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The impact of Medicare part D prescription drug benefit program on generic drug prescription

A study in long-term care facilities

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Abstract

To examine whether the Medicare Part D program had an impact on the generic drug prescription rate among residents in long-term care facilities.

We analyzed prescription data for 3 drug classes (atypical antipsychotic, proton pump inhibitor, and statin) obtained from a regional online pharmacy serving long-term care centers in Pennsylvania from January 2004 to December 2007.

Difference-in-difference is used as a primary analysis method, and different regression methods (probit and multinomial) are used to accommodate different types of outcome measures.

Contrary to expectations, the Part D program did not have a statistically significant impact on the generic prescription rate in the long-term care setting during the study period. Only the statin class showed a dramatic increase in generic drug prescriptions, mainly due to the loss of patent protection for one of the most popular brand-name drugs in the class.

The complex dynamics of the prescription drug market, particularly the availability of generic versions of popular prescription medications, had a bigger role in increasing the prescription rate of generic drugs than the Part D program. This warrants the need to relax prescription medicines' patent policies and for further study on the impact of such policies.

Abbreviations: AA = atypical antipsychotic, AARP = American Association of Retired Persons, ANDA = abbreviated new drug application, DID = difference-in-difference, DSS = decision support systems, FDA = Food and Drug Administration, ICD9 = International Classification of Diseases, ninth revision, IV = intravenous, NDA = new drug application, NDC = National Drug Code, OTC = over the counter, PPI = proton pump inhibitor.

Keywords: difference-in-difference analysis, generic drug, Medicare Part D, medication prescription

1. Introduction

National prescription drug expenditures have been rising continuously, topping over $328 billion in 2016.[1] Within prescription drug spending categories, out-of-pocket payments by consumers accounted for nearly 13.7% of these expenditures in the same year. This is a significant percentage compared with out-of-pocket payments for hospital care (3%) and physician and clinical services (8.9%).

The federal government initiated the Medicare Part D program, effective on January 1, 2006, to subsidize prescription drug expenditures for Medicare beneficiaries to help control the high out-of-pocket payments and high volume of prescription drugs for this population.[2] Medicare Part D was designed as a voluntary enrollment program for the eligible US population, and enrollees who were eligible for both Medicaid and Medicare (termed *dual eligible*) were automatically assigned to the Part D plan. The Part D program shifts financial responsibility for prescription drugs from consumers, Medicaid, and other private-sector options to Medicare, making Medicare the nation's largest prescription drug purchaser. Policy makers have stipulated greater use of generic drugs to reduce federal as well as consumer spending. Insurers have also promoted generic drugs by sending coupons for generic drugs to covered members and free generic drug samples to physicians.[2] By use of generic drugs, the program beneficiaries also reduce the risk of hitting the "Donut Hole," a gap between the initial coverage limit and the catastrophic coverage threshold. Half of the sample Part D beneficiaries under the Kaiser Part D plan in northern California, for example, fell in this gap,[3] and the additional spending on the prescription drugs by Medicare beneficiaries residing in long-term care facilities amounted to more than $500 per person in 2001 compared to the community-dwelling beneficiaries.[4] Thus, the risk of falling in the donut hole among the beneficiaries in long-term care facilities is considerably higher than the community-dwelling counterparts and requires our attention considering the association between the coverage gap and the lower medication adherence.[5]

In 1984, the entry of generic drugs to the market became easier through the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act).[6] However, decisions on drug prescription are often made at the discretion of individual physicians without consulting patients, especially residents in

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long-term care centers, whose average age is 65 or older[7] and who are often unable or unwilling to offer their opinions on the choice of medications despite their high dependency on prescription drugs compared with their peers in community dwellings.[8] Considering the lack of patients' involvement in decision making, and the estimated demand for long-term care, which will double in the next 30 years,[9] we are facing a critical challenge for health care delivery. The challenge highlights the importance of investigating health care policies and issues that are relevant to long-term care residents. Therefore, examining prescription patterns at long-term care centers in the presence of the Part D program may shed light on prescription choice under conservative circumstances.

According to previous studies, the slow rate of increase in prescription drug spending in 2007 is partially attributed to the Part D program,[10] which has also increased utilization of generic drugs.[11] However, the existing literature is divided on the effect of Part D on prescription drugs. One study showed that Medicare Part D reduced the elderly population's medication costs by 18.4% even though it increased prescription drug usage by 12.8%,[12] whereas another study found no significant change in out-of-pocket expenditures by the dual eligible after the implementation of Part D.[13] The similar finding suggests that Part D increased the drug and decreased out-of-pocket costs, but the results are mixed for dual eligible.[14]

Studies on generic drugs are also divided into 2 folds. While one study revealed that generic drugs may not reduce patients' out-of-pocket payments in specific cases,[15] another found that it is expected that patients will reduce their total prescription costs by switching to generic equivalents from brand-name drugs.[16] More recently, there has been a systematic effort to uncover the drivers of the generic drug use.[17] However, no studies have explicitly examined the effect of the program on the change in physicians' prescription patterns in long-term care centers, as most studies attempt to address the overall prescription cost based on macro-level data. In this study, we try to fill the gap in the existing literature by investigating the influence of the Part D program on the generic drug prescription rate in the less-explored settings of long-term care facilities.

2. Methods

2.1. Data

The prescription drug data used in this study include orders delivered to 24 long-term care facilities in Pennsylvania from January 2004 to December 2007 by a regional online pharmacy. Data includes facility information, prescription orders, patient demographics, diagnoses, unique physician identifiers, and the sources of patients' drug coverage. Our analysis does not include subsequent refills.

As the long-term care centers and the online pharmacy are located in Pennsylvania, where mandatory substitution law was adopted, multi-source brand drugs prescribed can be replaced by generic drugs while dispensing. Thus, to precisely capture the generic drug use, we label prescription orders as "brand" if the order is for a single-source brand drug and "generic" if the order is for either a generic or multi-source brand drug with an available generic version. The "brand name medically necessary" requirement is specifically noted as such by physicians, if needed. This alerts the pharmacist not to substitute a drug's generic equivalent for its brand-name version. Different strengths (20 mg, 40 mg, etc.) are considered separately if generic drug availability is different by strength.

We dropped patient records with unknown date of birth, invalid NDC (National Drug Code), and suspension or non-solid forms of drugs, such as intravenous (IV) solutions. IV or suspension medications have fewer alternatives; thus, it is difficult to observe transition or change in prescription rates, if any. Also, the general classification of drug tiers does not apply to these types of drugs. Supplementary classifications (ICD9 starting with V or E) are excluded from diagnosis counts.

We analyzed 3 classes of therapeutic drugs in this study. There are unobservable market variations that affect prescription choices in each class of drugs, and thus it is important to confine our study to limited drug classes. We carefully chose these 3 classes based on the rank order of the prescription volume and the pre-study availability of generic versions in each therapeutic class.[4] The selected therapeutic classes are atypical antipsychotics (for schizophrenia), HMG-CoA reductase inhibitors (statins: lipid-lowering drugs), and proton pump inhibitors (PPIs; for gastric acid management). Since each class includes single-source and multi-source brand drugs (meaning that pharmaceutically equivalent generic drugs are available), there is a choice between brand and generic versions. No new generic equivalent entered the market in 2 of the classes, atypical antipsychotics and PPIs, providing a clear study setting to investigate the impact of the Part D program by analyzing differences before and after Part D installment. In the statin class, the patent of one leading-brand drug, Zocor, expired on June 23, 2006, and 2 new generic drugs were introduced in this class during the study period. Thus, if we find a distinctive pattern between the previous 2 classes (atypical antipsychotics and PPIs) and the statin class, the difference could be attributed to other dynamics in the market, such as the entrance of new generic drugs.

We compiled the NDA (New Drug Application) and ANDA (Abbreviated NDA) approval dates for the drugs included in this study using the Food and Drug Administration (FDA) orange book. Irrespective of multiple strengths, only the first generic approval date under the same drug name is shown in Table 1. Suspensions and intravenous solutions are excluded, as mentioned earlier, and OTC (over-the-counter) drugs are excluded for the "All Drug" set (entire prescription orders from our study facilities). "Generic availability" indicates that there is a generic equivalent available in the class (Table 1).

2.2. Statistical analysis

We compared the prescription rates of brand and generic drugs in each drug class and estimated the impact of Part D on the generic prescription rate by using the difference-in-difference (DID) method using both a linear probability model and a multinomial logit model. The DID analysis is well-suited for our problem since there is a possible trend in the pattern of prescription choice, and a reasonably parallel trend between treated and controlled groups is observed. Generic drugs have become more prevalent over time due to the availability of insurance policies covering generic drugs at almost no cost as well as an increase in the number of approved generic drugs in the market.

Lichtenberg and Sun[12] used a similar method to evaluate the impact of Part D on cost savings and drug usage for enrollees by setting elderly (age 65 and older) as the treatment group and non-elderly as the control group because most Medicare enrollees are elderly (97.4%). However, in long-term care centers, the

Table 1

Study drugs with FDA approvals.

Brand Name	Generic name	Generic Availability	ANDA approval	NDA approval	Manufacturer
HMG-CoA reductase inhibitor (Statin)					
Lipitor	Atorvastatin	No		12/17/1996	Pfizer
Zocor	Simvastatin	Yes	6/23/2006	12/23/1991	Merck
Pravachol	Pravastatin	Yes	4/24/2006	10/31/1991	Bristol-Myers Squibb
Lescol	Fluvastatin	No		12/31/1993	Novartis
Crestor	Rosuvastatin	No		8/12/2003	AstraZeneca
Mevacor	Lovastatin	Yes	12/17/2001	8/31/1987	Merck
Altoprev	Lovastatin	No		6/26/2002	First Horizon
Proton Pump Inhibitors					
Prevacid	Lansoprazole	No		5/10/1995	Takeda
Nexium	Esomeprazole	No		2/20/2001	AstraZeneca
Protonix	Pantoprazole	Yes	8/2/2007	2/2/2000	Wyeth
Prilosec	Omeprazole	Yes	11/1/2002	9/14/1989	AstraZeneca
Prilosec OTC	Omeprazole	No		6/20/2003	Proctor and Gamble
Zegerid	Omeprazole	No		2/27/2006	Santarus
Aciphex	Rabeprazole	No		8/19/1999	Eisai Inc
Atypical Antipsychotic drug					
Risperdal	Risperidone	Yes	6/30/2008	12/29/1993	Ortho McNEil Janssen
Zyprexa	Olanzapine	No		9/30/1996	Eli Lilly
Seroquel	Quetiapine	No		9/26/1997	AstraZeneca
Geodon	Ziprasidone	No		2/5/2001	Pfizer
Abilify	Aripiprazole	No		11/15/2002	Otsuka
Clozaril	Clozapine	Yes	11/15/2002	9/26/1989	Novartis

ANDA = abbreviated new drug application, FDA = Food and Drug Administration, NDA = new drug application.

percentage of non-elderly in the Medicare program is higher (approximately 20% in our data) than in the general population, and thus distinguishing groups only by age is not sufficient. Furthermore, there are Medicare beneficiaries who opt not to enroll in Part D. Thus, we define 3 treatment groups in our study design:

1. dual enrollees (enrolled in both Medicaid and Medicare, hereafter referred to as *duals*),
2. elderly people who are enrolled in the Part D program but are not duals (hereafter referred to as *voluntary enrollees*), and
3. eligible members of the general population who are not duals (people with opportunity to enroll, hereafter referred to as *eligible*).

The control group is the non-elderly population (age <65 during the study period) not enrolled in Part D; some (20% among the non-elderly in our data) are on Medicare Part D due to disability, not age. Aside from age, other markers of eligibility (i.e., whether a patient is covered by Medicare) are not observable from the data, and thus we exclude non-senior enrollees.

Duals are considered separately because of their special characteristics, including automatic enrollment with no change in the cost-sharing structure. However, since there were changes to the formulary and funding sources under Medicaid and Part D, we categorize them as one treatment group. For dual enrollees, the gap between cost sharing of brand-name and generic drugs is only approximately 10% of that for non-dual enrollees under the standard benefit plan (cost-sharing source from the AARP standard Part D plan). Thus, we separate duals from the eligible population and expect to see very little change in prescription patterns, if any. In contrast, a shift from brand-name to generic drugs is expected for voluntary enrollees, since this group would be the most cost-conscious population, judging by their voluntary enrollment in the Part D program.

The unit of analysis is each prescription order record. The outcome measure, *Generic*, is a binary value indicating whether the prescribed drug is generic. This variable can take 3 values for the PPI class when taking the OTC drug (Prilosec OTC) into account. Thus, we use a multinomial logit model for the PPI class, and a linear probability model with physician fixed effects for the other 2 classes. The explanatory variables are $Part_{Di}$ (equal to 1 if Part D is in place when prescription i was ordered), $Treatmet_i$ (equal to 1 if a patient in order i is in the treatment group), and their interaction term, which is the variable of interest. We also control for patient-specific information (age, gender, number of diagnoses, monthly average number of medications). We include a variable for physician fixed effects because physicians make the key prescription decision, and thus we need to control for unobservable factors.[18] The model is as follows:

$$Generic_{ij} = \alpha + \beta_1 Part\,D_{ij} + \beta_2 Treatment_{ij} + \beta_3 Part\,D_{ij} \times Treatment_{ij} + \delta Patient_{ij} + \gamma_j + u_{ij}$$

(i = each prescription order, $Patient_i$ is a vector of patient characteristics values, δ = a vector of coefficients that correspond to patient characteristics variables, and j = physician)

To isolate the impact from new generic entries in the statin class, we added a new variable, *GenericEntry*, to the original model. *GenericEntry* is equal to 1 if the prescription is dated after June 23, 2006 (when the brand name Zocor lost its patent protection).

$$Generic_{ij} = \alpha + \beta_1 Part\,D_{ij} + \beta_2 Treatment_{ij} + \beta_3 Part\,D_{ij} \times Treatment_{ij} + \beta_4 GenericEntry_{ij} + \delta Patient_{ij} + \gamma_j + u_{ij}$$

To summarize, we conduct DID analyses with 3 treatment groups. These 3 analyses are conducted separately on 3 different

therapeutic classes as well as on the total prescription data including more than 700 drugs. Due to difficulties with fixed effect nonlinear models (logit or probit), such as data loss with conditional fixed effects and inconsistency with unconditional fixed effects, we use a (physician) fixed effect linear probability model,[19] allowing physician-level heterogeneity. The fixed effect linear probability model is commonly used in many other studies despite the possibility that the predicted value may lie outside the unit range due to problems with nonlinear fixed effects.[20]

3. Results

3.1. Descriptive data analysis

Figure 1 shows a clear transition to generic drugs in the statin drug class but not in atypical antipsychotic or PPI groups. For the statin class, the proportion of brand-name drugs dropped dramatically during the second half of 2006, and the decreasing trend continued until 2008. However, we do not see a large variation in the atypical antipsychotic and PPI classes, in which no other generic drug entered the market during the study period. In fact, the generic prescription rate for PPIs decreased in 2005, but this rate might have been affected by an OTC drug since Prilosec OTC was approved in 2003. However, the impact of OTCs on prescription drugs is beyond the scope of this study; hence it is excluded from further discussion, although we included it in our data analysis (Fig. 1).

Prescription trends of individual drugs are shown in Figure 2. Prescription rates of drugs are calculated semiannually. In the statin class, prescriptions for the generic drug simvastatin increased immediately after its ANDA approval, and simvastatin and Zocor together became the most prescribed statin drugs by the end of 2007. In the case of brand-name drugs, Figure 2 shows that the prescription rates of brand-name drugs either slowly decreased or stayed the same throughout our study period except Lipitor in the statin class (Fig. 2).

There is no noticeable time stamp when the brand drug prescriptions dropped off or the generic drugs took off among the AA (atypical antipsychotic) and PPI classes. The individual drug trend indicates that even within one therapeutic class there are many interactions and complexities. In 2004 and 2005, most statin prescriptions were for brand drugs, while the existing generic drug, lovastatin, was not widely prescribed. In 2006, when the generic drug simvastatin entered the market, it immediately became one of the highest-prescribed drugs because its brand counterpart, Zocor, was the second leading drug in this class.

Table 2 shows that patients taking different therapeutic drugs have similar demographic characteristics, including age and the average number of drugs they are prescribed. (Table 2)

3.2. Difference-in-difference analysis

The results in Table 3 validate our findings from the descriptive statistical analysis. In the absence of a new generic entry in the AA and PPI classes, we see that there is no statistically significant effect of Part D on the generic prescription rate for any of the 3 treatment groups. We can explain this in part by focusing on the characteristics of nursing home residents. A large proportion of this population is composed of dual enrollees who have virtually no change in their cost-sharing structure. In addition, physicians might be hesitant to switch prescriptions for residents who are already at higher risk given their age and the prevalence of multiple chronic conditions and medications. (Table 3)

In the analysis with voluntary enrollees as the treatment group in the statin class, the results show an approximately 20% increase in generic prescriptions after Part D became effective. This may be explained by the fact that this group is more cost-conscious because the cost-sharing gap between generic and brand-name prescriptions is higher than that for duals. However, the change cannot be solely attributed to the Part D program since the other drug classes do not show any significant effect of Part D enrollment; it is likely due to the entry of a popular generic drug, and the effect might be different for the control and treatment groups.

Results from the analysis separating the effect of generic drug availability on prescription rates reveal no statistically significant effect from Part D itself; significance in the DID coefficient for the voluntary group in the statin class disappears, and the new variable, *GenericEntry*, seems to absorb the effects. Therefore, we conclude that the increase in generic prescription rates for enrollees in the Part D program is likely driven by the entry of the generic drug simvastatin rather than the impact of the Part D program per se.

4. Discussion and limitation

Even with the technological aids that support physicians' prescription decision making, such as e-prescribing with decision support, this study does not find a statistically significant impact of Medicare Part D on physicians' prescription choices between generic and brand drugs in long-term care facilities in the case of the 3 most frequently prescribed drug classes among the residents: atypical antipsychotics, PPIs, and statins. This finding is similar to that of a previous study that found lower generic drug use among Part D enrollees.[21] There is an increase of approximately 20% in the generic drug prescription rate for the statin class that is likely due to dynamics in the therapeutic class market caused by the entry of new generic drugs, particularly of simvastatin, which is the generic equivalent of the popular brand-name drug Zocor. It is reasonable to expect that voluntary enrollees are more cost-conscious than dual enrollees, and thus relatively more generic drugs are prescribed for them. In our study, the increase in generic prescriptions in the overall population is most likely due to the availability of more generic drugs rather than enrollment in the Part D program.

Therefore, for the purpose of decreasing spending for prescription drugs in the Medicare program, policy makers and plan providers should promote the use of more generic drugs among Medicare beneficiaries, especially for Medicaid and Medicare dual enrollees. However, motivating generic utilization has a caveat: it may discourage R&D as Branstetter et al estimated a 7.9% decline in early-stage innovation in the same therapeutic market when there is a 10% increase in generic penetration,[22] which in turn may produce a negative impact in the long run if pharmaceutical companies are not financially motivated to develop new drugs.

This study has limitations due to the availability of the secondary data. The 6-month gap between Part D initiation and generic availability makes it hard to measure the impact of Part D enrollment alone in the statin class as well as the "All Drugs" set. Note that although many Medicare beneficiaries enrolled in Part D after January 2006,[23] most long-term care residents signed up for Part D immediately after the program was initiated. Thus, we

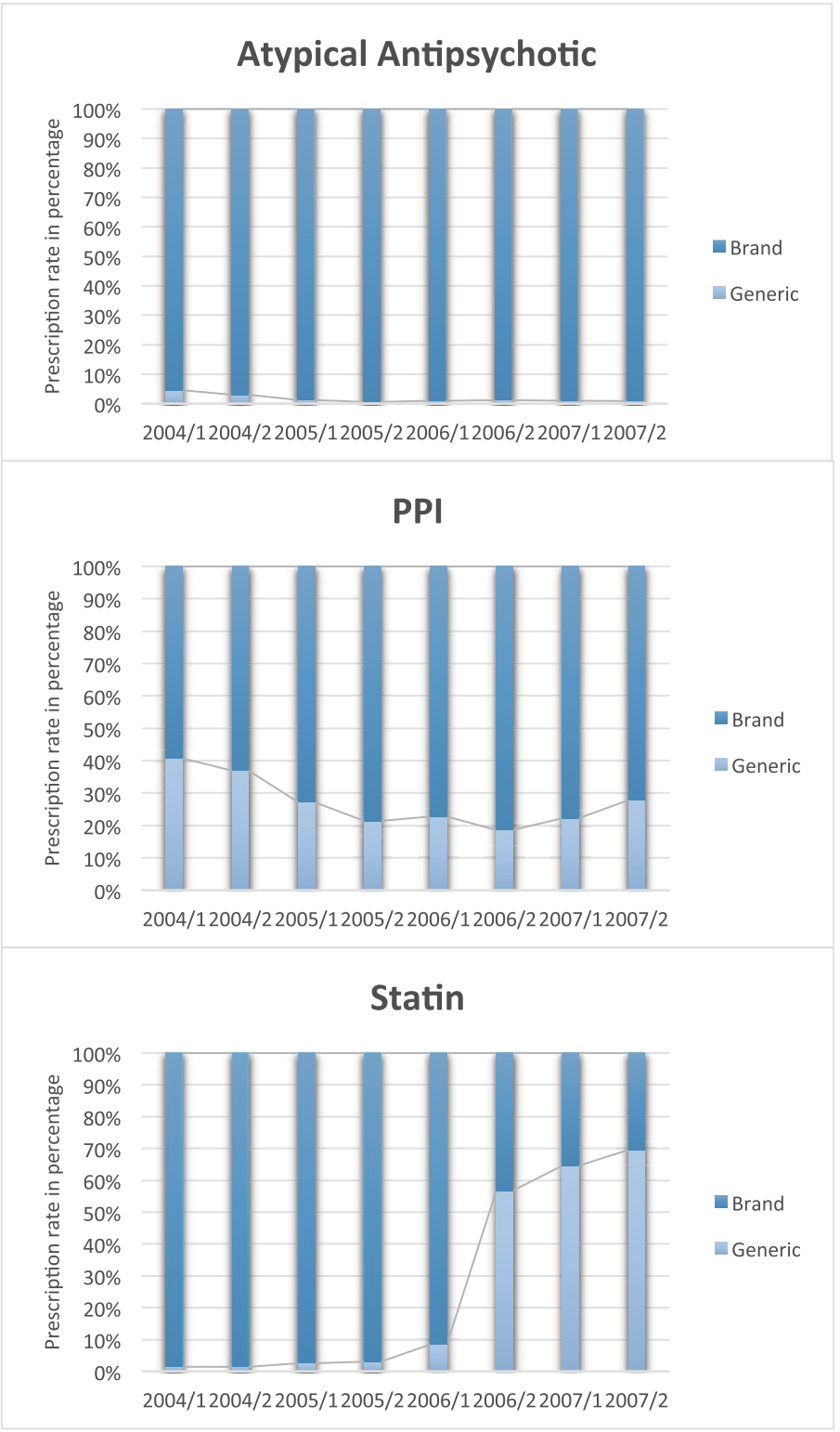

Figure 1. Generic vs Brand-name drug prescription composition for each therapeutic class.

expect less of a lag effect from Part D in the study population, and thus the potential underestimation of the impact of the Part D plan would be negligible.

In addition, it is important to analyze other drug classes that are similar to the 3 classes targeted in this study in terms of the availability of generic versions and prescription frequency for the target population to measure the consistency of the findings. Also, as our study is restricted to the state, extending the analysis to other states, non-online pharmacies, and different types of facilities will improve the generalizability of the study finding and

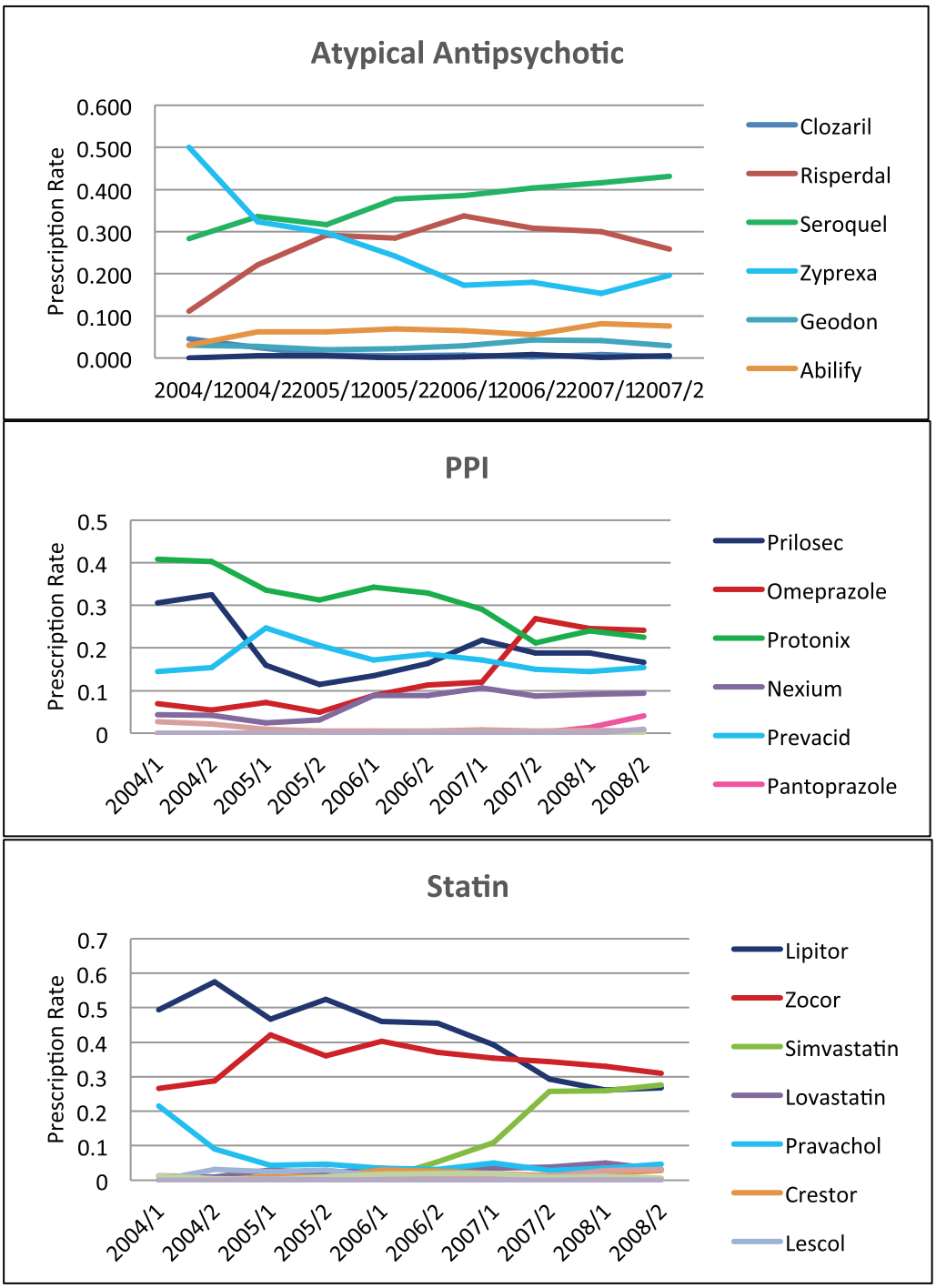

Figure 2. Prescription rate of individual drugs in each class.

help us gain further insights. Due to the differences between the operational mechanisms of long-term care pharmacies and other retail pharmacies,[24] pharmacy characteristics should also be analyzed. Finally, as the data do not provide the details of each plan, the study is limited by the potential confounding factors from Part D plan features[25] such as cost-sharing differences and pre-authorization.[26]

The long-term care centers in the study contracted with an online pharmacy in Pennsylvania that provides its proprietary e-prescribing tool embedding the Medicare Part D formulary to aid physicians' decision making. Thus, the long-term care facilities included in this study are presumably formulary compliant. Studies have shown that physicians using decision support systems (DSS) are likely to prescribe following the guideline from DSS than physicians who do not use such systems.[27,28] Therefore, it is reasonable to expect to see more generic drug prescriptions for Part D enrollees within this environment, and thus, any uptake in generic prescription would

Table 2

Demographic information on residents in 24 nursing homes.

Medication type	Number of Patients	Average age (as of 1.1.09)	Average diagnoses	Average Rx. count	Average drugs taken	Female Percentage
AA users						
Brand	2104	80.83	9.99	4.69	8.86	59%
Generic	21	79.6	10.0	4.48	8.62	57%
p-value	N/A	0.096	0.192	0.99	0.183	0.071
Total	2125	80.82	9.99	4.69	8.86	59%
PPI users						
Brand	2614	80.98	9.41	5.93	9.49	65%
Generic	871	79.89	9.34	5.79	9.44	64%
p-value	N/A	0.118	0.143	0.133	0.289	0.109
Total	3485	80.7	9.39	5.89	9.48	63%
Statin users						
Brand	1607	80.89	9.05	6.53	10.18	63%
Generic	558	79.87	9.01	6.49	10.10	64%
P value	N/A	.179	.274	.101	.109	.079
Total	2165	80.63	9.04	6.52	10.16	63%

AA = atypical antipsychotic, PPI = proton pump inhibitor.

Table 3

Effect of Part-D on generic drug prescription rate (Duals, Eligible, and Voluntary).

	Dual vs Non-eligible			
	AA	**PPI**	**Statin**	**All Drugs**
Part-D	−0.00532	−0.0368	0.428***	0.0537***
	(0.0204)	(0.0577)	(0.0649)	(0.0184)
Treatment	−0.0102	0.147*	0.101	−0.0737***
	(0.0355)	(0.0746)	(0.0625)	(0.0235)
Part-D x Treatment	0.00338	−0.0872	−0.000705	0.0306
	(0.0181)	(0.0569)	(0.0763)	(0.0204)
Observations	4237	2427	1257	61,654
	Eligible vs Non-eligible			
	AA	**PPI**	**Statin**	**All Drugs**
Part-D	−0.00903	−0.0616	0.398***	0.0481**
	(0.0225)	(0.0597)	(0.0588)	(0.0190)
Treatment	−0.0283	−0.130**	−0.0829**	−0.0303
	(0.0338)	(0.0593)	(0.0412)	(0.0188)
Part-D x Treatment	0.00984	0.0619	0.0148	0.0301
	(0.0232)	(0.0530)	(0.0705)	(0.0191)
Observations	5597	4694	2551	103,344
	Voluntary vs Non-eligible			
	AA	**PPI**	**Statin**	**All Drugs**
Part-D	−0.0140	−0.0261	0.441***	0.0477**
	(0.0235)	(0.0700)	(0.0673)	(0.0204)
Treatment	0.0257	−0.0174	−0.240	−0.111**
	(0.0504)	(0.279)	(0.153)	(0.0504)
Part-D x Treatment	0.00283	0.00811	0.207**	0.0887
	(0.0135)	(0.263)	(0.103)	(0.0549)
Observations	1182	838	433	19,080

	Statin Class		
	Dual	**Eligible**	**Voluntary**
Part-D	0.0547	0.0372	0.0372
	(0.0566)	(0.0510)	(0.0419)
Treatment	0.0366	−0.0527	−0.270*
	(0.0695)	(0.0344)	(0.147)
Part-D_Treatment	−0.0192	0.0110	0.0780
	(0.0712)	(0.0549)	(0.101)
Generic Entry	0.555***	0.560***	0.575***
	(0.0316)	(0.0300)	(0.0588)
	Patient's characteristics (age, gender, number of diagnoses, monthly drugs)		
Obs.	1257	2551	433

(.): robust standard error; Statistical significance.

AA = atypical antipsychotic, PPI = proton pump inhibitor.

* $P < .05$.

** $P < .01$.

*** $P < .001$.

have been overestimation. Despite the presumption and conditions favorable to genetic prescription, our finding does not provide a significant increase in generic prescription. This implies that the adoption of DSS does not provide enough assistance for the physicians to switch medications for long-term care residents due to barriers such as distrust in generic drugs among seniors with low health literacy.[29]

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