –6.7)
	Generic only	20	20	–1.13 (–1.81 to –0.45)	–5.8 (–9.3 to –2.3)
	LIS	20	21	1.00 [Reference]	1.0 [Reference]
Probability of Using an Oral Antidiabetic					
All	No coverage	0.15	0.12	–0.01 (–0.02 to –0.01)	–8.7 (–12.4 to –4.9)
	Generic only	0.20	0.17	–0.02 (–0.03 to –0.02)	–11.0 (–14.5 to –7.5)
	LIS	0.22	0.19	1.00 [Reference]	1.0 [Reference]
Brand-name	No coverage	0.06	0.04	–0.01 (–0.01 to 0.00)	–14.3 (–22.1 to –6.6)
	Generic only	0.08	0.05	–0.01 (–0.01 to 0.00)	–7.4 (–14.7 to –0.1)
	LIS	0.09	0.06	1.00 [Reference]	1.0 [Reference]
Generics	No coverage	0.13	0.10	–0.01 (–0.01 to 0.00)	–5.6 (–10.1 to –1.1)
	Generic only	0.18	0.15	–0.01 (–0.02 to –0.01)	–8.4 (–12.5 to –4.4)
	LIS	0.19	0.17	1.00 [Reference]	1.0 [Reference]
No. of Monthly Prescriptions for Oral Antidiabetics					
All	No coverage	0.17	0.12	–0.02 (–0.03 to –0.01)	–13.4 (–18.6 to –8.2)
	Generic only	0.25	0.19	–0.03 (–0.04 to –0.01)	–10.3 (–14.6 to –6.0)
	LIS	0.25	0.21	1.00 [Reference]	1.0 [Reference]
Brand-name	No coverage	0.05	0.02	–0.01 (–0.02 to –0.01)	–24.6 (–33.8 to –15.4)
	Generic only	0.06	0.03	–0.01 (–0.02 to –0.01)	–17.5 (–26.1 to –8.9)
	LIS	0.07	0.04	1.00 [Reference]	1.0 [Reference]
Generics	No coverage	0.12	0.10	–0.01 (–0.02 to 0.00)	–8.9 (–15.1 to –2.7)
	Generic only	0.18	0.16	–0.01 (–0.02 to –0.01)	–7.9 (–12.8 to –3.0)
	LIS	0.19	0.17	1.00 [Reference]	1.0 [Reference]
Monthly Pharmacy Spending for Oral Antidiabetics					
All	No coverage	8	5	–1.62 (–2.28 to –0.97)	–19.4 (–27.1 to –11.6)
	Generic only	11	7	–2.05 (–2.85 to –1.25)	–18.1 (–25.1 to –11.0)
	LIS	12	9	1.00 [Reference]	1.0 [Reference]
Brand-name	No coverage	7	4	–1.47 (–2.10 to –0.83)	–22.0 (–31.5 to –12.5)
	Generic only	9	4	–1.72 (–2.49 to –0.94)	–19.6 (–28.4 to –10.8)
	LIS	9	6	1.00 [Reference]	1.0 [Reference]
Generics	No coverage	2	1	–0.16 (–0.29 to –0.03)	–9.2 (–16.5 to –1.9)
	Generic only	3	2	–0.33 (–0.48 to –0.18)	–12.8 (–18.5 to –7.2)
	LIS	3	2	1.00 [Reference]	1.0 [Reference]

Abbreviation: LIS, low-income subsidies.
[a] Indicates average numbers in the pregap and within-gap periods (unadjusted raw data).
[b] Indicates adjusted estimates from the difference-in-difference model with the inverse of propensity score as a weight. The estimates measure changes in outcomes between within-gap and pregap periods in each study group, relative to the changes in outcomes in the comparison group (reference).
[c] Calculated as the difference-in-difference coverage gap effect divided by the pregap value.

A Language and Environment for Statistical Computing, version 2.12 [http://www.r-project.org/]).

RESULTS

CHARACTERISTICS OF THE STUDY POPULATION

Beneficiaries with depression were more likely to spend up to the coverage-gap threshold as their drug coverage improved. For example, among seniors with depression, 43.1% in the no-coverage group, 69.2% in the generic-only group, and 72.2% in the LIS group reached the gap threshold ($P < .05$).

Table 1 reports each group's characteristics after the propensity score adjustment. After the adjustment, all characteristics used in calculating propensity scores were comparable ($P > .05$) between each study group and the comparison group. On average, aged beneficiaries with depression have more than 4 other coexisting medical conditions, such as hypertension, heart failure, and diabetes mellitus. In particular, in the study groups, about 60% also had hypertension, more than 32% had heart failure, and 31.2% of the no-coverage group and 36.8% of the generic-only group had diabetes.

Table 3. Effect of the Coverage Gap on Nondrug Medical Use and Spending Among Elderly Beneficiaries Diagnosed as Having Depression in 2007

Service	Coverage Group	Unadjusted Data[a]		Coverage Gap Effect, Estimate (95% CI)[b]	Change, % (95% CI)[c]
		Pregap	Within-Gap		
Probability of Using a Medical Service					
Physician	No coverage	1.00	0.88	0.00 (–0.01 to 0.00)	–0.4 (–1.2 to 0.3)
	Generic only	1.00	0.92	0.00 (–0.01 to 0.00)	–0.4 (–1.2 to 0.5)
	LIS	0.99	0.92	1.00 [Reference]	1.0 [Reference]
Outpatient	No coverage	0.81	0.58	–0.04 (–0.05 to –0.02)	–4.3 (–6.1 to –2.5)
	Generic only	0.80	0.67	–0.02 (–0.04 to 0.00)	–2.6 (–4.6 to –0.5)
	LIS	0.81	0.67	1.00 [Reference]	1.0 [Reference]
Inpatient	No coverage	0.35	0.18	–0.02 (–0.04 to –0.01)	–6.8 (–11.4 to –2.1)
	Generic only	0.35	0.22	–0.04 (–0.06 to –0.02)	–10.9 (–16.3 to –5.6)
	LIS	0.33	0.20	1.00 [Reference]	1.0 [Reference]
Monthly Medical Spending					
Physician	No coverage	431	389	–37.54 (–58.49 to –16.60)	–8.7 (–13.6 to –3.9)
	Generic only	465	426	–29.54 (–51.49 to –7.60)	–6.4 (–11.1 to –1.6)
	LIS	373	368	1.00 [Reference]	1.0 [Reference]
Outpatient	No coverage	174	165	–26.33 (–45.40 to –7.25)	–15.1 (–26.1 to –4.2)
	Generic only	205	205	–13.89 (–35.07 to 7.29)	–6.8 (–17.1 to 3.6)
	LIS	197	203	1.00 [Reference]	1.0 [Reference]
Inpatient	No coverage	665	553	–29.12 (–100.10 to 41.86)	–4.4 (–15.1 to 6.3)
	Generic only	756	616	–83.69 (–167.19 to –0.20)	–11.1 (–22.1 to 0.0)
	LIS	669	600	1.00 [Reference]	1.0 [Reference]

Abbreviation: LIS, low-income subsidies.
[a] Indicates average numbers in the pregap and within-gap periods (unadjusted raw data).
[b] Indicates adjusted estimates from the difference-in-difference model with the inverse of propensity score as a weight. The estimates measure changes in outcomes between within-gap and pregap periods in each study group, relative to the changes in outcomes in the comparison group (reference).
[c] Calculated as the difference-in-difference coverage gap effect divided by the pregap value.

The mean length of time spent in the gap by the no-coverage group was 115 days, which, subtracted from 365, resulted in a pregap duration of 250 days. The mean length of time spent in the gap by the LIS group was 128 days and that by the generic-only group was 137 days.

EFFECTS OF THE COVERAGE GAP ON MEDICATION USE

Table 2 presents the effects of the coverage gap on the use of antidepressants, heart failure medications, and oral antidiabetics, respectively. We estimated these results from the difference-in-difference model with the propensity-score weighting. The 4 main findings follow.

First, in examining the use of all antidepressants, having a gap in drug coverage was associated with a significant reduction in all measures of use in the no-coverage and the generic-only groups. Second, with the exception of the outcome of using any generic medication, those with no coverage reduced their use of medications more than did those with generic-only coverage. For example, the no-coverage group reduced the number of monthly prescriptions for antidepressants by 12.1% (95% CI, 9.9%-14.3%), whereas the generic-only group reduced it by 6.9% (95% CI, 4.8%-9.1%). Third, most of the reduction in antidepressant use came from the reduction in the number of brand-name drugs. Relative to the comparison group, the no-coverage group reduced the average number of monthly prescriptions for antidepressants by 0.09 (95% CI, 0.07-0.11) or by 12.1% (95% CI, 9.9%-12.1%) from the pregap level. About 77% of this reduction (0.07 of 0.09) was attributed to decreased use of brand-name antidepressants and 23% to less generic antidepressant use. The findings for those with generic coverage were more pronounced: About 86% of the reduction in the use of overall antidepressants was attributed to the decreased use of brand-name drugs. Fourth, the pattern of the decrease in the use of heart failure drugs and antidiabetics in the gap was similar to that for the use of antidepressants. Relative to the comparison group, those with no coverage reduced their monthly number of antidepressants used by 12.1% (95% CI, 9.9%-14.3%), whereas they reduced their use of heart failure medications and antidiabetics by 12.9% (95% CI, 11.2%-14.7%) and 13.4% (95% CI, 8.2%-18.6%), respectively.

EFFECTS OF THE COVERAGE GAP ON NONDRUG MEDICAL SPENDING

Table 3 presents results on the effect of the coverage gap on nondrug medical spending broken down by physician, outpatient, and inpatient categories. The discontinuation of drug use in the gap did not lead to an increase in nondrug medical use. The probability of hospitalization was lower in the within-gap period compared with the pregap period in all 3 groups because, on average, the within-gap period was shorter than the pregap period. However, rates of hospitalizations fell more in the no-coverage and generic-only groups, relative to the LIS group. Physician spending also declined in the within-gap period compared with

the pregap period. Thus, after controlling for the comparison group, the gap was not associated with an increase in medical spending.

COMMENT

The major finding in this study is that, when faced with a full gap in drug coverage, beneficiaries with depression reduced antidepressant use by 12.1% per month in the coverage gap, similar to their reduction in the use of heart failure drugs (12.9%) and oral antidiabetics (13.4%). This reduction in use is also similar to the reduction in overall use of drugs found in other studies.[6]

We also found that most of the reduction in drug use came from reduction in the use of brand-name drugs. This result was stronger for those with generic coverage in the gap. Those with generic drug coverage reduced their antidepressant use by 6.9%, entirely attributable to reduction in use of brand-name antidepressants. We found no evidence that those with generic coverage shifted from brand-name to generic drugs in the coverage gap. We also found no evidence of any cost increases in nondrug medical care and spending, in part because of the average short follow-up period between reaching the gap and the start of the next yearly cycle.

Our before-after study design with a comparison group mitigates but might not eliminate the possible effects of selection biases due to unobserved characteristics. This design does not require that baseline characteristics in the comparison group be similar to those of the study group. We further used the propensity score weighting to balance the observed characteristics and the difference-in-difference approach adjusted for unobserved time-unvarying factors between the study and comparison groups.

To our knowledge, ours is the first study to evaluate the impact of the coverage gap using the national Part D data for beneficiaries with depression.[6,10,11,19] Compared with the overall elderly Medicare population, the magnitude of the coverage gap effects among elderly beneficiaries with depression is similar.[6] We did not observe an increase in nondrug medical spending, in part because of the short follow-up period[18]; whether spending would increase in the following year would depend in part on whether spending on drugs rebounds when coverage resumes.

If patients discontinue their appropriate medication therapy abruptly, they could be placing themselves at risk for medication withdrawal effects and for relapse or recurrence.[3] If they do not notice any effects, they might decide not to resume taking antidepressants. Thus, a gap in drug coverage could place older adults in harm's way, as a result of disruptions in appropriate maintenance antidepressant pharmacotherapy.[2,3]

Under the current provisions of the Affordable Care Act, in the next 10 years, beneficiaries still need to pay a substantial amount while in the gap, and they will stay in the gap for a longer period before their cumulative out-of-pocket spending reaches the catastrophic threshold (eg, $4550 in 2010). Facing such high out-of-pocket cost in this period could pose potential harm for beneficiaries, especially those with mental disorders. Our findings reinforce the necessity of evaluating the unique benefit design of Medicare Part D to create the best approach to cover the essential medications for beneficiaries whose total drug spending exceeds the coverage gap threshold.

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Online-Only Material: The eTable is available at http://www.archgenpsychiatry.com.

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