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RESEARCH ARTICLE

Falling into the Coverage Gap: Part D Drug Costs and Adherence for Medicare Advantage Prescription Drug Plan Beneficiaries with Diabetes

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Objective. To compare drug costs and adherence among Medicare beneficiaries with the standard Part D coverage gap versus supplemental gap coverage in 2006.
Data Sources. Pharmacy data from Medicare Advantage Prescription Drug (MAPD) plans.
Study Design. Parallel analyses comparing beneficiaries aged 65+ with diabetes in an integrated MAPD with a gap versus no gap ($n = 28{,}780$); and in a network-model MAPD with a gap versus generic-only coverage during the gap ($n = 14{,}984$).
Principal Findings. Drug spending was 3 percent (95 percent confidence interval [CI]: 1–4 percent) and 4 percent (CI: 1–6 percent) lower among beneficiaries with a gap versus full or generic-only gap coverage, respectively. Out-of-pocket expenditures were 189 percent higher (CI: 185–193 percent) and adherence to three chronic drug classes was lower among those with a gap versus no gap (e.g., odds ratio = 0.83, CI: 0.79–0.88, for oral diabetes drugs). Annual out-of-pocket spending was 14 percent higher (CI: 10–17 percent) for beneficiaries with a gap versus generic-only gap coverage, but levels of adherence were similar.
Conclusions. Among Medicare beneficiaries with diabetes, having the Part D coverage gap resulted in lower total drug costs, but higher out-of-pocket spending and worse adherence compared with having no gap. Having generic-only coverage during the gap appeared to confer limited benefits compared with having no gap coverage.

Key Words. Medicare, prescription drugs, diabetes

Medicare Part D outpatient prescription drug benefits were introduced in 2006 with the goal of improving beneficiary access to prescription drugs. To limit estimated federal program costs, the standard benefit design includes a gap in coverage after drug spending exceeds an annual threshold (U.S.$2,250 in 2006). After entering the gap, beneficiaries pay the full price of all pre-

scriptions until reaching catastrophic coverage. Individual plans, however, could offer Part D plans with more generous coverage including coverage during the standard gap.

Among the 22.5 million beneficiaries enrolled in a Part D plan in 2006, approximately 89 percent enrolled in a plan without gap coverage, with the remainder enrolled in more generous plans with generic-only or generic and brand coverage during the gap (The Kaiser Family Foundation 2007). Beneficiaries also could choose between Medicare Advantage Prescription Drug (MAPD, 6 million in 2006) plans, which bundle drug, inpatient, and outpatient benefits; and stand-alone Prescription Drug Plans (PDP, 16.5 million in 2006). Another 10.4 million beneficiaries received coverage through employer or union plans in 2006 (The Kaiser Family Foundation 2006).

Gaps in coverage may increase out-of-pocket spending for beneficiaries because they pay the full price of drugs filled during these periods; beneficiaries also may decrease drug use or treatment adherence, leading to decreases in total drug costs. Studies before Part D have found both effects, that is, total drug spending and adherence decrease for both discretionary and necessary drugs, while out-of-pocket expenditures increase (Tseng et al. 2004; Hsu et al. 2006). In at least some cases, lack of coverage leads to higher rates of downstream clinical events, including hospitalizations (Hsu et al. 2006). The Part D coverage gap involves substantial periods of uncovered drug use, but it affects only beneficiaries with high annual drug spending levels. How the Part D coverage gap affects drug spending and adherence depends in part on which and how many beneficiaries enter the gap, when during the year this occurs, and how beneficiaries respond.

The effect of the Part D program on adherence is controversial, and it depends in large part on the reference point (Zhang et al. 2009). While beneficiaries may face potentially substantial cost-sharing levels under Part D, including the coverage gap, many previously did not have coverage or had less generous coverage before the introduction of Part D. Some recent studies suggest that drug use and adherence have increased while patient out-of-pocket spending decreased with Part D (Lichtenberg and Sun 2007; Mad-

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den et al. 2008; Yin et al. 2008). Other studies, however, indicate that many beneficiaries experience cost-related nonadherence, especially among beneficiaries who enter the coverage gap (Neuman et al. 2007; Hsu et al. 2008).

There also is uncertainty about how much of a drug use barrier Part D cost-sharing creates, with some suggesting eliminating the Part D coverage gap entirely or at least providing generic drug coverage during the standard gap period (H.R. 3962 2009; Frank and Newhouse 2007). Within the Part D market, the number of plans providing at least some generic and brand-name drug coverage has increased from 5 percent of MAPDs in 2006 to 17 percent in 2008, and decreased from 2 percent of PDPs in 2006 to 0.1 percent (a single PDP) in 2008. The number of plans offering generic-only gap coverage has increased from 23 percent of MAPDs in 2006 to 34 percent in 2008, and from 13 percent of PDPs in 2006 to 29 percent in 2008 (Medicare Payment Advisory Commission 2006, 2008). These plans provide more generous coverage during the standard gap period to attract beneficiaries, often in exchange for higher premiums. Since 2006, more beneficiaries have been enrolling in plans offering at least some gap coverage (Medicare Payment Advisory Commission 2007, 2009). Although the program is now entering its fourth year, the effects of the coverage gap and existing types of gap coverage on total drug costs, out-of-pocket spending, and adherence are still unknown.

We conducted parallel analyses to compare Medicare beneficiaries with a coverage gap versus without a gap in an integrated delivery system MAPD, and to compare beneficiaries with a gap versus with generic-only gap coverage in a network-model MAPD. To focus on a group with substantial and regular need for drug therapy, we examined total and out-of-pocket drug spending and drug treatment adherence among Medicare beneficiaries with diabetes mellitus. About 20 percent of Medicare beneficiaries are estimated to have diabetes (Sloan et al. 2008), and these beneficiaries may be at particularly high risk of reaching the coverage gap because they are often prescribed multiple, chronic medications to control their diabetes and prevent cardiovascular complications (Tjia and Schwartz 2006). A recent industry report estimated that 33 percent of MAPD and 43 percent of PDP beneficiaries with diabetes reached the gap in 2006 (Karaca et al. 2008).

METHODS

Setting

The integrated, staff-model HMO offered a single MAPD plan for individual subscribers, with a coverage gap between U.S.$2,250 in total drug costs and

U.S.$3,600 in out-of-pocket expenditures in 2006. Individual subscribers had no deductible and U.S.$10 generic and U.S.$40 brand copayments for up to a 30-day supply before the gap. After U.S.$3,600 in cumulative annual out-of-pocket expenditures, beneficiaries had U.S.$3 generic and U.S.$10 brand copayments. In 2005, individual subscribers had generic-only benefits with U.S.$10 generic copayments (for up to a 100-day supply). In 2006, other MAPD beneficiaries with employer-supplemented insurance had no coverage gap and lower copayments than individual subscribers, that is, U.S.$5–30 generic and U.S.$10–75 brand copayments for up to a 100-day supply; their benefits were similar in 2005 as in 2006. The Integrated MAPD plans were available in California.

The network-model HMO offered two MAPD plans in 2006: one with a coverage gap as described above, and one with generic-only coverage during the gap. Neither plan had a deductible and both had a four-tier copayment before the gap: U.S.$8.50 for generics, U.S.$26– U.S.$27 for preferred brands, 50 percent coinsurance for nonpreferred brands, and 33 percent coinsurance for specialty drugs. During the gap, beneficiaries in the generic-only plan had U.S.$8.50 generic copayments, but no brand coverage. During catastrophic coverage, beneficiaries in both plans paid the greater of 5 percent coinsurance or U.S.$2 generic and U.S.$5 brand copayments. Beneficiaries with the standard coverage gap in 2006 were most commonly enrolled in MA plans with no or limited (e.g., capped) brand-name drug coverage in 2005; the majority of beneficiaries with generic-only gap coverage in 2006 had unrestricted generic and brand coverage in 2006. The gap plans were available in multiple states; the generic-only plan was only available in select counties within California, where beneficiaries had a choice of the two plans.

Study Design and Population

Our focus was to compare the standard Part D coverage gap with partial and complete gap supplementation; thus, we conducted comparisons holding other system variables constant. The two MAPD plan sponsors differ in their levels of integration, care management practices, plan offerings, geographic locations, and drug formularies, which could affect drug costs and adherence; therefore, we conducted separate, parallel analyses of beneficiaries with and without supplemental gap coverage within the same Medicare Advantage system. Specifically we compared the following:

- Beneficiaries with a coverage gap versus beneficiaries in employer-supplemented plans without gaps within an Integrated MAPD; and

- Beneficiaries with a gap versus beneficiaries with generic-only gap coverage within a Network MAPD.

The study included beneficiaries continuously enrolled from January 1, 2005 through December 31, 2006, 65+ years old, with ≥ 1 oral diabetes prescription dispensed in 2005. We selected the cohort based on prior year drug use to focus our analyses on the effects of Part D-related cost-sharing, and specifically the coverage gap, on costs and adherence for diabetes patients receiving ongoing drug therapy. We excluded dual-eligible beneficiaries (Medicaid-Medicare) and those receiving Medicare's low-income subsidy because they had substantially different cost-sharing levels. In analyses examining hypertension and lipid (cholesterol) drugs, we included the subset of beneficiaries who had ≥ 1 drug in the respective class dispensed in 2005.

Selection

Potential differential selection of Medicare drug plans is a concern for any nonrandomized study. By conducting separate within-system analyses, we mitigated concerns related to differential selection of plans offered by different plan sponsors. Within the Integrated system, there was only a single plan available for individual Part D subscribers, that is, the coverage gap plan. The benefits for beneficiaries with employer-supplemented insurance were determined at the employer, not the individual, level, which reduces selection concerns within the Integrated system. Within the Network system, however, over half of the study population lived in areas where they could choose between the basic coverage gap plans and the enhanced generic-only coverage plans, with a higher premium for the latter. To reduce potential selection bias that could result from healthier patients with lower levels of drug need choosing the less generous coverage gap plan, we excluded subjects in these plans that lived in areas where they also had a choice of the generic-only plan. Identifying beneficiaries with the same chronic condition, diabetes, further increases comparability by focusing on beneficiaries with more clinically homogeneous needs. In addition, we used propensity scores to reduce bias due to imbalances in measured characteristics of the comparison groups, for example, beneficiaries with generic-only gap coverage versus a standard coverage gap (with no choice of the generic-only plan).

Drug Expenditures

We examined total drug costs and out-of-pocket expenditures for Part D drugs using health plan pharmacy data. We also examined costs for three diabetes-

related classes: oral diabetes, hypertension, and lipid drugs. Total costs are the amount that beneficiaries would have paid if the drug was not covered by their plan (e.g., during the gap), and the amount includes the acquisition cost and dispensing fee. Out-of-pocket costs were calculated as patient costs and included copayments/coinsurance, or full price, during uncovered periods.

Drug Adherence

To measure annual and monthly adherence to oral diabetes, hypertension, and lipid drugs, we calculated the proportion of days covered (PDC) using dispensing data. Adherence was defined as having PDC $\geq$ 80 percent in the year or month for the entire regimen (Fung et al. 2007) and allowed drug supply to carry over from month to month. When examining adherence to oral diabetes drugs, we censored subjects if they were dispensed insulin to isolate changes in adherence from prescribed changes in the diabetes drug regimen (e.g., potential replacement of oral agent with insulin).

Analysis

To examine differences in annual 2006 total drug costs and out-of-pocket expenditures between beneficiaries with a coverage gap and those with either no gap or generic coverage, we used one-part general linear models and log transformed costs (Buntin and Zaslavsky 2004). To examine differences in adherence (PDC $\geq$ 0.80) to each of the three drug classes, we used logistic regression.

To examine changes in drug costs and adherence before and after beneficiaries exceed the coverage gap threshold, we plotted monthly differences among those who reached U.S.$2,250 in total drug costs aligned by the month in which they exceeded this threshold. Analyses were limited to the 6 months before and 3 months after subjects reached the gap threshold in 2006 because the majority exceeded the threshold in later months during the year. We estimated mean monthly costs and adherence levels for the gap versus supplemented gap groups using a generalized estimating equations approach and treating all subjects as if they were in each group; standard errors were estimated using the delta method (Oehlert 1992). Models included monthly indicators and interactions between month and coverage gap group to examine differences in each month before and after reaching the gap threshold. In sensitivity analyses, we conducted within-person fixed effects analyses, which are robust to time-stable unmeasured differences between groups; these analyses yielded consistent findings.

Propensity Scores

To calculate propensity scores, we estimated the probability of having a standard coverage gap (versus no gap or generic-only gap coverage) using logistic regression models and included the propensity score as a continuous variable in all analyses. The logistic models adjusted for age (65–74, 75–84, 85+), gender, plan membership tenure, and neighborhood socioeconomic status based on the 2000 U.S. Census and median household income at the block group level. We also adjusted for comorbidities (hypertension, hyperlipidemia, coronary artery disease, depression, osteoarthritis, and chronic kidney disease) based on diagnoses in 2005. As a proxy for diabetes severity, we included an indicator for use of oral diabetes medications alone or with insulin in 2005. When assessing costs or adherence for specific drug classes, we adjusted for the number of drugs in beneficiaries' 2005 regimens, and the mix of generic and brand drug use in 2005. In cost analyses, we controlled for prior year total drug spending for all Part D drugs or the respective drug class, depending on the outcome. Because beneficiary-level race/ethnicity was not available in both health systems, we did not include race/ethnicity in the propensity score. In sensitivity tests, we included census-based race/ethnicity (Network MAPDs) and individual-level race/ethnicity (Integrated MAPDs); point estimates and statistical inference for the main predictor (amount of gap coverage) were similar.

RESULTS

Table 1 presents the study population characteristics. In 2006, the Integrated MAPD had 16,654 diabetes beneficiaries with a coverage gap and 12,126 with no gap. In the Network MAPD, 11,034 had a coverage gap and 3,950 had generic gap coverage. In 2005, 93.3 percent (Integrated MAPD) and 85.5 percent (Network MAPD) of beneficiaries received ≥ 1 drug for hypertension; 83.3 percent (Integrated MAPD) and 58.0 percent (Network MAPD) received ≥ 1 drug for hyperlipidemia.

The percentage of subjects who exceeded U.S.$2,250 in total costs (i.e., reached the gap threshold) in 2006 varied across the four plans: 17.2 percent of subjects with a gap and 34.6 percent with no gap in the Integrated MAPD; and 34.2 percent of subjects with a gap and 36.5 percent with generic-only gap coverage in the Network MAPD.

Table 1: Study Population Characteristics

Characteristics		*Integrated MAPD*		*Network MAPD*	
		Coverage Gap	*No Coverage Gap*	*Coverage Gap*	*Generic-Only Gap Coverage*
	Total no.	16,654	12,126	11,034	3,950
Age	65–74 years	58.11%	58.44%	34.09%	35.95%*
	75–84 years	35.26%	35.35%	52.39%	49.90%
	85+ years	6.63%	6.20%	13.52%	14.15%
Gender	Female	49.68%	46.35%*	54.87%	50.43%*
Diabetes drug use	Orals and insulin in 2005	14.06%	16.13%*	9.67%	9.62%
	Orals only in 2005	85.94%	83.87%	90.33%	90.38%
Neighborhood income	<100% FPL	0.61%	0.41%*	0.61%	0.61%*
	100 to <200% FPL	10.06%	8.83%	14.47%	20.68%
	200 to <300% FPL	24.17%	25.32%	34.57%	29.37%
	300 to <400% FPL	25.03%	26.58%	25.18%	28.91%
	400%+FPL	34.92%	34.64%	19.18%	15.22%
	Unknown	5.22%	4.22%	5.99%	5.22%
Health system tenure	Joined in 2004 or later	13.51%	17.05%*	7.88%	7.59%
	Joined before 2004	86.49%	82.95%	92.12%	92.41%
Comorbidities	Hypertension	76.92%	77.50%	79.35%	78.76%
	Hyperlipidemia	64.47%	63.47%	68.35%	70.35%*
	Coronary artery disease	22.07%	24.04%*	25.86%	26.48%
	Depression	8.35%	8.54%	5.64%	6.91%*
	Osteoarthritis	14.21%	16.17%*	19.08%	20.53%*
	Chronic kidney disease	3.67%	4.07%	3.88%	8.05%*
Drug costs in 2006	>U.S.$2,250 in total drug costs (gap)	17.20%	34.55%*	34.22%	36.48%*
	>U.S.$3,600 in out-of-pocket expenditures (catastrophic)	0.95%	0.00%*	3.61%	2.10%*

Oral diabetes drug use in 2005	≥ 1 Oral DM Rx in 2005 (no.)	16,654	12,126	11,034	3,950
	Generic use only	87.62%	80.30%*	77.23%	75.90%*
	Brand and generic use	11.52%	18.51%	17.10%	20.00%
	Brand use only	0.86%	1.20%	5.66%	4.10%
HTN drug use in 2005	≥ 1 HTN Rx in 2005 (no.)	15,459	11,389	9,426	3,390
	Generic use only	82.96%	71.36%*	66.82%	74.31%*
	Brand and generic use	15.34%	26.02%	26.14%	21.68%
	Brand use only	1.70%	2.63%	7.04%	4.01%
Lipid drug use in 2005	≥ 1 Lipid Rx in 2005 (no.)	13,717	10,270	6,313	2,380
	Generic use only	91.33%	75.27%*	49.04%	55.34%*
	Brand and generic use	3.38%	5.63%	10.77%	11.30%
	Brand use only	5.29%	19.10%	40.19%	33.36%

Note. This table reports the column percentages of subjects with each sociodemographic and clinical characteristic. Subjects with a coverage gap had no coverage for brand or generic drugs after their annual total drug costs exceeded U.S.$2,250 and until their cumulative out-of-pocket expenditures reached U.S.$3,600. Subjects with generic gap coverage had generic-only coverage supplements during the coverage gap (i.e., no coverage for brand drugs only). Subjects with no gap had full brand and generic coverage (i.e., copayments) throughout the year, with no gaps in coverage. Neighborhood income is based on block-group median household income in the 2000 U.S. Census, and 1999 Department of Health and Human Services poverty thresholds.

*$p < .05$.

Drug Costs

In the Integrated MAPD, gap beneficiaries had 3 percent (95 percent confidence interval [CI]: 1–4 percent) lower total drug costs and 189 percent (CI: 185–193 percent) higher out-of-pocket expenditures for all Part D drugs during 2006 than those with no gap (Table 2). Network MAPD beneficiaries with a gap had 4 percent (CI: 1–6 percent) lower annual total costs, and 14 percent (CI: 10–17 percent) higher out-of-pocket expenditures compared with beneficiaries with generic-only gap coverage. In the Integrated MAPD, differences in total drug costs and out-of-pocket expenditures between beneficiaries with a gap and no gap were similar for three chronic drug classes (oral diabetes, hypertension, and lipid drugs) as for all Part D drugs. In the Network MAPD, there were no significant differences in total drug costs for the three chronic drug classes between those with a gap and with generic-only gap coverage, but out-of-pocket spending was greater among beneficiaries with a gap for each of the drug classes, for example, hypertension (difference = 15 percent, CI: 11–19 percent) drugs (additional details available on request).

Drug Costs among Beneficiaries Who Reached the Gap Threshold

We also examined differences in total drug costs and out-of-pocket expenditures among beneficiaries who reached the coverage gap threshold in 2006 (i.e., > U.S.$2,250 in total drug costs). In the Integrated MAPD, beneficiaries with a gap had 2 percent (CI: 0.1–5 percent) lower total Part D costs compared with beneficiaries with no gap; in the Network MAPD total costs were not significantly different between beneficiaries with a gap and those with generic-only gap coverage. Differences between the groups in out-of-pocket expenditures were greater when analyses were limited to subjects reaching the gap threshold in 2006 versus all subjects. In the Integrated MAPD, out-of-pocket spending was 284 percent (CI: 277–293 percent) higher in the gap versus no gap group; in the Network MAPD, spending was 23 percent (CI: 19–27 percent) higher in the gap versus the generic-only gap coverage group.

Figure 1 displays monthly drug costs in the 6 months before and 3 months after subjects exceeded the gap threshold, among the subset of beneficiaries with >U.S.$2,250 in total costs in 2006. In the Integrated MAPD, differences in total costs between the gap and no gap group grew in the months after reaching the gap threshold; however, total drug costs were similar between the gap and generic-only gap coverage groups in the Network MAPD. In the Integrated MAPD, there were differences between the gap and no gap groups in monthly out-of-pocket expenditures before reaching the gap thresh-

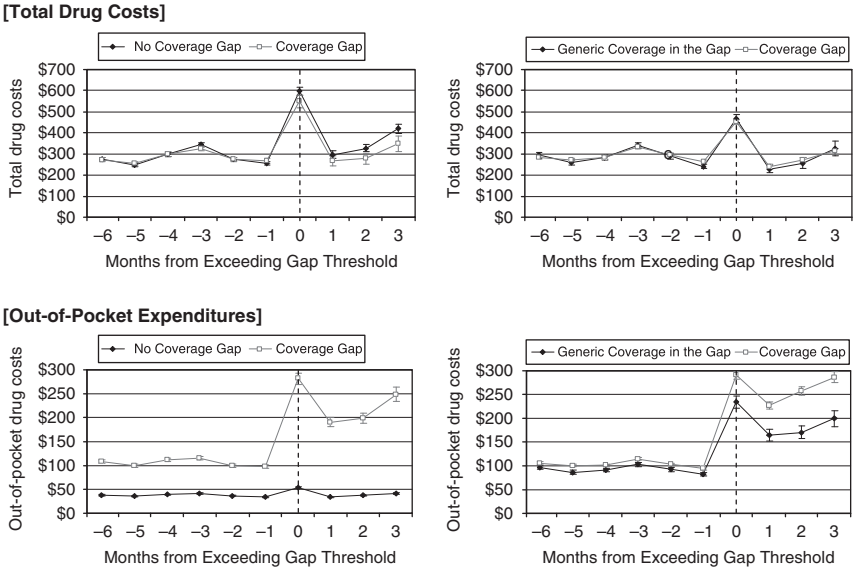
Table 2: Adjusted Annual Part D Drug Costs and Adherence to Three Diabetes-Related Drug Classes among All Subjects

Total Drug Costs (All Part D Drugs) in 2006	*Coverage Gap (TDC U.S.$)*	*No Gap or Generic-Only Gap Coverage (TDC U.S.$)*	*Relative Cost*	*(95% CI)*
Integrated MAPD (gap versus no gap)	1,750	1,802	0.97	(0.96, 0.99)
Network MAPD (gap versus generic-only gap coverage)	1,974	2,048	0.96	(0.94, 0.99)
Out-of-Pocket Expenditures (All Part D Drugs) in 2006	*Coverage Gap (OOP U.S.$)*	*No Gap or Generic-Only Gap Coverage (OOP U.S.$)*	*Relative Cost*	*(95% CI)*
Integrated MAPD (gap versus no gap)	806	279	2.89	(2.85, 2.93)
Network MAPD (gap versus generic-only gap coverage)	949	834	1.14	(1.10, 1.17)
Adherence to Three Drug Classes in 2006	*Coverage Gap (% Adherent)*	*No Gap or Generic-Only Gap Coverage (% Adherent)*	*Odds Ratio*	*(95% CI)*
Oral diabetes drugs				
Integrated MAPD (gap versus no gap)	61.7	66.0	0.83	(0.79, 0.88)
Network MAPD (gap versus generic-only gap coverage)	60.0	59.5	1.01	(0.97, 1.05)
Hypertension drugs				
Integrated MAPD (gap versus no gap)	66.3	71.5	0.78	(0.74, 0.83)
Network MAPD (gap versus generic-only gap coverage)	64.7	64.5	1.00	(0.96, 1.05)
Lipid drugs				
Integrated MAPD (gap versus no gap)	66.0	73.9	0.69	(0.65, 0.73)
Network MAPD (gap versus generic-only gap coverage)	58.6	56.2	1.05	(1.00, 1.10)

Notes. This table reports adjusted annual total drug costs and out-of-pocket expenditures in 2006, and relative costs for the gap versus supplemented gap groups, estimated using a one-part general linear model with log transformed costs. All comparisons are within individual health systems: in the Integrated MAPD, we compared having a coverage gap versus no gap; in the Network MAPD we compared having a coverage gap versus generic-only coverage during the gap. These estimates are adjusted for individual beneficiary characteristics, including prior year costs (in 2005) summarized by a propensity score of having a coverage gap. The table also reports the adjusted percent of beneficiaries in each group adherent to each of the three chronic drug classes, and the odds ratio of adherence for gap versus supplemented gap groups, estimated using logistic regression models and adjusted for beneficiary characteristics summarized by a propensity score. The difference in adherence to lipid drugs in the Network MAPD is not significant at the $p < .05$ level.

CI, confidence interval; OOP, out-of-pocket drug expenditures; TDC, total drug costs.

Figure 1: Adjusted Drug Costs in Months before and after Beneficiaries Reached the Gap Threshold among Subjects with >U.S.$2,250 in Total Drug Costs in 2006



Note. These graphs present adjusted monthly total (top panel) and out-of-pocket (bottom panel) drug costs for all Part D drugs in up to 6 months before (−6) and 3 months after (+3) beneficiaries exceeded the coverage gap threshold in 2006 (U.S.$2,250 in total drug costs). Subjects were aligned by the month they exceeded the gap threshold (month 0). All comparisons are within individual health systems: in the Integrated MAPD, we compared having a coverage gap versus no gap (left panels); in the Network MAPD we compared having a coverage gap versus generic-only coverage during the gap (right panels). Costs were estimated using a one-part generalized linear model with log transformed costs and a generalized estimating approach; we adjusted for covariates using a propensity score. Error bars represent 95 percent confidence intervals and were calculated using the delta method. Costs spike at month zero because subjects are aligned by the month in which their drug costs reached U.S.$2,250. Results in tabular format are available in the supporting information Appendix SA1.

old due to copayment differences; after reaching the gap threshold, out-of-pocket expenditures grew substantially among those with a gap. In the Network MAPD, beneficiaries with generic-only gap coverage had lower out-of-pocket expenditures in months after exceeding the gap threshold than those with no gap coverage, although spending increased in both groups.

Adherence to Chronic Drugs

Adherence in 2006, defined as having drug supply for 80 percent or more days in the year, was lower among subjects with a gap compared with full coverage during the gap (Table 2). Integrated MAPD beneficiaries with a gap had lower odds of adherence to each of the three drug classes than those with no gap (e.g., odds ratio = 0.83, CI: 0.79–0.88 for oral diabetes drugs). Differences between Network MAPD beneficiaries with a gap versus generic-only gap coverage in adherence to oral diabetes, hypertension, and lipid drugs were not statistically significant.

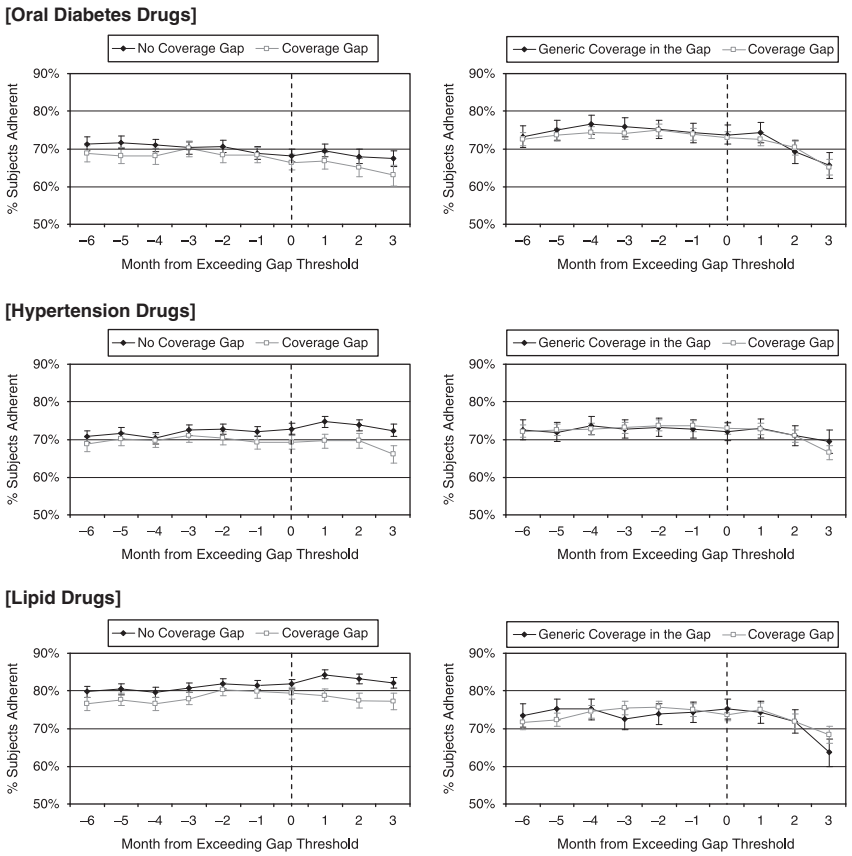
Figure 2 presents changes in adherences for each of the chronic drug classes in the months before and after subjects exceeded the gap threshold among subjects with > U.S.$2,250 in total drug costs in 2006. In both systems, the adjusted levels of adherence for each of the drug classes were similar in groups with and without gap coverage during the months before reaching the gap threshold. In months after reaching the gap, beneficiaries in the Integrated MAPD with a coverage gap had significantly lower levels of adherence to hypertension and lipid drugs versus those with no gap. In the Network MAPD, levels of adherence declined in both the gap and generic-only gap coverage groups in the months after subjects reached the gap, in particular for oral diabetes and lipid drugs, and there were no significant differences between the coverage groups.

DISCUSSION

We examined the effect of the Medicare Part D coverage gap on drug costs and adherence among beneficiaries with diabetes in two large health systems offering MAPD plans. Compared with having no coverage gap, having a gap was associated with lower total drug costs, but higher out-of-pocket spending and worse treatment adherence to three chronic drug classes. Compared with generic-only coverage during the gap, having a gap was also associated with lower total costs and modestly higher out-of-pocket expenditures; however, levels of adherence were similar between the groups.

Unexpectedly, the annual differences in total drug costs were smaller in the Integrated system (gap versus no gap) compared with the Network system (gap versus generic-only gap coverage). In monthly comparisons, however, we found larger differences in the Integrated MAPD among beneficiaries who exceeded the gap threshold in the months after exceeding it. These findings are consistent given that a smaller proportion of beneficiaries entered the gap

Figure 2: Adjusted Adherence in Months before and after Beneficiaries Reached the Gap Threshold among Subjects with >U.S.$2,250 in Total Drug Costs in 2006



Note. The *Y*-axis scale for all graphs is 50–90 percent. These graphs present the adjusted percent of subjects adherent to oral diabetes (top panels), hypertension (middle panels), and lipid (bottom panels) drugs in up to 6 months before and 3 months after beneficiaries exceeded the coverage gap threshold in 2006 (U.S.$2,250 in total drug costs). All comparisons are within individual health systems: in the Integrated MAPD, we compared having a coverage gap versus no gap (left panels); in the Network MAPD, we compared having a coverage gap versus generic-only coverage during the gap (right panels). Subjects were aligned by the month they exceeded the gap threshold (month 0). Odds of adherence were estimated using a generalized estimating approach with a logit link. We adjusted for covaritates using a propensity score; adjusted percentages were calculated treating all subjects as if they had a coverage gap or supplemented gap, respectively. Error bars represent 95 percent confidence intervals and were calculated using the delta method. Results in tabular format are available in thesupporting information Appendix SA1.

in the Integrated than Network system, and they suggest that cost-sharing effects could differ across delivery systems. Formal investigation of such potential interactions is beyond the scope of this study.

Possible Adverse Effects of a Coverage Gap

Out-of-pocket drug expenditures were substantially higher for beneficiaries with a gap versus no gap, and differences grew during the months after beneficiaries reached the gap. Recent surveys report that seniors in Part D, especially those who reached the gap or with greater comorbidity, cut back on other necessities because of drug costs (Hsu et al. 2008; Madden et al. 2008). Studies also suggest that higher out-of-pocket expenditures may be associated with worse medication adherence.

In fact, we found that at least some of the reduction in total costs appears to be due to lower adherence among beneficiaries with a gap. Compared with beneficiaries with no gap, adherence levels among beneficiaries with a gap were 4–8 percentage points lower for diabetes, hypertension, and hyperlipidemia drugs. Other studies have found similar adherence differences for these drug classes to be associated with worse clinical outcomes (Hsu et al. 2006). This finding raises concerns about the clinical consequences of gaps, and work is needed to examine whether Part D coverage gaps are associated with worse physiological outcomes, such as elevated glycated hemoglobin, or adverse clinical events, such as hospitalizations or mortality.

Differences between our findings and those of other recent studies that suggest that Part D has led to improvements in out-of-pocket costs and adherence for beneficiaries (Lichtenberg and Sun 2007; Madden et al. 2008; Yin et al. 2008) reflect differing perspectives and comparison groups. Part D has undoubtedly improved coverage for some Medicare beneficiaries, especially those with no drug coverage before Part D. As we enter the fifth year of the program, however, the goals of refining and improving the program are increasingly pressing, as are data examining where we want to be rather than from whence we came.

Limited Effects of Generic-Only Gap Coverage

An increasing number of Part D plans are offering enhanced drug benefits for higher monthly premiums. In theory, supplemental coverage during the gap could decrease out-of-pocket spending and mitigate inappropriate reductions in drug use; however, we observed only modest differences in annual out-of-pocket spending and no differences in adherence for persons with

generic-only gap coverage. Several factors could explain the limited value of generic gap coverage relative to the standard gap. First, within some therapeutic classes, there are no available generics, and for some patients the optimal drug regimen might not have a generic equivalent. Efforts are needed to evaluate approaches that could provide coverage for all clinically necessary brand and generic drugs, such as reference pricing, step-therapy arrangements, or better prescribing decision support.

The effects of generic-only gap coverage could also be limited if beneficiaries are unaware of or do not switch to available generic options; health plans should provide tools to inform patients and clinicians about lower-cost alternatives to help optimize drug regimens. In addition, generic coverage might not confer substantial cost benefits if beneficiaries are already using low-cost generics because out-of-pocket costs are similar when paying full cost versus a copayment. Levels of generic use in both Network MAPD plans were high in the baseline year.

In the Network MAPD, generic-only coverage was associated with higher total costs compared with having a coverage gap. At least some of this difference could be attributable to individual-level selection into the two plans. Over half of the study population lived in areas where they could choose between the Network gap or generic-only coverage plans, with a higher premium for the latter. To the extent that sicker patients with higher levels of drug need chose the more generous plan, we anticipate this would exaggerate any real differences between the gap and generic-only coverage plans; for example, patients with more severe disease could be more adherent to their regimens than less severe patients (Benner et al. 2002; Chapman et al. 2005).

Differences across Systems—Future Directions

We found intriguing differences in costs and adherence between the two systems, although the parallel study design was not meant to address this question. Within the Integrated system, the percent of beneficiaries with diabetes who reached the coverage gap and mean out-of-pocket drug costs was lower, and adherence was higher. This suggests organizational factors could mitigate some of the adverse effects of limited drug benefits, and it potentially reflects differences in the efficiency of care delivery. Future studies specifically designed to examine the role of the delivery structure and its interactions with drug benefits are needed.

Work is also needed to examine the effects of the coverage gap on drug use for other therapeutic classes, and effects within other patient populations.

While improving adherence to chronic drug therapies is an important goal of the Part D program, eliminating the gap or reducing cost-sharing for drug overall could also lead to increases in spending on drugs of more questionable or marginal clinical value. As Medicare spending growth threatens the solvency of the program, the need to identify drug benefit policies that achieve intended clinical and economic goals is critical.

LIMITATIONS

This study was conducted within MAPD populations and may not generalize to PDP beneficiaries. However, the structures examined in this study are similar to commonly available MAPD and PDP plans. Our subjects, especially within the Integrated system, may be more likely to receive disease management than PDP beneficiaries. In addition, individual MAPD subscribers in this study had generic-only benefits in 2005 and high baseline generic use; importantly, the effect of the gap would likely be larger among beneficiaries with greater brand-name drug use. The estimates in this study could provide conservative estimates of the potential adverse effects of the Part D coverage gap in the general Medicare population.

Adherence was measured using pharmacy-dispensing data and we did not capture whether beneficiaries actually took the drugs; however, this method has been validated in previous studies (Steiner et al. 1988; Steiner and Prochazka 1997). Moreover, related telephone interview studies conducted in these study populations yielded similar findings (Hsu et al. 2008; Duru et al., unpublished data). In the Integrated MAPD, the data did not capture prescriptions filled outside of the health system; however, beneficiaries had a strong financial incentive to fill within the system, even during the gap. In interview studies, beneficiaries rarely report going to nonsystem pharmacies (Hsu et al. 2008). The Network MAPD collects complete claims information on drugs filled at all pharmacies, including those filled during uncovered periods, for example, the gap.

This was a nonrandomized study; therefore, there may be unmeasured group differences. To mitigate potential selection bias, we controlled for a number of clinical and sociodemographic characteristics and focused on comparisons within single health systems. We also conducted longitudinal analyses among beneficiaries with > U.S.$2,250 in total drug costs to examine changes before and after reaching the gap threshold. In the Integrated MAPD, beneficiaries could not self-select between the available plans; supplemental benefits during the gap were determined at the employer level. In the Network

MAPD, however, all subjects in the generic-only coverage plan had a choice of a lower cost plan with no gap coverage, and they may be unobservably sicker compared with those who chose the gap plan. To mitigate potential selection bias, we restricted the comparison of beneficiaries in the generic-only gap coverage plan to beneficiaries in a coverage gap plan who did not have a choice of the generic-only plan, and we adjusted for measured covariates using a propensity score; despite these adjustments, unmeasured selection may remain, but it would likely exaggerate group differences. We examined our outcomes among beneficiaries with diabetes receiving chronic mediation therapy before Part D. Because these subjects likely required continuing drug therapy throughout the year and were more clinically homogeneous than the general population, our outcome measures may be less susceptible to potential selection differences.

Conclusion

Having a gap in Part D prescription drug benefits is associated with slightly lower total drug costs, but higher out-of-pocket spending and worse adherence to chronic medications compared with having no gap among MAPD beneficiaries with diabetes. The provision of generic-only drug coverage during the gap appeared to confer only limited advantage, with modest differences in out-of-pocket spending and no differences in adherence compared with beneficiaries with a coverage gap. Our findings reinforce the need to examine carefully the clinical and economic effects of all Part D drug benefit and delivery structures, with focus on approaches that provide the best value for beneficiaries who require multiple, chronic medications.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.

Table SA1. Adjusted Drug Costs in Months before and after Beneficiaries Reached the Gap Threshold among Subjects with >U.S.$2,250 in Total Drug Costs in 2006 (Plot Points for Figure 1).

Table SA2: Adjusted Adherence in Months before and after Beneficiaries Reached the Gap Threshold among Subjects with >U.S.$2,250 in Total Drug Costs in 2006 (Plot Points for Figure 2).