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Medication Adherence and the Use of Generic Drug Therapies

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Abstract

Objective—to assess if the lower copayments often charged for generic drugs explains the improved drug adherence associated with use of generic drugs.

Methods—We analyzed 2001–2004 healthcare claims data from 45 large employers. Study subjects were aged 18 years +, had 1 or more of 5 study conditions (hypercholesterolemia, hypertension, hypothyroidism, seizure disorders, and type 2 diabetes), and new use of generic-only or brand-only drug therapy for that condition. We measured adherence as the medication possession ratio (MPR), and adequate adherence as MPR >= 80%. Logistic regressions were conducted to assess adequate adherence adjusting for copayments.

Results—We identified 327,629 new users of drug therapy for the study conditions. Proportion of individuals starting generic therapies ranged from 9% in hypothyroidism to 45% in hypertension. After 1 year of therapy, 66.2% of individuals with hypothyroidism achieved MPR >= 80% compared to 53.4% with hypertension, 53.2% with hypercholesterolemia, 52.0% with diabetes, and 42.2% with seizure disorders. Logistic regressions of adequate adherence showed generics were associated with higher adherence relative to brands in 2 conditions (hypercholesterolemia AOR 1.52, 95% CI: 1.44–1.60; diabetes AOR 1.06, 95% CI: 1.01–1.12, p<.05), with lower adherence in 2 conditions (hypertension AOR 0.75, 95% CI:.73-.77; hypothyroidism AOR 0.86, 95% CI:.78-.94, p<.05), and no difference in seizure disorders. In comparison, the likelihood of achieving MPR >= 80% with $0 copayments relative to $1-$9 ranged from AOR 1.32 for seizure disorders (95% CI: 1.41–1.43) to AOR 1.45 for hypothyroidism (95% CI: 1.43–1.48).

Conclusion—Generic prescribing was associated with improved medication adherence in 2 of 5 study conditions, and the effect was modest. Copayments of $0 were associated with improved adherence across all study conditions.

Keywords

adherence; type 2 diabetes; hypertension; hypercholesterolemia; hypothyroidism; and seizure disorders

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Precis: This study assessed the impact of generic prescribing on medication adherence in new users of chronic drug therapy to treat 1 of 5 common conditions.

Take-Away Points: Generic prescribing was associated with both increases and decreases in medication adherence as well as no effect, depending on the study condition. Instead, copayments of $0 were a more consistent predictor of increased adherence. The clinical implication of these findings is that cost-related nonadherence and associated negative consequences will likely increase if pharmacy benefits are constructed in such a way as to promote generics without consideration of copayments.

Introduction

One of the best documented barriers to medication adherence is high out-of-pocket costs, even among individuals with prescription drug insurance.[1] Numerous studies have found that increased drug copayments are associated with decreased use of prescription drugs, even for highly effective medications used to treat chronic conditions such as diabetes mellitus, hypertension and hypercholsterolemia.[2–5] As a consequence, it is generally assumed that any government or private health plan policy that reduces copayments will enhance medication adherence.

A current trend in pharmacy benefits is to require relatively small copayments for generic drugs while charging much higher copayments for brand drugs as part of tiered formulary plans. In 2007, employer plans charged, on average, $11 for generic drugs, $25 for preferred brand drugs, and $43 for nonpreferred brand drugs.[6] The wide difference in copayments between generic and brand drugs is especially apparent in the Medicare Part D prescription drug plans, where enrollees pay $25 to $60 more for covered brand drugs compared to covered generic drugs.[7] These types of tiered pharmacy benefits steer patients toward generics, which lowers total prescription drug cost but also decreases overall prescription drug use, including for essential therapies.[2] Little is known about why prescription drug use decreases with the introduction of pharmacy benefits that offer incentives for using generics, but the reductions in prescription use are greater than those observed with uniform copayment increases across all brand and generic drugs.[8] This suggests that the relationship between adherence and use of generics may encompass more factors than simply lower copayments. For instance, nonfinancial factors such as chronic disease burden and mood disorders have been found to influence cost-related nonadherence.[1] In addition, research finds consistently that tiered copayments are not associated with lower out-of-pocket costs to individuals but rather with lower costs to the employers and health plans.[8, 9] Higher out-of-pocket costs are associated with decreased adherence.

Few previous studies have explicitly evaluated the relationship between generic drugs and medication adherence and those findings are mixed. Furthermore, none to our knowledge explicitly examined the use of generics and medication adherence rates after accounting for the amount of copayments. Two studies of a plan's switch to a generic-only formulary found significant reductions in the overall use of prescriptions, including decreases in the essential use of ACE inhibitors and statins by patients with diabetes and coronary artery disease, and increases in self-reported financial burden.[10, 11] Conversely, a recent study of a tiered pharmacy benefit found adherence was 12.6% higher for patients initiated on generic medications.[12] These studies may not be directly comparable, though, since switching to generics may be a distinct behavior from initiating generics. Nevertheless, none of these analyses accounted for the independent role of copayments, or evaluated whether their findings remained constant across different medical conditions. Our prior research revealed variation in adherence across different medical conditions that might have been influenced by differential access to generic drug formulations.[13] The objective of this study was to explicitly test the relationship between generic use and adherence after adjusting for copayments and to see if the relationship held across different medical conditions.

Methods

Study population and data sources

The study data were drawn from the 2001–2004 MarketScan Research databases (MEDSTAT, Ann Arbor, MI). These are secondary data sets of employer-sponsored medical care claims, prescription drug claims, and health care encounter data from approximately 45 large U.S. employers, and public organizations. The data are based on a

nationwide sample but are limited in generalizability for certain groups, particularly for employees and their dependents of small and medium firms and the unemployed. Each year of the data set contains medical care information on 3 to 6 million individuals, and scientific studies based on this data source have been reported in more than 40 peer-reviewed articles.[14] The encounter files contain age, sex, geographic residence, and eligibility information. The prescription claims file includes the national drug codes, date of purchase, quantity dispensed, days' supply, and expenditure information for each dispensing. The medical claims file contains payment information, diagnoses, procedure codes, and type of provider. For this analysis, we linked the annual files to create a longitudinal panel of continuous observations for each subject.

The study sample included individuals who were aged 18 years or older and had a diagnosis of 1 or more of 5 conditions: hypercholesterolemia, hypertension, hypothyroidism, seizure disorders, or type 2 diabetes. Details of the sample selection are described in a prior study.[13] Briefly these conditions were selected because they are common and treated with chronic drug therapy that is available in generic and brand formulations. In addition, the study subjects must have initiated new drug therapy for that condition during the period January 1, 2002 to December 31, 2003. Our analysis employed a new user study design to compare the patient groups at the same point in time relative to the initiation of therapy.[15] New drug therapy was defined as a dispensing of a study drug for that condition after at least 1 year of no dispensing of a study drug for that condition. Individuals were excluded if they had missing values or a value of zero or less for the quantity dispensed of the newly initiated study medication (n=11,972), had less than 1 year of follow-up observation after the first dispensing of the study medication (n=588,278), or used both generic and branded therapy during the first year of therapy (n=16,909).

Medication adherence

We used the Medication Possession Ratio (MPR) to measure prescription drug adherence.[16] The MPR is the days supply of medication dispensed during the follow-up year divided by the number of days in the year. A recent review of adherence measures shows MPR is a reliable measure of adherence.[17] Our calculation included dispensings for the initial study drug therapy as well as for all other study drug therapies for that condition. Overlaps in the dispensing days of different generic drug therapies were eliminated, under the assumption that leftover supplies from earlier refills were discarded to begin the newer medication (e.g., a change in therapy). Overlaps in the dispensing days of the same generic drug therapies were summed, under the assumption that earlier refills were still taken by the patient as part of the same regimen (e.g., an early refill). The value of the days supply was truncated if the supply extended beyond the time period of observation. In addition, MPR values > 100% were truncated to a value of 100%. Overadherence is difficult to interpret as we were unable to differentiate between inappropriate behaviors such overuse and early refills or appropriate behaviors such as changes in drug regimens, combination therapies, or multiple dispensings to achieve a specific dose. Adequate adherence was defined as MPR >=80%, although sensitivity analyses were conducted at MPR >=60%.

Other measures

Generic formulations of the study drugs were identified using a generic product indicator variable for each drug in each year of the database to flag generic preparations. The study copayment was identified as the modal value of all copayments provided for any study medications dispensed during the year, as used previously.[18, 19] The mean copayment and standard deviation (SD) for each condition are as follows: seizure disorders $15.1 (13.5 SD); hypothyroidism $9.9 (7.7 SD); type 2 diabetes $13.5 (12.9 SD); hypercholesterolemia $18.8 (15.5 SD); and hypertension $13.1 (12.5 SD). Based on the modal copayment distribution,

individuals were categorized as having copayment levels of $0, low ($1–$9), medium ($10–$29), and high (30$+). In addition, we evaluated the effect of prescription drug adherence with the following covariates: age, sex, plan type, geographic residence and comorbidity level. Comorbidity level was generated using the Diagnostic Cost Group Hierarchical Condition Category (DCG/HCC) system (DxCG, Boston, MA).[20, 21] The DCG/HCC risk adjuster creates a single score for each individual based on the diagnosis fields of claims records. Each individual was assigned an index date based on the first dispensing of the newly-initiated drug therapy. Data from the year prior to the index date were used to calculate the comorbidity risk score. Data from the year after the index date were used to measure adherence and copayment level.

Statistical analysis

Bivariate statistics were used to assess the unadjusted means and frequency distributions of the study variables. Logistic regression models were used to estimate the associations (adjusted odds ratios and 95% confidence intervals) between adequate adherence and generic medication use for each disease state. Multicollinearity was assessed using the Variance Inflation Factor (VIF), and the general rule of thumb that VIF >10, which indicates severe multicollinearity. None of the VIF values for our copayment variables or generic variables in any of the models exceeded the value of 4, and most were less than 2.5.

Results

We identified 327,629 individuals with 1 of 5 chronic medical conditions and newly-initiated drug therapy for that condition (Table 1). The average age of the subjects was 57 years, 53% were female, and the mean comorbidity score was 0.56 +/−12.3. Approximately 40% of the subjects lived in the southern part of the United States, followed by 31% in the north central region. Preferred provider organizations were the most common type of health coverage (38%), followed by comprehensive plans (31%) and point-of-service plans (21%). About 48% had hypercholesterolemia, 38% hypertension, 13% type 2 diabetes, 9% hypothyroidism, and 1% had seizure disorders.

Table 2 shows a distribution of individuals by use of generics and copayment levels for study medication. The proportion initiated on generic drug therapy was: 6% hypercholesterolemia, 9% hypothyroidism, 27% seizure disorders, 37% type 2 diabetes, and 45% hypertension. In general, most generic users paid copays within the range of $1 to $9, comprising 58% to 74% of these populations in each disease group. However, brand users paid a wider range of copays that varied by disease. For instance, copays of $30 or more were paid by 53% of brand users with hypercholesterolemia, compared to 12% of brand users with hypothyroidism. Interestingly, brand users and generic users were equally likely to pay $0 copays, except in one case: 12% of brand users with hypercholesterolemia paid $0 copays compared to 6% of generic users with hypercholesterolemia.

Figure 1 shows the distribution of new users by the median copayment paid for the study drug therapy. In general, new users initiated on generic drugs paid out-of-pocket, on average, $5 for their prescription, while new users initiated on brand drugs paid out-of-pocket, on average, $10 to $20 for their prescription. This figure also shows that the variation around generic copayments is modest, with the interquartile range within $4 to $10 for all conditions, while the variation around brand copayments is larger, with the interquartile range spanning $5 to $25.

Figure 2 shows the overall proportion of individuals achieving adequate adherence. Individuals with seizure disorders had the lowest rates of adherence: 43% of brand users achieved MPRs greater than or equal to 80% and it was 39% for generic users. Individuals

with hypothyroidism achieved the highest MPRs, approximately two-thirds of the population, regardless of brand or generic use. Use of generics was significantly associated with higher adherence only if the treatment was for hypercholesterolemia (62% vs. 53% (p<. 0001). Conversely, use of generics was significantly associated with lower adherence when the treatment was for hypertension (47% vs. 59% (p<.0001). There was no difference in adherence between brand and generic users for those with diabetes or seizure disorders.

Table 3 shows the multiple regression results. In Model 3 with the full model specification, use of generics was associated with higher adherence relative to use of brands in two conditions (hypercholesterolemia AOR 1.52, 95% CI: 1.44–1.60 a; diabetes AOR 1.06, 95% CI: 1.01–1.12, with lower adherence in two conditions (hypertension AOR 0.75, 95% CI:. 73–.77; hypothyroidism AOR 0.86, 95% CI:.78–.94), and no difference in seizure disorders, after controlling for copayment levels and other covariates. In comparison, $0 copayments were associated with adequate adherence across all five conditions. For instance, relative to $0 copayments, the likelihood of achieving adequate adherence decreased for all conditions with $1–9 copayments, ranging from AOR 0.47 for seizure disorders (95% CI: 0.32–0.68) to AOR 0.83 for hypothyroidism (95% CI: 0.91), controlling for generic use and other covariates. Exceptions to the higher adherence with the $0 copayment occurred only at the highest copayment levels ($30+) for individuals with hypothyroidism or hypertension. The sensitivity analysis with adequate adherence set at MPR >=60% showed similar results.

Discussion

In this study of over 300,000 privately-insured adults aged 18 or older, we found the use of generic drug therapy was inconsistently associated with improved adherence, and the effects were generally small. In two of five chronic conditions, patients were more likely to achieve MPR levels of 80% or higher if taking generics rather than brands: only patients with hypercholesterolemia or diabetes achieved adherence improvement if taking generic drug therapy rather than brands, after controlling for differences in copayments. Conversely, patients with hypertension or hypothyroidism experienced lower adherence if taking generic drug therapy rather than brands, and patients with seizure disorders experienced no difference in adherence. Rather, a $0 copayment was the strongest and most consistent predictor of adequate adherence in the study conditions, regardless of the use of generics or brands.

What could account for this inconsistency in adherence levels by use of generics found in our study? This study cannot answer this question, however, at least one study has found that some patients rate generics as less important than brand drugs and importance rating predicts adherence.[22] It is also possible, that some issues specific to certain medications, such as the bioequivalence of generic levothyroxine may be influencing these results.[23] Also, some conditions have had generic drug therapies available for more years than others, and have also had more generic choices from which to select. The number of unique generic drug name products for our study conditions were: hypertension (76 brands; 45 generics), type 2 diabetes (16 brands; 9 generics), seizure disorders (8 brands; 6 generics), hypercholesterolemia (8 brands; 1 generic), and hypothyroidism (4 brands; 2 generics). Although, the relationship between such differences and our finding is not clear. We investigated the possibility that the magnitude of difference between generic and brand copayments influenced adherence, but could discern no clear pattern. For instance, the copayment differential between generics and brands was greatest for hypercholesterolemia ($19.5 brand vs. $7.1 generic) and hypertension ($18.5 vs. $6.6 generic) yet generic use had the opposite influence on adherence in these two conditions. Our sensitivity analysis lowering the adequate adherence level to >60% showed nearly identical results, and an ad hoc analysis excluding mail order prescriptions also revealed no consistent patterns.

Our study offers several unique contributions that distinguish it from other studies. First, our study population is incidence users whereas nearly all other studies of cost-sharing and adherence examined prevalence users.[2, 3, 5] It has been our experience that incidence users are different from prevalence users, most notably their adherence levels are generally lower than those of prevalent users (at least 10 percentage points lower). Furthermore, our measure of adherence included a broad range of drug classes and our sample selection criteria included few exclusions, whereas most other studies focus on individual drug classes and specific patient populations. In our review of the literature, we could find no other comparable studies for external validation. Thus, the strength of our study is in the uniform comparison of the relative effect of generic use on adherence across five different patient populations in the first year of therapy.

This study had several limitations. The selection of chronic medical conditions was a somewhat arbitrary process that was limited to conditions treated most often with prescribed drug therapies taken on a regular and daily basis. For instance, arthritis was not selected due to the common use of over-the-counter medications and medications on an as needed basis. There were also overlaps in the samples since we did not limit the individuals to a primary diagnosis. The largest overlap was 17% and it occurred between the samples for hypertension and hypercholesterolemia. This study used the MPR and pharmacy claims records to measure adherence, and thus our analysis assessed rates of medication acquisition rather than medication exposure. However, research has demonstrated predictive validity for measuring the cumulative exposure of medications with acquisition data.[24] Indeed, our measure of adherence depends on the accuracy of the days supply information, although we have no evidence of measurement bias related to the drug class or specific disease state being treated.[25] The MPR provides only one aspect of adherence, and other types of adherence measures may provide different results, although we have no evidence to suspect that generic use is sensitive to the particular adherence metric.[26] In addition, we have no information about whether the drug therapy was prescribed for primary or secondary prevention for certain conditions. Lastly, we excluded individuals taking both generics and brands. These individuals may have impacted the results for certain patient groups more than others, although this criterion affected only about 10% of the sample.

Despite these limitations, this study offers one of the first uniform assessments of the impact of generic use on adherence across multiple conditions and after controlling for copayments. We conclude that a $0 or very low copayment will more consistently improve adherence than use of generics, and the improvement will be larger, at least for the five chronic medical conditions studied here. This finding is not surprising given that lowering the copayment is a more direct way to lower a patient’s out-of-pocket burden than prescribing generics. However, this finding should also serve as an important reminder that adherence may be at-risk when copayments increase, even if generics are available. The clinical implication of these findings is to discourage prescribing practices and formulary designs that promote generic drug therapies as an across-the-board solution to cost-related nonadherence: cost-related nonadherence and associated negative consequences will likely increase if pharmacy benefits are constructed in such a way as to promote generics without consideration of copayments.

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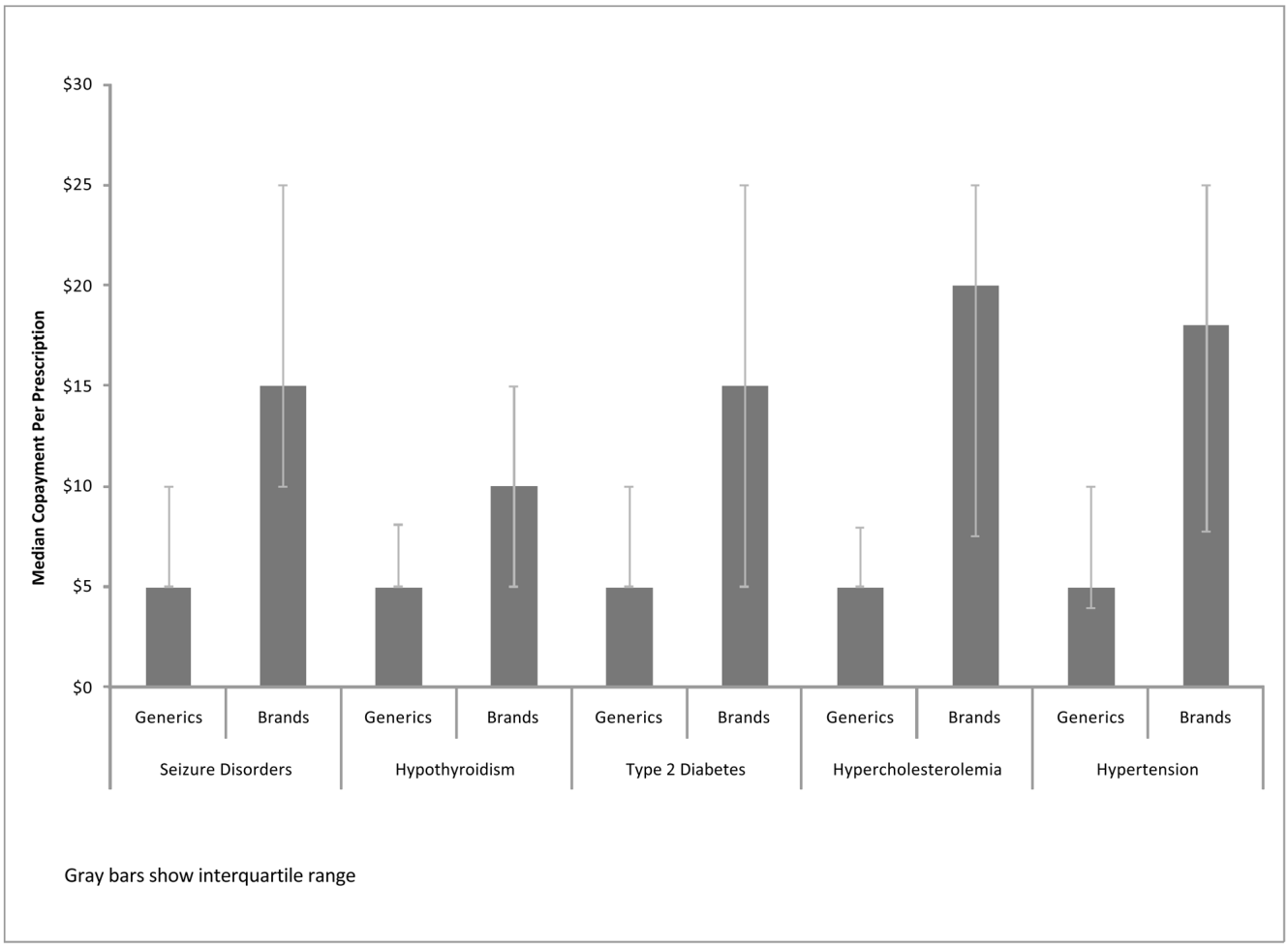

Figure 1. Distribution of Copayments for Study Drugs
Gray bars show interquartile range

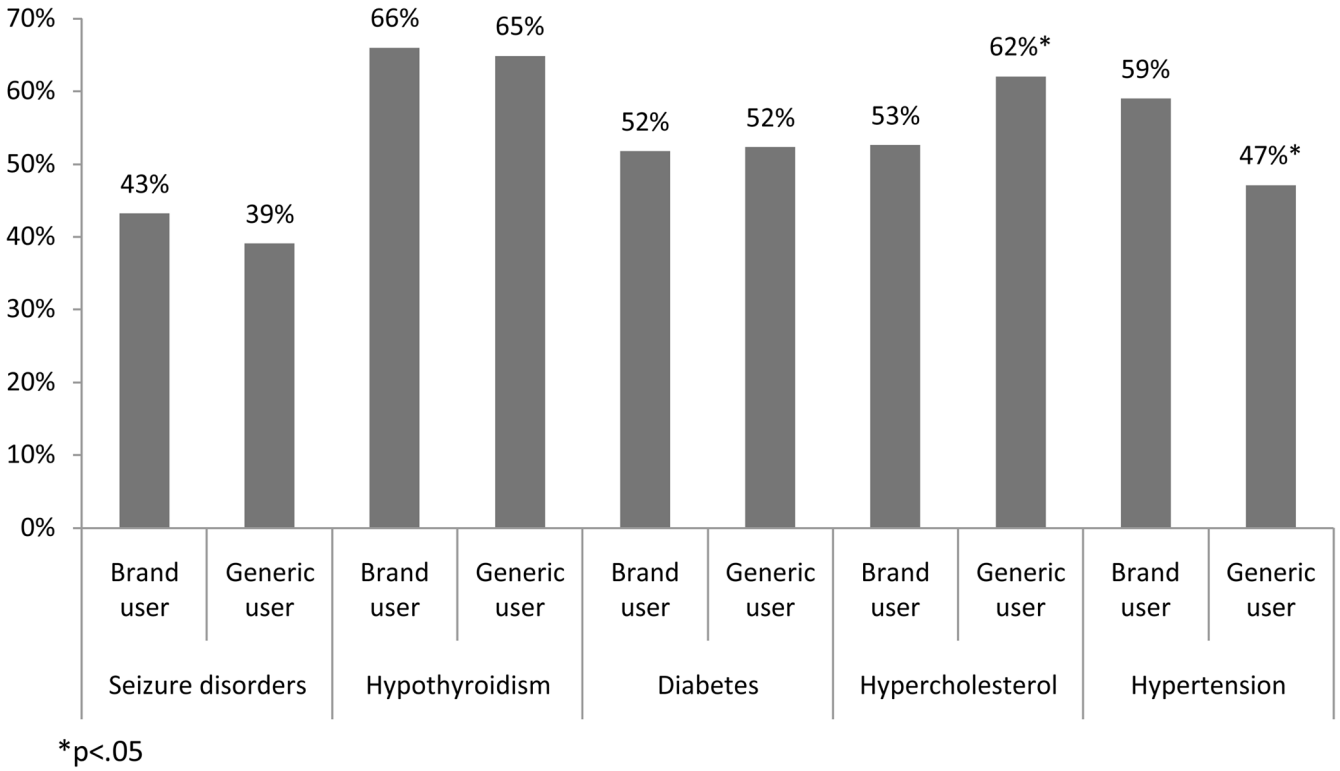

Figure 2. Proportion of Individuals Achieving Adequate Adherence (MPR>=80%) by Use of Generics
*p<.05

Table 1

Characteristics of Study Population, n=327,629

	Value
Age, mean (SD)	56.6 (12.3)
Comorbidity score, mean (SD)	0.56 (.60)
Gender, %	46.8
Male	53.2
Female	
Geographic residence, %	
Northeast	10.6
North Central	31.2
South	40.4
West	17.7
Type of Health Plan, %	
Comprehensive	31.1
Preferred Provider Organization	38.3
Point-of-Service	20.9
Health Maintenance Organization	8.7
Exclusive Provider Organization	1.0
Selected chronic conditions*, %	
Hypercholesterolemia	47.8
Hypertension	38.3
Type 2 Diabetes	12.6
Hypothyroidism	9.3
Seizure Disorders	0.6

* Not mutually exclusive categories

Table 2

Distribution of New Drug Users by Use of Generics and Drug Copayment

		Copayment Level (n)				
		$0	**$1–9**	**$10–29**	**$30+**	**total**
Seizure Disorders	Generic Users	46	296	115	29	486
	Brand Users	110	199	495	538	1342
Hypothyroidism	Generic Users	207	2067	458	63	2795
	Brand Users	2879	9972	11723	3201	27775
Type 2 Diabetes	Generic Users	1699	8809	3714	935	15157
	Brand Users	3344	4941	6370	11434	26089
Hypercholesterolemia	Generic Users	633	6960	1670	555	9818
	Brand Users	17449	20376	31695	77241	146761
Hypertension	Generic Users	5752	36705	11897	2044	56398
	Brand Users	7199	11709	16322	33769	68999

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Table 3

Logistic Regressions Evaluating Adequate Adherence by Use of Generics

Predictors of Adequate Adherence	Seizure disorders	Hypothyroidism	Diabetes	Hypercholesterolemia	Hypertension
n	**1,828**	**30,570**	**41,246**	**156,579**	**125,397**
Model 1: Use of Generics, unadjusted					
Generics (ref: brands)	0.84 (.68–1.03)	0.94 (.86–1.01)	1.02 (.98–1.06)	1.47* (1.41–1.53)	0.62* (.60–.63)
Model 2: Use of Generics adjusted for only copayments					
Generics (ref: brands)	0.95 (.75–1.21)	0.91* (.84–.99)	1.02 (.98–1.07)	1.53* (1.46–1.60)	0.69* (.68–.71)
Copayment levels					
$0 (reference)					
$1–9	0.49*	0.80*	0.75*	0.66*	0.68*
$10–$29	0.63*	0.71*	0.72*	0.60*	0.79*
>=$30	0.70	1.30*	0.77*	0.82*	1.00
Model 3: Use of Generics adjusted for copayments and other characteristics+					
Generics (ref: brands)	0.88 (.69–1.14)	0.86* (.78–.94)	1.06* (1.01–1.12)	1.52* 1.44–1.60	0.75* (.73–.77)
Copayment levels					
$0 (reference)					
$1–9	0.47*	0.83*	0.73*	0.68*	0.72*
$10–$29	0.61*	0.84*	0.80*	0.66*	1.02
>=$30	0.75	1.57*	0.92	0.93*	1.32*

+adjustments were age, gender, plan type, geographic residence, and normalized comorbidity risk score

*Statistically significant (p<.05)

Appendix

List of Study Diseases, diagnostic codes, and Study Therapeutic Drug Classes

Disease states	ICD-9-CM codes	Therapeutic drug classes*
Diabetes	250.x0 or 250.x2	a-glucosidase inhibitors, Sulfonylureas, Thiazolidinediones, Meglitinides, Biguanides
Hypertension	401.X	Beta-adrenergic blockers, ACE inhibitors, Angiotensin II receptor antagonists, Calcium channel blockers, Diuretics
Hypercholesterolemia	272.X	Statins
Seizure disorders	345.X	Hydantoins, Carbamazepine, Lamotrigine, Barbiturates, Primidone, Topiramate, Valproic acid derivatives, Sulfonamides
Hyopothyroidism	244.X	Thyroid preparations

*Includes all generic and brand-name forms of the medication as well as combination products. When determining adherence rates, days supply dispensed of other less commonly dispensed agents for the disease states were used in the calculations, include: centrally acting antiadrenergics, peripherally acting antiadrenergics, vasodilators, and eplerenone for hypertension; bile acid sequestrants, fibrates, ezetimibe, and niacin for hypercholesterolemia; succinimides, felbamate, gabapentin, levetiracetam, oxcarbazepine, and tiagabine for seizure disorders.