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# Gains in medication affordability following Medicare Part D are eroding among elderly with multiple chronic conditions

**Huseyin Naci**[1], **Stephen B Soumerai**[1], **Dennis Ross-Degnan**[1], **Fang Zhang**[1], **Becky A Briesacher**[2], **Jerry H Gurwitz**[2], and **Jeanne M Madden**[1]

[1]Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA

[2]Division of Geriatric Medicine and Meyers Primary Care Institute, University of Massachusetts Medical School Worcester, MA

## Abstract

Elderly Americans, especially those with multiple chronic conditions, face difficulties paying for prescriptions, resulting in worse adherence and discontinuation of therapy ("cost-related medication nonadherence" or CRN). We investigated whether the gains in medication affordability attributable to Medicare Part D implementation in January 2006 persisted during the six years that followed. Overall, we found continued incremental improvements in medication affordability in the early years of Part D (2007–2009), which then eroded during more recent years (2009–2011). Among elderly beneficiaries with four or more chronic conditions, we observed an increase in the prevalence of CRN from 14.4% in 2009 to 17.0% in 2011, reversing previous downward trends. Similarly, the prevalence of forgoing basic needs in order to purchase medicines among the sickest elderly decreased from 8.7% in 2007 to 6.8% in 2009, then rose to 10.2% in 2011. Our findings highlight the need for targeted policy efforts to alleviate the persistent burden of drug treatment costs in this vulnerable population.

## Introduction

Elderly Americans typically have few financial resources available for prescription drugs.[1] High out-of-pocket drug costs are associated with worse adherence and medication discontinuation.[2] Such cost-related medication nonadherence (CRN) can lead to adverse health outcomes including worse health status and increased risk of hospitalization.[3–5]

Adequate adherence to medications is particularly important for seniors with multiple chronic conditions. Effective and efficient care for a growing elderly population with multiple chronic conditions is among the most important challenges the US health care system faces.[6] Yet, older individuals with multiple chronic conditions are at especially high risk of CRN due to intensive medication use and high out-of-pocket costs.[7]

**Correspondence to:** Dr. Jeanne Madden, Drug Policy Research Group, Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, 133 Brookline Avenue, 6th Floor, Boston, MA 02215, Tel: (617) 509-9953, Fax: (617) 859-9853, jeanne_madden@harvardpilgrim.org.

The Medicare Part D drug benefit was implemented in 2006 to increase economic access to medicines by decreasing beneficiaries' out-of-pocket drug expenditures.[8] Early evaluations of Part D indicated modest but significant nationwide reductions in CRN and forgoing basic needs to pay for medicines in 2006,[9] which were sustained in 2007.[10] Improvements in ability to afford medicines were not consistent across subgroups.[9–11] In particular, improvements in CRN among elderly with four or more chronic conditions lagged behind improvements for healthier beneficiaries.[9] Nevertheless, Part D resulted in significant increases in prescription drug use and lower out-of-pocket drug costs among almost all subgroups of the Medicare population.[12]

In 2008, the US entered the worst economic recession since the Great Depression. Between 2007 and 2010, the housing market collapsed, financial markets sank into turmoil, and family incomes, home prices, and investment portfolio values fell;[13] wealth for elderly households declined by approximately 20% between 2007 and 2009.[14,15] The recession and its aftermath left many elderly Americans facing unprecedented economic uncertainty.[16] In addition, over the years following Part D implementation, changes in Part D plan benefits potentially introduced barriers to drug therapy and shifted costs onto patients.[17–19]

There have been no published reports on the prevalence of CRN among the multimorbid elderly in Medicare since 2008.[10,20] In this study, we evaluate recent national trends in CRN and spending less on basic needs to afford medicines among elderly beneficiaries by illness burden, and explore the extent to which improvements in affordable access to medications resulting from Part D persisted during subsequent years.

## Methods

### Data Source and Sample

We used the Access-to-Care (ATC) files of the Medicare Current Beneficiary Survey (MCBS), the principal national survey for Medicare beneficiaries. Administered by the Centers for Medicare and Medicaid Services (CMS), the MCBS is a longitudinal, nationally representative rotating panel survey of approximately 16,000 disabled and elderly Medicare enrollees, who are representative of 42.5 million beneficiaries nationwide. Respondents provide information on health care utilization, expenditures and sources of payments, health insurance coverage, health status and functioning, and a variety of demographic and behavioral factors.[21]

The MCBS ATC files used in this study included the annual "always enrolled" beneficiary population, i.e., excluding individuals who newly enrolled in Medicare or died during a given calendar year. ATC data primarily consist of responses to the main fall interview, following a four-year panel survey design. The annual replenishment strategy replaces those who have completed survey participation, died, or been lost to follow-up, ensuring a representative sample in each calendar year. The average response rate across the study years (2006–2011) was 79.7% among first-time respondents and 67.0% among all respondents. We included all community-dwelling elderly respondents (approximately 79% of the total, excluding persons under 65 years and those residing in long-term care facilities)

from 2006 through 2011 (n = 70,067 person-years). Accounting for overlapping samples among years, the total number of individual respondents was 31,713.

### Outcome Measures

Since 2004, the MCBS fall interview has included a set of questions on the affordability of medications which were developed in collaboration with CMS, tested for reliability,[22] and used in several studies by the research team.[7,9–11,22,23] The main outcomes for this study were cost-related medication nonadherence (hereafter referred to as CRN) and spending less on other basic needs to afford medicines (forgoing basic needs).[22,24,25] We used our validated binary composite measure of CRN if a respondent answered yes/ever during the current year to any of the following questions: “did not fill a prescription because of cost?”; “skipped doses to make the medicine last longer?”; “taken smaller doses of a medicine to make the medicine last longer?”; “delayed filling prescription because of cost?”; or, “any medicines prescribed for you that you did not get?” in combination with “reason you did not obtain the medicine was you thought it would cost too much”. We also examined a separate binary measure of having spent less money on food, heat, or other basic needs in order to have money for medicine.[7,9–11]

### Statistical Analysis

We estimated the rates and 95% confidence intervals (CIs) of demographic and health characteristics of respondents. Covariates included previously validated predictors of CRN:[7,26] age and sex, in addition to self-reported income, race, health status,[27] and presence of specific diseases or conditions. Morbidities included cardiac disease, hypertension, diabetes, cancer, stroke, arthritis, dementia, psychiatric disorder (including depression), neurological disorder (excluding stroke), and pulmonary illness (including asthma and chronic obstructive pulmonary disease). We then calculated the unadjusted annual prevalence of CRN and spending less on basic needs with 95% CIs for all study years (2006–2011), as well as for 2004 and 2005 to illustrate pre-Part D levels. All survey analyses were weighted to represent the national population of community-dwelling elderly Medicare beneficiaries, using the annual cross-sectional survey weights provided in the MCBS.[28]

To model changes in CRN and spending less on basic needs in the years since Part D implementation, we used logistic regression models. Dividing the study years into two periods, our models compared the odds of CRN and spending less on basic needs between pairs of years (2009 vs. 2007, and 2011 vs. 2009), as well as the entire period (2011 vs. 2007). The year 2007 was the first for which the Part D benefit was fully implemented; 2009 was the first year following the financial market collapse in September 2008, which triggered public awareness of the economic crisis and steep declines in multiple indicators, including the unemployment rate, family income and wealth, and housing prices.[29–31] During our final study period (2009 to 2011), external data suggest that scattered signs of economic recovery did not often translate into improved conditions for the elderly; rather, most indicators such as income and savings showed continued stagnation.[16,32–34]

As in previous reports,[9,10] our models controlled for interview sequence, demographic characteristics (sex, age, income, and race), and health status (number of morbidities and health status). We repeated these analyses separately for eight subgroups based on the number of chronic conditions (0–3 and ≥4), income (<$25 000 and ≥$25 000), and type of prescription drug coverage (Part D low-income subsidy, Medicare Advantage, stand-alone prescription drug plan, and non-Part D).[7,26] All analyses were conducted in STATA version 12 (StataCorp LP, College Station, TX). This study was reviewed and approved by the Human Subjects Committee of the Harvard Pilgrim Health Care Institute.

## Results

### Characteristics of Elderly Medicare Beneficiaries

The demographic and health characteristics of the community-dwelling elderly Medicare beneficiary population were similar across study years (Exhibit 1). The proportion reporting four or more conditions increased from 26.7% in 2007 to 27.6% in 2011. During the same period, the proportion enrolled in Medicare Part D increased, particularly for Medicare Advantage plans (17.7% to 21.4%), while non-Part D drug coverage plans became less common.

### Unadjusted Changes in Medication Affordability

An estimated 14.9% of elderly beneficiaries experienced CRN in 2005, and 11.3% in 2007 after the full implementation of Medicare Part D (Supplementary Appendix Exhibit 1). Following a downward trend until 2009, when 10.2% of beneficiaries had CRN, the estimated prevalence of CRN subsequently increased to 10.8% in 2011. Similarly, the percentage of beneficiaries forgoing other needs to pay for medicines declined after Part D (8.8% in 2005 to 5.6% in 2007), reaching 4.0% in 2009. In 2011, 5.3% of elderly beneficiaries cut back on basic needs to afford medications.

Between 2007 and 2011, elderly beneficiaries with non-Part D prescription drug coverage had consistently lower rates of CRN and spending less on basic needs than those participating in Medicare Part D (Exhibit 2). The risk of foregoing basic needs to afford medications among beneficiaries receiving the low-income subsidy was higher than that among other coverage groups. We observed similar increases in both measures across all major prescription drug coverage categories between 2009 and 2011.

### Changes in Medication Affordability by Morbidity Burden

Across all study years, elderly with multiple chronic conditions had more problems affording their medications than other elderly (Exhibit 3). In 2005, prior to Part D, an estimated 20.3% of elderly beneficiaries with four or more chronic conditions experienced CRN. In the early years following the initial Part D impact,[9] both measures of economic barriers to paying for medicines continued to decline slightly: the prevalence of CRN decreased from 15.1% in 2007, after Part D, to 14.4% in 2009. However, this trend reversed in subsequent years, rising to 17.0% in 2011. Similarly, the percentage of sicker beneficiaries forgoing other needs to pay for medicines declined after Part D implementation (12.3% in 2005 to 8.7% in 2007). These declines subsequently continued under Part D until

the outcome reached its lowest point in 2009 (6.8%). However, by 2011, the prevalence of forgoing basic needs had risen again to 10.2% of sicker beneficiaries.

Among elderly beneficiaries with three or fewer chronic conditions, prevalence of CRN also declined sharply following Medicare Part D implementation (from 15.7% in 2005 to 9.9% in 2007), and continued declining until 2009, leveling off in subsequent years. The prevalence of spending less on basic needs declined from 7.6% in 2005 to 4.5% in 2007 and 2.9% in 2009, rising slightly to 3.5% in 2011.

### Adjusted Changes in Medication Affordability

Exhibit 4 shows the changes in CRN and spending less on basic needs over time estimated using multivariate models. The direction of change between 2007 and 2009 for both outcomes was consistently downward for all groups. Then, between 2009 and 2011, the prevalence of affordability problems remained fairly stable among elderly beneficiaries with three or fewer chronic conditions, while the sickest elderly experienced pronounced increases. The odds of CRN among elderly beneficiaries with four or more conditions increased significantly by 20% between 2009 and 2011 (OR: 1.20, 95% CI: 1.03, 1.40) (Supplemental Appendix Exhibit 2). Similarly, we detected a significant increase in the odds of forgoing basic needs in order to purchase medicines between 2009 and 2011 (OR: 1.54, 95% CI: 1.30, 1.82), reversing the previous downward trends (OR 2009 vs. 2007: 0.81, 95% CI: 0.67, 0.99).

In subgroup analyses by major prescription drug coverage categories, there was a significant increase in the odds of spending less on basic needs among elderly beneficiaries in Medicare Advantage prescription drug plans (OR 2011 vs. 2009: 1.62, 95% CI: 1.23, 2.12), and those with non-Part D coverage (OR 2011 vs. 2009: 1.42, 95% CI: 1.09, 1.85). We did not observe any other significant changes in either measure in these subgroup analyses (Exhibit 4; Supplemental Appendix Exhibit 3).

An examination of the full 6-year period of observation confirms that early gains were reversed among the sickest beneficiaries. Elderly beneficiaries with four or more chronic conditions had significantly worse outcomes in 2011 compared to 2007 (CRN OR: 1.18, 95% CI: 1.02, 1.36; forgoing basic needs OR: 1.25, 95% CI: 1.04, 1.51). We also observed that the prevalence of foregoing basic needs to afford medications among the sickest elderly in 2011 was no longer significantly better than the level reported in 2005, *prior to Part D implementation* (OR 2011 vs. 2005: 0.86, 95% CI: 0.72, 1.04). By contrast, there was no reversal among the healthier group. Those with fewer conditions had significantly better outcomes in 2011 as compared to 2007, though their improvements appeared to occur mainly between 2007 and 2009.

## Discussion

In this study, we investigated recent national trends in CRN and forgoing other basic needs to pay for medicines among elderly Medicare beneficiaries. Strikingly, we found that financial barriers to prescription drug therapy represent a continuing problem for the sickest Medicare beneficiaries, who are at higher risk of CRN due to illness burden, intense

medication needs, and high out-of-pocket costs.[7] For the first time since 2004, when affordability indicators were added to a nationally representative survey of elderly Medicare beneficiaries, a trajectory of improvements in both CRN and forgoing basic needs reversed course around 2009: drug affordability deteriorated significantly in subsequent years among the sickest elderly. In 2011, elderly individuals with four or more chronic conditions were worse off in terms of both outcomes than they had been in 2007. In fact, the risk of foregoing basic needs among this key group in 2011 was not significantly better than it had been prior to Part D, suggesting that both the original Part D impact and interim improvements may have been eliminated.

Several factors likely reversed the early gains in medication affordability following Part D implementation, and disproportionately affected the sickest elderly. The severe economic downturn in the US shrank incomes, asset values, and wealth for all age groups including the elderly. Elders also had high rates of mortgage delinquency, which has been associated with CRN.[35] It is very likely that new economic strains affected the ability of elderly beneficiaries with multiple chronic conditions to afford their medications. During the same period, the zero cost-of-living adjustment (COLA) in social security may have also affected medication affordability.[36]

In addition, there is evidence of reduced drug coverage generosity in recent years.[18,19] Over our observation period, Part D plans increased premiums and more have begun to charge deductibles. Plans have also generally increased patient copayments within formulary tiers, and more frequently applied restrictions such as prior authorization requirements.[17,19,37] While these benefit changes may have been designed to steer patients toward less expensive medications, they may also have had the effect of introducing barriers to drug therapy and shifting the overall drug cost burden toward patients, particularly those with multiple chronic conditions.

We investigated whether the recent worsening trends in medication affordability could be attributed to changes in beneficiaries' type of prescription drug coverage, and found that there were generally similar increases across all major coverage sources. It is therefore unlikely that Part D plan changes alone were responsible for rising problems of access to medications. Indeed, published reports documented similar reductions in generosity more generally in US health insurance, which potentially compounded the effect of the economic downturn.[38,39] Such changes across the healthcare system could explain why elderly Americans are reporting persistent affordability problems while news reports simultaneously exclaim that "[total US] spending on prescription drugs fell for the first time on record".[40]

The Affordable Care Act (ACA) is set to broaden access to public and private health insurance and improve Medicare Part D coverage. Specifically, by 2020, CMS will gradually phase out the Medicare Part D coverage gap (or "doughnut hole") in which beneficiaries who have reached a defined total drug spending threshold must then pay 100% out of pocket until they reach a "catastrophic" level. The ACA has provided financial relief to elderly beneficiaries in the coverage gap by persuading pharmaceutical companies to offer a 50% discount on branded drugs starting in 2011, and by gradually adding government subsidies to fill the remaining gap for brand and generic drugs.

Given the constant evolution of policies affecting the Medicare population, policymakers and researchers must closely monitor trends in affordability such as those we highlight here, and support more in-depth investigation of the underlying causes. Policymakers should also consider additional strategies to help the sickest beneficiaries, who clearly remain burdened by medication costs. Policy options include increased outreach to and participation in the Part D low-income subsidy for qualified individuals in need.[41] Beneficiaries may also need more assistance in selecting a Part D plan that fits their medical and financial circumstances, given reports that they often choose plans that require more out-of-pocket spending than necessary.[42] Programs focusing on clinicians and pharmacists can help patients mitigate excessive costs, for example, by substituting lower-cost therapies with comparable benefit-harm profiles.[43] Increasing low-income subsidy enrollment and assisting beneficiaries with better choices can potentially improve affordability for Medicare beneficiaries in all current coverage categories.

The findings of this study should be interpreted in light of its limitations. We are able to describe recent reversals in affordability, but the data do not permit us to definitively determine the root causes. For example, data on actual drug utilization and out-of-pocket spending by MCBS respondents are not yet available for the most recent years of observation, and the recession literature does not clearly pinpoint the timing of harms as they affected specific population segments, such as the elderly. In addition, self-reports could be subject to reporting and recall biases. Nevertheless, the affordability measures used in our study have been validated[22,24,25] and used extensively in previous studies,[7,9–11,23,44] and we expect potential misreporting of CRN behavior to be consistent over time.

Perhaps unsurprisingly, we detected more statistically significant changes in our measure of cutting back on basic needs to afford medications, as compared to the CRN measure. This suggests that the basic needs question may be a more direct measure of patients' economic hardship and more sensitive to changes in financial circumstances over time. CRN addresses specific clinical behaviors that are subject to influences beyond economic hardship, such as ongoing health system efforts to increase adherence and providers' ability to adapt regimens to patients' economic circumstances. In tandem, these measures have demonstrated their sensitivity and utility as a barometer of medication affordability in a stable survey population.

The body of research evaluating the impact of Medicare Part D provided unequivocal evidence of population-level decreases in out-of-pocket costs and increased medication use following its implementation in 2006.[12,45] Nevertheless, using data on a nationally representative sample of Medicare beneficiaries, we provide updated evidence that many elderly Americans face persistent, and indeed, worsening, economic barriers to prescription drug therapy. Our finding that the gains in medication affordability among elderly with multiple chronic conditions following Part D were later lost during a period of both economic downturn and benefit changes highlights a pressing need to find new ways to ensure economic access to drug treatment for vulnerable Medicare beneficiaries.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Endnotes


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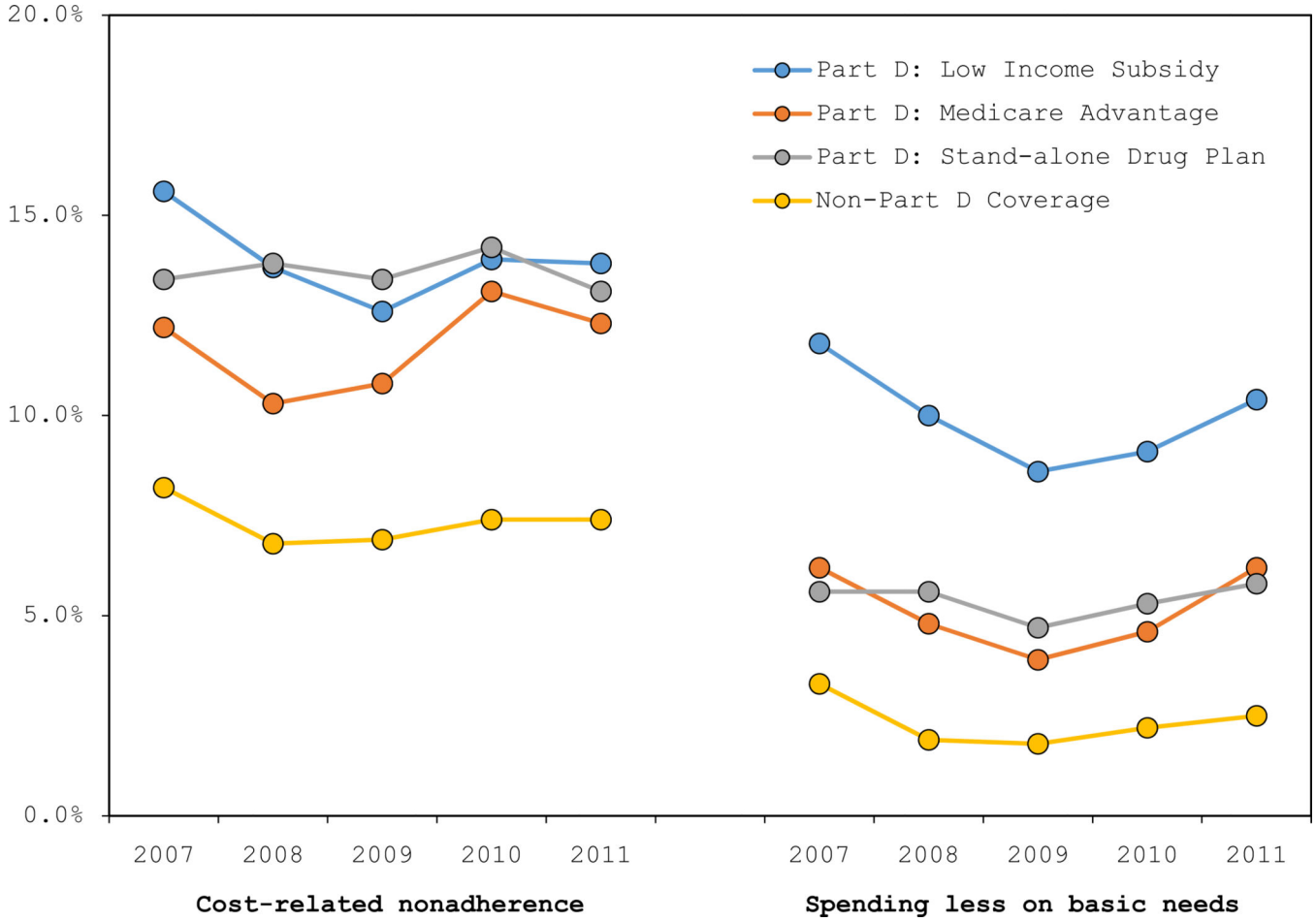


**Exhibit 2.**

Prevalence of CRN and spending less on basic needs among the overall population of community-dwelling elderly Medicare beneficiaries by prescription drug coverage type (2007–2011).a, b.

Source: Authors'analysis.

Notes:

[a] Non-Part D coverage includes employer-sponsored coverage for current or retired workers as well as Tricare for veterans, self-purchased plans, and other public and private coverage.

[b] Prevalence of affordability problems among those with no prescription drug coverage (<4% of elderly) is not included due to sparse data.

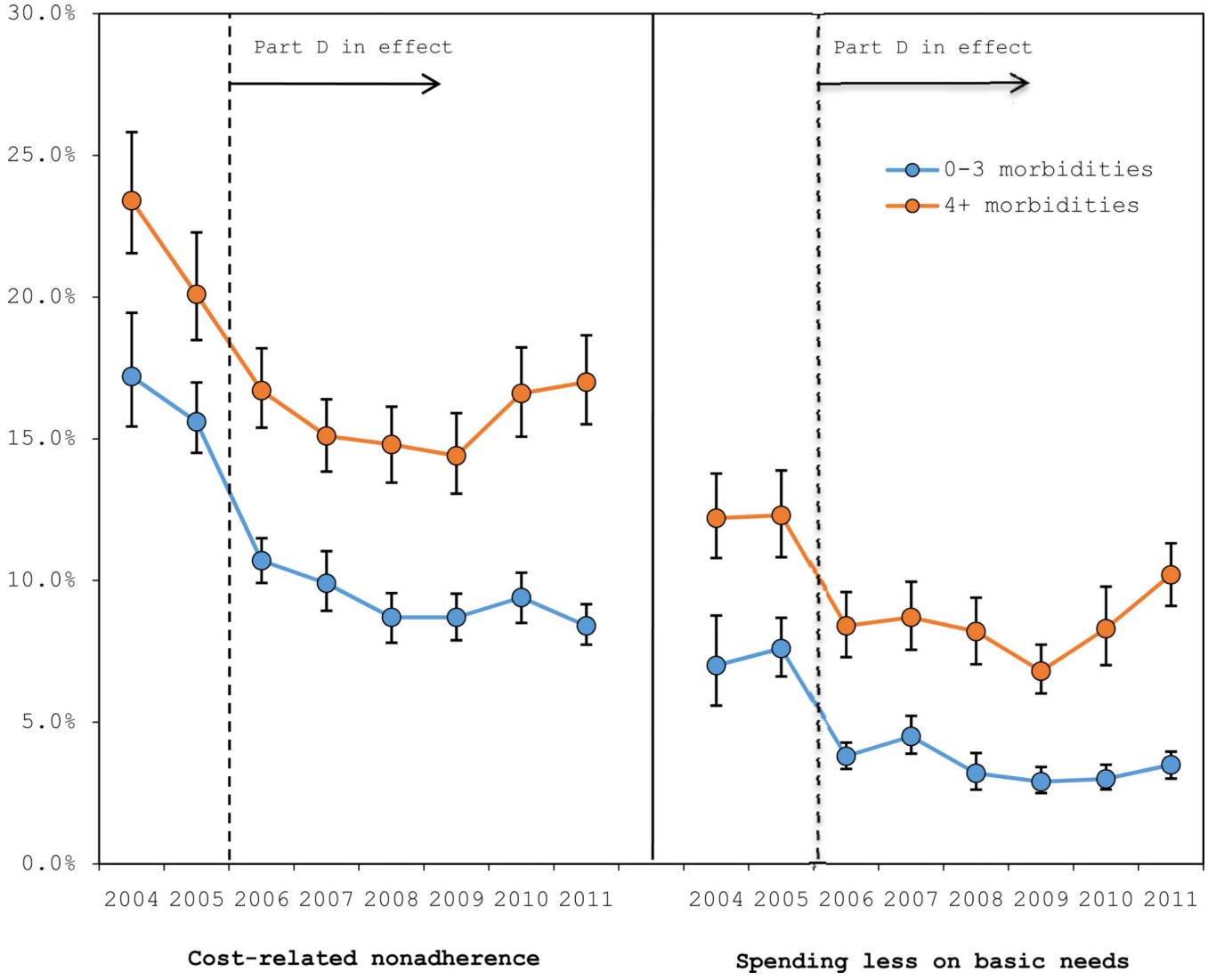


**Exhibit 3.**

Prevalence of CRN and spending less on basic needs among community-dwelling elderly Medicare beneficiaries by burden of chronic conditions (2004–2011).a, b, c

Source: Authors'analysis

Notes:

[a] Estimated with survey weights to represent the national population of community-dwelling elderly Medicare beneficiaries.

[b] Error bars represent 95% CIs around prevalence rates.

[c] Corrected CRN measure not available prior to 2006. Due to a survey field error, our composite measure of CRN did not fully capture "not filling a prescription" and omitted "delay filling" in 2004 and 2005. We estimated 2004 and 2005 values in the figure above by applying the relative increase in CRN (corrected measure vs. the underestimate without the newly captured data) observed during 2006–2011.

## Exhibit 1

Characteristics of community-dwelling elderly Medicare beneficiaries in 2007, 2009, and 2011.

| | % | | |
|---|---|---|---|
| **Characteristics** | **2007 (n = 12,190)** | **2009 (n = 11,393)** | **2011 (n = 11,600)** |
| Female sex | 56.4 | 56.1 | 56.3 |
| Age groups | | | |
| 65–74 | 50.8 | 52.2 | 53.0 |
| 75–84 | 36.5 | 34.3 | 33.3 |
| ≥85 | 12.7 | 13.5 | 13.6 |
| Income, <$25,000[a] | 49.6 | 46.1 | 43.8 |
| Black race | 7.7 | 7.9 | 8.0 |
| Number of morbidities | | | |
| 0–3 | 73.3 | 73.3 | 72.4 |
| ≥4 | 26.7 | 26.7 | 27.6 |
| Self-reported health status | | | |
| Excellent, very good, or good | 78.7 | 81.0 | 80.7 |
| Fair or poor | 21.3 | 19.0 | 19.3 |
| Prescription drug coverage[b] | | | |
| Part D: Low-Income Subsidy | 13.9 | 13.2 | 14.0 |
| Part D: Medicare advantage plan | 17.7 | 20.3 | 21.4 |
| Part D: Stand-alone drug plan | 23.3 | 23.4 | 24.4 |
| Non-Part D coverage | 42.2 | 39.8 | 36.9 |
| None | 2.9 | 3.3 | 3.3 |

Source: Authors' analysis.

Notes:

[a] MCBS variable, not adjusted for inflation.

[b] Estimated using a combination of self-reported and CMS administrative data, available in the MCBS ATC. Presented hierarchically, such that beneficiaries with a mix of coverage types are counted in the category appearing first. "Non-Part D coverage" includes employer-sponsored drug coverage for current or retired workers, Tricare for veterans, self-purchased plans, and other public and private coverage sources; non-Part D sources above may not all qualify as "creditable". (Reference: Centers for Medicare and Medicaid Services (CMS). What is creditable coverage? 2006; http://www.cms.gov/Medicare/Prescription-Drug-Coverage/CreditableCoverage/Downloads/whatiscreditablecoverage.pdf. Accessed March 13, 2013.)

## Exhibit 4

Changes in CRN **(A)** and spending less on basic needs **(B)** among overall and sub-groups of community-dwelling Medicare beneficiaries (See Supplemental Appendix Exhibit 1 for details).

**(A) Cost-related medication nonadherence**

| | | Adjusted OR [a] | | |
|---|---|---|---|---|
| | | ***Period 1*** | ***Period 2*** | ***Overall Period*** |
| Group | No. [b] | 2009 vs. 2007 | 2011 vs. 2009 | 2011 vs. 2007 |
| Elderly | 69,697 | 0.90 | 1.05 | 0.95 |
| No. of morbidities | | | | |
| 0–3 | 49,650 | 0.86 | 0.97 | 0.83* |
| ≥4 | 20,047 | 0.98 | 1.20* | 1.18* |
| Income, US$ | | | | |
| <25,000 | 34,776 | 0.94 | 0.99 | 0.94 |
| ≥25,000 | 34,889 | 0.84 | 1.12 | 0.95 |
| **(B) Spending less on basic needs** | | | | |
| Elderly | 69,656 | 0.71** | 1.34** | 0.96 |
| No. of morbidities | | | | |
| 0–3 | 49,629 | 0.65** | 1.18 | 0.77* |
| ≥4 | 20,027 | 0.81* | 1.54** | 1.25* |
| Income, US$ | | | | |
| <25,000 | 34,748 | 0.78** | 1.25* | 0.98 |
| ≥25,000 | 34,876 | 0.57** | 1.60** | 0.90 |

Source: Authors' analysis.

Notes:

[a] Adjusted for younger age, female sex, non-white race, income <$25,000, poor health, survey participation, and having 4 or more morbidities.

[b] Numbers of person-years in subgroups do not necessarily add up to overall number of observations. Numbers vary with response rates and availability of data on subgroups.

* P<0.05

** P<0.001