ORIGINAL ARTICLE

Medicare Beneficiaries and Free Prescription Drug Samples: A National Survey

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BACKGROUND: New policies regulating physician/pharmaceutical company relationships propose to eliminate access to free prescription drug samples. Little is known about the prevalence of patient activity in requesting or receiving free prescription drug samples, or the characteristics of patients who access drug samples.

OBJECTIVE: To determine the prevalence of free sample access and to examine demographic, clinical, and insurance characteristics of Medicare beneficiaries who access free samples.

DESIGN: Cross-sectional study.

PARTICIPANTS: A national sample of 13,847 Medicare beneficiaries participating in the fall 2004 Medicare Current Beneficiary Survey.

MEASUREMENTS AND MAIN RESULTS: Prevalence of free prescription drug sample access (self-reported request for or receipt of free drug samples) and the demographic, clinical, and insurance characteristics of Medicare beneficiaries who accessed drug samples. Overall, 48.3% (95% confidence of interval [CI]: 46.6%, 49.9%) of Medicare beneficiaries reported accessing free drug samples. Access was higher among beneficiaries reporting cost-related medication nonadherence compared to those without (77.7% (95% CI: 74.5%, 80.6%) vs 43.0% (95% CI: 41.4%, 44.7%)). Multivariable analysis revealed cost-related medication nonadherence (CRN) to have the strongest relationship with accessing drug samples (adjusted odds ratio [AOR] 4.43 [95% CI: 3.64, 5.39]). Compared to beneficiaries with generous drug benefits from Medicaid, beneficiaries who lacked prescription drug benefits were more likely to access drug samples (AOR 2.42 [95% CI: 2.06, 2.85]). Beneficiaries with drug coverage from employer-sponsored plans or partial coverage (Medicare HMO, self-purchased Medicare supplement, or state-sponsored low-income plans) were also more likely to access drug samples (AOR 2.02, 1.74, respectively). Having 2–3 or ≥4 comorbidities (vs 0–1 comorbidities) also increased

the likelihood of accessing drug samples (AOR 1.60 (95% CI: 1.44, 1.79) and 2.00 (95% CI: 1.74, 2.29)).

CONCLUSIONS: Accessing free prescription drug samples is prevalent among many categories of beneficiaries, especially among individuals with cost-related medication nonadherence and poor health status. Policies restricting or prohibiting drug sample distribution may adversely impact access to medications among patients in high-risk groups.

KEY WORDS: free samples; pharmaceutical companies; Medicare.

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BACKGROUND

Growing concern about the nature, extent, and potential consequences of interactions between physicians and pharmaceutical companies has led to the development of policies limiting drug representative access to physicians.^{1,2} Some of these policies also bar physicians from accepting anything of financial value from pharmaceutical companies, including drug samples.^{3–6} Policies that restrict the use of drug samples have the goal of limiting the influence of free drug samples on medical judgment.¹ However, there is concern that restricting access to free drug samples may jeopardize access of medications for patients who would otherwise skip doses or delay refills because of cost. Cost-related medication nonadherence (CRN) is a significant problem and many patients use drug samples as a strategy to lower out-of-pocket drug costs and increase access to prescription drugs.^{7,8}

Free drug samples are a major component of the pharmaceutical industry's marketing strategy. The retail value of free drug samples is over half of the industry's marketing budget and equal to almost \$16 billion in 2004.⁹ Although most physicians report that their main motivation in distributing drug samples is to reduce the cost impact on patients,¹⁰ there is little empirical evidence showing that patients' financial need determines who receives free drug samples. One small study in a single geographic region reported lack of insurance associated with sample medication use¹¹ and another study from a single managed care organization found that use of drug samples was associated with reported financial access

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problems.¹² Neither study is generalizable to a national population. There is conflicting evidence about whether the availability of drug samples affects physician drug choice away from the evidence-based treatment of choice,^{10,13} or whether physicians are more likely to continue prescribing brand-name medication after patients request samples during an office visit.^{14,15}

Little is known about the prevalence of patient activity in requesting or receiving free prescription drug samples, or the characteristics of patients who access drug samples. We conducted this study of a national sample of Medicare beneficiaries to determine the prevalence of free sample access, and to examine demographic, clinical, and insurance characteristics of Medicare beneficiaries who access free samples.

METHODS

Data Source and Sample

The Medicare Current Beneficiary Survey (MCBS) from 2004 was the data source employed in this study. The MCBS is a continuous face-to-face panel survey of a representative national sample of approximately 16,000 Medicare beneficiaries conducted by the Centers for Medicare and Medicaid Services (CMS) since 1991. Measures include demographic information, income, living arrangements, health status, functioning, health behaviors, health insurance coverage, health care utilization and expenditures, and access to medical care.

The sample for the MCBS is drawn from CMS's data on enrollment for all Medicare beneficiaries according to a multistage sampling plan. Geographic primary sample units (PSUs, $n=107$) consist of groups of counties that are representative of the nation as a whole and ZIP codes within them. Systematic random samples are selected within age strata in each sampled ZIP code, with oversampling of vulnerable subgroups such as younger disabled beneficiaries and the oldest (85 years of age and older).

Respondents are interviewed in person 3 times a year using Computer-Assisted Personal Interviewing (CAPI), resulting in very high response rates (initially about 85%). The typical MCBS interview lasts approximately 1 hour. Annual interview cycles begin with the fall Access to Care interview, which includes questions on demographic and household composition, as well as health insurance, health status, and health care utilization. Subsequent interviews collect detailed information on health care use and expenditures, including prescription medication use. The full interview cycle is completed over 4 years.¹⁶ The measures of drug sample use that are presented here were collected in the fall, 2004 MCBS which included 14,500 non-institutionalized Medicare beneficiaries.¹⁷

Measures of Health Status, SES, and Drug Coverage

To measure health status, we used the of the number of self-reported categories of chronic medical conditions, including cardiovascular disease, hypertension, stroke, cancer, diabetes, arthritis, dementia, psychiatric disorder (including depres-

sion), neurological conditions (other than stroke), pulmonary conditions (including asthma and chronic obstructive pulmonary disease), and an existing MCBS measure of self-rated health status (excellent, very good, good, fair, poor) which strongly predicts mortality and other health outcomes.¹⁸

The MCBS survey measures household income in increments of \$5,000. We report income in the following categories ($\leq \$10,000$; \$10,001–\$20,000; \$20,001–\$40,000; $> \$40,000$). The 2 lowest income categories roughly correspond to the 100% and 200% federal poverty thresholds, respectively.¹⁹ We also report the following additional variables from the MCBS Access to Care file: race (African American, White, other), whether Hispanic, education level (less than high school), ability to perform activities of daily living, and type of health insurance coverage for prescription drugs in the last year. We defined the following levels of drug coverage: no drug coverage, partial drug coverage (Medicare HMO, self-purchased Medicare supplement with drug coverage, or state-sponsored low-income plans), and generous drug coverage (employer-sponsored drug coverage) or Medicaid drug coverage.⁷ Previous studies have demonstrated that Medicaid and employer-sponsored drug coverage plans are the most generous in terms of broader product coverage and lower cost-sharing, whereas the plans classified as partial coverage tend to include higher cost-sharing and lower spending allowances ("caps").^{8,20}

Measure of Free Drug Sample Access

In 2004, the MCBS incorporated detailed measures of drug cost-reduction strategies, including accessing free prescription drug samples from a doctor. The cost-related nonadherence to medications (CRN) and drug samples responses that are presented here were collected in the fall 2004 MCBS. Specifically, the MCBS used several measures of CRN based on previously validated measures⁸: how often have you "skipped doses to make the medicine last longer" and "taken smaller doses of a medicine to make the medicine last longer". Both items were asked with reference to the current survey year. Possible responses were often, sometimes, and never. Beneficiaries were also asked about drug cost-reduction strategies, including "Have you often, sometimes, or never asked for or received free samples from your doctor or health provider?" For analysis, all responses of often and sometimes skipping or taking smaller doses were combined into a single measure of CRN; responses of often and sometimes asking for or receiving drug samples were combined into a single indicator of accessing drug samples.

Statistical Analysis

We describe the demographic and health characteristics of the study population and determine the prevalence of access to drug samples by demographics, socioeconomic status, insurance status and health variables. To construct national estimates appropriately, we used the sample weights included in the MCBS file and the Taylor expansion method for weighting and variance calculation recommended by the MCBS Technical Documentation.²¹ We used weighted multivariable logistic regression to construct adjusted confidence intervals for the dependent variable in the model (drug sample access) and the influence of each independent variable and to

Table 1. Prevalence of Accessing Free Drug Samples by Demographic and Socioeconomic Characteristics among Medicare Beneficiaries

Predictor	Number (n)	Percent accessing drug samples (%)	95% CI
Overall	—	48.3	46.6–49.9
Age			
<55 yrs	1,663	47.3	43.8–50.8
55–64 yrs	665	52.0	47.2–56.9
65–74 yrs	5,207	47.3	47.4–51.7
75–84 yrs	4,606	49.5	47.4–51.7
85+ yrs	1,706	46.3	43.7–48.8
Gender			
Male	6,172	44.9	43.0–46.8
Female	7,675	50.9	49.0–52.9
Race			
White	11,607	50.0	47.8–51.2
African American	1,342	42.9	38.3–47.5
Other [†]	864	40.0	35.3–45.0
Hispanic or Latino			
Non-Hispanic	12,751	49.1	47.5–50.7
Hispanic	1,079	38.4	34.4–42.7
Education Level			
No high school	4,096	46.5	44.2–48.8
High School	4,196	48.3	45.9–50.6
Above High School	5,483	49.5	47.3–51.7
Marital Status			
Married	6,940	50.3	48.5–52.1
Single	6,902	45.9	43.9–47.9
Income			
≤\$10,000	2,857	41.0	38.5–43.6
\$10,001–\$20,000	3,666	50.1	48.1–52.1
\$20,001–\$40,000	4,114	49.5	47.0–52.0
>\$40,000	2,330	48.1	45.2–50.9
Metropolitan Residence			
Rural	3,574	53.6	49.6–57.5
Metro	10,273	46.6	44.9–48.4
Self-Rated Health			
Excellent	2,047	38.1	35.6–40.7
Very good	3,572	48.4	46.0–50.7
Good	4,411	48.6	46.2–50.9
Fair	2,593	52.2	49.9–54.5
Poor	1,193	57.2	53.6–60.7
Number of Comorbid Conditions			
0–1	3,607	37.0	34.9–39.2
2–3	6,562	49.9	48.0–51.9
4+	3,507	56.8	54.5–59.1
ADL			
0	9,537	45.9	44.2–47.7
1–2	2,864	53.8	51.4–56.2
3+	1,193	56.7	53.5–60.0
Drug Coverage			
Medicaid	1,662	32.3	29.4–35.3
None	4,893	53.4	51.2–55.6
Partial Coverage	2,840	45.4	42.7–48.2
Employer	4,452	49.3	47.0–51.6
Self-Reported Cost-Related Nonadherence to Medications (CRN)			
None	11,723	43.0	41.4–44.7
Present	2,105	77.7	74.5–80.6

ADL activities of daily living, CI confidence interval

*All of the tables in this article exclude respondents with missing values for drug sample requests, CRN and income. For all tables, numbers of beneficiaries (N=13,847) represent the actual sample sizes in the Medicare Current Beneficiary Survey (MCBS); however, all analyses used provided MCBS sampling weights and the Taylor series linearization technique to obtain estimates and standard error.

[†]Other includes other, American Indian/Alaskan Native, and Asian.

control for potential confounders, including sociodemographic characteristics, type of prescription drug coverage and health status.²² By conducting stratified analyses (by CRN) and constructing models that both included and omitted CRN, we found almost no difference in results obtained from the different models. Therefore, we included CRN in the final model and present those results. The *F*-adjusted mean residual test to assess goodness-of-fit for complex sample survey data produced a *p* value of 0.86 for the final model; this suggests no evidence of lack of fit.²³

All analyses were performed in Stata 9.2 (Stata Corporation, College Station, TX, USA). This study was determined to be exempt from human studies review requirements by the Institutional Review Board of Harvard Pilgrim Health Care.

Table 2. Adjusted Predictors of Accessing Free Drug Samples from Multivariable Logistic Regression*

Predictor	OR	95% CI
Self-Reported Cost Related		
Nonadherence to Medications (None) [†]		
Present	4.43	3.64–5.39
Age (<55) [†]		
55–64 yrs	1.19	0.97–1.46
65–74 yrs	1.20	0.95–1.51
75–84 yrs	1.09	0.86–1.38
85+ yrs	1.11	0.88–1.41
Gender (Male) [†]		
Female	1.34	1.22–1.49
Race (White) [†]		
African American	0.78	0.64–0.94
Other	0.75	0.60–0.92
Hispanic or Latino (non-Hispanic) [†]		
Hispanic	0.78	0.65–0.94
Education Level (Above High School) [†]		
High School	0.91	0.81–1.01
No High School	0.93	0.84–1.03
Marital Status (Married) [†]		
Single	0.85	0.77–0.94
Income (≤\$10,000) [†]		
\$10,001–\$20,000	1.10	0.97–1.25
\$20,001–\$40,000	1.09	0.94–1.28
>\$40,000	1.13	0.93–1.38
Metropolitan Residence (Rural) [†]		
Metro	0.82	0.69–0.96
Self-Rated Health (Excellent) [†]		
Very good	1.37	1.20–1.56
Good	1.26	1.09–1.46
Fair	1.37	1.18–1.59
Poor	1.39	1.15–1.68
Number of Comorbid Conditions (0–1) [†]		
2–3	1.60	1.44–1.79
4+	2.00	1.74–2.29
ADL (0) [†]		
1–2	1.16	1.04–1.29
3+	1.18	0.99–1.40
Drug Coverage (Medicaid) [†]		
None	2.42	2.06–2.85
Partial Coverage	1.74	1.44–2.10
Employer	2.02	1.70–2.40

ADL activities of daily living, CI confidence interval

*Data are given as odds ratio (95% confidence interval). Numbers in boldface are statistically significant at *P*<.05. See Table 1 footnotes for exclusions and numbers of beneficiaries

[†]Indicates the reference group

RESULTS

The fall 2004 study sample included 13,847 disabled and elderly Medicare beneficiaries after excluding respondents with missing values for drug sample requests or CRN ($n=58$) and income ($n=595$). Almost 35% of the sample lacked prescription drug benefits and half reported an annual household income of \$20,000 or less. Approximately one quarter reported being in fair or poor health and having 4 or more chronic comorbid conditions. Fifteen percent report cost-related medication nonadherence.

Approximately 48.3% (95% CI: 46.6%, 49.9%) of the sample reported accessing drug samples (Table 1). The prevalence of accessing drug samples was highest among beneficiaries reporting cost-related nonadherence compared to those without (77.7% [95% CI: 74.5%, 80.6%] vs 43.0% (95% CI: 41.4%, 44.7%)). Prevalence of access was also high among beneficiaries in any annual income category $> \$10,000$. For example, the proportion of near-poor beneficiaries (annual income \$10,001–\$20,000) accessing free samples was 50.1% (95% CI: 48.1%, 52.1%), whereas the proportion of poor beneficiaries (annual income $\leq \$10,000$) was 41.0% (95% CI: 38.5%, 43.6%). Beneficiaries without drug coverage had a higher prevalence of requests than other drug coverage categories, but accessing drug samples was prevalent among broad subgroups of beneficiaries (Table 1). For example, drug sample access was also common among beneficiaries with employer drug coverage (49.3% [95% CI: 47.0%, 51.6%]) and higher income (annual income $> \$40,000$: 48.1%, [95% CI: 45.2%, 50.9%]).

Multivariable analysis revealed that CRN had the strongest relationship with the probability of accessing drug samples (AOR 4.43 [95% CI: 3.64–5.39]). Lack of prescription drug coverage was also strongly associated with increased odds of accessing drug samples compared to having generous Medicaid drug coverage (AOR 2.42 [95% CI: 2.06, 2.85]). It is surprising to note that having employer-sponsored drug coverage also significantly increased the odds of accessing drug samples compared to those with Medicaid coverage (AOR 2.02 [95% CI: 1.70, 2.40]) as did having partial drug coverage from a Medicare HMO, self-purchased Medicare supplement, or state-sponsored low-income plan (AOR 1.74 [95% CI 1.44–2.10]). Although higher annual income was associated with higher prevalence of accessing drug samples in unadjusted analyses, this did not persist after adjustment ($> \$40,000$ v $< \$10,000$: AOR 1.13 (95% CI: 0.93, 1.38)).

The likelihood of accessing drug samples was highly related to both health and disease burden (Table 2). Beneficiaries with poorer health status, measured in several ways, were more likely to access drug samples, including those with 2–3 and 4 or more comorbid conditions (AOR 1.60 [95% CI: 1.44, 1.79] and 2.00 [95% CI: 1.74, 2.29], respectively) compared to 0–1 comorbid conditions and those with self-reported health other than excellent (Table 2).

African-American and Hispanic beneficiaries were less likely than white beneficiaries to access free prescription drug samples (AOR 0.78 [95% CI: 0.64, 0.94] and AOR 0.78 [95% CI: 0.65, 0.94], respectively). Geographic residence in a metropolitan area compared to a rural area also was associated with lower likelihood of accessing drug samples (AOR 0.82 [95% CI 0.69, 0.96]). Age and educational attainment were not significantly associated with accessing drug samples after adjustment (Table 2).

DISCUSSION

This study provides a nationally representative estimate of the activity of requesting or receiving free prescription drug samples among Medicare beneficiaries. We found that almost 50% of Medicare beneficiaries accessed drug samples, and that this was most common among beneficiaries who reported cost-related nonadherence to medications. Accessing drug samples was also common among many subgroups of beneficiaries, including those with higher incomes and prescription drug benefits, a finding also reported by Cutrona et al.²⁴ These findings indicate that the request and receipt of drug samples is a common and widespread practice, and that policies restricting access to drug samples would affect a wide range of beneficiaries.

Our findings suggest that CRN is the factor most strongly related to accessing drug samples after adjustment for health status, socioeconomic characteristics, and drug coverage. One explanation for this finding is that many beneficiaries may be relying on drug samples to alleviate medication costs. Other studies describe the use of drug samples as an important strategy to reduce cost-related nonadherence to medications^{7,25} and a majority of physicians consider drug samples an important source of medications for indigent patients.¹⁰ However, another explanation is that drug samples may lead to CRN by inducing the use of expensive, brand-name medications in lieu of less expensive alternatives. Given the cross-sectional nature of the data, we are unable to disentangle this relationship and caution against attributing causality of accessing drug samples to CRN.

We also found that having prescription drug benefits does not reduce the likelihood of accessing drug samples. Although lack of prescription drug benefits doubles the odds of accessing drug samples, having employer-sponsored and partial drug coverage also increased the odds of drug sample access. This is partially explained by the out-of-pocket expenses known to result from prescription benefit design features such as benefit caps, high deductibles, and formulary restrictions.^{26,27} Another explanation is that the population of individuals with drug coverage who access drug samples represents a mixture of 2 subgroups: individuals struggling to afford their co-pays and individuals who prefer drug samples in lieu of paying for medications. At least 1 other study also reported a high prevalence (50%) of free drug sample receipt by elderly Preferred Provider Organization (PPO) enrollees with tiered drug benefits.¹² Another part of the explanation for the use of drug samples across beneficiaries with and without drug benefits is that drug samples are distributed for non-economic reasons, including the initiation of therapeutic trials to evaluate early effectiveness, adverse effects or dose adjustment before the purchase of a full prescription.¹⁰

Clinical factors were also associated with increased drug sample access, including having a greater illness burden and having poorer health. This is not surprising given the large medication burden among many elderly individuals. We also found that race/ethnicity was an important factor, in that African-American, Hispanic, and other non-white beneficiaries were less likely to ask for or receive free prescription drug samples. Other studies have not explored racial or ethnic variation in the request and use of drug samples. It is unclear whether this represents an example of racial disparities in

medication access, racial differences in patient–physician relationships and communication, or a far more complex relationship that we were unable to discern with our study variables. These findings merit further investigation.

The limitations of our study deserve comment. First, we were unable to measure the actual distribution or receipt of drug samples. Therefore, interpretation of our findings as estimates of actual use of drug samples in the Medicare population should be made cautiously. Second, we were unable to describe the characteristics of the medications being requested. It is therefore unclear if the drug samples requested or received were for essential (i.e., drugs whose withdrawal could have important effects on morbidity or mortality or drugs primarily used for symptomatic relief) or non-essential medications.²⁸ Finally, we were unable to determine whether CRN led to drug sample requests or whether drug sample use led to CRN. Although we examined the effect of including CRN in the final model by conducting separate analyses stratifying models by CRN, and including and omitting CRN from the multivariable model, we found little difference among the models. Although the inclusion of CRN in the final model does not affect the other parameter estimates, we caution against inferring causality between CRN and drug sample access.

In summary, our study finds that requesting or receiving drug samples is common among a broad spectrum of Medicare beneficiaries. Of concern is our finding that this activity is more common among beneficiaries with CRN and poorer health. Many physicians dispense drug samples to help their patients reduce expenses,¹⁰ but growing concerns about relationships between physicians and the pharmaceutical industry have led to new policies restricting drug samples distribution.^{29,30} Because drug samples are distributed for a variety of reasons other than patient financial need, it is difficult to precisely estimate the impact that these policies will have on beneficiaries with CRN. Restricting access to drug samples may, paradoxically, reduce CRN by limiting the prescribing and use of expensive, brand-name drugs. In either case, it is clear that these policies will affect a wide spectrum of patients and will likely accelerate the current downward trend in the use of free drug samples by physicians.^{2–6} Although the Medicare Part D drug benefit will reduce CRN for many beneficiaries, multiple studies demonstrate that many patients will still experience significant out-of-pocket expenditures and will likely still experience cost-related nonadherence under Part D.^{31,32} In developing policies that restrict the use of samples, health care systems, medical groups, and individual physicians should consider the impact of such restrictions on patients who are reliant on samples and prone to cost-related medication nonadherence. Alternative options for providing essential medications to these high-risk patients should be considered.

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