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The Effect of Transitioning to Medicare Part D Drug Coverage In Seniors Dually Eligible for Medicare and Medicaid

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Abstract

Objectives—In January, 2006, patients dually eligible for Medicaid and Medicare (Dual Eligibles) were automatically enrolled in Medicare Part D prescription drug plans. This transition affected formulary coverage for many patients, causing widespread concern about compromised access to essential medications. We evaluated medication use, out-of-pocket spending and medication switching during the transition period for Dual Eligibles.

Setting and Participants—We used patient-level pharmacy dispensing data for Dual Eligibles older than 65 from January 2005 to December 2006 from a large pharmacy chain with stores in 34 states.

Design and Measurements—Changes in utilization, patient copayments, and medication switching were analyzed using interrupted time trend analyses. We evaluated utilization and spending for five study drugs: clopidogrel, proton pump inhibitors, warfarin, and statins (essential drugs covered by Part D plans) and benzodiazepines (not covered through Part D, but potentially covered through Medicaid).

Results—Drug use for 13,032 Dual Eligibles was evaluated. There was no significant effect of the transition to Medicare Part D on use of all study drugs, including the uncovered benzodiazepines. Cumulative reductions were seen in copayments for all covered drugs after implementation of Part D, ranging from 25% annually for PPIs to 53% for warfarin. However, there was a larger increase in copayments, 91% annually, for benzodiazepines after the transition. We found a 3.0 times greater rate of switching medications for the proton pump inhibitors, but no significant change in the other study drug classes.

Conclusion—These findings in a single, large pharmacy chain indicate that the transition plan for Dual Eligibles led to less medication discontinuation and switching than many had expected. The substantially increased cost-sharing for benzodiazepines highlights the importance of implementing a thoughtful transition plan when executing such a national policy.

Keywords

Medicare Part D; prescription drug coverage; elderly; Medicaid; Dual Eligibles

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INTRODUCTION

Passage of the Medicare Part D drug benefit aimed to increase access to prescription drugs for America's seniors without coverage. However, Part D affected more than just those seniors who were previously inadequately insured. Many seniors who were dually eligible for Medicaid and Medicare (Dual Eligibles) experienced a change from state-run programs to a program developed by the federal government, funded jointly by federal and state governments, and administered by private plans. Approximately 6.6 million dually eligible seniors were automatically enrolled in a Medicare Part D prescription drug plan on January 1st, 2006.¹ Little is known about how these Dual Eligibles were affected by this change in coverage.

Dual Eligibles had the opportunity to select the Part D plan of their choice prior to Jan. 1, 2006; those who did not enroll on their own were enrolled automatically in Part D to minimize gaps in coverage and to guarantee that low income patients were enrolled in a plan with a low income subsidy. Patients who were automatically enrolled were placed in plans with fully subsidized premiums, and medication copayments were subsidized for patients who reached the Part D coverage gap (the donut hole).² Patients who were not satisfied with the plan automatically selected for them had the opportunity to switch to another low income subsidy plan.³

Despite efforts to simplify the transition to Part D, many researchers and policy experts expressed concern about how Dual Eligibles fared during their transition in coverage.⁴⁻⁶ Prior to the transition to Part D, many Medicaid beneficiaries experienced very generous drug coverage with few formulary restrictions.⁷ After the transition, the overwhelming majority of these patients found themselves enrolled in tiered pharmacy benefit plans that required differential copayments for some drugs and placed new administrative barriers (e.g. prior authorization) to influence the use of others.⁸ These changes led some Dual Eligibles to pay more for the same medications they were previously taking, and other Dual Eligibles may have been required to switch to specific medications that were preferred by the individual prescription drug plans.⁹ To assist with these changes in coverage, more than half of states required plans to relax formulary restrictions during the transition period in an effort to minimize medication discontinuation.⁴ Surveys of Dual Eligibles indicate that there was substantial confusion at the time of transition as they dealt with new and often more restrictive formularies.¹⁰⁻¹¹ However, little is known about whether the changes in coverage affected the use of essential medications or patients' out-of-pocket spending.

We evaluated electronically recorded pharmacy transactions for patients over the age of 65 enrolled in Medicaid before the implementation of Part D on January 1, 2006, and assessed drug use, out-of-pocket spending and medication switching in dually-eligible beneficiaries after the transition to Medicare Part D insurance.

METHODS

The human subjects review boards of the Brigham and Women's Hospital approved the study.

In time-trend analyses using pharmacy dispensing data from before and after the implementation of Medicare Part D, we assessed how drug use and out-of-pocket spending were affected in the year after implementation.

Data Sources and Study Population

We obtained records of all prescription drugs dispensed to subjects over age 65 at a large pharmacy chain operating in 34 states from October 1, 2004 through March 31, 2007. The database included unique de-identified subject numbers, patient zip codes, and for each dispensed drug, the out-of-pocket payment amount, the National Drug Code (NDC), and quantity dispensed. Drug prices were imputed as 80% of the average wholesale price for each NDC.^{7, 12, 13} Patients who received drug coverage through Medicaid between January 1, 2005 and January 1, 2006 were identified in the database if 80% or more of their transactions were paid, at least in part, by Medicaid. Considering that patients may use more than one pharmacy chain and data would be lost if they used another chain, we required that patients had minimal dispensing activity within the same pharmacy chain in the last quarter of 2004 and the first quarter of 2007.

Study drugs

We selected four classes of medication for analysis that were covered by Part D: warfarin, HMG CoA receptor inhibitors (statins), proton pump inhibitors (PPIs), and clopidogrel. These classes included both expensive (clopidogrel) and less expensive but essential drugs (warfarin) and those used to treat symptomatic conditions (clopidogrel, PPIs) as well as drugs used to treat asymptomatic conditions (statins). For all four classes, generic medications were available or became available during the study period. Three drugs became available as generics during the study period: pravastatin, simvastatin and clopidogrel. We also included a fifth class, benzodiazepines, which was explicitly excluded from Part D coverage; no plans with low-income subsidies covered benzodiazepines (although some higher premium plans were permitted to add coverage for these medications).¹⁴ However, since Medicaid programs cannot legally discriminate based on age, Dual Eligibles continued to be entitled to Medicaid prescription benefits if a drug was not covered under Part D. Thus, if a state covered the Dual Eligible's prescription for a benzodiazepine prior to January 1, 2006, it would continue to do so under Part D,¹⁴ for patients savvy enough to identify this source of coverage. Inclusion of benzodiazepines allows us to compare the effect of use in classes of medication for which the transition to Part D was specifically considered (warfarin, statins, PPIs, clopidogrel) and for drugs for which coverage in the transition period was poorly defined and coordinated (benzodiazepines).

Study Outcomes

To estimate the effect of the introduction of the Part D drug coverage, we calculated drug use as days supply of the medication recorded at dispensing and co-payments in US dollars per 30 days supply for each calendar month from January 1, 2005 through December 31, 2006 in all subjects who were enrolled in Medicaid in 2005. We calculated monthly rates of switching between drugs within the class and switching from branded to generic or generic to branded versions of the same drug. The numerator each month was the number of subjects switching, while the denominator was the total number of patients filling a prescription within that drug class in that month.

We used dispensing information from July 1 through December 31, 2005 to characterize our study population, including age, sex, region of residence (Appendix A), median income level and population density of residential ZIP code, the number of different drugs used, and specific use of anticoagulants, loop diuretics, nitrates, or anti-diabetic drugs. Using the dispensed prescription drugs during this time period, we also assessed the Chronic Disease Score¹⁵ as a summary measure of health status that has been shown to have reasonable validity.¹⁶

Statistical Analysis

We used segmented linear regression to estimate sudden changes in levels of monthly rates of drug use or out-of-pocket spending during three periods: 1) the year before implementation, 2) the first 2 months immediately after implementation of Part D (the transition period), and 3) during the remainder of the first year after implementation of Part D (stable Part D period).¹⁷ We also evaluated the change in rate of drug use (the slope) in the period before implementation and in the stable Part D period. To estimate changes in level and slope attributable to the introduction of the Medicare Part D policy, we used regression models that included a constant term, a linear time trend (months 1 to 12 of 2005), and binary indicators and linear time trends for the transition and stable Part D periods.¹⁸ To calculate cumulative changes in utilization and out-of-pocket spending attributable to Part D in the year after implementation, we summed the differences between the predicted values from the full regression model and those obtained by extrapolating the pre-Part D trend into the Part D period. Details of the regression models are described in Appendix B.

RESULTS

Our sample included 13,032 dually eligible beneficiaries who used Medicaid as a source of drug coverage in 2005. The mean age of the sample was 75.9 years (std dev = 7.1) and the sample represented broad geographic diversity although the Northeast United States was not represented (Table 1). The overwhelming majority of Dual Eligible seniors (92%) had used more than 4 different medications in the 6 months before Part D, and sizable fractions had a chronic disease score of 4 or higher (59%), used antidiabetic drugs (30%), and/or nitrates (15%).

Our time trend analysis found little effect of the implementation of Medicare Part D on use of the study drugs. (Figure 1.) No statistically significant increases or decreases were seen in the use of PPIs, warfarin, clopidogrel, statins or benzodiazepines after implementation of Part D. (Table 2.) Trends indicated increased use for all study drugs except benzodiazepines, for which there was a non-significant trend of decreased use.

Significant changes in copayments occurred with the implementation of Part D. (Table 2.) For warfarin, there was a \$0.41 drop in copayment requirements per month at the time of implementation, with no immediate change in PPIs, clopidogrel or statins. In the remainder of the year after implementation, statin, warfarin and clopidogrel copayments decreased. Cumulative copayments decreased from January - December 2006 in all covered drugs, ranging from 25% for PPIs to 53% for warfarin. These reductions reduced annual cumulative out-of-pocket expenses for Dual Eligibles by \$6.15 for PPIs, \$6.62 for statins, \$10.58 for warfarin, and \$18.42 for clopidogrel.

However, there was a large and statistically significant increase in copayment levels for benzodiazepines; copayments increased 91% after transition, raising cumulative out-of-pocket costs by \$28.99 annually for benzodiazepines.

Our evaluation of medication switching behavior within drug classes found mixed results. (Figure 2.) We found a 2.99% (95% CI: 1.34% to 4.65%) greater rate of switching (either from brand to another brand within the class, brand to generic, or generic to brand) in PPIs after implementation of Part D compared with the baseline switching rate. No changes in switching rates that were temporally associated with implementation of Part D were seen in the other classes we evaluated. All changes were modest when compared to the brisk 10.6% increase in switching in the statins that coincided with the month that simvastatin became available as a generic, a change that did not coincide with the implementation of Part D.

Even greater rates of switching were seen when clopidogrel became available as a generic, with switching rates greater than 20% in the first month after entry.

DISCUSSION

To our knowledge, this study is the first empirical evaluation of prescription drug use, costs and switching among Dual Eligibles during the transition from Medicaid drug coverage to Medicare Part D drug coverage based on pharmacy dispensing data. Many researchers and policy experts have expressed concerns about how shifting drug coverage may have adversely affected prescription drug use and increased patient out-of-pocket spending while requiring Dual Eligibles to switch their medications.^{10, 11, 19} However, our evaluation of electronic pharmacy transaction data did not corroborate these concerns. For the Part D covered drugs we evaluated, statins, warfarin, clopidogrel, and PPIs, we found no statistically significant reduction in drug use at the time of the transition to Medicare Part D. We also found trends of reduced out-of-pocket drug spending for these classes, with significant reductions in spending for warfarin in the transition period, and reductions in out-of-pocket expenses for warfarin, clopidogrel and statins over the remainder of 2006. These findings did not extend to benzodiazepines, a class of medications not covered under Medicare Part D, which had a poorly defined plan for coverage after implementation of Part D. Congress' decision not to include benzodiazepines led to a non-significant trend of decreased use, and patients who used these drugs paid significantly more out-of-pocket.

There was less medication switching stimulated by the implementation of Medicare Part D than had been feared. We did find almost a 3-fold increase in switching in the PPI class immediately upon implementation. However, there is convincing evidence to suggest that all medications in this class have similar efficacy,^{18, 20–22} and little reason to believe that this would lead to adverse health outcomes. It is likely that this switching caused the reduced spending we found without causing changes in overall utilization. In the other classes we evaluated, switching rates were not significantly different before and after implementation of Part D. The lack of switching after implementation may have been due to State regulations requiring drug plans to assist patients with coverage during the transition period and by the inclusive coverage offered by many plans for these classes of essential medications.

It is interesting to note that there was less change in benzodiazepine use after Part D implementation than might have been expected, especially considering the substantial increase in out-of-pocket spending requirements for these medications (an average cumulative increase of almost \$30 per benzodiazepine user). A large and convincing body of evidence indicates a strong relationship between out-of-pocket cost requirements and prescription drug use for many classes of chronic and acute medications used to treat symptomatic and asymptomatic medications alike.^{16–23} Some of the stability of use of benzodiazepines may have been due to efforts by State Medicaid programs to continue to provide benefits for this class for Dual Eligibles, which allowed some patients to continue to purchase benzodiazepines. Our findings also raise some concern that previous studies examining the relationship between copayments and drug use may not apply to controlled substances. Further evaluation of this relationship, and the relevant cost cutoffs that affect behavior, is warranted for this class of medications.

Our findings are limited by the fact that we evaluated prescription drug activity from a single pharmacy chain. The chain has broad representation in the South, West and Mid-West United States, but has no clients in the Northeast. While we expect that this chain serves a representative sample of patients, further evaluation in other chains would be useful. We evaluated a limited sample of medication classes which are generally used chronically, and

our findings may not be generalized to acute, short-term medications. Use of pharmacy data also has limitations. Some patients may have filled prescriptions at different pharmacies. While we required continuous use indicated by filling at least one prescription in the last quarter of 2004 and the first quarter of 2007 at the study pharmacy, not all prescriptions may have been filled at the chain. However, we would expect that the transition to Part D could have lead some patients to switch their pharmacies, which suggests that drug use may have been even greater after implementation of Part D than our data would indicate, and our findings may be conservative.

We describe results of the net effects of Part D on Dual Eligibles who were Medicaid beneficiaries throughout 2005. Some patients may have chosen to enroll in a Medicare Advantage program at the time of Part D introduction and would have been lost for this analysis. We are not aware of any evidence that there was a significant increase in Medicare Advantage enrollment at the time of Part D auto-enrollment. Similarly, some Dual Eligibles may have chosen to enroll in another private or employer-sponsored source of insurance at the time of Medicare Part D implementation; we do not believe significant migration of this poor, elderly population to private insurance to be likely. Additionally, some of the difficulties associated with the transition may have been delayed several months as states required plans to assist in covering previously covered drugs during the transition period. However, our time-trend analyses evaluated changing drug use, costs and spending over the year after implementation, which should have been enough time to identify meaningful changes in the outcomes of interest.

These findings have important implications for the Medicare Part D program. The Centers for Medicare and Medicaid Services and individual States automatically enrolled dually eligible beneficiaries into Part D programs with a low-income subsidy and required participating Medicare Part D plans to assist in coverage at the point of the transition. Despite concerns that these efforts were insufficient to protect Dual Eligibles during the transition, our findings suggest that these efforts were effective. A pre-specified plan for the transition led to less medication discontinuation and switching than many had expected. However, a less organized transition occurred for the benzodiazepine class, leading to increased costs, suggesting that the careful consideration of transition complexities was instrumental in maintaining adequate coverage for the essential, covered medications we evaluated. Further study of benzodiazepine use after the passage of recent legislation relaxing restrictions on benzodiazepine coverage would be informative.

Our findings also can ease the concerns about the difficulty in transition whenever new prescription drug policies are implemented. Fear about medication discontinuation and adverse health outcomes are often invoked as a reason to obstruct new policy implementation. As we continue to try to identify improved prescription drug coverage designs, we must be willing to implement and test new coverage strategies. Our findings suggest that thoughtful preparation for transition to new coverage designs and use of strategies to ease the burden of transition may serve as an effective means of protecting patients without impeding progress.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix A: States by Region

Northeast: Connecticut, Maine, Massachusetts, New Jersey, New Hampshire, New York, Pennsylvania, Rhode Island, and Vermont.

South: Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia and West Virginia (plus the District of Columbia), Alabama, Kentucky, Mississippi and Tennessee, Arkansas, Louisiana, Oklahoma and Texas

Midwest: Ohio, Indiana, Michigan, Illinois, Wisconsin, Iowa, Kansas, Missouri, Minnesota, Nebraska, South Dakota, and North Dakota.

West: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, New Mexico, Nevada, Oregon, Utah, Washington, and Wyoming.

Appendix B: Details of the Regression Models

Analyses of the effect of Medicare Part D introduction on level and trends of copayments and days supply dispensed among Medicaid patients

Outcome = $\beta_0 + \beta_1 \text{time} + \beta_2 \text{transition period indicator} + \beta_3 \text{post Part D indicator} + \beta_4 \text{time post Part D} + e$

Outcomes were days of drug supply available to Medicaid patients, copayment per 30 day supply, and % of cohort members switching to a different drug each month.

Cumulative changes in utilization or copayments

To calculate changes in utilization or copayments under Part D (from January 2006 to August 2006) compared with the extrapolated baseline trend without Part D, we calculated the area between the predicted values from models A and B below. Model A was fitted including all datapoints from Jan. 2005 through Aug. 2006. Model B was fitted for the pre-period (Jan. 2005 to Dec. 2005) and used to project what would have happened in Jan. 2006 through Dec. 2006 in the absence of Medicare Part D.

Model A: Copay/30 days supply (or days supply) = Copay/30 days supply (or days supply) = $\beta_0 + \beta_1 \text{time} + \beta_2 \text{transition period indicator} + \beta_3 \text{post Part D indicator} + \beta_4 \text{time post Part D} + e$

Model B: Copay/30 days supply (or days supply) = $\beta_0 + \beta_1 \text{time} + e$

Figure 1. Utilization of and patient co-pay for selected essential drugs among Dual Eligible seniors.*

* The January and February 2005 datapoints were omitted from this figure because days covered is affected by dispensings received in the previous 1 – 2 months. We did not analyze dispensing data from the end of 2004, so we did not have an accurate measure of days covered in January and February 2005.

Figure 2. Monthly probabilities of switching between drugs. Switching includes switching between distinct generic entities and switching between branded and generic versions of a single drug

* The July 2006 datapoint for statins, attributable to the entrance of generic simvastatin onto the market, was omitted from the statistical analysis. Similarly, dates after August were omitted for clopidogrel because generic clopidogrel became available in September.

Table 1

Characteristics of 13,032 Dual Eligible patients who continuously filled prescriptions in one pharmacy chain over the study period.

	N (%)
Patient age on December 31, 2005	
66–70 years	3,599 (27.62)
71–75 years	3,325 (25.51)
76–80 years	2,740 (21.03)
81+ years	3,368 (25.84)
Gender, female	10,019 (76.88)
Region	
Northeast	0 (0.00)
South	2,634 (20.21)
Mid-West	5,241 (40.22)
West	5,157 (39.57)
Median income in zip code*	
<\$20,000	376 (2.92)
\$20,000 – \$39,999	6,667 (51.85)
\$40,000 – \$59,999	4,598 (35.76)
>\$60,000	1,217 (9.46)
Population density per square mile*	
<160	3,163 (24.60)
160 to 650	2,089 (16.25)
651 to 2520	2,965 (23.06)
> 2520	4,641 (36.09)
No. of different generics in 2005	
0–3	1,040 (7.98)
≥4	11,992 (92.02)
Chronic Disease Score in 2005	
0–3	5,293 (40.62)
≥ 4	7,739 (59.38)
Use of anticoagulants	1,201 (9.22)
Use of loop diuretics or digoxin	897 (6.88)
Use of nitrate	1,892 (14.52)
Use of antidiabetics	3,893 (29.87)

* According to patient ZIP code of residence and national survey data. Information was missing for 174 patients.

Changes in utilization and co-payment trends under Medicare Part D for selected medication groups. All comparisons are relative to the 2005 baseline trends.

Table 2

Medication groups	Transition Period (January 06 – February 06)		Stable Part D period (March 06 – December 06)		Cumulative change		
	Change in level (95% CI [‡])	Change in level (95% CI [‡])	Change in slope (95% CI [‡])	Change in slope (95% CI [‡])			
2a: Utilization in Days Covered:							
Statins	1406	–10,455 to 13,267	8801	–4,310 to 21,912	1,397	–540 to 3,333	153,679 (+13%)
PPIs	2838	–3,951 to 9,627	5308	–1,769 to 12,385	925	–113 to 1,963	100,372 (+13%)
Warfarin	–150	–2,502 to 2,202	1653	–798 to 4,105	17	–343 to 376	16,984 (+7%)
Clopidogrel	–271	–3,070 to 2,528	1566	–1,352 to 4,483	–99	–527 to 329	10,644 (+3%)
Benzodiazepines	–2881	–7,622 to 1,860	–2290	–7,776 to 3,196	368	–456 to 1,191	–12,117 (–3%)
2b: Copayments in US \$:							
Statins	\$0.16	–\$0.18 to \$0.49	–\$0.49	–\$0.83 to –\$0.15	–\$0.04	–\$0.09 to \$0	–\$6.62 (–28%)
PPIs	–\$0.27	–\$0.86 to \$0.33	–\$0.57	–\$1.17 to \$0.03	\$0	–\$0.08 to \$0.09	–\$6.15 (–25%)
Warfarin	–\$0.41	–\$0.74 to –\$0.08	–\$0.84	–\$1.17 to –\$0.51	–\$0.03	–\$0.08 to \$0.02	–\$10.58 (–53%)
Clopidogrel	–\$0.39	–\$1.18 to \$0.41	–\$1.34	–\$2.14 to –\$0.54	–\$0.09	–\$0.21 to \$0.02	–\$18.42 (–51%)
Benzodiazepines	\$2.03	\$1.52 to \$2.54	\$2.47	\$1.96 to \$2.99	\$0	–\$0.07 to \$0.08	\$28.99 (+91%)

[‡] CI = confidence interval