

# Cost-Related Medication Nonadherence and Spending on Basic Needs Following Implementation of Medicare Part D

Jeanne M. Madden, PhD

Amy J. Graves, MPH

Fang Zhang, PhD

Alyce S. Adams, PhD

Becky A. Briesacher, PhD

Dennis Ross-Degnan, ScD

Jerry H. Gurwitz, MD

Marsha Pierre-Jacques, BA

Dana Gelb Safran, ScD

Gerald S. Adler, MPhil

Stephen B. Soumerai, ScD

IN PERHAPS THE MOST EXTENSIVE restructuring of the Medicare system since its introduction in 1965, Congress passed the Medicare Prescription Drug Improvement and Modernization Act in the fall of 2003. Before the Medicare Prescription Drug Improvement and Modernization Act, millions of individuals who were elderly and disabled had insufficient or no insurance coverage for outpatient medications.<sup>1-3</sup> In the face of these economic barriers, several large surveys in the United States have shown that older individuals have resorted to behaviors such as skipping doses, reducing doses, and letting prescriptions go unfilled.<sup>4-9</sup> Such cost-related medication nonadherence (CRN) is associated with increased risk of myocardial infarction, stroke, and preventable hospitalization.<sup>10</sup>

See also pp 1929 and 1954.

**Context** Cost-related medication nonadherence (CRN) has been a persistent problem for individuals who are elderly and disabled in the United States. The impact of Medicare prescription drug coverage (Part D) on CRN is unknown.

**Objective** To estimate changes in CRN and forgoing basic needs to pay for drugs following Part D implementation.

**Design, Setting, and Participants** In a population-level study design, changes in study outcomes between 2005 and 2006 before and after Medicare Part D implementation were compared with historical changes between 2004 and 2005. The community-dwelling sample of the nationally representative Medicare Current Beneficiary Survey (unweighted unique n=24 234; response rate, 72.3%) was used, and logistic regression analyses were controlled for demographic characteristics, health status, and historical trends.

**Main Outcome Measures** Self-reports of CRN (skipping or reducing doses, not obtaining prescriptions) and spending less on basic needs to afford medicines.

**Results** The unadjusted, weighted prevalence of CRN was 15.2% in 2004, 14.1% in 2005, and 11.5% after Part D implementation in 2006. The prevalence of spending less on basic needs was 10.6% in 2004, 11.1% in 2005, and 7.6% in 2006. Adjusted analyses comparing 2006 with 2005 and controlling for historical changes (2005 vs 2004) demonstrated significant decreases in the odds of CRN (ratio of odds ratios [ORs], 0.85; 95% confidence interval [CI], 0.74-0.98;  $P=.03$ ) and spending less on basic needs (ratio of ORs, 0.59; 95% CI, 0.48-0.72;  $P<.001$ ). No significant changes in CRN were observed among beneficiaries with fair to poor health (ratio of ORs, 1.00; 95% CI, 0.82-1.21;  $P=.97$ ), despite high baseline CRN prevalence for this group (22.2% in 2005) and significant decreases among beneficiaries with good to excellent health (ratio of ORs, 0.77; 95% CI, 0.63-0.95;  $P=.02$ ). However, significant reductions in spending less on basic needs were observed in both groups (fair to poor health: ratio of ORs, 0.60; 95% CI, 0.47-0.75;  $P<.001$ ; and good to excellent health: ratio of ORs, 0.57; 95% CI, 0.44-0.75;  $P<.001$ ).

**Conclusions** In this survey population, there was evidence for a small but significant overall decrease in CRN and forgoing basic needs following Part D implementation. However, no net decrease in CRN after Part D was observed among the sickest beneficiaries, who continued to experience higher rates of CRN.

JAMA. 2008;299(16):1922-1928

www.jama.com

**Author Affiliations:** Department of Ambulatory Care and Prevention, Harvard Medical School and Harvard Pilgrim Health Care, Boston, Massachusetts (Drs Madden, Zhang, Adams, Ross-Degnan, and Soumerai, and Mss Graves and Pierre-Jacques); Division of Geriatric Medicine and Meyers Primary Care Institute, University of Massachusetts Medical School, Worcester (Drs Briesacher and Gurwitz); Department of Medicine, Tufts University School of Medicine

and Blue Cross Blue Shield of Massachusetts, Boston (Dr Safran); and Office of Research, Development, and Information, Centers for Medicare & Medicaid Services, Baltimore, Maryland (Mr Adler).

**Corresponding Author:** Jeanne M. Madden, PhD, Department of Ambulatory Care and Prevention, Harvard Medical School and Harvard Pilgrim Health Care, 133 Brookline Ave, 6th Floor, Boston, MA 02215 (jeanne\_madden@hms.harvard.edu).

Since January 2006, Medicare beneficiaries may elect to purchase a prescription drug benefit (Part D), subsidized by Medicare and available through private plans.<sup>11</sup> Additional subsidies are available to low-income beneficiaries and some individuals with very high drug costs. Recent data have shown that only approximately 10% of Medicare beneficiaries remain without prescription coverage after Medicare Part D implementation compared with rates of 25% to 38% in the preceding years.<sup>2,4,9,12-18</sup> The Congressional Budget Office projected total federal spending on Part D to be \$850 billion over the first 10 years.<sup>19</sup>

There have been no published studies using longitudinal data to examine possible changes in CRN before and after Medicare Part D implementation. We report changes in the prevalences of CRN and spending less on basic needs (eg, food) to afford medicines among 24 234 nationally representative, community-dwelling Medicare enrollees who participated in the Medicare Current Beneficiary Survey (MCBS) during the fall seasons of 2004, 2005, and 2006. We estimated changes in CRN among respondents between 2005 and 2006, before and after Part D implementation, controlling for changes observed in identically defined populations in the 2 years before Part D implementation. To avoid selection biases due to greater Part D enrollment among sicker and poorer beneficiaries,<sup>20,21</sup> we conducted full population analyses including all respondents regardless of Part D enrollment. Subgroup analyses were conducted to examine changes in populations with demographic and health characteristics associated with CRN (eg, fair to poor health).<sup>5</sup>

## METHODS

### Data Source and Sample

The Centers for Medicare & Medicaid Services conducts the MCBS based on a representative sample of Medicare beneficiaries drawn from Medicare en-

rollment data.<sup>22</sup> The MCBS is the principal national survey for informing and evaluating health policies for Medicare beneficiaries. A 4-year rotating panel design with annual replenishments ensures continued generalizability and allows longitudinal analyses. The annual survey population of approximately 15 700 Medicare enrollees is selected using a multistage sampling plan, with oversampling of vulnerable subgroups such as the disabled and the oldest old. The MCBS conducts a baseline interview between September and December covering demographic and household factors, as well as health insurance, health status, and experiences with health care. This general interview is repeated yearly for the following 3 years. Additional thrice-annual interviews collect detailed information on health care use and expenditures, with reviews of respondents' insurance statements and receipts to enhance data accuracy. Interviews are conducted in person with computer assistance. The MCBS produces 2 data files annually, access to care (ATC) and cost and use (CAU). Since 2004, the MCBS has included in the fall interview and the ATC file a module of questions on different aspects of CRN, developed by the study team.<sup>4-6,23</sup> We used MCBS data from only the ATC files in our analyses, because CAU files containing data on health care utilization after implementation of Part D will not become available until 2009. We included all community-dwelling respondents (approximately 94% of total) from 2004 through 2006 (n=14 500 for 2004, n=14 701 for 2005, and n=14 732 for 2006). Accounting for overlap among years, the total number of individual respondents in this study was 24 234. Average ATC response rates across panels in this period were 72.3%.

### Study Variables

In 2004, the MCBS incorporated a battery of validated measures of CRN ("decide not to fill or refill a prescription because it was too expensive"; "skipped doses to make the medicine last longer";

"taken smaller doses of a medicine to make the medicine last longer"), as well as a companion measure of extreme compensatory behaviors ("spent less money on food, heat, or other basic needs so that you would have money for medicine").<sup>5</sup> Previous work has shown that all 4 measures exhibit high test-retest reliability<sup>23</sup> and construct validity.<sup>4-6</sup>

As described previously,<sup>5</sup> we constructed a summary indicator of CRN for analysis that took the value *yes* if a respondent indicated *yes/ever during the current year* on any of the following: "skipped doses to make the medicine last longer"; "taken smaller doses of a medicine to make the medicine last longer"; or "any medicines prescribed for you that you did not get" in combination with "(a reason or the main reason) you did not obtain the medicine was you thought it would cost too much" or "decide not to fill or refill a prescription because it was too expensive." Preliminary analyses revealed that the reported prevalence of CRN and spending less on basic needs was higher in initial MCBS interviews than in subsequent annual interviews, irrespective of calendar year. We controlled for this interview sequence effect by incorporating MCBS sample replenishments in all years, estimating changes before and after Part D implementation relative to a historical period with same sequence effect, and adjusting all models for interview sequence.

From the MCBS ATC file, we used previously validated covariates<sup>3,6,24-27</sup> to explore possible differences in population groups over time and as control variables in regression analyses. These covariates were all self-reported by survey respondents: age; sex; income; education; race and Hispanic ethnicity (by using categories defined by investigators); general health status (by using a single-item measure<sup>28</sup> dichotomized into fair or poor vs good, very good, or excellent); functional status (by using a 6-item assessment of limitations in activities of daily living<sup>29</sup>); and presence of specific diseases or conditions.

### Statistical Analyses

First, we described the rates (and 95% confidence intervals [CIs]) of demographic and health characteristics of the population in 2004, 2005, and 2006, weighted to represent the overall population of community-dwelling Medicare beneficiaries. We calculated unadjusted annual prevalences of CRN and spending less on basic needs with 95% CIs from 2004 to 2006.

To model changes in CRN and spending less on basic needs over time, we used a logistic regression model and the full population in each calendar year to predict the odds of CRN (1=yes, 0=no) by year. The key covariates in the model were

2 indicators for response year (2006, 2005), with 2004 as the reference year. In addition to the odds ratio (OR) of CRN in 2005 vs 2004 produced directly by the model, we used contrast terms to estimate the OR of CRN for 2006 vs 2005. Finally, we calculated a ratio of these 2 ORs, namely 2006 vs 2005 relative to 2005 vs 2004. This approach estimated the change in study outcomes following Part D implementation, controlling for historical year-to-year changes in the absence of Part D.

Our model controlled for interview sequence, demographic characteristics (sex, age, income, race), and health status (number of morbidities, general health status) using dummy

variables, and applied MCBS cross-sectional survey weights.<sup>22</sup> We corrected for the clustering at the primary sampling unit level inherent in the MCBS design,<sup>22</sup> thereby also controlling for repeated responses by individuals over time.<sup>30</sup> The odds of forgoing basic needs were modeled separately using the same approach. We then repeated both analyses separately in 9 subgroups based on demographic and health characteristics determined earlier<sup>5</sup> to be associated with CRN (eg, disabled vs elderly, fair to poor vs good to excellent health, number of morbidities, and lower [ $< \$25\,000$ ] vs higher [ $\geq \$25\,000$ ] income).

Because ORs can sometimes exaggerate risk ratios (RRs), we also converted ORs into RRs by using previously validated methods<sup>31,32</sup> and repeated the analyses. The results using RRs were nearly identical to those from the OR models. However, as no established methods exist for constructing precise CIs or *P* values for ratios of RRs, we report the results from the OR models.

We assessed the robustness of our results by conducting 3 alternative analyses: adjustment for repeated measures on the same individuals across survey years by using unweighted general estimating equation regression models; adjustment for drug coverage status<sup>5</sup> before Part D implementation for a subgroup of long-term survey respondents; and 2-year continuous cohort models stratified by interview sequence to investigate individual pre-post changes in mutually exclusive comparison groups (2005 to 2006 vs 2004 to 2005). These alternative approaches had little to no impact on estimates of changes in CRN and forgoing basic needs after Part D implementation. We also determined that there were no differences in these outcomes between respondents who reinterviewed vs those who were lost to follow-up.

All analyses were conducted by using Stata version 10 (StataCorp LP, College Station, Texas), and the a priori level of statistical significance was  $P < .05$ . This study was reviewed and approved by the Human Subjects Committee of Harvard Pilgrim Health Care.

**Table 1.** Demographic and Health Characteristics of Community-Dwelling Medicare Beneficiaries, 2004-2006<sup>a</sup>

Characteristics	% (95% Confidence Interval)		
	2004 (n = 14 500)	2005 (n = 14 701)	2006 (n = 14 732)
Female sex	55.8 (55.0-56.6)	55.8 (54.9-56.6)	55.2 (54.2-56.1)
Age, y <sup>b</sup>			
≤55	7.9 (7.4-8.5)	7.8 (7.3-8.2)	8.0 (7.4-8.6)
56-64	7.0 (6.4-7.6)	7.3 (6.7-8.0)	7.5 (6.9-8.2)
65-74	42.7 (41.9-43.6)	42.5 (41.6-43.3)	42.5 (41.7-43.4)
75-84	32.2 (31.3-33.1)	32.4 (31.6-33.2)	31.6 (30.9-32.2)
≥85	10.2 (9.7-10.6)	10.1 (9.7-10.5)	10.4 (10.0-10.9)
Income, US\$ <25 000	58.9 (57.1-60.6)	57.5 (55.8-59.1)	55.1 (53.4-56.8)
Race			
Black	9.7 (8.1-11.5)	9.4 (7.9-11.2)	9.4 (7.9-11.2)
White	83.9 (82.0-85.6)	84.3 (82.4-86.0)	84.0 (82.4-85.6)
Other	6.4 (5.7-7.3)	6.4 (5.6-7.2)	6.5 (5.8-7.4)
Hispanic ethnicity	7.8 (6.7-9.1)	7.7 (6.6-8.9)	7.8 (6.7-9.1)
Education			
>High school	41.0 (39.2-42.9)	42.1 (40.2-44.1)	42.6 (40.7-44.5)
High school diploma	30.4 (29.1-31.8)	30.4 (29.0-31.9)	30.9 (29.7-32.1)
No high school diploma	28.6 (27.2-30.0)	27.5 (26.0-29.0)	26.6 (25.2-28.0)
No. of morbidities <sup>c</sup>			
0-1	28.1 (27.0-29.1)	26.5 (25.5-27.5)	25.9 (24.9-27.0)
2-3	47.9 (46.9-48.9)	47.0 (46.1-47.9)	48.1 (47.1-49.1)
≥4	24.0 (23.2-24.9)	26.5 (25.6-27.5)	26.0 (25.0-27.0)
No. of limitations in activities of daily living <sup>d</sup>			
0	70.7 (69.3-72.0)	70.0 (68.9-71.2)	69.9 (68.3-71.6)
1-2	20.6 (19.6-21.7)	21.0 (20.0-22.1)	20.4 (19.2-21.6)
≥3	8.7 (7.9-9.6)	8.9 (8.3-9.7)	9.7 (8.9-10.6)
Self-reported health status			
Excellent, very good, or good	73.0 (72.0-74.1)	73.2 (72.1-74.3)	73.3 (72.2-74.5)
Fair or poor	27.0 (25.9-28.1)	26.8 (25.7-27.9)	26.7 (25.6-27.8)

<sup>a</sup>Percentage bases excluded those participants with missing values. Values were missing for no more than 2% of respondents per characteristic. Percentages were calculated with national survey weights. Race and Hispanic ethnicity were defined by investigators.

<sup>b</sup>Respondents younger than 65 years were defined as disabled.

<sup>c</sup>Morbidity categories included cardiac disease, hypertension, cerebrovascular disease, lung disease, cancer, diabetes mellitus, arthritis, psychiatric disorder or depression, dementia, and other neurological conditions.

<sup>d</sup>Limitations in activities of daily living indicate reduced functional status.

## RESULTS

### Characteristics of Medicare Beneficiaries, 2004-2006

The demographic and health characteristics of the community-dwelling Medicare population in 2004, 2005, and 2006 were very similar (TABLE 1). A majority had low incomes (<\$25 000). Disabled, nonelderly beneficiaries represented approximately 15% of the weighted sample. More than 72% of beneficiaries were estimated to have at least 2 morbid conditions.

### Unadjusted Changes in Study Outcomes for Medicare Beneficiaries, 2004-2006

The FIGURE displays unadjusted year-to-year changes in the prevalence of CRN and spending less on basic needs to afford medicines among community-dwelling Medicare beneficiaries. We observed a larger absolute decrease in CRN following Medicare Part D implementation (from 14.1% in 2005 to 11.5% in 2006) than occurred between 2004 and 2005 (15.2% to 14.1%, respectively). At the same time, while forgoing basic needs increased slightly between 2004 and 2005 (10.6% to 11.1%, respectively), there was a 3.5 percentage point decrease (to 7.6%) in this measure after Medicare Part D implementation in 2006. The overlaps in 95% CIs for the above measures between 2004 and 2005 and the lack of overlap in 95% CIs between 2005 and 2006 suggest significant overall declines in unadjusted CRN and forgoing basic needs from 2005 to 2006 compared with historical changes.

### Adjusted Changes in CRN

TABLE 2 shows overall estimated changes in CRN and spending less on basic needs after the implementation of Part D from logistic regression analyses. The 2006 vs 2005 OR for CRN relative to historical changes was 0.85 (95% CI for ratio of ORs, 0.74-0.98), and the corresponding OR for forgoing basic needs after Part D implementation was 0.59 (95% CI for ratio of ORs, 0.48-0.72).

### Findings for Subgroups Based on Health Status and Income

Results from the subgroup analyses are shown in TABLE 3. As expected, prevalence rates in all 3 years indicated that CRN was strongly associated with disabled status, poorer self-reported health, higher numbers of morbidities, and lower income. For example, in 2005, before Part D implementation, the prevalence of CRN among disabled, nonelderly beneficiaries was 29.7%, while the prevalence of forgoing basic needs was 24.6%. Among elderly beneficiaries, these rates were 11.3% and 8.7%, respectively. Beneficiaries in fair to poor health status reported nearly double the rate of CRN (22.2%) and 3 times the rate of forgoing basic needs (21.3%) in 2005 compared with those in good to excellent health.

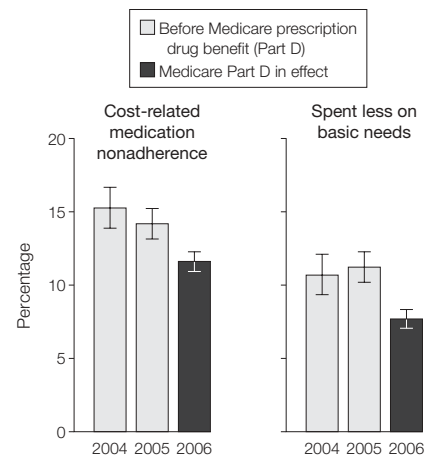
We did not detect any significant changes in CRN following Part D implementation among the clinically more vulnerable subgroups (disabled, fair to poor health, and 4 or more morbidities), although among disabled respondents the sample was relatively small and the direction of change was downward (ratio of ORs, 0.90; 95% CI, 0.69-1.16;  $P = .41$ ) (Table 3). Among the subgroups with fair to poor health or 4 or more morbidities, the ratios of ORs were 1 or more, suggesting no change in CRN after Part D implementation. Among those participants with 0 to 3 morbidities or good to excellent health, the ratio of ORs suggest some decreases in CRN (in the case of 0-1 morbidities, the decrease was not significant). There were modest and significant decreases in CRN among lower-income beneficiaries, controlling for changes from 2004 to 2005, but not for higher-income beneficiaries (Table 3).

The risk of forgoing basic needs declined among all subgroups relative to historical changes, although the decrease was not significant for the nonelderly disabled beneficiaries.

## COMMENT

The inclusion of prescription drug coverage in Medicare represents the largest expansion of the program in more than

**Figure.** Unadjusted Prevalence Rates of Cost-Related Medication Nonadherence and Spending Less on Basic Needs to Afford Medicines Among Community-Dwelling Medicare Beneficiaries, 2004-2006



Survey results weighted to national Medicare population. Total number was approximately 37 to 38 million; item response rates, survey sample size, and Medicare target population vary by year and study measure. Error bars represent 95% confidence intervals around rates.

40 years; it came after decades of media and scientific reports on the increasing financial burden of life-saving medicines for Medicare enrollees,<sup>1</sup> nonadherence due to costs,<sup>4-7,9</sup> and subsequent adverse health outcomes.<sup>10</sup> A principal goal of Medicare Part D implementation was to increase economic access to medications, especially among vulnerable poor and chronically ill populations. This is the first controlled study to our knowledge in a nationally representative sample of Medicare beneficiaries of changes in CRN and financial hardship after implementation of Part D.

Our data suggest that the implementation of Part D was associated with a modest but significant decrease in the prevalence of CRN. In absolute terms, unadjusted prevalences of CRN and spending less on basic needs to afford medicines decreased 2.6 and 3.5 percentage points, respectively (adjusted ratios of ORs were 0.85 and 0.59, respectively). Similar results were found for elderly Medicare beneficiaries, but our findings were inconclusive for the nonelderly disabled beneficiaries. We did not observe a net decrease in CRN among in-

dividuals who were seriously ill with fair to poor health or at least 4 morbidities; however, these groups reported some reductions in forgoing basic needs to afford medication. Those beneficiaries with incomes less than \$25 000 also experienced significant decreases in CRN and forgoing basic needs, relative to historical trends.

The finding of only small absolute changes following implementation of Part D was predictable given our full-population design, which included all noninstitutionalized MCBS respondents, regardless of whether they enrolled in Part D. Many Medicare beneficiaries already had drug coverage before Part D implementation. Probably less than 25% of Medicare beneficiaries acquired drug coverage for the

first time in 2006, while drug coverage was strengthened for other beneficiaries, particularly those in Medicare Advantage plans (managed care).<sup>9</sup> Our findings provide an estimate of the national effect of the policy, rather than the effect on specific population subgroups who enrolled in Part D. The population-level approach is not subject to selection biases that result from higher rates of Part D enrollment among patients who are seriously ill.<sup>20,21</sup>

The lack of observed change in CRN following Part D implementation among disabled individuals and those in poorer health deserves comment. We have shown here and in previous studies<sup>4-7</sup> that disabled individuals and other Medicare beneficiaries in poor health have very high and persistent CRN over time,

caused in part by intensive use of medication and high out-of-pocket medication expenditures.<sup>8,16,33-35</sup> Furthermore, those individuals not enrolling in Part D or switching to Part D from other drug coverage would not be expected to exhibit substantial changes in CRN. For example, disabled beneficiaries were more likely than elderly beneficiaries to have had Medicaid drug coverage before 2006 (30% vs 7%),<sup>5</sup> and Medicaid recipients were autoenrolled into Part D plans. Less healthy beneficiaries who did enroll in a Part D plan would have paid substantially more in co-payments than other beneficiaries and would more likely have been in the “doughnut hole” coverage gap (100% co-payments after first \$2250 in total drug costs) by the end of the year, when this survey was con-

**Table 2.** Overall Changes in Cost-Related Medication Nonadherence and Spending Less on Basic Needs to Afford Medicines Following Part D Implementation Among Community-Dwelling Medicare Beneficiaries<sup>a</sup>

Outcome Measures	No. of Observations	No. of Respondents	OR (95% CI)		Ratio of ORs (95% CI) <sup>b</sup>	P Value for Ratio of ORs
			2005 vs 2004	2006 vs 2005		
Cost-related medication nonadherence	43 011	23 792	0.91 (0.83-0.99)	0.78 (0.71-0.86)	0.85 (0.74-0.98)	.03
Spent less on basic needs to afford medicines	42 923	23 776	1.07 (0.94-1.21)	0.63 (0.55-0.72)	0.59 (0.48-0.72)	<.001

Abbreviations: CI, confidence interval; OR, odds ratio.

<sup>a</sup>Models adjusted for number of years' participation in Medicare Current Beneficiary Survey, sex, age group, income level, race, general health status, and number of morbidities, as defined in Table 1. All covariates were statistically significant in both models at the *P* = .05 level, except “other” race (white = reference category) in both models, and second and third year of MCBS participation (4th year = reference category) in cost-related medication nonadherence model. All results weighted to national population.

<sup>b</sup>2006-2005 vs 2005-2004.

**Table 3.** Changes in Cost-Related Medication Nonadherence and Spending Less on Basic Needs to Afford Medicines Following Part D Implementation Among Subgroups of Community-Dwelling Medicare Beneficiaries<sup>a</sup>

Subgroup Model	No. <sup>b</sup>	Cost-Related Medication Nonadherence					Spent Less on Basic Needs				
		Unadjusted Prevalence, %			Ratio of ORs (95% CI) <sup>c</sup>	P Value for Ratio of ORs	Unadjusted Prevalence, %			Ratio of ORs (95% CI) <sup>c</sup>	P Value for Ratio of ORs
		2004	2005	2006			2004	2005	2006		
Elderly	35 583	12.6	11.3	8.6	0.83 (0.70-0.98)	.03	8.2	8.7	5.0	0.49 (0.39-0.61)	<.001
Nonelderly disabled	7 428	29.5	29.7	27.2	0.90 (0.69-1.16)	.41	24.1	24.6	21.8	0.84 (0.64-1.09)	.18
Health status											
Good to excellent	31 294	11.9	11.2	8.4	0.77 (0.63-0.95)	.02	7.2	7.4	4.7	0.57 (0.44-0.75)	<.001
Fair to poor	11 717	24.1	22.2	20.1	1.00 (0.82-1.21)	.97	19.8	21.3	15.4	0.60 (0.47-0.75)	<.001
No. of morbidities											
0-1	11 332	10.3	9.6	6.7	0.74 (0.53-1.04)	.08	6.7	6.5	3.6	0.55 (0.37-0.82)	.004
2-3	20 570	15.0	14.4	11.4	0.79 (0.64-0.97)	.03	9.5	10.7	6.9	0.52 (0.40-0.68)	<.001
≥4	11 109	20.8	18.0	16.3	1.04 (0.83-1.30)	.76	16.7	16.4	12.4	0.68 (0.53-0.87)	.002
Income, \$											
<25 000	25 897	17.7	17.3	14.1	0.78 (0.66-0.92)	.003	14.1	15.0	11.0	0.60 (0.49-0.74)	<.001
≥25 000	17 114	11.5	9.7	8.4	1.02 (0.79-1.32)	.88	5.6	5.9	3.4	0.53 (0.36-0.79)	.002

Abbreviations: CI, confidence interval; OR, odds ratio.

<sup>a</sup>All results weighted to national population.

<sup>b</sup>Total number of observations for cost-related medication nonadherence in 2004, 2005, and 2006. There are 88 fewer total observations for the spent less on basic needs outcome.

<sup>c</sup>2006-2005 vs 2005-2004.

ducted.<sup>11</sup> Overall, our findings suggest that the intensive medicine needs and financial barriers to access among the sickest beneficiaries may not have been fully addressed by Part D. A decrease in CRN in the lower income group may reflect that the Medicare drug benefit provided additional subsidies to some low-income beneficiaries.<sup>11</sup>

The consistent reduction in the prevalence of forgoing food and basic needs to pay for medications merits discussion. To the extent that Part D reduced the burden of out-of-pocket prescription costs, a common initial effect of Part D might be to loosen constraints on the purchasing of food and other basic needs. Consequently, helping beneficiaries purchase medication may have economic and social effects that transcend medication adherence per se. Previous studies have documented that hunger and food insecurity are commonplace among careseekers in a public hospital setting<sup>36</sup> and that some patients face difficult choices between food and medicines.<sup>37</sup>

This study has several limitations. We lack data on actual use of medications and health services after Part D implementation, because 2006 utilization measures will not be available in the MCBS until 2009. Nevertheless, our measures of CRN and cutting back on basic needs are important intermediate outcomes of the Medicare drug benefit and have been shown to be reliable and valid in several previous studies.<sup>4-6,9,23</sup> We used measures of CRN in fall MCBS surveys over 3 successive years (2004, 2005, and 2006). The 2006 round was conducted 9 to 12 months after the launch of Part D, by which time much of the initial confusion<sup>38-40</sup> should have subsided.

An additional CRN measure (delayed filling prescription because of cost) was added to the survey in 2006, but could not be used in our longitudinal analyses. Also in 2006, the MCBS began to ask all respondents directly about not filling prescription because of cost (instead of asking only a subset that first reported having failed to obtain a prescription for any reason). Although the summary CRN measure we used was

fully comparable across the 3 years of observation, this measure underestimates CRN. A more complete summary measure, including all the CRN information available in the 2006 survey, would have resulted in a prevalence of CRN 37% higher for 2006 (15.8% instead of 11.5% in the Figure). This undercounting is in addition to the well-established observation that people, particularly elderly persons, underreport their health-related and finance-related difficulties.<sup>41-43</sup> The reasons for higher CRN among first-time respondents are unknown, but our design and alternative analyses largely precluded any confounding by duration of survey participation.

The 2 years of prepolicy data provide an important comparison and context for our analyses. However, an even longer prepolicy series would provide more clarity. Other factors unrelated to Part D (such as contemporaneous changes in the financial condition of Medicare beneficiaries) may have influenced observed changes in CRN before and after Part D implementation. Thus, our results should be considered early evidence until longer-term data are available. Nevertheless, the decreases we found in CRN and spending less on basic needs to afford medicines after Part D implementation were consistent across analytic approaches and suggest a positive population-level effect of the drug benefit. Characteristics known to predict CRN<sup>5</sup> were nearly identical across the 3 years we observed (eg, self-reported health, number of morbidities), and controlling for these factors did not alter our conclusions. The reasons for an apparent historical decrease in CRN (between 2004 and 2005) are not known, but downward secular trends may have existed, possibly reflecting uptake of Medicare-approved drug discount cards<sup>44</sup>; state-level and industry-sponsored assistance programs<sup>3,6,45</sup>; increased use of generics; or purchasing via Internet or mail.<sup>46,47</sup> Our design controlled for such secular effects.

In conclusion, we found small but significant population-level decreases in CRN and spending less on basic

needs to afford medicines, nearly a year after an unprecedented shift in Medicare policy—the implementation of the Part D drug benefit. Those beneficiaries in poor health or with multiple morbidities who had substantially higher baseline CRN did not experience decreases in CRN associated with Part D implementation, although they did report reductions in spending less on basic needs. Further research is needed to determine which specific aspects of Part D did or did not alleviate the persistent burden of medication costs. Part D claims data, linked to detailed Part D plan characteristics, must be made available to study the impact of the new Medicare drug benefit on actual utilization of medications and health outcomes.

**Author Contributions:** Dr Madden had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Madden, Zhang, Adams, Briesacher, Ross-Degnan, Gurwitz, Safran, Soumerai. **Acquisition of data:** Madden, Pierre-Jacques, Safran, Adler, Soumerai.

**Analysis and interpretation of data:** Madden, Graves, Zhang, Adams, Briesacher, Ross-Degnan, Gurwitz, Pierre-Jacques, Safran, Soumerai.

**Drafting of the manuscript:** Madden, Soumerai.

**Critical revision of the manuscript for important intellectual content:** Madden, Graves, Zhang, Adams, Briesacher, Ross-Degnan, Gurwitz, Pierre-Jacques, Safran, Adler, Soumerai.

**Statistical analysis:** Madden, Graves, Zhang, Pierre-Jacques.

**Obtained funding:** Madden, Zhang, Adams, Briesacher, Ross-Degnan, Gurwitz, Safran, Soumerai.

**Administrative, technical, or material support:** Madden, Graves, Pierre-Jacques, Safran, Adler, Soumerai.

**Study supervision:** Madden, Soumerai.

**Financial Disclosures:** Drs Madden and Adams, and Ms Pierre-Jacques report receiving research support from AstraZeneca. Drs Zhang, Adams, Ross-Degnan, and Soumerai, and Ms Graves report receiving research support from Eli Lilly. Dr Zhang also reports receiving research support from Pfizer and Sanofi-Aventis. Dr Briesacher reports receiving research support and consulting fees from Novartis. Dr Gurwitz reports receiving research support from GlaxoSmithKline. Dr Safran and Mr Adler did not report any financial disclosures.

**Funding/Support:** This study was supported by grants R01AG028745 and R01AG022362 from the National Institute on Aging (NIA), and the Harvard Pilgrim Health Care Foundation. Drs Zhang, Briesacher, Ross-Degnan, Gurwitz, and Soumerai are investigators in the Health Maintenance Organization Research Network Center for Education and Research in Therapeutics, which is supported by grant 2U18HS010391 from the US Agency for Healthcare Research and Quality.

**Role of the Sponsor:** The funding organizations did not participate in the design or conduct of the study, in the collection, analysis, or interpretation of the data, or in the preparation, review, or approval of the manuscript.

**Additional Contributions:** Franklin Eppig, JD (Centers for Medicare & Medicaid Services [CMS]), integrated measures of cost-related medication nonadherence into the Medicare Current Beneficiary Survey (MCBS), and Andrew Shatto, BS (CMS), provided assistance with data access and definition. Michael Law, MSc (Harvard Medical School [HMS] and Harvard Pilgrim Health Care [HPHC]), provided helpful advice on modeling strategies; Alan Zaslavsky, PhD (HMS), and Ken Kleinman, ScD (HMS and HPHC), both provided statistical advice; and Robert LeCates, MA (HMS and HPHC), provided assistance during manuscript preparation. Mr LeCates' salary was partially supported by the NIA grants mentioned above. All others mentioned did not receive any direct compensation.

## REFERENCES

- Soumerai SB, Ross-Degnan D. Inadequate drug coverage in Medicare: a call to action. *N Engl J Med*. 1999; 340(9):722-728.
- Adams AS, Soumerai SB, Ross-Degnan D. The case for a Medicare drug coverage benefit: a critical review of the empirical evidence. *Annu Rev Public Health*. 2001;22:49-61.
- Federman AD, Adams AS, Ross-Degnan D, Soumerai SB, Ayanian JZ. Supplemental insurance and use of effective cardiovascular drugs among elderly Medicare beneficiaries with coronary heart disease. *JAMA*. 2001; 286(14):1732-1739.
- Safran DG, Neuman P, Schoen C, et al. Prescription drug coverage and seniors: findings from a 2003 national survey. *Health Aff (Millwood)*. 2005(suppl Web exclusives):W5-152-W5-166.
- Soumerai SB, Pierre-Jacques M, Zhang F, et al. Cost-related medication nonadherence among the elderly and the disabled: a national survey one year before the Medicare drug benefit. *Arch Intern Med*. 2006; 166(17):1829-1835.
- Safran DG, Neuman P, Schoen C, et al. Prescription drug coverage and seniors: how well are states closing the gap? *Health Aff (Millwood)*. 2002 (suppl Web exclusives):W253-W268.
- Briesacher BA, Gurwitz JH, Soumerai SB. Patients at-risk for cost-related medication nonadherence: a review of the literature. *J Gen Intern Med*. 2007; 22(6):864-871.
- Hanson KW, Neuman P, Dutwin D, Kasper JD. Uncovering the health challenges facing people with disabilities: the role of health insurance. *Health Aff (Millwood)*. 2003(suppl Web exclusives):W3-552-W3-565.
- Neuman P, Strollo MK, Guterman S, et al. Medicare prescription drug benefit progress report: findings from a 2006 national survey of seniors. *Health Aff (Millwood)*. 2007;26(5):w630-w643.
- Heisler M, Langa KM, Eby EL, Fendrick AM, Kabeto MU, Piette JD. The health effects of restricting prescription medication use because of cost. *Med Care*. 2004;42(7):626-634.
- The Henry J. Kaiser Family Foundation. The Medicare Prescription Drug Benefit Fact Sheet, June 2006. [http://www.kff.org/medicare/upload/7044\\_04.pdf](http://www.kff.org/medicare/upload/7044_04.pdf). Accessed March 6, 2008.
- The Henry J. Kaiser Family Foundation. Overview of Medicare Part D Organizations, Plans and Benefits by Enrollment in 2006 and 2007, November 2007. <http://www.kff.org/medicare/upload/7710.pdf>. Accessed January 3, 2008.
- The Henry J. Kaiser Family Foundation. Medicare Chartbook 2005, Summer 2005. <http://www.kff.org/medicare/upload/Medicare-Chart-Book-3rd-Edition-Summer-2005-Report.pdf>. Accessed January 3, 2008.
- Poisal JA, Chulis GS. Medicare beneficiaries and drug coverage. *Health Aff (Millwood)*. 2000;19(2):248-256.
- Crippen DL. "Projections of Medicare and Prescription Drug Spending" statement before the Committee on Finance, United States Senate, March 7, 2002. <http://www.cbo.gov/ftpdocs/33xx/doc3304/03-07-MedicareSpending.pdf>. Accessed February 28, 2008.
- Stuart B, Simoni-Wastila L, Chauncey D. Assessing the impact of coverage gaps in the Medicare Part D drug benefit. *Health Aff (Millwood)*. 2005(suppl Web exclusives):W5-167-W5-179.
- Stuart B, Shea D, Briesacher B. Dynamics in drug coverage of Medicare beneficiaries: finders, losers, switchers. *Health Aff (Millwood)*. 2001;20(2):86-99.
- Laschober MA, Kitchman M, Neuman P, Strabic AA. Trends in Medicare supplemental insurance and prescription drug coverage 1996-1999. *Health Aff (Millwood)*. 2002(suppl Web exclusives):W127-W138.
- Congress of the United States, Congressional Budget Office. An analysis of the President's budgetary proposals for fiscal year 2006, March 2005, page 42. CBO report. <http://www.cbo.gov/ftpdocs/61xx/doc6146/03-15-PresAnalysis.pdf>. Accessed March 6, 2008.
- Levy J, Weir DR. Take-up of Medicare Part D and the SSA subsidy: early results from the Health and Retirement Study, Prepared for the 9th Annual Joint Conference of the Retirement Research Consortium, "Challenges and Solutions for Retirement Security." Washington, DC; August 9-10, 2007. <http://www.mrrc.isr.umich.edu/publications/conference/pdf/U/M07-06A0807C.pdf>. Accessed December 14, 2007.
- Heiss F, McFadden D, Winter J. Who failed to enroll in Medicare Part D, and why? *Health Aff (Millwood)*. 2006;25(5):w344-w354.
- Centers for Medicare & Medicaid Services. Sourcebook Series: Health and Health Care of the Medicare Population. 2002 Technical Documentation for the Medicare Current Beneficiary Study. <http://www.cms.hhs.gov/mcbs/downloads/HHC2002appendixA.pdf>. Accessed December 14, 2007.
- Pierre-Jacques M, Safran DG, Zhang F, et al. Reliability of new measures of cost related medication nonadherence. *Med Care*. In press.
- Adams AS, Soumerai SB, Ross-Degnan D. Use of antihypertensive drugs by Medicare enrollees: does type of drug coverage matter? *Health Aff (Millwood)*. 2001;20(1):276-286.
- Blustein J. Drug coverage and drug purchases by Medicare beneficiaries with hypertension. *Health Aff (Millwood)*. 2000;19(2):219-230.
- Briesacher BA, Stuart B, Ren X, Doshi JA, Wrobel MV. Medicare beneficiaries and the impact of gaining prescription drug coverage on inpatient and physician spending. *Health Serv Res*. 2005;40(5 pt 1):1279-1296.
- Stuart B, Shea D, Briesacher B. Prescription drug costs for Medicare beneficiaries: coverage and health status matter. *Issue Brief (Commonw Fund)*. 2000; (365):1-9.
- DeSalvo KB, Fan VS, McDonnell MB, Fihn SD. Predicting mortality and healthcare utilization with a single question. *Health Serv Res*. 2005;40(4):1234-1246.
- Katz S. Assessing self-maintenance: activities of daily living, mobility and instrumental activities of daily living. *J Am Geriatr Soc*. 1983;31(12):721-726.
- Samdal CE, Swensson B, Wretman J. *Model Assisted Survey Sampling (Springer Series in Statistics): Sections 4.5-4.6*. 2nd ed. New York, NY: Springer Verlag; 2003.
- Zhang J, Yu KF. What's the relative risk? a method of correcting the odds ratio in cohort studies of common outcomes. *JAMA*. 1998;280(19):1690-1691.
- Robbins AS. What's the relative risk? a method to directly estimate risk ratios in cohort studies of common outcomes. *Ann Epidemiol*. 2002;12(7):452-454.
- Briesacher B, Stuart B, Doshi J, Kamal-Bahl S, Shea D. Medicare's disabled beneficiaries: the forgotten population in the debate over drug benefits. [http://www.commonwealthfund.org/usr\\_doc/briesacher\\_disabled.pdf?section=4039](http://www.commonwealthfund.org/usr_doc/briesacher_disabled.pdf?section=4039). Accessed December 20, 2007.
- Crystal S, Johnson RW, Harman J, Sambamoorthi U, Kumar R. Out-of-pocket health care costs among older Americans. *J Gerontol B Psychol Sci Soc Sci*. 2000; 55(1):S51-S62.
- Schoenberg NE, Kim H, Edwards W, Fleming ST. Burden of common multiple-morbidity constellations on out-of-pocket medical expenditures among older adults. *Gerontologist*. 2007;47(4):423-437.
- Nelson K, Brown ME, Lurie N. Hunger in an adult patient population. *JAMA*. 1998;279(15):1211-1214.
- Kersey MA, Beran MS, McGovern PG, Biras MH, Lurie N. The prevalence and effects of hunger in an emergency department patient population. *Acad Emerg Med*. 1999;6(11):1109-1114.
- Kaiser Family Foundation. Early experiences of Medicare beneficiaries in prescription drug plans, August 2006. <http://www.kff.org/medicare/upload/77552.pdf>. Accessed December 6, 2007.
- Kaiser Family Foundation. The transition of dual eligibles to Medicare Part D prescription drug coverage: state actions during implementation. <http://www.kff.org/medicaid/upload/7467.pdf>. Accessed December 19, 2007.
- Kaiser Family Foundation. Voices of beneficiaries: early experiences with the Medicare drug benefit. <http://www.kff.org/medicare/upload/7504.pdf>. Accessed December 19, 2007.
- Levkoff SE, Cleary PD, Wetle T, Besidine RW. Illness behavior in the aged: implications for clinicians. *J Am Geriatr Soc*. 1988;36(7):622-629.
- Fried LP, Storer DJ, King DE, Lodder F. Diagnosis of illness presentation in the elderly. *J Am Geriatr Soc*. 1991;39(2):117-123.
- Poisal JA. Reporting of drug expenditures in the MCBS. *Health Care Financ Rev*. 2003;25(2):23-36.
- Thomas CP, Wallack SS, Martin TC. How do seniors use their prescription drug discount cards? *Health Aff (Millwood)*. 2005(suppl Web exclusives):W5-180-W5-190.
- Chisholm MA, DiPiro JT. Pharmaceutical manufacturer assistance programs. *Arch Intern Med*. 2002; 162(7):780-784.
- The Henry J. Kaiser Family Foundation. Prescription drug trends fact sheet. <http://www.kff.org/medicare/upload/3057-04.pdf>. Accessed March 6, 2008.
- Smith C, Cowan C, Heffler S, Catlin A; National Health Accounts Team. National health spending in 2004: recent slowdown led by prescription drug spending. *Health Aff (Millwood)*. 2006;25(1):186-196.