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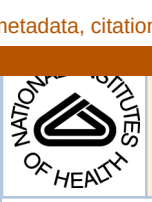

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J Clin Psychopharmacol. Author manuscript; available in PMC 2013 February 01.

Published in final edited form as:

J Clin Psychopharmacol. 2012 February ; 32(1): 3–10. doi:10.1097/JCP.0b013e31823fb5c4.

Medicare Part D's impact on antipsychotic drug use and costs among elderly patients without prior drug insurance

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Abstract

Medicare Part D's implementation improved access to and affordability of prescription drugs for the elderly without prior drug insurance. Effects for specific drugs and drug classes are less well understood. We assessed Part D's impact on antipsychotic medication (APM) utilization and out-of-pocket costs among elderly without prior drug insurance. Retail pharmacy claims from 3 nationwide pharmacy chains were used to analyze two time-series designs: 1) a Policy Model, to obtain a policymaker's perspective: what was the overall impact of Part D on APM use and costs among elderly without drug insurance in 2005 with the *opportunity* to enroll?, and 2) a Clinical Model, to obtain a clinician's perspective: what would happen to elderly without drug insurance in 2005 who *did* enroll in Part D—would they be able to get APMs? At what cost? Subgroup analyses among Part D enrollees evaluated potentially different effects for patients who received a subsidy and patients who used anti-dementia drugs. In the Policy Model, Part D implementation was associated with a 5% increase in APM use and a 37% reduction in out-of-pocket costs, suggesting a modest need for APMs among all previously uninsured elderly. Patients who did enroll in Part D (Clinical Model) had a 97% increase in APM use and a 62% decrease in out-of-pocket costs, suggesting that patients who needed APMs were able to access them at low cost

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Conflicts of interest:

Dr. Polinski is a consultant to Buccaneer Computer Systems and Service, Inc on a contract from the Centers for Medicare and Medicaid Services. Within the past 5 years, Dr. Polinski's spouse was employed by DePuy Orthopaedics, a subsidiary of Johnson & Johnson, and had Johnson & Johnson stock totaling < $3,100 in value. Dr. Brookhart has received investigator-initiated grant support from Amgen and has participated, without receiving an honorarium, on Amgen advisory boards. He has received consulting fees from Kaiser Permanente and McKesson Health Solutions. Dr. Glynn has a current investigator-initiated unrestricted grant from Astra-Zeneca to study statins, and receives and is co-investigator of a grant from Novartis for the design and monitoring of a randomized trial. Dr. Schneeweiss is a paid member of the Scientific Advisory Board of HealthCore and a consultant to HealthCore, World Health Information Science Consultants, LLC and Research Triangle Institute. Dr. Schneeweiss is Principal Investigator of the Brigham and Women's Hospital DEcIDE Center on Comparative Effectiveness Research funded by AHRQ and of the Harvard-Brigham Drug Safety and Risk Management Research Center funded by FDA. Within the past 5 years, Dr. Schneeweiss was funded by an investigator-initiated grant from Pfizer which has ended. Opinions expressed here are only those of the authors and not necessarily those of the agencies.

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through the Part D program. Part D implementation was associated with increased use and affordability of APMs for elderly without prior drug insurance.

INTRODUCTION

Medicare Part D's 2006 implementation is associated with both a 6–19% overall increase in drug utilization and a 13–18% decrease in out-of-pocket costs.[1–6] Changes for specific drugs are less well understood and vary depending on drugs, disease, and/or the population studied.[7–9] Part D's impact on the use of and costs for antipsychotic medications (APMs) is of particular interest to clinicians and policymakers. Legislation required Part D plans to cover "all or substantially all" APMs because access to a wide number of choices was considered to be therapeutically important.[10] Still, plans were able to apply utilization management tools such as prior authorization, step therapy, and quantity limits to potentially restrict use. While the APMs are FDA-approved for the treatment of schizophrenia and bipolar mania, in the elderly, they are recommended for and most often prescribed "off-label" to ameliorate the behavioral symptoms of dementia.[11] Although concerns persist about effectiveness and increased risks of adverse events among elderly APM users with dementia,[12–16] APMs may be the best treatment option for some elderly patients. Atypical APMs, which account for most use among the elderly,[17] are quite expensive,[18] and so Part D's implementation may have removed financial barriers to APM use for patients but increased financial costs for payers.

In this study, we evaluate the impact of Part D's 2006 implementation on changes in days' supply of and out-of-pocket costs for APMs among patients without prior drug insurance using interrupted time-series designs. Our study takes a multi-faceted approach. In a "Policy Model," we examine Part D's effect on uninsured elderly who had the opportunity to obtain drug insurance and did or did not enroll in Part D. This model answers the policymaker's question—what was Part D's *overall* effect on uptake of APMs and out-of-pocket costs among previously uninsured patients who could now obtain drug insurance?[19] Then, in a "Clinical Model," we investigate Part D's impact on the subset of previously uninsured patients that did enroll in Part D. This model answers the clinician's questions—if my patient enrolls in Part D, will he be able to obtain APM medications? At what cost?[19] Among enrollees, we also consider whether receiving a subsidy to help defray drug costs affects utilization. Our study provides evidence regarding Part D's impact on APM utilization and costs in a previously uninsured elderly population and discusses Part D's policy-related and clinical implications.

METHODS

Study population

The primary population of interest was elderly patients age 65+ with no drug insurance in 2005. Because patients without drug insurance cannot be identified via insurance claims, we used prescription transaction records from three nationwide retail pharmacy chains. Each individual and his corresponding prescriptions could be identified within a given pharmacy chain, but we could not link patient data across pharmacy chains. Therefore, because data would be lost if patients filled prescriptions at an out-of-chain pharmacy, we established a closed cohort of patients who filled ≥1 prescription in 2005 and ≥1 in the last six months of 2006 within a given pharmacy chain, although among older adults, pharmacy loyalty is known to be high.[20] This approach allows us to study a population of uninsured elderly who filled multiple prescriptions at one pharmacy over time—those who had demonstrated need for medications and might most benefit from Part D's implementation. From this population,

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we selected only those patients who filled ≥1 prescription for an APM during the study period, January 1, 2005–December 31, 2006.

Because detailed drug insurance plan (third party payment) information was not available, we applied a previously tested algorithm[21] that considers drug costs, out-of-pocket costs, and Part D's benefit structure to empirically assign patients' drug insurance status. Drug costs were calculated as 80% of the average wholesale price (AWP) for each National Drug Code, as recommended by the Department of Health and Human Services.[22] Patients were considered *uninsured in 2005* if the co-payment amount for ≥80% of their prescriptions was ≥60% of the AWP for all prescriptions costing ≥$20. Patients were considered *Part D insured in 2006* if, between January 1, 2006 and the date when the cumulative price of the patient's prescriptions reached $2,000, the out-of-pocket payment for ≥80% of their prescriptions was <50% of the AWP for all prescriptions costing ≥$20 or if 80% of their out-of-pocket payments were flat amounts, e.g. $10.00. Prescriptions with costs <$20 were not considered in the algorithm because the copayments for such drugs were more likely to exceed 60% of the AWP, artificially making patients appear uninsured. Patients remained *without drug insurance in 2006* if they did not meet the *Part D insured in 2006* definition. This algorithm was designed to have high specificity at the cost of lower sensitivity in order to ensure that patients who were classified as having no drug insurance truly did not have coverage.[21] Sensitivity analyses that used more and less stringent criteria to identify uninsured patients had little influence on the number of patients identified.[21, 23]

Patients who enroll in Part D are potentially eligible to receive a low income subsidy (LIS) based on their income and assets. Therefore, among Part D enrollees, it was of interest to determine whether receiving a subsidy affected APM utilization. We identified *full subsidy patients* based on Medicare regulations that limited these patients' out-of-pocket payments to ≤$3 for a generic and ≤$5 for a branded drug during 2006. In contrast, patients who qualify for a partial subsidy paid ≤15% co-insurance for each prescription fill; however, Part D plans could and did vary their co-insurance and co-payment requirements, so patients receiving a partial subsidy might pay the same amount as a patient who did not receive a subsidy. Without plan-specific data, nor information on patients' income or assets, we could not accurately identify patients who received a partial subsidy. Therefore, patients who received a partial subsidy or no subsidy were grouped together. The study was approved by the Brigham and Women's Hospital Institutional Review Board.

Study design

The study considered two individual data-level time-series designs. The "Policy Model" examined all patients with no drug insurance in 2005 who had the opportunity to enroll in Part D, thus investigating Part D's impact among all patients potentially affected by the policy and producing a "net impact" of the policy. January 1, 2006, the date of Medicare Part D implementation, was the exposure. The exposure was well-defined and affected all patients at the same time. Two segments defined the time series: a 12-month baseline period (January–December 2005) and a 12-month post-Part D period (January–December 2006). In the Policy Model, Part D's impact was evaluated by comparing the actual experience of patients who did or did not enroll in Part D versus the (hypothetical and counterfactual) experience of the same group of patients if Part D had not been introduced. The counterfactual experience was predicted by extrapolating patients' pre-Part D experience to the post-Part D period. Therefore, the counterfactual experience included patients who would have changed their behavior regardless of whether Part D was implemented or not. The inclusion of these patients is important when, for example, a policymaker wants to consider the total costs attributable to a new program among both patients who enroll in the new program and patients who avoid it.[19]

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Our second design, the "Clinical Model" examines only those patients who had no drug insurance in 2005 and did enroll in Part D in 2006. The Clinical Model differs from the Policy Model in that it measures Part D's impact among Part D "compliers" (those who did enroll in Part D) and compares their experience to the extrapolated, counterfactual experience of the same group of patients had they not enrolled in Part D.[19] The Clinical Model answers the questions "If my uninsured patient enrolls in Part D, will he be able to obtain APMs? At what cost?" In the Clinical Model, patients' covariates might affect when and whether a patient enrolled in Part D. Therefore, all patients were aligned at their respective *enrollment date*, the date of the first of two consecutive prescriptions in 2006 at which the patient was insured under Part D. We The Part D enrollment date, the exposure, was set as time zero. Two segments defined the time series: Twelve 30-day periods before the enrollment date and up to twelve 30-day periods afterwards. In a Clinical Model sub-analysis, we compared APM utilization among those who received a full subsidy versus those who received either a partial subsidy or no subsidy at all. Because Medicare legislation already dictated that full subsidy beneficiaries would pay <$3 for a generic and <$5 for a branded drug, and because of our inability to separate partial and no subsidy beneficiaries, we did not conduct a subgroup analysis for changes in APM costs. A second sub-analysis in the Clinical Model examined potential differences in APM utilization between patients who received an antidementia drug during 2005–2006 and patients who did not. These patients might be more likely to be taking APMs to treat symptoms of dementia as compared to patients who had no anti-dementia drug fills.

Model designs and comparisons

For both time-series designs, the basic analytic model included initial intercept and slope terms (describing the baseline outcome level (*intercept*) and the months since baseline (*month*)), a term to indicate whether Part D had been implemented (*policy,* Policy Model) or whether a person had enrolled in Part D (*enroll,* Clinical Model), and a second slope term that described months since Part D implementation (*policy_month*, Policy Model) or months since enrollment in Part D (*enroll_month,* Clinical Model). For both scenarios, we lagged the time effect by one month to allow for changes to be reflected in prescription fills. More complex models (e.g., including interaction terms, more segments) might be constructed, but for this comparison, we restricted the analysis to a basic and predefined model. The subgroup models for subsidy status and users of anti-dementia drugs included additional terms to account for the two groups being compared (Appendix).

Basic Policy Model: $Outcome = \beta_0 + \beta_1\ month + \beta_2\ policy + \beta_3\ policy\_month$

Basic Clinical Model: $Outcome = \beta_0 + \beta_1\ month + \beta_2\ endoll + \beta_3\ enroll\_month$

Study outcomes

Total days' supply of APMs per month was calculated for each model. For a given patient in a given month, we summed the days' supply for all APM prescriptions filled in that month and report the standardized days' supply per 1,000 patients. The second outcome was the total out-of-pocket costs for APMs per 30 days' supply, calculated for each month. For a given patient in a given month, we summed the out-of-pocket costs for that month, divided these by the APM days' supply for that month, and multiplied the result by 30 days.

Patient covariates

We assessed baseline age, sex, geographic region of residence, and two measures of disease burden, the number of unique medications used[24] and the Chronic Disease Score,[25] using dispensing data. Using patients' zip code, we obtained population density and median household income data from the Census.[26]

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Statistical analysis

We assessed baseline characteristics for patients in the Policy Model and patients in the Clinical Model. To assess Part D's impact on the days' supply of and out-of-pocket costs for APMs, our regression models relied on the Central Limit Theorem to model normally distributed outcomes with an identity link. Based on past experience,[23] we used a first-order autoregressive covariance structure[27] to account for the dependence between data points. Models were tested with and without the inclusion of the time-varying covariates, number of unique medications and Chronic Disease Score, as described above. In sensitivity analyses, we considered alternative distributional assumptions for the outcomes (negative binomial, Poisson, Gamma) as well as alternative covariance structures as suggested by others.[27–29]

RESULTS

Of 1.5 million pharmacy patrons age 65+, 114,766 (8%) had no drug insurance from any source during 2005 and were identified as continuous users of one pharmacy chain. Of these, 1,957 (2%) patients filled ≥1 prescription for an APM during 2005 or 2006 and were included in our primary study cohort for the Policy Model analyses (Table 1). Over half (N=1,073) of the primary study cohort with no drug insurance in 2005 did enroll in Part D in 2006; only these patients were included in the Clinical Model analyses. The majority of patients in both the Policy and Clinical Model cohorts were female, with a mean age of 80±8 years. Patients in the Clinical Model cohort were slightly less healthy: 43% had a Chronic Disease Score of 4 or greater, compared to 40% of patients in the Policy Model cohort. Of those who enrolled in Part D, only 64 (6%) received a Part D full subsidy (data not shown). Thirty-six percent (382) of Part D enrollees had ≥1 prescription for an anti-dementia drug in 2005–2006.

Under the Policy Model, Part D implementation was associated with an overall 5% increase in days' supply over the 12 months of 2006 (Figure 1a). In January 2005, the baseline days' supply (per 1,000 patients) was 8,941 (95% CI, 8,312–9,570) (Table 2, Policy Model results). Every month, the days' supply was increasing by 159 (95% CI, 90–227) the slope. Part D implementation in January 2006 was associated with an immediate, non-significant level decrease of -223 (95% CI, -824 – 377) days' supply, and for every month thereafter, an additional increase of 151 (95% CI, 49 – 254) days' supply was observed, a slope change.

Figure 1b displays the Clinical Model results for the days' supply outcome. Among those who did enroll in Part D, Part D implementation was associated with an immediate level increase of 8,007 (95% CI, 7,078–8937) days' supply (per 1,000 patients), followed by a decrease of 227 (95% CI, -381 - -73) days' supply in each month after Part D implementation, a slope change (Table 2, Clinical Model results). This decrease may reflect the high rates of discontinuation of these drugs shown in other studies.[30] Alternatively, because our data source had no information on vital status or enrollment, some patients may have died or changed pharmacies after meeting the cohort eligibility criterion of filling at least one prescription during the last 6 months of 2006. Finally, because we aligned patients at their Part D enrollment date in the Clinical Model, there were fewer patients who had 12 months of post-Part D experience. Although we standardized our utilization estimates to account for the number of patients contributing data, it may be that patients who enrolled in Part D earlier were less likely to fill APM prescriptions than those who enrolled later in the year. Even with this decline, Part D was associated with a 97% increase in APM use during 2006 among those who did enroll in the program.

In the subgroup analysis comparing Part D's impact on APM use among those who received a Part D full subsidy versus those that received a partial or no subsidy, there was no significant difference in APM use between the 2 groups in 2005. At Part D implementation,

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APM utilization increased immediately for both groups, and each patient who received a full subsidy used an additional 4 days supply (95% CI, 0.5 – 8), a level change, per month as compared to all other patients. There was no significant difference between the two groups in APM use in each month after Part D implementation (data not shown). There were no significant differences in APM utilization between anti-dementia drug users and non-users before or after Part D implementation (data not shown).

During the 12 months of 2006, out-of-pocket costs decreased 37% among those who had an opportunity to enroll in Part D as described in the Policy Model (Figure 2b). Specifically, Part D implementation was associated with an immediate level decrease of $31 (95% CI, (-$36 - -$25) in out-of-pocket costs per 30 days' supply, and for every month after implementation, out-of-pocket costs decreased an additional $2 (95% CI, -$3 - -$1) per 30 days' supply (Table 2, Policy Model results).

Among those patients who did enroll in Part D, the Clinical Model, total out-of-pocket costs decreased 62% in 2006 (Figure 2b). Enrollment in Part D was associated with an immediate $86 (95% CI, (-$96 - -$76)) decrease in out-of-pocket costs per 30 days' supply and a $4 (95% CI, $3 - $5) increase in out-of-pocket costs per 30 days' supply in each month thereafter (Table 2, Clinical Model results). Sensitivity analyses using alternate distributional assumptions and covariance structures for both the days' supply and out-of-pocket cost outcomes produced similar results (data not shown).

DISCUSSION

The 5% increase in use of APMs and 37% decrease in out-of-pocket costs per 30 days' supply observed in 2006 among all patients suggest that Part D was successful in improving access to and the affordability of APMs for elderly patients without previous drug insurance. From the policymaker's perspective (the Policy Model), this increase indicates that there was a modest unmet need for APMs among this vulnerable, previously uninsured elderly population. From the clinician's perspective (the Clinical Model), the results are also reassuring. Previously uninsured, vulnerable elderly who did enroll in Part D saw a dramatic 62% decrease in their out-of-pocket costs per 30 days' supply and a correspondingly dramatic 97% increase in their APM utilization during 2006. In the subgroup analysis, full subsidy patients who saw their costs reduced more than those of other patients used only slightly more days supply of APMs. However, these results are preliminary as there were few full subsidy patients and partial subsidy patients could not be distinguished from those who received a full subsidy.

Early studies of Part D's impact on medication use overall produced strikingly similar estimates of its effect. For example, two studies using prescription claims from a large pharmacy chain found 5–13% absolute increases in days of therapy and 13–19% decreases in out-of-pocket costs.[4, 5] A third study that used claims from a prescription transaction manager found that compared with a cohort of patients aged 58–64, patients 65+ experienced an 8.1% days supply increase and a 17.2% decrease in out-of-pocket costs from 2005–2006.[3] Studies of specific medication classes have found similar changes in drug utilization following Part D implementation, but the magnitude of these changes varies by drug class. For example, a study in a single Medicare Advantage plan found 44% increases from 2005 to 2006 in the number of monthly prescriptions for both lipid-lowering medications and for oral anti-diabetic drugs among patients without prior drug coverage who newly enrolled in Part D.[31] In a study using retail pharmacy claims from the same three pharmacy chains as our study, Schneeweiss et al. found an increase in defined daily dose of statins (22%), clopidogrel (11%) and proton pump inhibitors (37%) in 2006 among previously uninsured elderly who had the opportunity to enroll in Part D.[23] Our smaller 5%

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increase in APM use in the Policy Model may reflect the unmet need for APMs among the uninsured population versus the unmet need for statins or oral anti-diabetic drugs, medications that are indicated for use by many more patients. Finally, Chen et al. observed a 7% increase in antidepressant and an 18% increase in antipsychotic prescriptions in 2006 as compared to 2005 among community-dwelling seniors who patronized a large pharmacy chain.[32] The 18% increase in APMs is three times that of the increase we found in our comparable Policy Model population. However, Chen et al.'s results are difficult to interpret because their population included patients both with and without drug insurance in 2005 and because their utilization measure did not adjust for changes in study sample size from 2005 to 2006.

The reductions in out-of-pocket costs per 30 days' supply that we found in the Policy Model population (37%) and the Clinical Model populations (62%) are similar to those observed in other studies of those with no drug insurance prior to Part D implementation. Schneeweiss et al. noted out-of-pocket cost decreases of 52% for statins, 58% for clopidogrel, and 56% for proton pump inhibitors during 2006 in a population similar to our Policy Model population.[23] Across all medications classes, Zhang et al. observed a 45% reduction in the proportion of drug costs that were paid out-of-pocket in 2006 as compared to 2005 in a group with no prior drug coverage who newly enrolled in Part D.[33]

The differences between our Policy Model and Clinical Model results reflect the self-selection of patients into the Part D program. In contrast to the Policy Model results, which combine the experiences of patients who both did and did not enroll, the Clinical Model results describes only the population that did enroll in Part D. Clinical Model patients likely believed that by enrolling in Part D, they would gain improved access to and reduce out-of-pocket spending for their prescription drugs. These patients were also sicker and used more medications in 2005 than did the larger population examined by the Policy Model. Because the Clinical Model reflects the experience of those who "complied" with the policy and enrolled, it is not surprising that the magnitude of changes in APM utilization and out-of-pocket costs are much stronger than those for the Policy Model population. Still, both models are of use. For policymakers who want to determine the real-world costs and utilization implications of offering improved insurance coverage, the Policy Model offers this perspective. For clinicians and others who wish to see if their patients who needed APMs were able to access them after Part D enrollment, the Clinical Model offers that perspective.

Retail pharmacy data offer a prime opportunity to study the drug utilization patterns of previously uninsured patients who, by definition, do not have insurance claims prior to obtaining drug insurance. However, there are limitations to using these data. Firstly, one cannot capture prescription fills that take place outside a given retail pharmacy chain. In order to mitigate against the possibility of outside pharmacy use, we required multiple fills in a single pharmacy chain during both the baseline year, 2005 and the study year, 2006. Further, while among all U.S. residents of any age, 80% use a single pharmacy in a given year,[34] pharmacy loyalty among those aged 65+ is known to be much higher. In a study of low-income elderly, patients filled 96% of prescriptions at a single pharmacy location during the course of a year and 97% within a single pharmacy chain.[20] Therefore, our requirement of consistent pharmacy use coupled with data on pharmacy loyalty among the elderly offer reassurance that most prescriptions are recorded. On the other hand, our results may only be generalizable to those elderly that tend to patronize a particular pharmacy or pharmacy chain. If prescriptions for APMs were filled outside of the pharmacy chains we studied, then our results would represent a conservative estimate of use in this population. Researchers using retail pharmacy data must also be mindful of potentially unrecorded prescription fills that take place under a retailer's $4 generic program. These programs are of limited concern

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in our study, however, as our study period is 2005–2006. The first $4 generic program did not begin until September 2006[35] and the retail pharmacies we studied did not begin their programs until some months later. Further, the majority of new APM use is among the atypical medications,[17] none of which are available generically, making the most-used APMs ineligible for inclusion in these programs. Uninsured elderly who did not fill any prescriptions would not appear in retail pharmacy claims and are a population best studied through the use of survey methods. However, Part D's implementation would offer these patients the same opportunity for improved access to medications and reduced costs as those elderly who we did study.

Another limitation of retail pharmacy claims is that they do not provide information as to whether increased APM use had a beneficial impact on the health of the previously uninsured elderly, nor do they indicate the underlying reason for the APM prescriptions. Because the prevalence of elderly patients with bipolar disorder and schizophrenia is small (~1.9%),[36, 37] fulfilling the unmet need for APMs among these patients would not explain a 5% increase in APMs days' supply among the population who had the opportunity to enroll in Part D, nor the 97% increase in APMs days' supply among the population that did enroll. In fact, many APM prescriptions may have been filled for other indications such as treating the behavioral symptoms of dementia. Of our Part D enrollees, 36% filled a prescription for an anti-dementia drug during 2005–2006, suggesting that a sizeable portion of APM use was to treat dementia symptoms. Elderly patients with dementia who use APMs have 1.6–2.0 times the risk of adverse events and death as compared to non-users.[13–16] In practical terms, this means that for every 664 elderly patients with dementia taking APMs, one will experience an adverse event.[15] Therefore, while Part D reduced out-of-pocket burden and enhanced patients' ability to fill their prescriptions, in the case of the APMs, it may have had the unintentional consequence of causing harm. Clinicians, patients' families and even patients themselves may argue that when the benefits that APMs provide to some elderly patients are weighed against the risks of harm, improved access under Part D is a positive outcome overall. On the other hand, policymakers might contend that increased risks and harms, regardless of any potential benefit, should not be funded with taxpayer monies.

As the provisions of the Patient Protection and Affordable Care Act of 2010[38] are implemented and health reform occupies center stage, policymakers, researchers, and clinicians will grapple with how to best evaluate the population-level effects of these health policy changes and their specific impact on mental health care and APM use. Our results regarding Part D's impact on APM utilization and costs in a population with no previous drug insurance can be used as a baseline to assess the impact of health care expansion for uninsured Americans and to evaluate changes in insurance coverage for others. These future evaluations will be crucial to ensuring the judicious use of our limited health care resources.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The authors acknowledge Alex Pedan and Laleh Varesteh of Adheris, Inc. for providing the data.

Sources of funding: National Institute on Aging T32 AG000158 (Dr. Polinski); National Institute of Mental Health R01 5U01MH079175-02 (Dr. Schneeweiss)

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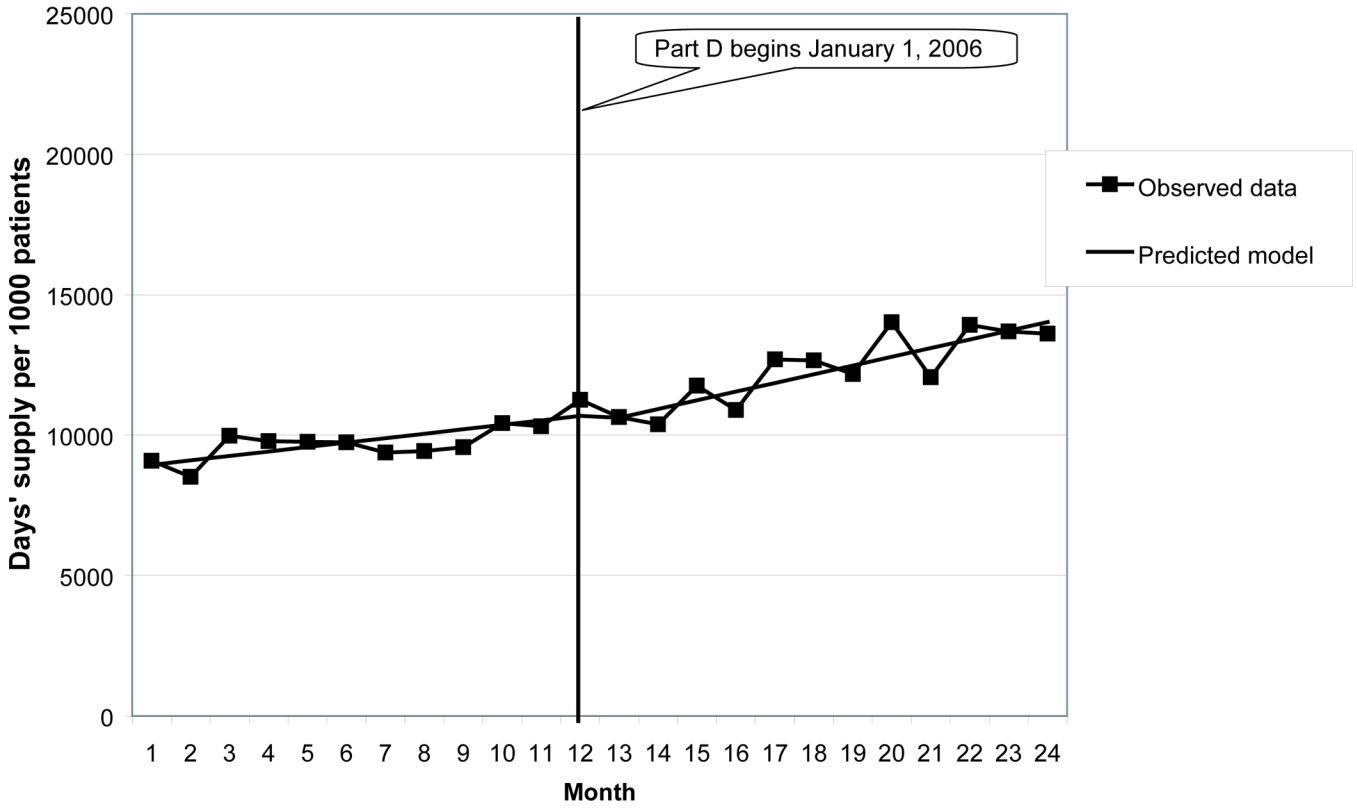

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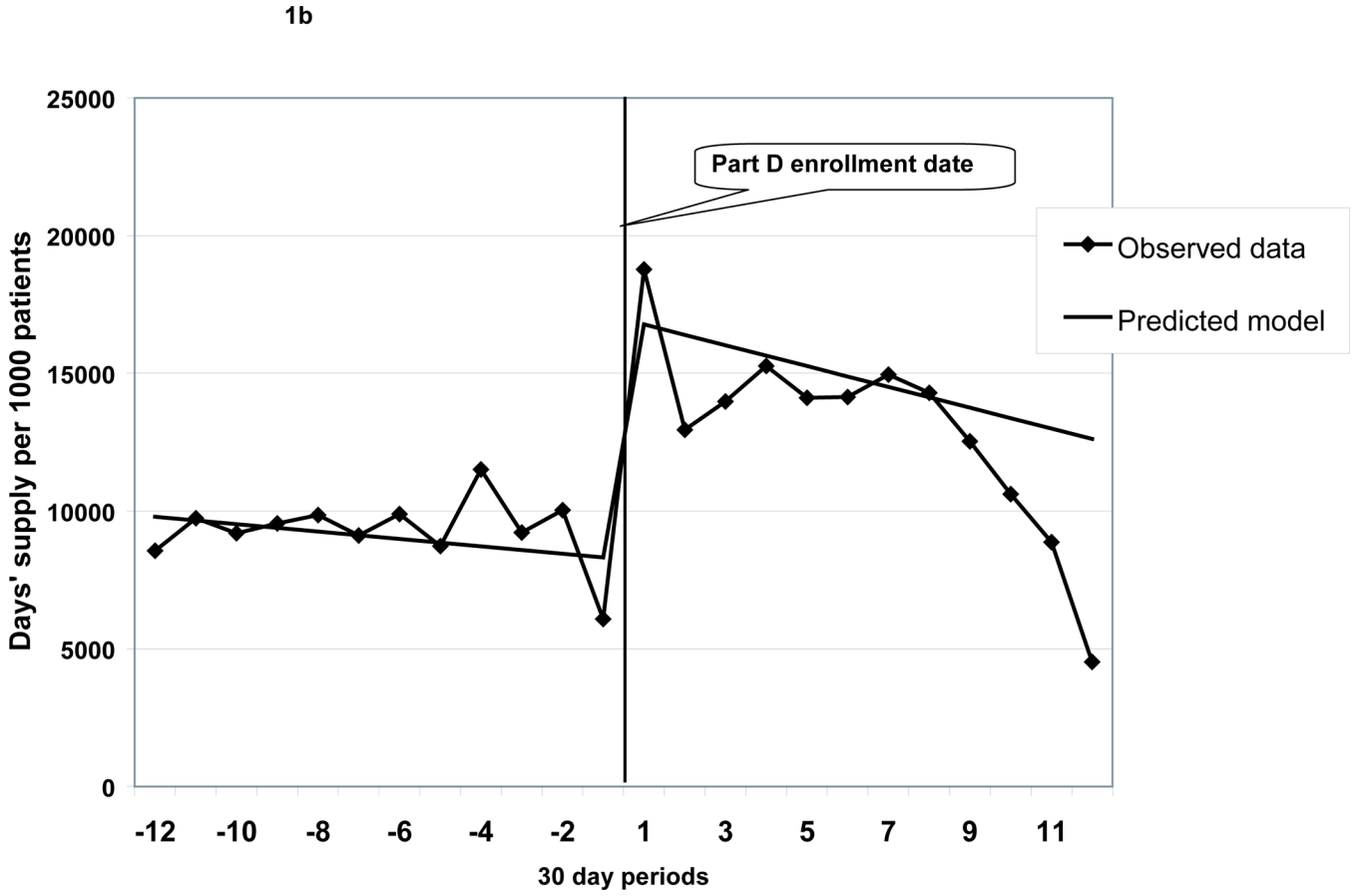

Figure 1.
a. Part D's impact on APM use among all uninsured patients who did or did not enroll in Part D in 2006 (Policy Model)
b: Part D's impact on APM use among only those patients who enrolled in Part D in 2006 (Clinical Model)

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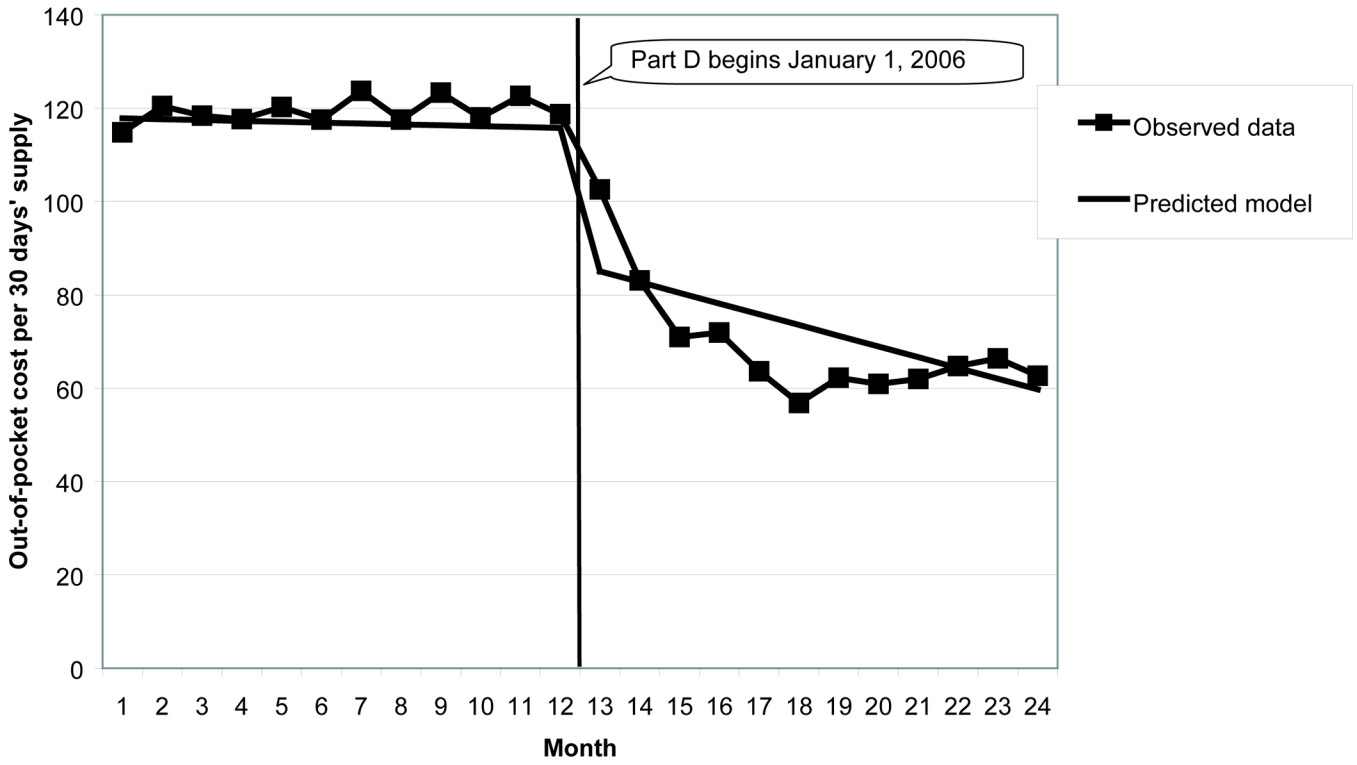

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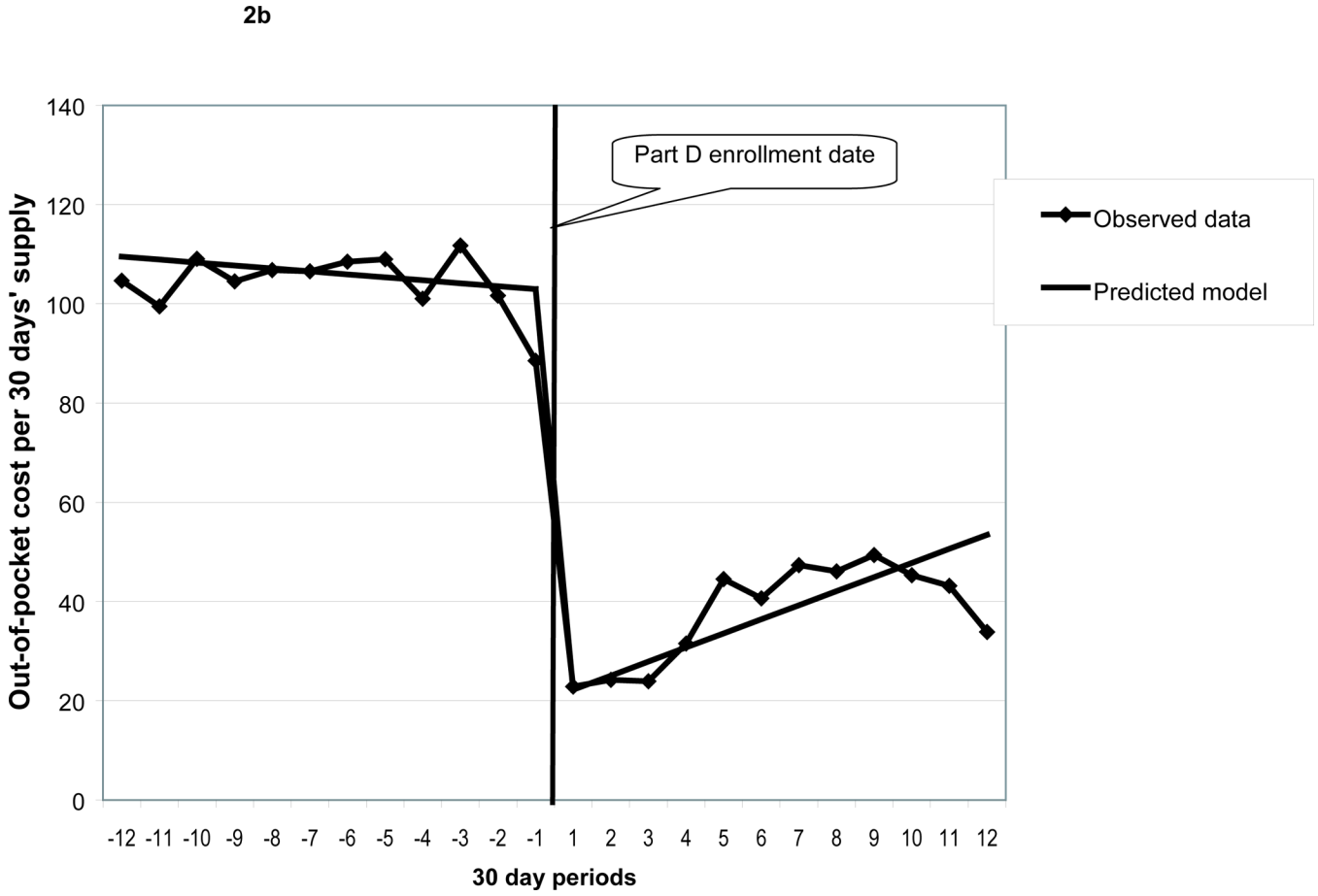

Figure 2.
a. Part D's impact on out-of-pocket costs among all uninsured patients who did or did not enroll in Part D in 2006 (Policy Model)
b. Part D's impact on APM use among only those patients who enrolled in Part D in 2006 (Clinical Model)

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Table 1

Baseline characteristics of patients with no drug insurance in 2005

	All patients with the opportunity to enroll in Medicare Part D (The Policy Model)	Patients who enrolled in Medicare Part D (The Clinical Model)
	N (%) or mean ± SD	
N	1957 (100.0)	1073 (54.8)
Age, in years as of January 1, 2006	80.2 ± 7.6	79.5 ± 7.6
65 – 74	503 (25.7)	309 (28.8)
75 – 84	865 (44.2)	474 (44.2)
85+	589 (30.1)	290 (27.0)
Female gender	1354 (69.2)	730 (68.0)
Region of residence		
Midwest	469 (24.0)	260 (24.2)
Northeast	40 (2.0)	22 (2.1)
South	727 (37.2)	426 (39.7)
West	721 (36.8)	365 (34.0)
Population density (persons/square mile)	1750.9 ± 2328.2	1615.2 ± 2168.1
<500	821 (42.0)	481 (44.8)
500 – 999.99	213 (10.9)	111 (10.3)
1,000 – 1,499.99	152 (7.8)	88 (8.2)
1,500+	738 (37.7)	373 (34.8)
Median income	47568.6 ± 19199.8	46390.3 ± 18268.5
<$20,000	28 (1.4)	18 (1.7)
$20,000 – $39,999	759 (38.8)	434 (40.5)
$40,000 – $59,999	740 (37.8)	404 (37.7)
> $60,000	397 (20.3)	197 (18.4)
Number of unique medications, July – December 2005	10.0 ± 5.9	10.5 ± 5.6
5 or less	440 (22.5)	195 (18.2)
6 – 9 medications	627 (32.0)	341 (31.8)
10 – 14 medications	518 (26.5)	323 (30.1)
15+ medications	372 (19.0)	214 (19.9)
Chronic Disease Score, July – December 2005	3.3 ± 2.9	3.4 ± 2.9
0	432 (22.1)	210 (19.6)
1 – 3	736 (37.6)	406 (37.8)
4+	789 (40.3)	457 (42.6)

* Population density and median income were missing for 33 (1.7%) of all patients and 20 (1.9%) of patients who enrolled in Part D

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Table 2

Part D's impact on APM use and costs among all uninsured patients (Policy Model) and among only those patients who enrolled in Part D (Clinical Model)

	All uninsured patients (Policy Model)		**Patients who enrolled in Part D (Clinical Model)**	
	Days' supply per 1,000 patients	**Out-of-pocket costs per 30 day supply (in US $)**	**Days' supply per 1,000 patients**	**Out-of-pocket costs per 30 day supply (in US $)**
Baseline intercept (Pre-Part D level)	8941 (8312 – 9570)	118 (112 – 124)	9130 (8294 – 9967)	118 (109 – 126)
Baseline time trend (Slope change per month)	159 (90 – 227)	0 (−1 – 0)	−125 (−205 - −45)	−1 (−2 – 0)
Effect of Part D implementation (Part D level change)	−223 (−824 – 377)	−31 (−36 - −25)	8007 (7078 – 8937)	−86 (−96 - −76)
Time trend after Part D implementation (Part D slope change per month)	151 (49 – 254)	−2 (−3 - −1)	−227 (−381 - −73)	4 (3 – 5)