

The Health Effects of Restricting Prescription Medication Use Because of Cost

Michele Heisler, MD, MPA,*†‡ Kenneth M. Langa, MD, PhD,*†§|| Elizabeth L. Eby, MPH,*
A. Mark Fendrick, MD,† Mohammed U. Kabeto, MS,† and John D. Piette, PhD*†‡

Background: High out-of-pocket expenditures for prescription medications could lead people with chronic illnesses to restrict their use of these medications. Whether adults experience adverse health outcomes after having restricted medication use because of cost is not known.

Methods: We analyzed data from 2 prospective cohort studies of adults who reported regularly taking prescription medications using 2 waves of the Health and Retirement Study (HRS), a national survey of adults aged 51 to 61 in 1992, and the Asset and Health Dynamics Among the Oldest Old (AHEAD) Study, a national survey of adults aged 70 or older in 1993 (n = 7991). We used multivariable logistic and Poisson regression models to assess the independent effect on health outcomes over 2 to 3 years of follow up of reporting in 1995–1996 having taken less medicine than prescribed because of cost during the prior 2 years. After adjusting for differences in sociodemographic characteristics, health status, smoking, alcohol consumption, body mass index (BMI), and comorbid chronic conditions, we determined the risk of a significant decline in overall health among respondents in good to excellent health at baseline and of developing new disease-related adverse outcomes among respondents with cardiovascular disease, diabetes, arthritis, and depression.

Results: In adjusted analyses, 32.1% of those who had restricted medications because of cost reported a significant decline in their health status compared with 21.2% of those who had not (adjusted

odds ratio [AOR], 1.76; confidence interval [CI], 1.27–2.44). Respondents with cardiovascular disease who restricted medications reported higher rates of angina (11.9% vs. 8.2%; AOR, 1.50; CI, 1.09–2.07) and experienced higher rates of nonfatal heart attacks or strokes (7.8% vs. 5.3%; AOR, 1.51; CI, 1.02–2.25). After adjusting for potential confounders, we found no differences in disease-specific complications among respondents with arthritis and diabetes, and increased rates of depression only among the older cohort. **Conclusions:** Cost-related medication restriction among middle-aged and elderly Americans is associated with an increased risk of a subsequent decline in their self-reported health status, and among those with preexisting cardiovascular disease with higher rates of angina and nonfatal heart attacks or strokes. Such cost-related medication restriction could be a mechanism for worse health outcomes among low-income and other vulnerable populations who lack adequate insurance coverage.

Key Words: insurance, health care expenditures, prescription medications, chronic illness, health services accessibility

(*Med Care* 2004;42: 626–634)

Both prescription drug use and expenditures have increased dramatically in the past decade, yet many American adults have either limited or no prescription drug insurance coverage.^{1,2} In 1999, noninstitutionalized Medicare beneficiaries paid out-of-pocket for nearly half of their prescription drug costs, or an average of \$410 per beneficiary.³ Out-of-pocket prescription medication expenditures for adults with multiple chronic diseases are more than twice that amount.⁴

A growing body of research has documented significant rates of underuse of medications as a result of the burden of out-of-pocket cost, especially among vulnerable populations.^{5–8} For example, Steinman et al. found that 8% of elderly people in the United States without drug coverage reported restricting medications because of cost, with rates as high as 16% among those with annual incomes less than \$10,000 and 21% among nonwhites.⁹ Patients faced with reduced prescription drug coverage fill fewer prescriptions, including those for medications essential for treating cardiovascular disease and diabetes.^{10–16}

The views expressed in this paper are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs. Dr. Heisler is a VA HSR&D Career Development Awardee. Dr. Langa was supported by a Career Development Award from the National Institute on Aging (K08 AG19180), a New Investigator Research Grant from the Alzheimer's Association, and a Paul Beeson Physician Faculty Scholars in Aging Research award.

From the *Veterans Affairs Center for Practice Management & Outcomes Research, VA Ann Arbor Healthcare System, Ann Arbor, Michigan; the †Department of Internal Medicine, ‡Michigan Diabetes Research and Training Center, the §Institute for Social Research, and the ||Patient Safety Enhancement Program, University of Michigan School of Medicine, Ann Arbor, Michigan.

Reprints: Michele Heisler, MD, MPA, HSR&D Field Program, PO Box 130170, Ann Arbor, MI 48113-0170. E-mail: mheisler@umich.edu.

Copyright © 2004 by Lippincott Williams & Wilkins

ISSN: 0025-7079/04/4207-0626

DOI: 10.1097/01.mlr.0000129352.36733.cc

There is controversy in the current policy debate on prescription medication coverage about the extent to which patients who take less of their prescribed medications because of cost experience adverse health outcomes as a consequence.^{2,6,17} Evidence on the effects of cost-related medication restriction is limited to cross-sectional studies^{18,19} and observational time-series analyses based on pharmacy claims data. The time-series analyses showed that public sector policies limiting drug coverage led to fewer filled prescriptions^{11,12} and to increased nursing home admissions²⁰ and use of acute care services.^{10,21,22} These studies, however, lacked information on the actual mechanisms for these aggregate effects.

The hypothesis that restricting medications because of cost contributes to adverse health consequences has not been explicitly tested longitudinally using individuals' own reports of their medication use. Accordingly, we analyzed data from 2 cohort studies with nationally representative samples of middle-aged and older adults to assess the health consequences of restricting medication use because of cost, especially among chronically ill patients. We hypothesized that restricting medication use because of out-of-pocket costs, even after controlling for health status, comorbidities, and sociodemographic characteristics, would adversely affect patients' subsequent reported health status and disease-related outcomes. We further hypothesized that we would find greater impacts of restriction on health outcomes among a cohort of older—and therefore possibly more physically frail—adults, compared with a younger cohort.

METHODS

Study Population

The Health and Retirement Study (HRS) and Asset and Health Dynamics Among the Oldest Old (AHEAD) study are nationally representative, biennial longitudinal studies sponsored by the National Institute of Aging and undertaken by the University of Michigan's Institute for Social Research. These studies target community-dwelling adults in the contiguous United States, with oversampling of blacks, Latinos, and Florida residents, and gather in-depth economic, financial, and health information from respondents. In 1998, the 2 studies were combined, with identical survey procedures and questionnaires.

For the HRS cohort, interviews were initially conducted in 1992 in 7702 households (82% response rate), yielding 9824 participants between 51 and 61 years old for the initial interview. AHEAD respondents included 7443 men and women 70 years of age or older at the initial interview in 1993 (80.4% response rate).²³ Subsequent face-to-face and telephone interviews have been conducted at 2-year intervals (with the exception of a 1-time 3-year interval for the AHEAD cohort between 1995 and 1998).

AHEAD respondents were first asked about cost-related medication restriction in the 1995 wave, and HRS respondents answered the same question in 1996. Thus, we used data from these 2 waves of interviews as our study's baseline. We then looked at reported health outcomes using respondents' 1998 interviews, the next wave conducted for both groups and the last wave for which final data were available.

Of the 17,991 HRS/AHEAD respondents in our baseline years, all community-dwelling participants who reported taking prescription medications regularly ($n = 12,132$) were potentially eligible for the current study. We excluded nonage eligible spouses or partners ($n = 2071$) and HRS respondents under 65 who reported being covered by Medicare in 1996 ($n = 569$), because they likely had qualifying medical conditions such as renal failure or disabilities not fully measured in the survey. Because our outcome measures were based on self-report, we also excluded respondents in the sample with cognitive impairment as measured by a well-validated cognitive status instrument ($n = 412$).^{24,25} Between the 1995/1996 and 1998 waves, 1089 respondents (12.0% of our eligible baseline cohort) were lost to follow up or died. Of those 1089 respondents, 30% could not be confirmed as alive or dead, 64% were confirmed dead, and 6% were confirmed alive. There were no significant differences between respondents in 1998 and those lost to follow up with respect to medication restriction ($P = 0.41$), race ($P = 0.21$), arthritis ($P = 0.99$), psychiatric illness ($P = 0.93$), or smoking status ($P = 0.68$) at baseline. Those lost to follow up were more likely to be older, unmarried, and nondrinking, with lower incomes, poorer self-reported health status, lower body mass indexes (BMIs), and higher rates of lung disease, cardiovascular disease, cancer, hypertension, and diabetes (all significant at $P < 0.05$). Our final weighted sample consisted of 7991 respondents (3649 from AHEAD and 4342 from HRS).

Subpopulations With Different Conditions at Baseline

To assess whether respondents experienced a significant decline in their health status over the study period, we identified respondents who at baseline reported their health as being "good," "very good," or "excellent" in response to the standard question, "Would you say your health is excellent, very good, good, fair, or poor?" ($n = 5650$).

To examine disease-specific complications of cost-related medication restriction, we identified all respondents reporting each of the following chronic illnesses for which medications have been shown to affect clinical outcomes: cardiovascular disease, diabetes, arthritis, and depression. Respondents at risk for adverse cardiovascular outcomes included those who reported either hypertension, a "heart condition," a prior stroke, or diabetes at their baseline interview ($n = 5959$). Analyses of new-onset diabetic kidney

disease and proteinuria were restricted to respondents reporting diabetes at baseline ($n = 1362$). Patients with arthritis included respondents who indicated that a doctor had ever told them that they have arthritis or rheumatism ($n = 4507$). Finally, we identified respondents with significant depressive symptoms at baseline based on their responses to the 8-item version of the CES-D depression scale ($n = 1043$).^{26,27} Following scale norms, we considered any score greater than 3 to indicate depression.

Principal Independent Variable

In the 1995/1996 waves, all respondents were asked, "At any time in the last 2 years have you ended up taking less medication than was prescribed for you because of the cost?" Participants were classified into whether they answered "yes" or "no" to this question.

Covariates

Because cost-related medication restriction could be associated with other factors that also increase respondents' risk for adverse health outcomes, we estimated its independent effect on outcomes, adjusting for potential confounding by an extensive set of socioeconomic, clinical, and behavioral variables. Socioeconomic covariates included annual household income (defined as the total of all sources of income over the prior year, including income from work, Social Security benefits, private pensions, and other investments²³), educational level, age, sex, and race (white vs. minority). Potential clinical and behavioral confounders included self-reported health status, BMI (<25 kg/m², 25–29.9 kg/m², and >30 kg/m²), alcohol consumption (none, mild/moderate, heavy), and current smoking status, along with the presence of comorbid conditions. Alcohol consumption was defined as none if respondents reported never drinking alcohol, as mild/moderate if they reported no binge drinking or consumed less than 21 drinks/week if male and less than 14 drinks/week if female, or as heavy if they reported any binge drinking or 21 or more drinks/week if male and 14 or more if female. Baseline cardiovascular risk was measured using a 0–4 index representing the number of cardiovascular disease-related conditions reported in the 1995/1996 interviews (hypertension, diabetes, heart condition, and stroke). Other comorbid conditions included dichotomous variables indicating whether a doctor had told them that they had arthritis, chronic lung disease, cancer, and psychiatric illness. For the analyses of respondents with diabetes, we also adjusted for the number of doctor and emergency room visits over the time period, because the diabetes-related outcome we assessed was dependent on information conveyed by a doctor (see subsequently). We did not include insurance coverage as a covariate to avoid overadjustment, because insurance coverage was highly correlated with medication restriction. Because prior research suggests that medication restriction is a "down-

stream" effect of high out-of-pocket drug costs and/or inadequate insurance,⁹ including only the medication restriction variable allowed us to better test this potential mechanism for poor health outcomes.

Health Outcomes

To assess significant declines in reported health status among respondents who reported their health to be "excellent," "very good," or "good" at baseline, we created a dichotomous outcome variable defined as reporting fair or poor health versus good, very good, or excellent health in 1998. In light of evidence that questionnaires about health status often do not detect clinically important differences among those who are in worse health at baseline,^{28,29} we did not evaluate those who reported going from "fair" to "poor" health. Respondents' self-reports of their health using this question have been found strongly to predict subsequent health outcomes, including mortality, in numerous studies.³⁰

For analyses of respondents with cardiovascular disease, we constructed 2 measures of adverse cardiovascular outcomes occurring in the 2 years subsequent to respondents' baseline interview. The first variable indicated whether respondents reported in 1998 that they had experienced angina in the prior 2 years; and the second variable indicated whether they reported having a heart attack or stroke since their baseline survey.

For analyses of respondents with diabetes, we created a dichotomous outcome variable based on the 1998 question, "Has your diabetes caused you to have trouble with your kidneys or protein in your urine [in the past 2 years]?"

To evaluate arthritis-related complications, we created 2 variables. The first represented whether respondents reported in 1998 a higher number of specific physical activities they either could not or did not do than at baseline. The second outcome variable indicated an increase in pain from baseline (based on comparing responses to the question "When [your] pain is at its worst, is it mild, moderate, or severe?"). Respondents were also considered to have worse pain if they reported any degree of pain in 1998 but no pain at baseline.

To assess more severe depression as an outcome among respondents who met criteria for depression at baseline, we compared unadjusted and adjusted means of respondents' scores on the CES-D depression scale in 1995/1996 and 1998.

Data Analyses

We conducted bivariate analyses comparing the baseline characteristics and outcomes of restrictors and nonrestrictors using second-order Pearson statistics for dichotomous variables³¹ and adjusted Wald statistics for continuous variables.³² We then used multivariable logistic or Poisson regression to examine the independent effects of cost-related

medication restriction, controlling for respondents' age, gender, race, annual household income, educational level, health status, comorbidities, current smoking status, current alcohol consumption, and BMI. In analyses of the disease-specific adverse outcomes among respondents with specific chronic illnesses, we included the other comorbidity variables as well as self-reported health status as covariates, along with all the previously mentioned sociodemographic variables.

We conducted each analysis for the combined sample and then separately for the cohort 65 years or younger at baseline (HRS) and those 72 years or older at baseline (AHEAD). In all analyses, we adjusted for the complex sampling design of the surveys and for the person-level analytic weights provided by HRS/AHEAD to obtain correct population estimates. We used base-year weights, because these are more appropriate when the goal is to model or describe the future experiences of the base-year population. These were also appropriate for our study, because there was no association between medication restriction and attrition. Finally, we repeated all analyses, including respondents with dementia ($n = 412$), with no effect on our findings.

Regression diagnostic procedures yielded no evidence of substantive multicollinearity, heteroscedasticity, or influential outliers in any of the logistic models. To account for overdispersion using the Poisson model, we alternatively used a negative binomial model and found no difference in the results. We performed all analyses with STATA 7³³ using publicly available data files (<http://hrsonline.isr.umich.edu>). An Institutional Review Board at the University of Michigan approved the surveys. The data used for this study contained no unique identifiers, so respondent anonymity was maintained.

RESULTS

Sample Characteristics

A total of 7991 respondents met study eligibility criteria and completed the 1995/1996 and 1998 interviews. Of these, 546 (187 in the AHEAD cohort and 359 in the HRS cohort) reported that they had restricted prescription medication use because of cost (Table 1). A total of 243 respondents in good to excellent health at baseline, 444 of those with cardiovascular disease, 124 of those with diabetes, 415 of those with arthritis, and 189 of those with depression reported restricting medication use because of cost. In bivariate analyses, those who restricted medications were more likely than nonrestrictors to be younger, women, and Latino, black, or Asian American. Those who restricted had lower educational levels and annual household incomes, and were more likely to have no insurance or insurance without full prescription medication coverage (all $P < 0.001$). They also reported significantly worse self-reported health status at baseline, higher BMIs, more

reported comorbidities, and were more likely to be current smokers, but less likely to be mild/moderate or heavy drinkers.

Health Outcomes

In both unadjusted and adjusted analyses of respondents who reported good to excellent health at baseline, those who restricted prescription medications were more likely to experience a significant decline in their self-reported health status (see Table 2). Controlling for their sociodemographic and baseline clinical characteristics, 32.1% of those who had restricted medications reported a significant decline, compared with 21.2% of those who had not (adjusted odds ratio [AOR], 1.76; confidence interval [CI], 1.27–2.44).

After adjusting for potential confounders, respondents with cardiovascular disease who restricted medications reported higher rates of angina (11.9% vs. 8.2%; AOR, 1.50; CI, 1.09–2.07) and experienced higher rates of nonfatal heart attack or stroke than nonrestrictors (7.8% vs. 5.3%; AOR, 1.51; CI, 1.02–2.25). (Table 2)

Among diabetic respondents, there were no significant differences between restrictors and nonrestrictors in rates of new kidney problems (Table 2). Likewise, there were no differences among respondents with arthritis in rates of pain or physical limitations associated with medication restriction. Finally, although in the unadjusted analyses, respondents with depression who reported restricting medications had significantly worse scores on their CES-D depression scale in the subsequent wave than those who did not restrict, the differences were no longer statistically significant in the adjusted analyses.

In adjusted age-stratified analyses of health outcomes, those 72 or older at baseline who restricted had approximately 92% higher odds of a significant decline in health (44.7% vs. 29.7%; AOR, 1.92; CI, 1.21–3.04). Also, those in the younger age cohort who restricted had 57% higher odds of a decline in health (21.4% vs. 14.8%; AOR, 1.57; CI, 1.01–2.43). Those 72 or older at baseline with cardiovascular disease who restricted had twice the odds of experiencing angina than nonrestrictors after adjusting for potential confounders (18.8% vs. 10.5%; AOR, 1.97; CI, 1.19–3.26). There were no significant differences in risk of angina for those 65 or younger. The older age cohort also had a significant increase in the risk of more severe depression (CES-D score 4.20 vs. 3.63; adjusted Incident Rate Ratio, 1.16; CI, 1.02–1.31). There were no significant differences in the risk of more severe depression among those in the younger age cohort. In the age-stratified analyses of respondents with diabetes and arthritis, the adjusted impact of medication restriction was not associated with adverse disease-related outcomes in either age cohort.

TABLE 1. Baseline Characteristics of Respondents (n=7,991)*

	Restricted Medications due to Cost (n=546)	No Restrictions In Medications (n=7445)	P Value
Age (mean ± SD)	66.9 ± 10.7	69.8 ± 10.4	<0.001
Female (%)	72.5	61.4	<0.001
Ethnicity (%)			
Non-Hispanic White	69.5	87.2	<0.001
Non-Hispanic Black	17.5	7.4	
Hispanic	10.8	4.2	
Other	2.1	1.3	
Education, in years (mean ± SD)	10.5 ± 3.9	12.1 ± 3.2	<0.001
Annual household income (median, 25–75 percentile)	10,425 (4,140–22,900)	23,644 (8,780–51,164)	<0.001
Insurance status (%)			
No insurance	17.9	2.8	<0.001
Insurance with no drug coverage	37.5	26.1	
Insurance with partial or full drug coverage	44.6	71.1	
Self-reported health status (%)			
Excellent	4.1	11.6	<0.001
Very Good	13.4	28.8	
Good	29.0	32.5	
Fair	35.6	19.7	
Poor	18.0	7.4	
Number of chronic illnesses (mean ± SD)	2.7 ± 1.6	2.0 ± 1.2	<0.001
Comorbidities (%) [‡]			
Cardiovascular disease [§]	80.0	74.1	<0.01
Arthritis	76.6	55.6	<0.001
Cancer	3.0	2.4	0.40
Chronic lung disease	21.9	10.2	<0.001
Psychiatric illness	31.9	12.8	<0.001
Current smoking (%)	22.5	11.2	<0.001
Current alcohol consumption (%)			
None	69.3	52.2	<0.001
Mild/moderate	23.9	38.8	
Heavy	6.8	9.1	
BMI (%)			
<25	33.6	41.9	<0.001
25–29.9	39.6	38.7	
30+	26.8	19.5	

*All results have been adjusted for the survey's complex design and analytic weights. Because of rounding, percentages may not equal 100.

[†]Continuous variables were compared using t-tests (or adjusted Wald tests). Categorical variables were compared with Pearson χ^2 statistics.

[‡]Percentages do not equal 100%, as many respondents had more than one co-morbidity.

[§]History of a heart condition, diabetes, high blood pressure, or a prior stroke

DISCUSSION

This longitudinal study is the first to demonstrate significantly worse health outcomes among individuals who reported restricting their use of prescription medications because of cost. After adjusting for important socioeconomic characteristics and baseline health conditions and behaviors,

cost-related medication restriction was associated with almost twice the odds of experiencing a significant decline in overall health over 2 years of follow up. The association of poor disease-specific health outcomes with cost-related medication restriction was strongest among those with cardiovascular disease; there was a 50% increase in the odds of suffering

TABLE 2. Risk of Adverse Health Outcomes of Respondents Who Reported Restricting Prescription Medications Due to Cost at Baseline Vs. Respondents Who Did Not Restrict Medications

	Unadjusted			Adjusted		
	Restricted Medications due to Cost [†] (%)	No Restriction [†] (%)	Odds Ratio (95% CI)	Restricted Medications due to Cost [†] (%)	No Restriction [†] (%)	Adjusted Odds Ratio [‡] (95% CI)
A. Respondents in good to excellent health (n=5650)*						
Significant decline in health status	36.5	20.1	2.29 (1.73–3.03)	32.1	21.2	1.76 (1.27–2.44)
B. Respondents with cardiovascular disease [§] (n=5959)						
Angina	21.8	11.6	2.12 (1.65–2.72)	11.9	8.2	1.50 (1.09–2.07)
Cardiovascular event	11.3	7.6	1.54 (1.12–2.13)	7.8	5.3	1.51 (1.02–2.25)
C. Respondents with diabetes (n=1345)						
New kidney problems or protein in urine	9.4	7.5	1.28 (0.56–2.94)	7.4	6.4	1.16 (0.43–3.18)
D. Respondents with arthritis (n=4507)						
More pain or new pain	20.2	17.0	1.24 (0.94–1.63)	16.0	15.4	1.04 (0.77–1.41)
More physical limitations	39.9	42.2	0.91 (0.72–1.15)	37.9	41.4	0.86 (0.66–1.13)
E. Respondents with depression (n=1043)						
CES-D depression score [¶] (mean)	4.43	3.91	1.13 (1.03–1.24)	3.62	3.41	1.06 (0.97–1.16)

*A significant decline was defined as subsequently reporting health to be “fair” or “poor” in 1998

[†]Percentages are the weighted estimates.

[‡]All odds ratios are adjusted for age, race/ethnicity, annual household income, education, self-reported health status, smoking status, alcohol consumption, body mass index, and the presence of other co-morbidities (cardiovascular disease index, chronic lung disease, cancer, psychiatric problems, and arthritis). The regression assessing new kidney problems also adjusts for number of doctor and emergency room visits.

[§]Respondents who reported at baseline that they had any of the following conditions: hypertension, heart condition, stroke, or diabetes.

^{||}Either a non-fatal stroke or a non-fatal heart attack

[¶]Risk measure for the CES-D scale is the Incident Rate Ratio

angina and a 51% increased odds of having a nonfatal myocardial infarction or stroke among those who restricted their medication use.

Our findings provide evidence that, contrary to some claims,¹⁷ adults with chronic illnesses who restrict prescription medications because of cost experience adverse health outcomes. We did not, however, find worse disease-related outcomes for all of the specific conditions we examined. Restrictors with arthritis did not report worse pain or physical limitations in the subsequent wave, nor did respondents with diabetes who restricted medications experience higher rates of new proteinuria or kidney disease. Failure to find a differ-

ence in arthritis outcomes could be the result of suboptimal management of arthritis in practice, availability of equally effective over-the-counter pain medications, or the possibility that respondents on multiple medications could choose not to forgo their pain medications and instead restrict medications for other less acute conditions (eg, statins). In the case of diabetes, higher rates of kidney disease from restriction of diabetes medications would likely require a longer period of follow up to detect. These negative findings are also noteworthy because restrictors at baseline reported worse health and more comorbidities than those who did not restrict. Although we used multivariate methods to adjust for these

and other salient respondent characteristics, a concern about the validity of our findings is that we did not adjust adequately for these differences and thus, because of unmeasured, systematic differences between groups, would find worse outcomes on all measures among those who restricted. This was not the case.

In age-stratified analyses, we found significant declines in overall health status, worse cardiovascular outcomes, and increased depression in older Medicare-eligible individuals who restricted their medication use because of cost. These findings confirm our hypothesis that elderly adults with chronic conditions could be especially vulnerable to adverse health effects of cost-related medication restriction. We also found, however, that restriction was associated with an increased risk of a decline in health among younger non-Medicare eligible individuals. This is an important finding in light of the current debate over whether and how to enhance prescription drug insurance coverage for different populations. Although policymakers are currently focusing on pharmacy benefits for Medicare-eligible adults, our findings suggest that prescription drug coverage for adults in late middle age and not yet eligible for Medicare could contribute to decreasing the risk of adverse health outcomes.

In our study, like in other studies on this topic,^{9,13,18} the majority of respondents who restricted medications because of cost had health insurance that lacked full prescription coverage (82.1%). Our findings suggest that cost-related medication restriction could be a key mechanism by which adults who lack insurance coverage (or are underinsured) could experience worse health outcomes. A recent study by Baker and colleagues, for example, also using several waves of the Health and Retirement Study, found that lack of health insurance was associated with an increased risk of a decline in overall health over a 4-year period.²⁹ That study did not look separately at outcomes among adults with specific chronic illnesses, or at medication restriction or other possible mechanisms by which lack of insurance might lead to worse outcomes. Given the critical importance of prescription medications for treatment of chronic illnesses, the extent to which medication restriction mediates worse outcomes among chronically ill adults who lack adequate insurance or experience other barriers to health care needs to be explicitly studied.

By examining longitudinal outcomes in a nationally representative sample of adults, our study adds to the body of research on the adverse impact of cost-related medication restriction on health status and disease outcomes.¹⁸ As drug costs continue to escalate and the numbers of adults with chronic illnesses grow, it will be increasingly important for healthcare systems and physicians to develop strategies effectively to screen patients for cost-related underuse of medications and provide assistance to these patients. Moreover, public and private insurers will need to craft benefit packages

that provide appropriate coverage while taking into account both the cost of prescription coverage and downstream costs of preventable acute events.^{6,21,34-36} Longitudinal analyses should track the effects of different cost-sharing approaches for prescription coverage to compare how they affect use of essential medicines, health outcomes, and costs. Future research also should continue to examine whether more extensive prescription medication coverage among adults with chronic illnesses might in fact be associated with greater cost savings.^{37,38}

Several potential limitations should be considered when interpreting our results. First, we lacked information on which specific medications respondents had restricted and the duration and magnitude of their restriction. Moreover, to ensure that medication restriction preceded our examined health outcomes, we assessed medication restriction at baseline and health outcomes reported in the subsequent survey wave. For those respondents who might have only restricted medications once or twice, it is not clinically plausible that this degree of restriction would lead to an adverse health outcome several years later. In another national survey we conducted, however, we found that almost 80% of those who reported ever restricting medication use because of cost used less medication than prescribed more than once a month.³⁹ Second, we only included in our analyses respondents who reported taking prescription medications. It is possible that some respondents chose not to take prescription medications at all because of cost constraints and thus would not be included in our analyses. Third, our data on health outcomes were self-reported and thus subject to biases associated with such survey methods. Previous studies, however, that have evaluated the validity and reliability of self-reported chronic conditions such as hypertension, diabetes, and stroke and of medication use have shown excellent agreement between medical records and self-reports.^{33,40-42}

Fourth, as noted previously, the differences we found in health outcomes could be the result of other factors associated with medication restriction that we did not measure. For example, we only controlled for comorbidities for which we had data. If the differences we found were exclusively the result of increased disease burden among those who restricted, however, one might expect worse outcomes in both age cohorts for all the health conditions we studied as opposed to the pattern we found. Adding indicators of respondents' insurance coverage to our multivariable regression models also had no significant effects on the strength of the association between medication restriction and the outcomes. Moreover, even if some of the differences stemmed from other unmeasured factors, our results are still cause for concern, because they suggest that vulnerable adults with the greatest potential need for medications are also the most likely to restrict medication use because of cost. Fifth, in the subgroup analyses, because the numbers of respondents who

reported restricting were relatively small, we could have had insufficient power to detect differences. Finally, the follow-up period for the assessed outcomes was relatively short (with the longest possible interval between restricting medications and outcomes being 5 years). The long-term effects of medication restriction likely would be even more widespread and severe than those we found.

In conclusion, our nationally representative study found that older Americans who restrict medications because of cost face an increased risk of adverse health outcomes. In the past 5 years, significant advances have been made in developing and expanding the use of prescription medications that clearly improve health outcomes, especially in the field of cardiovascular disease.^{43,44} Many of these new medications, however, are expensive, and their costs are often borne by individuals rather than third-party payers, leading to cost-related medication restriction, especially among low-income and other vulnerable populations.⁹ As medications become even more effective, differential access to prescription drugs because of cost could further exacerbate disparities in health outcomes between rich and poor Americans. Policies that reduce the likelihood of cost-related restriction of effective medications are essential to achieve the full potential of these medications and optimize health outcomes. Moreover, individual clinicians need actively to assess whether their patients could be facing problems paying for prescription medications and be aware of strategies to address these problems.

REFERENCES

- Pourat N, Rice T, Kominski G, et al. Socioeconomic differences in Medicare supplemental coverage. *Health Aff (Millwood)*. 2000;19:186–196.
- Steinwachs DM. Pharmacy benefit plans and prescription drug spending. *JAMA*. 2002;288:1773–1774.
- 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.
- Hwang W, Weller W, Ireys H, et al. Out-of-pocket medical spending for care of chronic conditions. *Health Aff (Millwood)*. 2001;20:267–278.
- Strickland WJ, Hanson CM. Coping with the cost of prescription drugs. *J Health Care Poor Underserved*. 1996;7:50–62.
- Cox ER, Jernigan C, Coons SJ, et al. Medicare beneficiaries' management of capped prescription benefits. *Med Care*. 2001;39:296–301.
- Stuart B, Grana J. Ability to pay and the decision to medicate. *Med Care*. 1998;36:202–211.
- Sandman D, Schoen C, Downey D, et al. *New York Seniors and Prescription Drugs: Seniors Remain at Risk Despite State Efforts*. The Commonwealth Fund, December 2002.
- Steinman MA, Sands LP, Covinsky KE. Self-restriction of medications due to cost in seniors without prescription coverage. *J Gen Intern Med*. 2001;16:793–799.
- Tamblyn R, Laprise R, Hanley JA, et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. *JAMA*. 2001;285:421–429.
- Soumerai SB, Avorn J, Ross-Degnan D, et al. Payment restrictions for prescription drugs under Medicaid. Effects on therapy, cost, and equity. *N Engl J Med*. 1987;317:550–556.
- Martin BC, McMillan JA. The impact of implementing a more restrictive prescription limit on Medicaid recipients. Effects on cost, therapy, and out-of-pocket expenditures. *Med Care*. 1996;34:686–701.
- Federman AD, Adams AS, Ross-Degnan D, et al. Supplemental insurance and use of effective cardiovascular drugs among elderly medicare beneficiaries with coronary heart disease. *JAMA*. 2001;286:1732–1739.
- Johnson RE, Goodman MJ, Hornbrook MC, et al. The effect of increased prescription drug cost-sharing on medical care utilization and expenses of elderly health maintenance organization members. *Med Care*. 1997;35:1119–1131.
- Bazargan M, Barbre AR, Hamm V. Failure to have prescriptions filled among black elderly. *J Aging Health*. 1993;5:264–282.
- Artz MB, Hadsall RS, Schondelmeyer SW. Impact of generosity level of outpatient prescription drug coverage on prescription drug events and expenditure among older persons. *Am J Public Health*. 2002;92:1257–1263.
- Anonymous. As copays rise, more patients skip Rx therapy. *Connect*. December 12, 2002.
- Kennedy J, Erb C. Prescription noncompliance due to cost among adults with disabilities in the United States. *Am J Public Health*. 2002;92:1120–1124.
- Piette J, Wagner T, Potter M, et al. Health insurance status, medication self-restriction due to cost and outcomes among diabetes patients in three systems of care. *Med Care* (in press).
- Soumerai SB, Ross-Degnan D, Avorn J, et al. Effects of Medicaid drug-payment limits on admission to hospitals and nursing homes. *N Engl J Med*. 1991;325:1072–1077.
- Soumerai SB, Ross-Degnan D. Inadequate prescription-drug coverage for Medicare enrollees—a call to action. *N Engl J Med*. 1999;340:722–728.
- Soumerai SB, McLaughlin TJ, Ross-Degnan D, et al. Effects of a limit on Medicaid drug-reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. *N Engl J Med*. 1994;331:650–655.
- Soldo BJ, Hurd MD, Rodgers WL, et al. Asset and health dynamics among the oldest old: an overview of the AHEAD study. *J Gerontol B Psychol Sci Soc Sci*. 1997;52(spec no):1–20.
- Brandt J, Spencer M, Folstein M. The telephone interview for cognitive status. *Neuropsychiatry Neuropsychol Behav Neurol*. 1988;1:111–117.
- Langa KM, Chernew ME, Kabeto MU, et al. National estimates of the quantity and cost of informal caregiving for the elderly with dementia. *J Gen Intern Med*. 2001;16:770–778.
- Steffick D, HRS Health Working Group. *Documentation of Affective Functioning Measures in the Health and Retirement Study*. Ann Arbor, MI: Survey Research Center, University of Michigan; 2000.
- Radloff LS. The CES-D Scale: a self-report depression scale for research in the general population. *Journal of Applied Psychologic Measurement*. 1997;1:385–401.
- Baker DW, Parker RM, Williams MV, et al. The relationship of patient reading ability to self-reported health and use of health services. *Am J Public Health*. 1997;87:1027–1030.
- Baker DW, Sudano JJ, Albert JM, et al. Lack of health insurance and decline in overall health in late middle age. *N Engl J Med*. 2001;345:1106–1112.
- Idler EL, Benyamini Y. Self-rated health and mortality: a review of twenty-seven community studies. *J Health Soc Behav*. 1997;38:21–37.
- Rao JNK, Scott AJ. On chi-squared tests for multiway contingency tables with cell proportions estimated from survey data. *Ann Stat*. 1984;12:46–60.
- Korn EL, Graubard BI. *Analysis of Health Surveys*. New York: John Wiley; 1999.
- Stata Statistical Software*, release 7.0. College Station, TX: Stata Corp; 2001.
- Joyce GF, Escarce JJ, Solomon MD, et al. Employer drug benefit plans and spending on prescription drugs. *JAMA*. 2002;288:1733–1739.
- Fendrick AM, Smith DG, Chernew ME, et al. A benefit-based copay for prescription drugs: patient contribution based on total benefits, not drug acquisition cost. *Am J Manag Care*. 2001;7:861–867.
- Tseng CW, Brook RH, Keeler E, et al. Impact of an annual dollar limit or “cap” on prescription drug benefits for Medicare patients. *JAMA*. 2003;290:222–227.

37. Lichtenberg FR. Are the benefits of newer drugs worth their cost? Evidence from the 1996 MEPS. *Health Aff (Millwood)*. 2001;20:241–251.
38. Lichtenberg FR. Do (more and better) drugs keep people out of hospitals? *Am Econ Rev*. 1996;86:384–388.
39. Piette JD, Heisler M, Wagner TH. Cost-related under-use among chronically ill adults: what treatments do people forego? How often? Who is at risk? *Am J Public Health* (in press).
40. Rost K, Roter D. Predictors of recall of medication regimens and recommendations for lifestyle change in elderly patients. *Gerontologist*. 1987;27:510–515.
41. West SL, Savitz DA, Koch G, et al. Recall accuracy for prescription medications: self-report compared with database information. *Am J Epidemiol*. 1995;142:1103–1112.
42. Brown JB, Adams ME. Patients as reliable reporters of medical care process. Recall of ambulatory encounter events. *Med Care*. 1992;30:400–411.
43. Anonymous. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. *Lancet*. 2002;360:7–22.
44. Yusuf S, Sleight P, Pogue J, et al. Effects of an angiotensin-converting-enzyme inhibitor, ramipril, on cardiovascular events in high-risk patients. The Heart Outcomes Prevention Evaluation Study Investigators. *N Engl J Med*. 2000;342:145–153.