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Generic-Only Drug Coverage in the Medicare Part D Gap and Effect on Medication Cost-Cutting Behaviors for Patients with Diabetes Mellitus: The Translating Research into Action for Diabetes Study

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OBJECTIVES: To examine the association between drug coverage during the Medicare Part D coverage gap and medication cost-cutting behaviors of beneficiaries with diabetes mellitus who use and do not use insulin.

DESIGN: The study was cross-sectional.

SETTING: A network-model health system.

PARTICIPANTS: 2007 survey of Medicare Advantage Part D (MAPD) and Prescription Drug Plan (PDP) beneficiaries who entered the gap by October 2006 (N = 1,468, 57% response rate).

MEASUREMENTS: The primary predictor variable was no gap coverage versus generic-only gap coverage. Seven cost-cutting behaviors were examined as dependent variables, including cost-related nonadherence (CRN) to any medication. Covariates included race or ethnicity, education, health status, income, and comorbidities, as well as generic medication use in the first quarter. Logistic regression models were constructed using nonresponse weights to generate predicted percentages.

RESULTS: In multivariate analyses, beneficiaries taking insulin were less likely to report CRN if they had generic-only gap coverage than if they had no gap coverage (16% vs 29%, $P = .03$). No differences in CRN according to type of gap coverage were seen between beneficiaries not taking insulin.

CONCLUSION: Medicare beneficiaries using insulin are at high risk of CRN. Generic-only coverage during the gap is associated with an attenuated risk of CRN in insulin users, possibly because of savings on other, generic medications. Future research should evaluate CRN within alternative benefit designs covering selected brand name medications, such as insulin, during the gap. *J Am Geriatr Soc* 58:822–828, 2010.

Key words: Medicare Part D; pharmaceutical use; diabetes

The “standard” Medicare Part D prescription drug benefit has a gap in coverage after total drug costs exceed an annually adjusted threshold (\$2,510 in 2008).¹ During the coverage gap, beneficiaries with the standard benefit are responsible for 100% of the cost of their medications. Recent studies have found that many Part D beneficiaries with a coverage gap use less medication than prescribed because of cost and go without necessities such as food or rent to afford medications.^{2–6} Beneficiaries with diabetes mellitus and other chronic diseases may be at particular risk, given a high likelihood of entering the coverage gap because of their multidrug regimens.^{7–11} High cost sharing for chronically ill beneficiaries was also associated in pre-Part D studies with poorer health and more emergency department visits and hospitalizations.^{7,12–14}

Although the majority of Part D plans provide no drug coverage during the gap, several plans have tried to bridge the gap with coverage for generic medications only (generic-only gap coverage).¹⁵ These plans discontinue coverage for brand name medications, such as insulin, once patients enter the gap. Only one study has focused on whether providing generic-only drug benefits during the gap

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significantly lowers cost-related nonadherence (CRN). One study used Medicare Advantage Part D (MAPD) data and found that, after entering the coverage gap, beneficiaries who retained coverage for generic medications filled only 3% fewer prescriptions each month, whereas beneficiaries without any coverage filled 14% fewer prescriptions each month.⁶ Describing the ability of generic-only coverage to reduce CRN is crucial because the downside of more-generous drug coverage for beneficiaries includes higher monthly premiums.¹⁶ There are no published studies examining CRN according to type of gap coverage in Medicare beneficiaries with diabetes mellitus, including those taking insulin.

As part of the Translating Research into Action for Diabetes (TRIAD) Study, a cross-sectional survey of beneficiaries with diabetes mellitus enrolled in Part D in 2006 who exceeded the cost threshold for gap entry by the end of the third quarter was conducted. It was hypothesized that beneficiaries with diabetes mellitus (those who did and did not use insulin) and generic-only gap coverage would be less likely to report CRN, report forgoing necessities due to financial hardship, and report treatment substitutions than beneficiaries with a standard Part D coverage gap.

METHODS

Setting

Beneficiaries were sampled from a multistate network-model system that offered two different Part D benefit designs. One design had a standard coverage gap between \$2,250 in total drug costs and \$3,600 in out-of-pocket drug costs, and the other provided generic-only medication coverage during this gap. Beneficiaries could have either of the cost-sharing designs through an MAPD plan or through a stand-alone PDP plan. Neither design included a deductible, and both had four copayment tiers: \$8.50 for generics, \$26 to \$27 for preferred brands, 50% coinsurance for nonpreferred brands, and 33% coinsurance for specialty drugs. During the coverage gap, beneficiaries enrolled in a plan with generic-only coverage continued to have an \$8.50 generic copayment but no coverage for brand name drugs, whereas those with a complete gap in coverage paid full cost for all drugs, including generics. The health plans did not operate their own pharmacies, and all beneficiaries filled all of their prescriptions at outside pharmacies.

All MAPD plans had the same formulary, whereas two slightly different formularies were available to PDP beneficiaries. The three formularies provided identical drug coverage for almost all diabetes-related (antiglycemic, antihypertensive, and lipid-lowering) medications, including generic metformin, four generic sulfonylureas, two generic 3-hydroxy-3-methylglutaryl-coenzyme A reductase inhibitors or statins, and two angiotensin-receptor blockers as preferred brands, but there were two major differences between the MAPD formulary and the PDP formularies; the PDP formularies did not cover insulin analogs (other than NPH insulin) as preferred brands, and the PDP formularies did not include a third-option statin as a preferred brand.

Study Design and Participants

TRIAD is a multicenter study of diabetes mellitus care in managed care settings,¹⁷ and this analysis is drawn from a TRIAD survey specifically examining the effect of Medicare Part D. The institutional review board at the University of California at Los Angeles approved the research protocol. For the current study, data were drawn from a cross-sectional survey of Part D beneficiaries with diabetes mellitus. To be eligible for the survey, beneficiaries had to be continuously enrolled in a Medicare Advantage plan from January 1, 2005, to December 31, 2005, and an MAPD plan from January 1, 2006, to December 31, 2006, or newly enrolled in a PDP plan between November 15, 2005, and March 1, 2006. PDP enrollees were also required to have been continuously enrolled through December 31, 2006. Because specific dates of Part D enrollment were not available for PDP members at the time of sampling, participants who enrolled after January 1, 2006 were not excluded.

Plan members who were aged 65 and older by January 1, 2005; could complete the survey in English or Spanish; and had total drug costs in 2006 that exceeded the \$2,250 gap threshold by October 1, 2006, were randomly sampled. Beneficiaries who could not provide informed consent, were enrolled in Medicare solely because of their end-stage renal disease status, or were too ill to participate were excluded. Because Medicare Part D does not include a coverage gap for beneficiaries with the low-income subsidy, they were also excluded. The survey was fielded between April and October 2007. Potential participants were offered the option of completing a computer-assisted telephone interview (CATI) or a self-administered written survey to report their experiences in 2006. The coverage gap may influence medication-taking behavior before the gap, because beneficiaries may preemptively reduce or alter medication use to avoid gap entry, as well as during the gap itself. Therefore, the survey focused on identifying medication cost-cutting behaviors during the entire 2006 calendar year.

Variables and Measurement

Dependent variables included seven separate medication cost-cutting behaviors during 2006: skipped doses, delayed or stopped refills altogether, or otherwise used any medication less often than prescribed (CRN); went without food, rent, or other essentials to afford medication (forgoing necessities because of financial hardship); switched to a cheaper medication such as a generic (generic substitution); split pills according to their doctor's advice; used an over-the-counter substitute instead of their prescribed medication; used a mail-order pharmacy to fill prescriptions; or called different pharmacies to find the lowest price for a given medication. The last five strategies were classified as "substitution" strategies, in which beneficiaries sought to change the medication they used or where they purchased the medication but were not necessarily less adherent. These items have been used previously in analyses examining the financial burden of prescription drugs.¹⁸ In the subset of CATI respondents who reported any CRN during 2006, a follow-up question was asked to determine the specific medication or medications that were used less often than prescribed because of cost.

Several survey-based covariates, specifically race or ethnicity, education, income, self-rated health status (excellent, very good, good, fair, poor), and a claims-based summed comorbidity score, were measured. The comorbidity score included six chronic conditions from the survey: congestive heart failure, chronic obstructive pulmonary disease, depression, non-skin cancer, history of myocardial infarction, and history of cerebrovascular accident. Annual income was measured at the residential census tract level and used as a proxy to represent individual income for participants with missing income data. The percentage of all unique medications the patient was taking in the first quarter of 2006 that were generic was included as a covariate. This variable was derived from administrative claims. For the 66 (3.1%) participants who did not fill prescriptions in the first quarter of 2006, the percentage of generic medications was calculated using data from the second quarter. Two participants did not fill any prescriptions until the third quarter of 2006 and were excluded from all analyses.

Claims data were also used to measure the number of unique medications each patient was taking, the percentage of patients who were taking a single-source brand name medication without a generic equivalent, and the total medication cost for each participant in 2006, although these variables were not included as covariates in the multivariate models because the interpretation of statistical relationships is not entirely straightforward (e.g., higher medication costs may result in lower adherence, whereas lower adherence and less medication use may result in lower costs). Administrative claims data were also used to determine the Part D enrollment date for each participant and to identify participants who exited the coverage gap and received "catastrophic coverage" to assist with their prescription drug costs.

Statistical Analyses

Age and sex data from the administrative claims were used to construct nonresponse weights, using raking techniques with multiple iterations.¹⁹ Multivariate logistic regression analyses were constructed using SAS PROC LOGISTIC (SAS Institute, Inc., Cary, NC) to examine the association between the use of medication cost-cutting behaviors and no gap coverage or generic-only coverage in separate analyses of those who did and did not use insulin. The percentage of missing data was less than 10% for all covariates. Seventeen percent of beneficiaries were missing individual data for income, and this variable was "back-filled" using the median income of their residential census tract. Participants with missing data other than income were excluded from the multivariate analyses. To increase interpretability of the results, odds ratios were converted into predicted percentages, and 95% confidence intervals were calculated for each result.

In sensitivity analyses, results did not differ between participants who completed CATIs and written surveys. Using inpatient and outpatient claims data for the MAPD sample, a claims-based comorbidity score including 15 conditions for the self-reported comorbidity measure was substituted; no major differences from the results of the main model were observed. In addition, the results did not

change appreciably after exclusion of the 16% of participants who enrolled in Part D after January 1, 2006, or of the 11% of participants who entered catastrophic coverage during 2006. Therefore, only the results from the main analyses examining the full sample are reported.

RESULTS

The analytical sample included 1,468 participants with diabetes mellitus who completed the survey (crude response rate 57.3%). The approximate distribution of benefit designs was 65% standard coverage ($n = 928$) and 35% generic-only gap coverage ($n = 540$). In unadjusted analyses, demographic and clinical characteristics including age, education, income, self-rated health, and comorbidity scores were similar between participants without gap coverage and those with generic-only coverage (Table 1). Participants without gap coverage were more likely to be enrolled in an MAPD plan (81%) than those with generic-only gap coverage (52%, $P < .001$). Participants without gap coverage were also more likely to be taking insulin (34%) than those with generic-only gap coverage (28%, $P = .02$). In additional unadjusted analyses, no differences between the two groups were seen in number of medications or total medication costs in the first quarter of 2006 or the entire year (Table 1). Participants without gap coverage had higher out-of-pocket costs in the first quarter of 2006 than those with generic-only gap coverage (\$313 vs \$278, $P = .002$) and were more likely to exit the gap (12% vs 8%, $P = .01$).

After nonresponse weighting and multivariate adjustment, generic-only gap coverage was associated with lower rates of reported CRN than no gap coverage in participants using insulin (16% vs 29%, $P = .03$, Table 2). No differences according to type of gap coverage were seen for other cost-cutting behaviors in insulin users. In participants not using insulin, no differences in rates of CRN were seen according to type of gap coverage (Table 3), although participants not using insulin who had generic-only gap coverage were less likely than those with no gap coverage to switch any medication to a cheaper alternative (36% vs 46%, $P = .01$) or call different pharmacies to find the lowest price for their medication (22% vs 36%, $P < .001$).

Of all CATI respondents who reported any CRN (those who did and did not use insulin), 59% reported using at least one antiglycemic, antihypertensive, or lipid-lowering medication less often than prescribed because of cost (data not shown). Of CATI respondents using insulin who reported any CRN, 13% reported using less insulin than prescribed, whereas 87% reported cutting down on another medication because of cost (data not shown).

DISCUSSION

This is the first study in the peer-reviewed literature to report the use of medication cost-cutting behaviors specifically in Medicare Part D beneficiaries with diabetes mellitus and to what extent these behaviors are associated with drug benefits of varying generosity during the coverage gap. The data indicate that, for Part D beneficiaries who use insulin, generic-only coverage significantly attenuates the reduction in filled prescriptions after reaching the gap. Although generic-only coverage is associated with a lower likelihood of CRN in beneficiaries who use insulin, approximately 15%

Table 1. Unadjusted Participant Characteristics According to Type of Gap Coverage

Characteristic	No Gap Coverage (n = 928)	Generic-Only Gap Coverage (n = 540)	P- Value
Benefit design			
Gap coverage	None	Generic medications only	
Copayments			
Generic for 30-day supply, \$	8.50	8.50	
Preferred brand for 30-day supply, \$	26–27	26–27	
Other brand, % coinsurance	50	50	
Specialty drugs, % coinsurance	33	33	
Demographics			
Age, mean ± SD	75.7 ± 5.7	75.6 ± 6.2	.76
Race or ethnicity, %			.08
White (n = 1,050)	75	78	
Latino (n = 216)	16	15	
Asian or Pacific Islander (n = 35)	3	2	
African American (n = 39)	4	1	
Other (n = 40)	3	4	
Female, %	55	53	.41
Education, %			.78
< High school (n = 291)	21	20	
High school graduate (n = 439)	31	31	
Some college (n = 411)	29	29	
≥4 years college (n = 270)	18	20	
Median annual income, \$*			.16
< 25,000 (n = 516)	37	32	
25,000–39,999 (n = 374)	25	26	
≥40,000 (n = 578)	38	42	
Health status			.12
Excellent to very good (n = 225)	16	16	
Good (n = 513)	34	39	
Fair to poor (n = 684)	50	45	
Mean comorbidity score (n = 1,416)	1.3 ± 1.1	1.3 ± 1.2	.70
Using insulin, %	34	28	.02
Type of Part D Plan			<.001
MAPD plan (n = 1,034)	81	52	
PDP (n = 434)	19	48	
Completed computer-assisted telephone interview survey (vs written)	69	71	.44
Utilization measures			
Number of medications in 2006, mean ± SD	13.7 ± 5.1	13.4 ± 4.9	.18
Total medication costs in Quarter 1 2006, median, \$*	937	892	.13
Total medication costs for the entire 2006 year, median, \$	3,343	3,508	.07
Median out-of-pocket medication costs in Quarter 1 2006, \$*	313	278	.002
Exited the gap (reached catastrophic coverage) in 2006, %	12	8	.01
Generic medications in Quarter 1 2006, %*	60	61	.43
Taking a single-source brand medication in 2006 (no generic equivalent), %	100	100	...

All Medicare Advantage Prescription Drug (MAPD) plans and stand-alone prescription drug (PDP) plans (whether offering generic-only gap coverage or no gap coverage) include the same copayment structure: \$8.50 for 30 days' supply of a generic medication, \$26–27 for 30 days' supply of a preferred brand medication, 50% coinsurance for nonpreferred brands, and 33% coinsurance for specialty medications.

* These variables were calculated from Quarter 2 claims for the 66 patients (3.1%) with no prescription fills in Quarter 1.

of all beneficiaries with generic-only coverage still report CRN. Generic-only coverage during the gap did not change the proportion of beneficiaries who reported having to go without basic necessities to pay for their medications.

The finding of frequent CRN in insulin users with a coverage gap probably reflects the lack of alternative ther-

apeutic options for these patients, who have probably already failed oral antiglycemic therapy. There are no generic, less-expensive versions of any biological agents, including insulin, so people who use insulin face a steep increase in out-of-pocket medication costs during the gap. If they are unable to afford all of their medications during the gap,

Table 2. Adjusted Predicted Percentages of Medication Cost-Cutting Behaviors According to Type of Gap Coverage in Beneficiaries Using Insulin

Cost-Cutting Behavior	%		P Value
	No Gap Coverage (n = 314)	Generic-Only Gap Coverage (n = 152)	
Cost-related nonadherence			
During 2006, because of the amount you had to pay, did you use any medication less often than the doctor prescribed, either by skipping doses, stopping the medication altogether, or deciding not to fill a new prescription?	29	16	.03
Forgoing necessities due to financial hardship			
During 2006, did you go without some necessity (such as food, rent, or other basics) because of the amount that you would have to pay for a prescription medication?	15	18	.55
Substitution			
During 2006, because of the amount you had to pay for prescription medications, did you use an over-the-counter medication instead?	11	11	.87
During 2006, because of the amount you had to pay for prescription medications did you split pills (e.g., break them in half) according to your doctor's advice?	20	17	.47
During 2006, because of the amount you had to pay for prescription medications did you switch to a cheaper medication, such as a generic one?	45	51	.38
During 2006, because of the amount you had to pay for prescription medications did you use a mail-order pharmacy to fill your prescriptions?	44	50	.37
During 2006, because of the amount you had to pay for prescription medications did you call different pharmacies to find the lowest price for your medications?	38	40	.77

All models incorporate nonresponse weights and are adjusted for age, sex, race or ethnicity, education, comorbidity score, median income of residential census tract, percentage of generic prescriptions in Q1 2006, and plan type (Medicare Advantage Prescription Drug, stand-alone prescription drug).

these patients may use less of their other medications than prescribed or in some cases even cut down on the amount of insulin they use. Although there are no published reports examining this issue, these findings are consistent with a

recent abstract showing that 24% of beneficiaries who used insulin who had a coverage gap discontinued at least one medication during the gap.²⁰ The somewhat lower rates of CRN observed in beneficiaries who used insulin with

Table 3. Adjusted Predicted Percentages of Medication Cost-Cutting Behaviors by Type of Gap Coverage in Beneficiaries Not Using Insulin

Cost-Cutting Behavior	%		P-Value
	No Gap Coverage (n = 614)	Generic-Only Gap Coverage (n = 388)	
Cost-related nonadherence			
During 2006, because of the amount you had to pay, did you use any medication less often than the doctor prescribed, either by skipping doses, stopping the medication altogether, or deciding not to fill a new prescription?	18	14	.24
Forgoing necessities due to financial hardship			
During 2006, did you go without some necessity (such as food, rent, or other basics) because of the amount that you would have to pay for a prescription medication?	8	8	.91
Substitution			
During 2006, because of the amount you had to pay for prescription medications, did you use an over-the-counter medication instead?	9	6	.14
During 2006, because of the amount you had to pay . . . did you split pills (e.g., break them in half) according to your doctor's advice?	22	18	.31
During 2006, because of the amount you had to pay . . . did you switch to a cheaper medication, such as a generic one?	46	36	.01
During 2006, because of the amount you had to pay . . . did you use a mail-order pharmacy to fill your prescriptions?	51	53	.67
During 2006, because of the amount you had to pay . . . did you call different pharmacies to find the lowest price for your medications?	36	22	<.001

All models incorporate nonresponse weights and are adjusted for age, sex, race or ethnicity, education, comorbidity score, median income of residential census tract, percentage of generic prescriptions in Q1 2006, and plan type (Medicare Advantage Prescription Drug, stand-alone prescription drug).

generic-only coverage in the gap may be due to an indirect benefit from savings on other generic medications, resulting in lower total out-of-pocket costs.

The number of Medicare Part D plans providing generic-only gap coverage has increased in recent years, from 13% of PDPs and 23% of MAPD plans in 2006 to 25% and 34%, respectively, in 2009.¹⁵ The value of this coverage has been debated, because the higher premiums charged to patients, particularly by PDP plans that serve the majority of Medicare beneficiaries, may outweigh the financial benefits expected during the coverage gap.^{16,21} Premiums for generic-only coverage are generally lower in MAPD plans, because the plans are able to subsidize the cost of providing generic-only gap coverage with revenues they receive for providing other Medicare services within an integrated system. Beneficiaries who use insulin, who have high out-of-pocket medication costs during the gap, represent a group of patients for whom higher premiums associated with generic-only coverage may be worthwhile, in terms of providing savings on other medications and reducing overall costs. Additional studies are needed to evaluate these findings in other settings, including the specific cost savings to patients with different monthly Part D premiums and different types of medication regimens.

Other, more-direct options to address the matter of CRN in older adults with diabetes mellitus include permitting the marketing of generic insulin or covering brand name medications during the gap. Existing laws prohibit generic drug manufacturers from marketing biological agents such as insulin in the United States. Even if pending legislation that would enable the production of generic insulin were to pass,^{22,23} the medications would not be available to consumers for several years. Alternatively, providing gap coverage for generics and some “essential” brand name medications for compounds without generic equivalents would be effective in minimizing CRN and financial hardship strategies. This type of benefit design, a variant of “reference pricing” used in many other countries,^{24,25} provides a financial incentive for patients in the gap to choose a cheaper generic over a more-expensive, “nonpreferred” brand name equivalent while still covering other brand name prescriptions. Although no plans offered this type of gap coverage in 2006, 4% of MAPD plans are providing it during 2009.¹⁵ Future studies should investigate the effectiveness of this design as it relates to medication-taking decisions and behaviors.

This study has several limitations. First, as with several prior studies that surveyed Medicare beneficiaries, patients’ self-report of medication cost-cutting behaviors was solely relied on. Recall bias may have influenced these patient reports. Second, it cannot be determined whether cost-cutting behaviors took place before, during, or after the coverage gap, although because some patients may have preemptively decreased their medication use in an attempt to delay or avoid the gap altogether, the coverage gap may have influenced cost-cutting behaviors before gap entry. The results were also similar after excluding patients who exited the gap and entered catastrophic coverage. Third, the results reflect patients enrolled in one health system and may not be generalizable to other systems with different formularies, deductibles, or other design features. Fourth, census-tract level income data were used as a proxy for individual income in a small minority of cases. Fifth, patients who did

not fill any prescriptions in 2006 were excluded from the sampling frame. Finally, this was a nonrandomized, study and there may be unmeasured group differences between beneficiaries who selected the standard gap plan and those who selected the generic-only plan. No significant differences were found between the groups in terms of observable clinical characteristics such as self-rated health, number of comorbidities, and number of medications. To mitigate potential selection bias, these characteristics were controlled for, and comparisons within a single health system were focused on. To the extent that patients with greater medication needs and costs chose more-generous plans, unmeasured selection may remain but would probably exaggerate group differences and would suggest even less of an advantage for beneficiaries to have the generic-only plan.

In conclusion, these results suggest that generic-only coverage during the Part D gap is associated with protection against cost pressures with respect to any CRN for patients with diabetes mellitus who are taking insulin. This may be because of savings on other generic medications that reduce the total out-of-pocket medication costs faced by beneficiaries who use insulin during the gap. Generic-only coverage is not associated with better protection against forgoing necessities compared to the standard coverage gap. Future research should investigate the effectiveness of health plan efforts to educate beneficiaries with diabetes mellitus about their prescription drug options, as well as the effects of alternative designs such as covering generics and essential brand-name medications such as insulin in the coverage gap.

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