Are Sample Medicines Hurting the Uninsured?

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Background: **Pharmaceutical representatives often give sample medications to physicians for distribution to patients. In chronic conditions such as hypertension, this practice can contribute to unnecessary medication changes, gaps in treatment, and inferior control of disease. The objective of the current study was to explore associations between use of free sample medicine, hypertension, and source of payment for health care.**

Methods: **Telephone interviews and chart reviews were conducted at two community health centers in California. Adults with hypertension who had at least three clinic visits in the previous year and either had no insurance or had Medicare or Medicaid were included.**

Results: **Seventy-one patients participated. Seventeen had received sample medicines up to three times within the previous year. Lack of insurance ($P < .01$) was associated with sample medicine use. No group differences were found for medication changes. In multiple regression analysis, uninsured patients who received sample medicines had higher diastolic blood pressure ($P = .01$).**

Conclusions: **Lack of insurance was the principle predictor of use of sample medications. Although cross-sectional design and covariance of independent variables limit conclusions, higher diastolic blood pressure was related to sample medication use in patients who did not have insurance. (J Am Board Fam Pract 2002;15:361–6.)**

Pharmaceutical companies promote new drugs by providing free samples to medical offices.[1,2] Presumably, after a satisfactory trial of samples, patients with chronic conditions receive a prescription for the same medication, thereby facilitating uninterrupted treatment.[2,3] If patients are uninsured or unable to afford these medications, clinicians might attempt to supply free samples continuously to spare patients the medication costs.[2,4,5]

Providing free samples to low-income patients can have negative consequences. Continued compliance with pharmaceutical regimens using sample medications depends on (1) patients visiting the physician's office before exhausting their supply of sample medication instead of simply calling the pharmacy for a refill, and (2) the physician receiving sufficient and timely supplies from the pharmaceutical representative to facilitate uninterrupted treatment. If these conditions are not met, other medications will be substituted, or gaps in treatment will occur. We hypothesize that this sequence of events occurs frequently in settings serving uninsured and financially disadvantaged patients. A result might be numerous changes in otherwise satisfactory regimens and unnecessary lapses in treatment of chronic conditions.[6–10]

In this article we describe and characterize the dispersal of free sample medicines to a low-income patient population with hypertension. We explore the relation between sample medication use and disease control. We studied hypertension because it is a common chronic condition with a simple measurement of treatment response (ie, blood pressure), and many companies distribute free samples of newer antihypertensive medications.[11]

Methods

Study Sample

Computerized billing records from two Fresno, Calif, area community health centers were used to generate a list of all outpatients who visited the clinics within the preceding 2 years and had a di-

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agnosis of hypertension. Patients of these two health centers are predominantly Mexican-Americans employed in the agriculture industry.

An initial chart review was conducted to determine which patients met the study's inclusion criteria. Eligible patients had a diagnosis of hypertension (documented either in the physicians progress notes or in the problem list) and were either uninsured or were enrolled in Medicaid or Medicare. Participants were required to have a telephone, to have been a clinic patient for more than 1 year, and to have had a minimum of three blood pressure readings within the preceding year.

Patients meeting these criteria were sent a bilingual (English and Spanish) introductory letter inviting them to participate in the study and be interviewed by telephone. They were given the opportunity to decline by returning a stamped and addressed postcard. Up to three attempts at telephone contact were made. Trained undergraduate students conducted telephone interviews in English or Spanish. Patients who could not be contacted after three attempts were excluded. No incentives were provided to respondents.

Survey

In a telephone interview written specifically for this study, patients were asked the year their hypertension was diagnosed and their current hypertension medications and dosages. We also asked whether they had visited health providers other than at the primary site, received free sample medication for their hypertension, run out of medications, missed dosages, or experienced side effects. Finally, we asked them to report exercise, smoking, and alcohol habits.

After the telephone interview we conducted a second, detailed chart review of all clinic visits for each participant during the previous 12 months to determine antihypertensive medication prescriptions and prescribing frequency including all changes, comorbid diseases, blood pressure at each clinic visit, serum creatinine levels, and total clinician visits.

Analysis

Data were entered into Microsoft Access 97 database software (Microsoft Corporation, Redmond, Wash) and analyzed using SAS statistical analysis software (SAS Institute Inc., Release 6.12, Cary, NC). Mean systolic and diastolic blood pressure for each participant was calculated from his or her total number of blood pressure readings (3–15). Means with standard deviations were calculated for normally distributed data, and medians with ranges for nonnormally distributed data. *t* Tests were used to test for differences between patients who did and did not receive free samples (normally distributed variables). For nonnormally distributed variables a two-sample median test was used to test for differences between the groups defined by receipt of free samples. Chi-square or Fisher exact statistics were used to test for differences in categorical outcomes between these same groups. Finally, stepwise multiple linear regression was used to estimate the strength of the relation between free sample medicine use and diastolic blood pressure.

Results

A total of 207 patients seen within the preceding year were determined to be eligible from initial review of billing records and chart reviews at the two participating health centers. We were unable to reach 75 (36%) after three attempts. Of the 132 patients that we were able to contact, 71 (54%) granted telephone interviews, and 61 (46%) declined to participate.

Sixty-five percent of participants came from one health center (Selma Community Health Center). Overall, 65% were female, and the mean age was 62 years. Spanish was the dominant language. Sixty-seven percent spoke Spanish only or Spanish and English. Respondents had hypertension for a median of 8 years and visited their physician seven times a year. Many participants were overweight (mean body mass index $\geq$ 34), and exercised rarely (59%). Almost all participants denied drinking alcohol more than rarely (99%), and few (16%) reported smoking. Twenty percent of participants had diabetes as well as hypertension. Only 1 patient suffered from renal insufficiency. The median number of medications taken for hypertension was one with a median of two new medications prescribed per year. Twenty-four percent of participants reported using free sample medications.

Participants who indicated they had received any sample medications in the last year or who had sample medication use noted in their medical record were placed in the sample medication group. Table 1 lists the characteristics and clinical parameters of the patients using sample medica-

Table 1. Characteristics of Patients With Hypertension Who Received Free Sample Medications.

Patient Characteristic	Used Free Samples (n = 17)	No Free Sample Use (n = 54)	*P* Value
Age, y, mean (SD)	59 (13)	64 (13)	.24
Female	10	36	.56
Language			
English only	4	20	.28
Spanish only	10	20	
English and Spanish	3	14	
Insured	9	51	<.01
Medicaid	5	38	
Medicare	2	5	
Medicaid and Medicare	2	8	
Visits per year, mean (SD)	8 (5)	7 (4)	.99
Duration of hypertension, y median (range)	7 (1–5)	9 (1–60)	.83
Body mass index, mean (SD)	31 (8)	34 (7)	.14
Diabetes	2	12	.49
Medication habits			
Ran out of medicine more than rarely	3	4	.36
Missed regular doses more than rarely	1	8	.67
Number of times received sample medications, median (range)*	2 (1–3)	0	NA
Medication changes during reference year, median (range)	1 (0–13)	0 (0–5)	.18
Number of antihypertensive medications taken during year, median (range)	3 (1–9)	2 (0–5)	.15
Mean systolic blood pressure, mm Hg (SD)	146 (17)	142 (15)	.42
Mean diastolic blood pressure, mm Hg (SD)	85 (10)	79 (9)	.03

*This variable was used to create the groups in this table.

tions and the patients not using sample medications. Forty-seven percent of the sample group was uninsured compared with 6% of the no-sample group ($P < .01$). Mean diastolic blood pressure was 85 mm Hg in the sample group and 79 mm Hg in the no-sample group ($P = .03$). Other trends were toward youth, leaner body mass, Spanish language, increased number of medication changes, and a higher total number of medications in the sample use group.

Table 2 itemizes the reasons why patients reported receiving free sample medications. Most uninsured patients said they received free samples because they could not afford medicine, whereas most patients with Medicaid or Medicare said that they used free samples because the physicians recommended them.

Finally, we used a multivariate model to address the relation between sample medication use and average blood pressure. Both sample medicine use ($P = .03$) and lack of insurance (uninsured vs Medicaid or Medicare, $P < .01$) were associated with higher diastolic blood pressure (but not systolic blood pressure) in the bivariate analysis. Age ($P < .01$) and insurance status ($P = .04$) were the only significant predictors of diastolic blood pressure in a stepwise multiple regression model that included age, weight, sex, duration of hypertension, insurance status, and history of sample medicine use. Insurance status and sample medicine use, however, exhibited strong collinearity: 47% of the

Table 2. Reasons Why Patients Received Samples.

Reason*	No Insurance (n = 8)	Medicare or Medicaid (n = 9)	Total
Physician suggestion	3	6	9
Patient request	1	0	1
Unable to afford medicine	7	4	11
Did not respond	0	1	1

*Participant could choose more than one reason.

group using sample medicines was uninsured, whereas 6% of the group not using samples was uninsured ($P < .01$). Indeed, when the stepwise regression model was repeated without insurance status, sample medicine use ($P = .05$) emerged along with age ($P < .01$) as a significant predictor of diastolic blood pressure.

To explore further the relationship between these two variables, we stratified sample medicine use by insurance status. Uninsured patients who did not receive free samples had an average diastolic blood pressure of 6.0 mm Hg lower than those who did receive sample medicines (83.5 [n = 3] vs 89.5 [n = 8]). Among insured patients, those who did not receive free samples had an average diastolic blood pressure 1.4 mm Hg lower than those who did receive samples (78.7 [n = 51] vs 80.1 [n = 9]). After stratification, neither of these differences is significant, but together they suggest a positive interaction between free sample use and lack of insurance, ie, either variable has a greater effect when the other is also present. As an illustration, we computed an additional stepwise regression model for *sample medicine plus lack of insurance* interaction term with age, weight, sex, duration of hypertension, insurance status, and history of sample medicine use. In this model only age ($P < .01$) and the interaction term were significant ($P = .01$; average diastolic blood pressure = 95.6–0.26 age + 8.4 *sample-insurance* interaction term; $R^2 = 0.24$; $P < .001$).

Discussion

Sample medications are ubiquitous in primary care practices.[2] Little is known, however, about how sample medications are actually used in practice. We found that in our community health center population, uninsured patients are much more likely than patients with Medicaid or Medicare to receive sample antihypertensive medicines. Physicians in our study might be using sample medicines as a long-term treatment option for uninsured patients who have chronic conditions such as hypertension. We also found that uninsured patients who have received sample medicines are more likely to have higher diastolic blood pressures independent of the effect of age and other known physiologic and socioeconomic risk factors.

Lack of health insurance has been linked to adverse health outcomes. Persons without insurance are less likely to obtain blood pressure checks, see a physician, or seek care for a serious condition. They are more likely than their insured counterparts to have risk factors for chronic diseases and have increased mortality.[12–16] The relation, if any, between insurance status and sample medication use, however, has not been studied.[17] Our findings add to the literature by showing a link between insurance status and sample medication use. They also suggest that sample medicines might be one (unintended) means by which uninsured status conveys diminished disease control.

It is not possible to determine from this study whether higher average diastolic blood pressures were the cause or effect of sample medication use. Either scenario is possible, and both are disconcerting. It is conceivable that reliance on sample medicines to treat hypertension in uninsured patients might actually result in higher average blood pressures as a result of the inherently uncertain availability of sample medicines and their packaging for short-term use. If, on the other hand, sample medicines are given simply to find effective treatment for higher blood pressures in uninsured patients, the same issues of availability and packaging could adversely affect a patient's ability to adhere to treatment recommendations.

Level of adherence to treatment recommendations can affect hypertension control.[18–20] This concern applies not only to patients given prescriptions for medications they might not be able to afford but also to patients given sample medications. We found that patients taking sample medicines had only modest mean elevations in diastolic blood pressure. These pressures might actually be the result of considerable reductions in pre-sample-medicine blood pressure, reflecting what most would consider a positive result of sample medicine use.

We theorized that if reduced treatment adherence were the mechanism for higher blood pressures in the sample medicine group, we would observe increased reports of numbers of medication changes, total medications prescribed, missed doses or side effects, or inadequate supply of medicine in this group during the reference year. Although there were trends toward increased numbers of medication changes and total antihypertension medications prescribed in the sample group, these findings were not significant (Table 1).

Somewhat unexpectedly, in the multivariate analyses age continued to have a modest inverse

association with diastolic blood pressure, although modestly so ($\beta = -0.22$). Although not significant, systolic blood pressures also tended to be higher in the younger age group. This finding could reflect residual confounding between age, insurance status, and sample medicine use, because insured patients included those with Medicare, which is primarily intended for the aged.

The study has several limitations that include nonstandardized measurement of blood pressures, cross-sectional design, reliance on patient self-reported data, and strong intercorrelation of independent variables. Requiring participants to have a telephone and the modest response rate and small sample size hamper generalizability. The collection of the outcome measure, blood pressure, was not standardized. Blood pressure measurements were collected from the medical record. In general, these pressures were measured using mercury sphygmomanometers. We gathered no information about calibration, reliability, or accuracy of these measurements. There is no reason, however, to suspect systematic bias in one direction based on the type of equipment used or the qualifications of the person obtaining the blood pressure measurements. The cross-sectional design renders uncertain the conclusions about the temporal relation of sample medicine use and blood pressure readings. Furthermore, reliance on self-reported data could be criticized. Even so, in at least one example, investigators found that self-reported data on nonadherence with hypertensive treatment regimens, when compared with pharmacy dispensing records and pill counts, were generally accurately reported.[19] The previously noted intercorrelations between such variables as insurance status, sample medicine use, and age make statistical isolation of the effects of each difficult.

Generalizability of our findings is vulnerable to response bias. Respondents were limited to 54% of those we reached by telephone. Although this small sample could have biased descriptive information or caused us to be unable to distinguish underlying differences between the group using sample medicine and the group not using sample medicine, it seems less likely to have produced spurious associations between blood pressure and other variables. Including the requirement that participants have a telephone as part of our inclusion criteria further restricted the study population and might have excluded patients in more dire circumstances. Finally, the inclusion of participants with Medicare only, which does not provide coverage for medication costs, blurs the distinction between the uninsured and Medicaid or Medicare groups. Thus, while our target population is likely to be comparable with those found in other southwestern US community health centers, generalization of these findings should be qualified by the sampling limitations described here. The study findings are less likely to generalize to other ethnic or socioeconomic groups.

In conclusion, sample medications are disproportionately given to uninsured patients in this setting. Uninsured status, combined with use of sample medicine, is associated with higher average diastolic blood pressure. Physicians should consider carefully their decision to offer free sample medications to treat such chronic conditions as hypertension, especially in uninsured patients.

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