Original Article

Impact of Medicare Part D on Out-of-Pocket Drug Costs and Medical Use for Patients With Cancer

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BACKGROUND: Medicare Part D was designed to reduce out-of-pocket (OOP) costs for Medicare beneficiaries, but to the authors' knowledge the extent to which this occurred for patients with cancer has not been measured to date. The objective of the current study was to examine the impact of Medicare Part D eligibility on OOP cost for prescription drugs and use of medical services among patients with cancer. **METHODS:** Using the Medical Expenditure Panel Survey (MEPS) for the years 2002 through 2010, a differences-in-differences analysis estimated the effects of Medicare Part D eligibility on OOP pharmaceutical costs and medical use. The authors compared per capita OOP cost and use between Medicare beneficiaries (aged ≥65 years) with cancer to near-elderly patients aged 55 years to 64 years with cancer. Statistical weights were used to generate nationally representative estimates. **RESULTS:** A total of 1878 near-elderly and 4729 individuals with Medicare were included (total of 6607 individuals). The mean OOP pharmaceutical cost for Medicare beneficiaries before the enactment of Part D was $1158 (standard error, ±$52) and decreased to $501 (standard error, ±$30), a decline of 43%. Compared with changes in OOP pharmaceutical costs for nonelderly patients with cancer over the same period, the implementation of Medicare Part D was associated with a further reduction of $356 per person. Medicare Part D appeared to have no significant impact on the use of medications, hospitalizations, or emergency department visits, but was associated with a reduction of 1.55 in outpatient visits. **CONCLUSIONS:** Medicare D has reduced OOP prescription drug costs and outpatient visits for seniors with cancer beyond trends observed for younger patients, with no major impact on the use of other medical services noted. ***Cancer* 2014;120:3378-84.** *© 2014 American Cancer Society.*

KEYWORDS: neoplasms, drug costs, Medicare Part D, models economic, prescription drugs/economics.

INTRODUCTION

The Medicare Prescription Drug, Improvement, and Modernization Act, enacted in 2003, was the largest overhaul of Medicare in its history. The Act's most important provision was the introduction of Medicare Part D on January 1, 2006, which provided outpatient prescription drug benefits to 43 million Medicare beneficiaries for the first time.[1] Studies have shown that Part D decreased out-of-pocket (OOP) costs for medications,[2-5] with no significant impact on the use of medical services[2] for patients without cancer. The impact of Medicare Part D on patients with cancer specifically is less clear.

Over the last decade, significant strides have been made in the advancement of cancer care that have impacted patients. With improved early detection and prevention in association with more personalized therapies, many types of cancer have decreasing cancer-specific mortality.[6] These advances, along with overall trends in health care spending, have created a high price tag for oncologic care. In an analysis of Surveillance, Epidemiology, and End Results-Medicare data, the national cost of cancer care in 2010 was $124 billion and is projected to rise to $157 billion in 2020, a 27% increase.[7] In 2010, the United States spent approximately 18% (>$2.7 trillion) of the gross domestic product on health care, with cancer care accounting for 5% of health care spending.[8] In addition to overall rising costs, trends in the increased use of oral chemotherapy and supportive medications are changing how cancer care is traditionally financed.

For patients, the effects of cost-sharing can lead to the inability to afford basic needs,[9-11] nonadherence with medications,[9,10] and bankruptcy.[9,12] Financial burdens are high even for those with insurance, but are especially challenging for at-risk populations.[11,13-16]

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In the current study, we sought to evaluate the overall policy impact of Medicare Part D on Medicare beneficiaries with a diagnosis of cancer using detailed health care use and expenditure data from a large, nationally representative sample of Medicare beneficiaries.

MATERIALS AND METHODS

Data

The Medical Expenditure Panel Survey (MEPS)[17] is sponsored by the Agency for Healthcare Research and Quality and the National Center for Health Statistics. The MEPS provides annual estimates of health care use, cost, payment sources, health insurance coverage, health status, and sociodemographic characteristics for the US civilian, noninstitutionalized population. The MEPS uses an overlapping panel design and surveys are collected through personal interviewing for a series of 5 rounds over 30 months. Each annual MEPS sample is approximately 15,000 households. At the time of completion of the interview portion of the MEPS and after permission is obtained from all the participants, the medical providers, facilities, and pharmacies are directly contacted by telephone to obtain information that respondents cannot accurately provide. For example, in the pharmacy component, accurate medication names and doses, quantities dispensed, and sources and amounts of payments were obtained directly from pharmacies. We used data pooled from the years 2002 through 2005 and 2007 through 2010.

We defined our cohort as noninstitutionalized individuals aged $\geq$65 years with data collected in all rounds. To avoid estimating the potential combined effect of other programs, we excluded those individuals concurrently enrolled in TRICARE, the Veterans Affairs program, or Medicaid.

An ideal group for a control group would be those covered by Medicare but without access to Part D benefits, but this group does not exist. Therefore, we used a near-elderly cohort as the control group due to their similarities with Medicare beneficiaries, as shown in other studies.[2,5,18,19] Similar to these studies, we restricted this group to those aged 55 years to 63 years. Individuals aged 64 years were excluded to avoid those who were partially eligible for Medicare Part D and those aged $<$55 years were excluded to avoid medication variation caused by the use of medications for reproduction and contraception.[20]

In both the cohort and control groups, we limited our analysis to those with "cancer" coded in the condition file of the MEPS database. A condition of cancer can be added to an individual in several ways. Cancer is considered a priority condition within the MEPS and therefore all participants in the survey are asked specifically if they have been diagnosed with cancer. A condition of cancer will also be added if the respondent reports cancer as a reason for a medical encounter or disability day.

Each medication was associated with a condition in the MEPS. The medication information (name, dose, quantity dispensed, and expenditure) is collected by surveyors during each interview and then confirmed with pharmacy data to obtain complete and accurate data. The association between a medication and condition is made in 2 ways: either by self-report from the interviews or by the *International Classification of Diseases, Ninth Revision* (ICD-9) code when the medication is verified with pharmacy data. When obtained through self-report, the associated condition is converted into an ICD-9 code by the MEPS coders. Each medication was further categorized as "cancer-related" or "noncancer-related" based on the association of the medication with an ICD-9 code for a cancer diagnosis. Within the "cancer-related" medications, they were further categorized based on the class of drug with the following categories: antineoplastic, central nervous system agents, topical, hormonal, cardiovascular agents, antiinfectives, gastrointestinal, respiratory, nutritional, metabolic agents, psychotherapeutics, genitourinary agents, coagulation, biologic agents, or miscellaneous/not otherwise categorized. These therapeutic classifications were designated by MEPS coders and are based on Lexicon Plus designations (Cerner Multum Inc, Denver, Colo).[21] Due to the concern for making an incorrect association between a medication and a cancer diagnosis, we took a random sample of 100 individuals and manually inspected the names of the medications and the condition with which they were associated.

Statistical Analysis

There were 2 pooled time periods: 2002 to 2005 and 2007 to 2010. These years were chosen because Medicare Part D was enacted in 2006 and these years allow a "before" and "after" time period for comparison. A sensitivity analysis including 2011 data in the post-Part D time period was performed as these data became available. All dollar amounts were adjusted to 2010 dollars based on the Consumer Price Index. Expenditures in this study refer to what is paid for health care services rather than charges. The rationale for using this definition is that charges can be a less approximate proxy for medical expenditures when there is significant discounting.

The primary dependent variables included OOP costs, medication use, hospitalizations, emergency

department visits, and outpatient visits. OOP costs are defined as direct payment for all prescription drugs by patients who reported having cancer as a condition. The number of new prescriptions and refills per person were used as measurements of prescription drug use during one year. Emergency department visits, outpatient visits, and inpatient hospitalizations were measured by the annual number of visits. For inpatient hospitalizations, the number of discharges included those hospitalizations for which the admission and discharge date were the same. In addition, we evaluated the total prescription drug costs that included both the payer and OOP costs.

Independent 2-group Student *t* tests were conducted for continuous variables and the chi-square test was used for categorical variables to compare the treatment and control groups at baseline in terms of age, sex, ethnicity, region, marital status, type of insurance coverage, poverty category, and number of comorbidities.

We used a differences-in-differences model to estimate the impact of Medicare Part D on each of our outcome variables.[22] A differences-in-differences model assumes that, in the absence of the treatment or in our case Medicare Part D, the average outcomes for the exposed and control groups would have followed parallel paths over time. This methodology has been used previously in studies evaluating intervention programs or policies.[23-26] A multivariate differences-in-differences model is written as:

$$\text{Outcome} = \text{B0} + \text{B1}\ \text{group} + \text{B2}\ \text{year} + \text{B3}\ (\text{group} \times \text{year}) + \text{other covariates}$$

in which "group" is the variable for the treatment and control groups and B1 is the coefficient that reflects the differences between the control and treatment groups. The variable "year" indicates whether the time period is before or after enactment of Medicare Part D, with B2 the coefficient demonstrating the change in outcomes in the absence of Medicare Part D and solely due to time trends. The output of interest for the current analysis was B3, which is an interaction term and measures the effect of the intervention on the treatment group.

Expenditure data regarding OOP and total costs are highly skewed and zero inflated.[27,28] To deal with these nonnormal distributions, we used a flexible 2-part model to accommodate both excess zeroes and skewed distribution of the nonzero values.[27] These data have been referred to as "semicontinuous" in the literature and can be viewed as arising from 2 distinct stochastic process, one of which governs the occurrences of zeroes and the second of which determines the observed values given a nonzero response.[29] This 2-part mixture model is an ideal choice for these data to accommodate both data-generating processes. A logit model was used for the first part and a generalized linear model (GLM) with a log link and gamma distribution was used in the second part.[30] We used a modified Park test to determine the distribution family for the GLM. We reported the standard errors (SEs) and *P* values of the interaction term of the GLM that represents individuals who had nonzero expenditures.

For the use variables (number of prescription drugs with refills, number of emergency department visits, number of outpatient visits, and number of hospitalizations), a zero-inflated negative binomial (zinb) was used. We used zinb regression, as opposed to the zero-inflated Poisson regression, because there was data dispersion in our outcome variables.[31] The zinb model arises from a theory that suggests that a separate process governs the excess zeroes versus the count values and they can be modeled independently. Therefore, the zinb model has 2 parts: a negative binomial count model and a logit model to predict excess zeroes. We reported the SEs and *P* values of the interaction term of the negative binomial regression that represents individuals who had nonzero use for each variable.

To analyze the category and drug class associated with each medication, we tabulated the percentage of medications that were "cancer-associated" with "noncancer-associated" medications. Within the cancer-associated medications, we further tabulated the portion from each drug class. This analysis was performed by pooling data from 2002 through 2010 and examining the Medicare group.

All the current analyses accounted for a MEPS complex sampling design and sampling weights were applied accordingly. Data were analyzed with Stata statistical software (version 13; StataCorp, College Station, Tex)

RESULTS

Sample and Baseline Characteristics

The data set included 8134 total individuals aged ≥55 years with cancer coded in the condition file in MEPS years 2002 through 2005 and 2007 through 2010. Of Medicare beneficiaries, there were 5742 individuals with cancer as a condition and 1013 were excluded due to dual Medicaid or TRICARE insurance. This resulted in 4729 individuals in the final analysis, which represents over 59 million Medicare beneficiaries. In the control group of near-elderly individuals, there were 2391 individuals with

TABLE 1. Demographic Characteristics of Medicare and Near-Elderly Individuals

Individual Characteristics	Variable Description	Medicare (n=4729) Mean (SE) or Percentage	Near-Elderly (n=1878)[a] Mean (SE) or Percentage
Mean age[b]		75.3 (0.2)	59.1 (0.09)
Mean no. of comorbidities[b]		3.72	2.89
Sex, %[b]	Female	46	53
Ethnicity, %[c]	White	94	92
	Black	4	5
	AI/AN	0	0
	Asian	1	2
	Pacific Islander	0	0
	Multiple	0	0
Region, %[d]	Northeast	20	22
	Midwest	22	20
	South	37	36
	West	21	21
Marital status, %[b]	Married	62	74
Type of insurance coverage[b]	Any private	62	91
	Public only	38	1
	Uninsured	0	7
Poverty category, %[b]	Poor/negative	6	4
	Near poor	5	2
	Low	17	6
	Middle	29	21
	High	42	66
Weighted population		59,078,399	23,456,385

Abbreviations: AI/AN, American Indian/Alaskan Native; SE, standard error of the mean.
[a] Elderly indicates Medicare beneficiaries aged ≥65 years, excluding those with concurrent Medicaid or TRICARE coverage. Near-elderly indicates those aged 55 years to 64 years, excluding those with concurrent Medicare, Medicaid, or TRICARE coverage.
[b] $P<.01$.
[c] P of .01 to .05.
[d] $P>.05$.

a cancer coded and 513 were excluded due to concurrent Medicare, Medicaid, or TRICARE coverage. This resulted in 1878 individuals between the ages of 55 and 64 years, which represents >23 million near-elderly.

Table 1 examines the demographic characteristics of the 2 groups. The average age of the Medicare beneficiaries was 75.3 years and the control group had a mean age of 59.1 years. Medicare beneficiaries tended to have more comorbidities (3.72 vs 2.89; $P<.01$), were less likely to be married (62% vs 74%; $P<.01$), and to have lower incomes (17% vs 6% in the low-income category). There were fewer females in the Medicare group (46% vs 53%; $P<.01$) and no significant differences with regard to ethnicity or region was noted within the 2 groups. Prescription drug coverage increased among individuals with Medicare from before Part D enactment (41%) to after (67.5%). In contrast, prescription drug coverage among the near-elderly remained stable before versus after Part D enactment (83.7% vs 81.1%).

Table 2 shows the adjusted differences-in-differences results for the outcomes of interest. The covariates included sex, age, year, region, number of comorbidities, and poverty status. Compared with changes in OOP medication costs for nonelderly patients with cancer over the same period, the implementation of Medicare Part D was associated with a further reduction of $356 ($P = .02$) per person with cancer. We did not observe a significant impact of Medicare Part D on medication use ($P = .79$), emergency department visits ($P = .85$), or hospital use ($P = .68$). There was a significant decrease in the number of total outpatient visits per year with implementation of Medicare Part D (1.55 decrease in the total number of outpatient visits; $P = .05$). In both the Medicare and near-elderly group, the OOP cost for prescription drugs decreased. In the Medicare group, OOP costs decreased from $1158 (±$52) to $501 (±$30), a decrease of $473. In the near-elderly group, OOP costs also decreased from $789 (± $67) to $645 (± $49). In a sensitivity analysis to evaluate more recent trends, we included 2011 data and therefore the time period after Medicare Part D enactment was from 2007 through 2011. When 2011 data were included, the implementation of Medicare Part D was associated with a further reduction in OOP costs of $419 compared with the near-elderly group.

To evaluate the percentage of total prescription drugs that were associated with cancer, we combined all Medicare individuals from 2002 through 2010. We

TABLE 2. Differences-in-Differences Analysis of the Impact of Medicare Part D on Variables[a]

Outcome Variable	2002 to 2005	2007 to 2010	Differences	Differences in Differences	*P*[b]
Out-of-pocket cost for prescription drugs[c]					
Elderly	1158	501	−657	−356	.02
Near-elderly	721	420	−301		
No. of prescriptions (with refills)					
Elderly	27.0	29.4	+2.4	+0.5	.79
Near-elderly	25.6	27.5	+1.9		
No. of emergency department visits					
Elderly	0.29	0.24	−0.05	0.06	.85
Near-elderly	0.35	0.34	+0.01		
No. of hospitalization (discharges)					
Elderly	0.36	0.30	−0.06	−0.05	.68
Near-elderly	0.35	0.34	−0.01		
No. of outpatient visits					
Elderly	3.65	1.97	−1.68	−1.55	.05
Near-elderly	1.41	1.28	−0.13		

[a] Model has been adjusted for age, year, region, number of comorbidities, poverty status, and sex.
[b] Standard errors (SE) and *P* values refer only to the population of individuals who had nonzero expenditures. For out-of-pocket expense, this is the SE and *P* value for the generalized linear model. For use variables, it is the SE and *P* value for the negative binomial mode.
[c] Out-of-pocket costs are adjusted based on the consumer price index in 2010 dollars.

TABLE 3. Drug Class of Cancer-Associated Drugs in Medicare Group[a]

Drug	Percentage of Total Cancer-Associated Drugs in Each Therapeutic Subclass
Antineoplastic	21.2
CNS agent (includes pain medications)	18.1
Topical	13.4
Hormonal	9.8
Cardiovascular agents	9.6
Antiinfective	9.1
Gastrointestinal	4.4
Respiratory	3.2
Miscellaneous	2.8
Nutritional	2.8
Metabolic agents	1.4
Psychotherapeutics	1.3
Genitourinary agents	1.2
Coagulation	1.0
Biologic agents	0.5

Abbreviation: CNS, central nervous system.
[a] Sample includes individuals with Medicare (n=1068) and with >0 cancer-associated prescriptions. There was a total of 1871 unique prescriptions.

randomly sampled 100 individuals to check face validity of the association between medication and associated diagnosis and we believed that there were appropriate associations coded. Of the total Medicare group in all years, 21% of the individuals had at least 1 medication that was specifically associated with cancer treatment. There were a total of 1068 individuals who had at least 1 cancer-associated medication, representing >12 million of the 59 million Medicare-eligible individuals with a cancer diagnosis. Of the total number of cancer-associated medications, the most common drug classes were antineoplastics (21.2%), central nervous system agents (18.1%), topical agents (13.4%), hormones (9.8%), and cardiovascular agents (9.6%) (Table 3). Of those individuals with at least 1 cancer-associated medication, 31.5% of the total medications were associated with cancer. Of all Medicare-eligible individuals, 6.9% of total medications were associated with cancer.

DISCUSSION

To our knowledge, this is the first analysis of the impact of Medicare Part D among individuals with a cancer diagnosis. In this analysis of the MEPS, it was found that Medicare Part D eligibility was associated with a significant reduction in OOP costs for prescription drugs for individuals with a diagnosis of cancer. When more recent 2011 data were included, Medicare Part D resulted in a further decrease in OOP costs. It is not possible to know from this analysis why Medicare Part D is having an even further beneficial impact on OOP costs in recent years, but a potential reason is that Medicare Part D is more effectively covering prescription drugs when compared with insurance plans of the near-elderly population. There was no statistically significant effect of Medicare Part D noted on medication use, emergency department visits, or hospitalizations. Therefore, we did not note any evidence that there was a cost offset related to implementation of Medicare Part D in those services and this finding has been confirmed in previous studies of a population of patients without cancer.[2,32,33] It is interesting to note that

we did see that Medicare Part D was associated with a reduction of outpatient visits of 1.55 beyond trends observed in the near-elderly group. The reasons for this decrease are beyond the scope of the current analysis, but it is possible that increased access to affordable prescription medications with Medicare Part D resulted in more controlled illness requiring less use of medical visits. Further studies could help to determine whether the findings of the current study represent a clinically significant decrease in outpatient use.

Of individuals with a cancer diagnosis, 21% have at least 1 medication that is associated with cancer treatment. This highlights that individuals with cancer have many other comorbidities for which they receive medications and that the majority of their OOP costs are not specifically associated with their cancer diagnosis. This also indicates that in the time period studied, antineoplastics in the form of oral chemotherapy or biologics comprised a small percentage of medications for an individual with a cancer diagnosis. With the increasing use of oral agents, this trend will need to be followed in the future.

The current study has several limitations. There are challenges in the inferences made by a differences-in-differences approach that are based on assumptions that may not hold true. For example, this approach requires that, in the absence of the treatment or, in the case of the current study Medicare Part D, the average outcomes for the exposed and control groups would have followed parallel paths over time. It is not certain that the near-elderly and Medicare populations would have experienced similar trends in use and expenditure if Medicare Part D had not been implemented. This analysis is also limited in that small sample sizes in the MEPS did not allow for a more granular analysis of specific drugs of interest (eg, high-cost drugs such as imatinib or capecitabine). Because there were so few individuals receiving a single drug, we were limited to using larger drug categories such as "antineoplastics." Another limitation is that the most recent data set was from 2011 and may not be recent enough to capture the cost implications of trends in oral agents. This study does not contain recent enough data to study the impact of health care reform, which was implemented in 2010, and this analysis will need to be repeated in the future to fully understand the impact of these changes in oncologic care. Another limitation to the use of this type of survey data are that the conditions and medications are self-reported.

In this era of health care reform, the overall cost of health care is rising and cancer treatments are among the most expensive. It will become increasingly important to understand whether our existing policies, including Medicare Part D, will adequately protect patients with cancer from unsustainable OOP burdens. Although the current analysis found that Medicare Part D reduced the OOP cost, in its existing form the policy is unlikely to be able to accommodate the rising cost and number of oral agents in oncology. For this reason, there must be additional policies beyond Medicare Part D to ensure affordable cancer care. At the state level, 29 states plus the District of Columbia have passed drug parity laws that address the disparity between insurance coverage of intravenous and oral agents by mandating equal cost-sharing. Federally, the Patient Protection and Affordable Care Act (ACA) contains provisions that will likely impact the OOP burden for patients with cancer. The ACA aims to close the coverage gap in Medicare Part D coverage by the year 2020; however, with high-cost drugs, even a small coinsurance percentage may translate into significant costs and burdens to most patients. In addition, the ACA imposes maximum individual and family annual limits on OOP costs for all services ($6350 and $12,700, respectively, in 2014). As cancer treatments become increasingly complex and costly, policies aimed at controlling OOP costs must also evolve so we can deliver high-quality, accessible, and affordable cancer therapies.

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