Cost Sharing and the Initiation of Drug Therapy for the Chronically Ill

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Background: Increased cost sharing reduces utilization of prescription drugs, but little evidence demonstrates how this reduction occurs or the factors associated with price sensitivity.

Methods: We conducted a retrospective cohort study of older adults with employer-provided drug coverage from 1997 to 2002 from 31 different health plans. We measured the time until initiation of medical therapy for 17,183 patients with newly diagnosed hypertension, diabetes, or hypercholesterolemia.

Results: For all study conditions, higher copayments were associated with delayed initiation of therapy. In survival models, doubling copayments resulted in large reductions in the predicted proportion of patients initiating pharmacotherapy at 1 and 5 years after diagnosis: for hypertension, 54.8% vs 39.9% at 1 year and 81.6% vs 66.2% at 5 years (P < .001); for hypercholesterolemia, 40.2% vs 31.1% at 1 year and 64.3% vs 53.8% at 5 years (P < .002); and for diabetes, 45.8% vs 40.0% at 1 year and 69.3% vs 62.9% at 5 years (P < .04). However, patients' rate of initiation and sensitivity to copayments strongly depended on their prior experience with prescription drugs. Those without prior drug use (26.1%, 10.4%, and 12.9%) initiated later (833, 1170, and 1402 days later in median time until initiation) and were far more price sensitive (increase of 34.5%, 20.1%, and 27.2% remaining untreated after 5 years when copayments doubled) than those with a history of drug use among patients with newly diagnosed hypertension, hypercholesterolemia, and diabetes, respectively. These results were robust to a wide range of sensitivity analyses.

Conclusions: High cost sharing delays the initiation of drug therapy for patients newly diagnosed with chronic disease. This effect is greater among patients who lack experience with prescription drugs. Policy makers and physicians should consider the effects of benefits design on patient behavior to encourage the adoption of necessary care.

Arch Intern Med. 2009;169(8):740-748

In the past decade, health plans have responded to rising prescription drug costs by implementing more restrictive insurance benefits, the hallmark of which has been increased cost sharing (ie, “co-payments”), multi-tier formularies, and mandatory generic substitution. Several studies have demonstrated that these new arrangements reduce overall drug utilization and expenditures and that the chronically ill are sensitive to out-of-pocket (OOP) costs. However, detailed mechanisms outlining how these reductions occur are lacking.

See also pages 737, 750, and 757

The interruption of drug therapy can have negative health consequences for the chronically ill, particularly for elderly patients, who have the highest rates of chronic disease and prescription drug use. Studies measuring the effect of pharmacy benefit design on drug treatment for the chronically ill are inconsistent, but surveys find cost to be the leading reason why elderly patients do not fill prescriptions, skip doses, or take smaller doses, followed by other causes, such as medication adverse effects and beliefs about whether drugs improve health. Most empirical studies of cost sharing have examined aggregate measures of utilization, such as total expenditures or days supplied, without explanations of how patients adjust their regimens. Although several studies suggest that price sensitivity depends on a drug’s therapeutic class, and that increased cost sharing may decrease “nonessential” drug use more than “essential” drug use, few studies have dissected the multiple mechanisms by which patients reduce their utilization in the face of higher cost sharing.

See Invited Commentary at end of article

To fill this gap, this study examines whether cost sharing affects the initiation of drug treatment for patients newly diagnosed with chronic disease. A sophis-
ticated understanding of the effects of drug benefits is cru-
ical for policy makers, who, rather than applying blunt
tools to control utilization, need to target those most at
risk for the potentially harmful effects of utilization
reductions.

METHODS

The RAND Human Subjects Protection Committee ruled that this
research was exempt from institutional review board approval.

DATA

We linked enrollment files, pharmacy claims, medical claims,
and the salient features of health plan benefits for retirees of
15 large employers from 1997 to 2002. Each employer offered
1 or more health plans to its elderly retirees for a total of 59
health plans covering 399,034 retirees. All but 2 employers that
offered multiple health plans provided a single drug benefit to
their retirees, such that retirees had no choice of drug ben-
efits. The content of the claims files have been described else-
where.3,5 The eText, eFigure 1, eFigure 2, and eTable provide
more details on the construction of our longitudinal data sets
from the raw claims (http://www.archintermed.com). Result-
ing data sets included 31 health plans (plan-year combina-
tions) covering 272,474 unique persons.

STUDY SAMPLE

Our algorithms to identify patients with newly diagnosed hy-
pertension (HTN), hypercholesterolemia (CHOL), and dia-
abetes (DIAB) from International Classification of Diseases, Ninth
Revision, Clinical Modification (ICD-9-CM) codes were de-
signed to ensure that “rule-out” diagnoses were excluded from
the sample. We required patients to be observed for at least their
first year in the data without any outpatient or inpatient phy-
sician visits with an ICD-9-CM code for the chronic disease (here-
after diagnosis) and without filling any disease-specific medi-
cations. Subsequent to this washout period, we required that
they have the diagnosis of interest recorded during a physi-
cian visit on at least 2 occasions, the first of which must have
occurred prior to or the same day as their first disease-specific
medication. The first diagnosis was the index date on which the
patient was considered newly diagnosed with the condition (eText,
eFigure 1, eFigure 2, and eTable). Studies that exam-
ined the validity of using claims data to identify patients with
chronic disease suggest our algorithm would yield specificity
levels of 0.85 to 0.90.6,11

Disease-specific medications were identified by matching the
pharmaceutical claims to the Redbook Database. Manual veri-
fications and edits were completed by the authors with clinical
experience (M.D.S. and J.J.E.). Medications for HTN in-
cluded angiotensin receptor blockers, angiotensin-converting
enzyme inhibitors, β-blockers, calcium channel blockers, thia-
zide diuretics, potassium-sparing diuretics, α1-inhibitors, α2-
agonists, and vasodilators. Medications for DIAB included in-
sulins, sulfonylureas, metformin, thiazolidinediones, and
α-glucosidase blockers. Medications for CHOL included sta-
sins, bile acid sequestrants, nicotinic acid, and fibric acid
derivatives.

OUTCOME VARIABLE

The primary outcome measure was the time until initiation of
prescription drug therapy, defined as the number of days be-
tween a patient’s first diagnosis and the filling of the first disease-
specific prescription. Because patients were observed from 2
to 6 years and may have been diagnosed at any time after their
first year in the data, the outcome is right-censored (ie, it was
possible that patients who were not observed initiating drug
therapy may have begun therapy after we ceased to observe
them).

EXPLANATORY VARIABLES

The main explanatory variable in our analysis was an index that
measured the generosity of a plan’s prescription drug benefits.
Multi-tier cost-sharing structures, in which drugs are separated
into different groups with different copayments, are now the stan-
dard for most prescription drug plans. For example, patients might
pay $5 for a 30-day supply for all drugs (1-tier plan), or $5 for
generics and $10 for brand-name drugs (2-tier), or $5 for gener-
ics, $10 for preferred brand-name drugs, and $25 for nonpre-
ferred brand-name drugs (3-tier). Many plans also offer dis-
counts for purchases made through mail-order or in-network
pharmacies. These complexities, in addition to mandatory ge-
neric substitution rules and restrictive formularies, mean that the
price a consumer will pay for a given drug depends not only on
its tier but also on where it is dispensed. To capture these fea-
tures, we developed a single index that summarized the average
annual OOP expense that members of a standard sample would
have paid for their prescription drugs had they faced the copay-
ments and restrictions of each plan. This OOP index is similar to
what would be calculated for the medical consumer price index,
but it is specific to each plan. Details on calculating the OOP in-
dex have been described elsewhere6 and are included in eFigure 2.
The OOP index ranked plans by their cost-sharing structure in a
manner consistent with their absolute and relative copayment lev-
els. We also calculated separate OOP indices for disease-specific
medications to measure the OOP burden for specific drug classes,
but these indices were highly correlated with the overall OOP in-
dex value and yielded the same results.

Covariates in the models included indicators for age categories;
an indicator for sex; median household income in the zip code of
residence; a categorical variable for urban residence; indicators for
the year of the index date to control for secular time trends; selected
outpatient medical benefits to include an exogenous measure of
outpatient medical utilization; and indicators for 13 comorbidity
conditions as health status controls, identified by ICD-9-CM codes from
physician visits in the year prior to a patient’s index date. Finally,
we included an indicator variable for any prescription medication
use in the year prior to the index date and, in some models, the
interaction of this indicator and the OOP index, to assess whether
prior use of prescription drugs affected time until initiation of drug
therapy and price responsiveness.

STATISTICAL ANALYSIS

Because the data were structured in a time-to-event framework,
we used survival analysis techniques. For unadjusted analyses, we
used Kaplan-Meier methods and log-rank tests to compare survival
functions. For adjusted analyses, we estimated 6 multivariate Cox
proportional hazards models. For each of the 3 study conditions,
we estimated main effects and interacted model. The main effects
models included the variables described, and the interacted mod-
els included the interaction between the OOP index and indica-
tor prior drug use. To make the results easier to understand, we
used the multivariate models to predict the effect of doubling co-
payments on the time to initiation for each study condition. For
the predictions, we chose to double an OOP index value near the
25th percentile for the plans in our sample (OOP index = 203), which
corresponded to a 1-tier $5/$10 retail/mail-order copayment plan.
This ensured that both the baseline and doubled copayment val-
We conducted multiple sensitivity analyses to assess the robustness of our results. First, to ensure that rule-out diagnoses were not affecting our findings, we tested the models using restrictive inclusion criteria designed to produce samples with more homogeneous and severe disease, including samples that required patients to have at least 3 outpatient physician visits for the disease condition after diagnosis, and required that the second and third visits be at least 30 days apart. Second, we examined whether the type of drug used prior to initial diagnosis changed our model outcomes. Specifically, we separated the effect of prior medications used to treat conditions that contributed additional cardiovascular risk (defined as drugs for HTN, CHOL, DIAB, coronary artery disease, congestive heart failure, and vascular disease) from remaining medications. Third, we examined patients who used a small supply of medications in the prior year—as little as 30 days worth of medications—as well as those patients who used only antibiotics in the prior year. Finally, we estimated models that included controls for physician visits; examined alternative definitions for comorbid conditions; excluded the oldest subjects (age > 80 years); and excluded plans requiring coinsurance, the least generous plans in our sample.

## RESULTS

### DESCRIPTIVE RESULTS

Table 1 summarizes the characteristics of our 3 study samples, which included 7879, 6450, and 4486 patients with newly diagnosed HTN, CHOL, and DIAB, respectively. Little overlap existed between the 3 samples; together, the analyses included 17,183 unique patients (Table 1). Within each sample, however, the study conditions were the most frequent—that is, HTN, CHOL, and DIAB. The samples included more women than men; age was similar across samples; for all conditions, nearly half of patients were between ages 65 and 74 years (46.3% for HTN, 54.1% for CHOL, 47.5% for DIAB). The mean (SD) duration of observation after diagnosis was 877 (540) days for HTN, 930 (544) days for CHOL, and 799 (533) days for DIAB. Age was similar across samples; for all conditions, nearly half of patients were between ages 65 and 74 years (46.3% for HTN, 54.1% for CHOL, 47.5% for DIAB). The samples included more women than men; as age increased, the proportion of men decreased. Most patients used at least 1 other medication in the year prior to the index date, but a substantial proportion from each group had no prior prescription drug use (26.1% for HTN, 10.4% for CHOL, and 12.9% for DIAB). Cardiovascular drugs, central nervous system drugs, and hormone and/or synthetic treatments were the most commonly used drugs in the year prior to diagnosis, accounting for 52% of prescriptions.

Overall, the mean (SD) OOP index value at the plan level was 305 (118), with an interquartile range of 220 to 370. Three-tier plans were the most prevalent in the sample and included the largest share of each sample’s patients (Table 2). In addition, 3-tier plans were, on average, the most generous plans, as measured by the OOP index. This was due to two factors. First, 3-tier plans had lower copayments for generic drugs (vs 1- and 2-tier plans) and preferred brand drugs (vs 2-tier plans) at retail pharmacies and
lower copayments at mail-order pharmacies across all tiers (vs 1- and 2-tier plans). Second, mail-order copayments were higher in 1- and 2-tier plans than in 3-tier plans. The 5 co-insurance plans were the least generous plans and had flat coinsurance rates of 25% (n=2), or 2-tier rates of 20% and 45% (n=1) or 35% and 60% (n=2).

Table 3 lists examples of pharmacy benefits and OOP index values for plans in the lower, median, and upper percentiles of the OOP index in our sample. Several formulations of plans, including 1-, 2-, and 3-tier plans, yielded OOP index values near those used for our predictions (OOP indexes of 205 and 410). As noted, the OOP index depended on the magnitude of both retail pharmacy and mail-order cost-sharing arrangements.

Table 1 displays the Kaplan-Meier survival estimates for the number of days until a patient’s first prescription for their newly diagnosed HTN, CHOL, or DIAB. The figure separates survival functions for patients in plans above and below the median OOP index. For all conditions, the rate of initiation was high in the first several months after diagnosis; subsequently, the rate of initiation slowed. Log-rank tests showed that for each condition, survival functions for patients in high- and low-OOP index groups were significantly different: P < .001 for HTN; P < .001 for CHOL; and P = .04 for DIAB. Thus, in the unadjusted data, higher cost sharing was associated with delayed initiation of drug therapy. At 5 years after diagnosis, the percentage (95% confidence interval) of patients remaining untreated with medications in our sample was 21.5% (19.9%-23.1%) for HTN, 36.0% (34.3%-37.8%) for CHOL, and 32.5% (30.1%-34.9%) for DIAB.

Multivariate Results

Figure 2 shows that doubling copayments resulted in large differences in the predicted time until initiation for all study conditions. When copayments doubled, the predicted percentage of patients with newly diagnosed HTN initiating pharmacotherapy fell from 54.8% to 39.9% at 1 year and from 81.6% to 66.2% at 5 years (P < .001). For patients with newly diagnosed CHOL, the proportion initiating pharmacotherapy fell from 40.2% to 31.1% at 1 year and from 64.3% to 53.8% at 5 years (P < .002). For patients with newly diagnosed
DIAB, initiation fell from 45.8% to 40.0% at 1 year and 69.3% to 62.9% at 5 years (P = .04). The difference in the median number of days until pharmacotherapy that resulted from doubling copayments was substantial for all study conditions (244 vs 776 days for HTN; 766 vs 1382 days for CHOL; and 527 vs 813 days for DIAB).

**Figure 3** demonstrates that the rate of initiation of drug therapy and the effect of doubling copayments depended on a patient’s history of prescription drug use. Compared with patients with no drug use in the year prior to the index date, patients with any drug use in that period initiated pharmacotherapy earlier and were much less price sensitive. For example, holding cost-sharing levels constant at the lower of our 2 predicted levels (OOP index, 205), the percentage of patients initiating drug therapy by 1 year after diagnosis was much larger among patients with a history of prior drug use for all study conditions: 60.7% vs 40.3% for HTN (P < .001); 41.9% vs 21.0% for CHOL (P < .001); and 48.4% vs 30.4% for DIAB (P < .001).

Doubling copayments among patients with a history of drug use resulted in small differences in the rate of initiation, and the model yielded statistically significant differences only for patients with newly diagnosed HTN or CHOL: 60.7% vs 54.4% at 1 year for HTN (P = .02); 42.0% vs 36.3% at 1 year for CHOL (P = .03); and 48.5% vs 48.0% at 1 year for DIAB (P = .85). By contrast, among patients without a history of drug use, the effect of doubling copayments resulted in large, statistically significant dif-
ferences in survival functions for all study conditions: 40.3% vs 16.6% at 1 year for HTN (P<.001); 21.1% vs 9.5% at 1 year for CHOL (P<.002); and 30.5% vs 12.9% at 1 year for DIAB (P<.001).

SENSITIVITY ANALYSES

We tested more homogeneous samples of higher disease severity; different types and quantities of drugs used in the prior year; various definitions of comorbid conditions; added controls for physician visits; exclusions of the oldest patients; and coinsurance plans (data not shown). None of these sensitivity analyses appreciably changed our model results.

Previous work has established that the chronically ill are sensitive to the cost of prescription drugs. Our study looked at 1 component of utilization: the initiation of drug therapy after diagnosis. We found that increased cost sharing delays the initiation of medications to treat newly diagnosed chronic disease, suggesting that OOP costs may prevent patients from initiating medically necessary care.

In addition, we found that the initiation of drug therapy and sensitivity to prices depends on a patient’s experience with prescription drug use. Relative to those without experience, patients with experience using prescription drugs were less price-sensitive and adopted therapy earlier, suggesting that patients differ in their willingness to initiate prescription drug therapy. For some patients, an initial resistance against treatment may be reduced once experience using prescription drugs is established. We found no threshold effect for the number of prior or concurrent medications at which the results of our models changed. Thus, our data suggest that OOP costs may prevent patients from initiating treatment—which could negatively impact health outcomes—but that patient sensitivity to prices strongly depends on whether patients have experience using prescription drugs.

Most prescription drug initiation occurred soon after diagnosis, with a subsequent slowing in the rate of initiation. Also, the effect of cost sharing on the rate of initiation was largest soon after diagnosis, but declined over time. However, the price sensitivity of patients without prescription drug experience declined less rapidly than for those with drug experience, indicating the persistent effect that increased copayments had in this population—a potential indication of a preference against drug therapy.

Our survival estimates were consistent with epidemiologic studies from the National Health and Nutrition Examination Survey (NHANES) III and other sources that estimate the proportion of patients who are aware they have a medical condition but remain untreated. In the study, the proportion of newly diagnosed patients who had not initiated anti-HTN, anti-CHOL, or anti-DIAB drug therapy by 5 years was 21.5%, 36.0%, and 32.5%, respectively. Consistent with our data, a variety of studies indicate that the proportion of patients aware of their hypertension but without drug treatment ranges from 8% to 68%; the Framingham Heart Study, 68.3% of patients with newly diagnosed HTN had not initiated antihypertensive therapy by 4 years, including 53.9% of those with stage 2 hypertension at baseline, and recent estimates range from 8% in a Veterans Affairs institution population to 38% to 55% in a community population. Untreated CHOL among those aware of their condition is a well-documented and chronic problem. Our estimate of the proportion diagnosed but untreated by 5 years is at the lower end of most population-based estimates, which range from 25% to 66%.

Figure 3. Effect of doubling copayments on the initiation of drug therapy for patients with newly diagnosed chronic disease with and without prior drug use. An out-of-pocket cost (OOP) index of 205 roughly corresponded to a 1-tier $5/$10 retail/mail-order copayment plan (actual OOP index, 206.7). An OOP index of 410 roughly corresponded to a 3-tier $5-$15-$20/$10-$20-$30 retail/mail-order copayment plan (actual OOP index, 425.7). Both values were well within the range observed in the sample. For patients with newly diagnosed hypertension, hypercholesterolemia, and diabetes, 26.1%, 10.4%, and 12.9% of each respective sample had no prescription drug use in the year prior to diagnosis.
Among patients diagnosed with DIAB, estimates of the proportion without drug treatment range from 8% to 47%; recent analyses of NHANES data yield estimates ranging from 19% to 28.6%. In fact, 23.2% of patients with DIAB who survived a myocardial infarction or stroke, a group likely to be hypervigilant about controlling cardiovascular risk factors, did not use antidiabetic medications. Although our estimate of the proportion of patients newly diagnosed with DIAB who remained untreated after 5 years was slightly higher than NHANES estimates, NHANES subjects carried their diagnoses for 2 to 3 times longer than our 5-year follow-up period, and the proportion of untreated patients with DIAB increases with age.

There are several limitations to our study. First, our sample may not be generalizable to a younger population. However, Medicare Part D has increased the proportion of elderly retirees who have prescription drug insurance. Thus, our results are particularly relevant for federal policy makers setting standards for Medicare Part D insurance packages.

Second, we could not completely control for selection of drug benefits. However, for all but 2 employers in the sample, employees had no choice of drug benefits, minimizing the possibility that employees selected plans suited to their anticipated needs, and patients with these 2 employers accounted for less than 2.5% of the sample. Excluding these patients did not change our results. Third, despite controls for comorbidities, disease severity may differ between patients with and without prior drug experience. Although administrative data do not contain detailed clinical information contained in medical charts, our sensitivity analyses examine more homogeneous and severe disease did not change our findings. One initial treatment option for patients newly diagnosed with less severe disease is to initiate nonpharmacological therapy such as diet modification and exercise. However, there was no priori reason that disease severity was correlated with benefit generosity, since almost no patients in our study had a choice of drug benefits plans. Furthermore, analysis of the NHANES data has shown that patients diagnosed with hypertension without pharmacologic treatment have, for example, disease severe enough to warrant treatment (systolic blood pressure >140 mm Hg).

Finally, although the data are a few years old, the phenomena studied here are likely to be generalizable and enduring ones. Our results suggest a novel distinction between groups of patients, some of whom are price-sensitive to prescription drugs and others who are not. Although most patients in our sample had experience using prescription drugs, the large impact of cost sharing on those without experience make this population a prime target for interventions to encourage the adoption of appropriate treatment, particularly for patients newly diagnosed with diseases that contribute cardiovascular risk. Future research should explore the mechanisms underlying our results, such as the factors that may influence the effect of cost sharing within specific patient populations, and should examine the health outcomes of varying times to initiation of drug therapy for chronic disease.

Our findings have implications for policy makers designing insurance benefits and for physicians treating patients with chronic disease. First, these results raise concerns about high cost-sharing levels for elderly, insured patients without experience using prescription drugs. Based on our findings, high cost-sharing levels could be a barrier to treatment for this population and possibly result in poor health outcomes. Physicians should also heed these findings when treating patients with newly diagnosed HTN, CHOL, or DIAB; those without experience with pharmacologic therapy may be less likely to initiate prescribed treatments and may be very sensitive to cost-sharing levels.

More broadly, these results add to the growing consensus that our reliance on blunt instruments to influence utilization, such as formularies and tiered copayments, which are primarily used to manage cost, need to be updated with more sophisticated tools that take into account therapeutic need as well as patients' complex responses to insurance benefits. For example, recent evidence indicates that among patients who initiated new medications for treatment of chronic disease, adherence is poorer for those who begin with high copayments than for those who begin with lower copayments that gradually increase. This suggests that new users are likely to be more price sensitive than continuing users and is congruent with our finding that patients with prescription drug experience are less price-sensitive. Lessons such as these need to be incorporated into benefits design to ensure that patients who require medical therapy are not discouraged from initiating treatment.

Accepted for Publication: November 3, 2008.

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Author Contributions: Dr Solomon had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Solomon, Goldman, Joyce, and Escarce. Acquisition of data: Solomon, Goldman, Joyce, and Escarce. Analysis and interpretation of data: Solomon, Goldman, Joyce, and Escarce. Drafting of the manuscript: Solomon. Critical revision of the manuscript for important intellectual content: Solomon, Goldman, Joyce, and Escarce. Statistical analysis: Solomon, Goldman, Joyce, and Escarce. Obtained funding: Solomon. Administrative, technical, and material support: Solomon. Study supervision: Solomon, Goldman, Joyce, and Escarce.

Financial Disclosure: Dr Goldman has received honoraria and consulting income from Amgen, Genentech, and UnitedHealth.

Funding/Support: This research was supported by grant R03 HS013869-01 from the Agency for Healthcare Research and Quality, Rockville, Maryland, with additional funding from the California HealthCare Foundation, Oakland, California. Data were provided by Ingenix Inc, Eden Prairie, Minnesota.

Role of the Sponsor: Neither the Agency for Healthcare Research and Quality nor California HealthCare Foun-
lication had any authority over the design or conduct of this study; the collection, analysis, preparation, or interpretation of the data; or the preparation of the manuscript.

Additional Information: The RAND Corporation is solely responsible for this article's content. The eText, eFigure 1, eFigure 2 and, eTable are available at http://www.archinternmed.com.

REFERENCES


C ost-related nonadherence (CRN) is common, and one-third of older adults take less medication than prescribed to reduce out-of-pocket costs. Common strategies to reduce out-of-pocket costs include splitting pills, skipping doses, or delaying refills, all secondary forms of nonadherence. Less attention has been paid to “primary” nonadherence, ie, not even filling the prescription. This strategy is the most effective way to reduce out-of-pocket costs, and primary nonadherence is practiced by 10% to 20% of patients.

Short of a randomized trial, the best way to understand the effect of out-of-pocket costs on primary or secondary nonadherence would be to undertake a large longitudinal study of older insured patients who are “exposed” to drug benefit plans of differing generosity and who go on to develop an incident diagnosis of a chronic condition that requires new treatment and then have to pay out-of-pocket. This subgroup analysis suggests that starting treatment far longer than those who had experience with prescription drugs. “Inexperienced” patients did, however, constitute a sizable and easily identified minority of the population (ie, 26% of those with new hypertension, 10% with dyslipidemia, and 13% with diabetes). The subgroup analysis suggests that starting a prescription medication for the first time for an asymptomatic condition and then having to pay out-of-pocket for the opportunity is too bitter a pill to swallow for many patients.

What do these provocative findings mean? For policymakers, it means that blunt instruments such as cost sharing lead to blunt effects, both intended (drug cost savings) and unintended (delays in the initiation of treatment and other forms of CRN that lead to suboptimal health and perhaps to increased total costs). More evidence-informed and patient-centered strategies to minimize the unintended consequences of cost sharing need to be developed and then tested in randomized trials or quasi-experimental studies.

For physicians, it means acknowledging that 10% to 20% of patients never fill our prescriptions and that we need to pay more attention to out-of-pocket costs and discuss them at every opportunity. Unfortunately,