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Health Services Research

The Impact of Reducing Cardiovascular Medication Copayments on Health Spending and Resource Utilization

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Objectives The aim of this study was to evaluate the impact of reductions in statin and clopidogrel copayments on cardiovascular resource utilization, major coronary events, and insurer spending.

Background Copayments are widely used to contain health spending but cause patients to reduce their use of essential cardiovascular medications. Reducing copayments for post–myocardial infarction secondary prevention has beneficial effects, but the impact of this strategy for lower risk patients and other drugs remains unclear.

Methods An evaluation was conducted of health care spending and resource use by a large self-insured employer that reduced statin copayments for patients with diabetes or vascular disease and reduced clopidogrel copayments for all patients prescribed this drug. Eligible individuals in the intervention company (n = 3,513) were compared with a control group from other companies without such a policy (n = 49,803). Analyses were performed using segmented regression models with generalized estimating equations.

Results Lowering copayments was associated with significant reductions in rates of physician visits (relative change: statin users 0.80; 95% confidence interval [CI]: 0.57 to 0.98; clopidogrel users: 0.87; 95% CI: 0.59 to 0.96) and hospitalizations and emergency department admissions (relative change: statin users 0.90; 95% CI: 0.80 to 0.92; clopidogrel users: 0.89; 95% CI: 0.74 to 0.90) although not major coronary events. Patient out-of-pocket spending for drugs and other medical services decreased (relative change: statin users 0.79; 95% CI: 0.75 to 0.83; clopidogrel users 0.74; 95% CI: 0.66 to 0.82). Providing more generous coverage did not increase overall spending (relative change: statin users 1.03; 95% CI: 0.97 to 1.09; clopidogrel users 0.94; 95% CI: 0.87 to 1.03).

Conclusions Lowering copayments for statins and clopidogrel was associated with reductions in health care resource use and patient out-of-pocket spending. The policy appeared cost neutral with respect to overall health spending.
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Nonadherence to cardiovascular medication is exceptionally common and results in preventable morbidity, mortality, and health spending (1). Reducing patient copayments for highly effective, evidence-based therapies has been proposed as a method of stimulating greater adherence that may also reduce health spending (2). This strategy has been met with particular

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Abbreviations and Acronyms

CI = confidence interval

ICD-9 = International Classification of Diseases-Ninth Revision

enthusiasm from employers and health plans throughout the United States. (3). The Patient Protection and Affordable Care Act, passed in March 2010 (4), calls for the creation of guidelines to facilitate the broader use of this strategy, which is generally called value-based insurance design or evidence-based plan design (5).

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The existing evidence supports the ability of copayment reductions to increase essential medication use (6), and economic models suggest that these changes in adherence should be associated with meaningful improvements in health and reductions in resource utilization and could consequently lower overall health spending (2,7–9). However, the empirical research evaluating the impact of actual medication copayment reductions on these outcomes is extremely limited (10,11).

The recently published MI FREEE (Post–Myocardial Infarction Free Rx Event and Economic Evaluation) trial demonstrated that lowering copayments for statins, beta-blockers, and renin-angiotensin system antagonists prescribed to patients recently discharged after myocardial infarction improved adherence and reduced rates of major vascular events (although not revascularization) without increasing overall health spending (12). However, the trial enrolled high-risk patients, and thus the generalizability of the results to other patient groups or other classes of evidence-based drugs is unclear.

A policy change introduced by a large Fortune 500 creates a natural experiment and the opportunity to help fill this knowledge gap. Pitney Bowes eliminated copayments for statins for patients with diabetes or patients receiving treatment for vascular disease and lowered them for clopidogrel among all patients prescribed this drug (13). Introduction of this policy resulted in improvements in statin and clopidogrel adherence of 3 and 4 percentage points, respectively (13). We evaluated whether this benefit design change also affected cardiovascular resource utilization, major coronary events, and insurer spending.

Methods

Setting and design. We used an interrupted time-series design with a concurrent control group to evaluate the effect of reducing copayments for cardiovascular medications on rates of medication filling, resource utilization, major coronary events, and spending. This method compares actual post-policy outcome rates with those that would have been expected if pre-policy outcomes were extrapolated into the future; the analysis also adjusts for trends in a comparison population for whom copayments were not changed.

The intervention group was drawn from employees and retirees of Pitney Bowes. The company provides pharmacy coverage using a 3-tier coinsurance design; beneficiaries also have access to an Internet-based health portal that contains information on chronic disease awareness and treatment as well as a voluntary disease management program. These programs were introduced several years before the January 1, 2007 copayment reductions, and the company did not introduce any new disease management programs or otherwise change their benefits structure during the study period. Copayments for nondrug services also remained constant during this time period. For example, copayments for primary care physician office visits among Pitney Bowes beneficiaries were $20 in both 2006 and 2007.

The control group consisted of employees of other companies who were insured by Horizon Blue Cross Blue Shield of New Jersey, the largest insurer in New Jersey. Similar to Pitney Bowes, Horizon offers disease management programs for patients with chronic diseases but did not introduce any new programs during the study period or change copayments for the medications being studied. Pitney Bowes and Horizon both use the same pharmacy benefit manager.

We combined complete paid pharmacy and medical services claims data to create a relational database consisting of all filled prescriptions, procedures, inpatient and outpatient physician encounters, hospitalizations, long-term care admissions, and deaths for all patients studied. All traceable person-specific identifying factors were transformed into anonymous, coded study numbers to protect subjects' privacy. The institutional review board of Brigham and Women's Hospital approved this study.

Cohort eligibility. We created separate cohorts to study copayment reductions for statins and clopidogrel based on methods we have described previously (13). The statin cohort consisted of patients who filled prescriptions for any medication in this class between January 1, 2006, and December 31, 2007. Because statin copayments were eliminated only for patients with diabetes or vascular disease, we restricted both the intervention and the control groups to patients who fulfilled these eligibility criteria used by Pitney Bowes. Specifically, we included only patients who had 1 or more claim for a ≥14-day supply of a diabetes medication or equipment (test strips or kits, insulin injection devices, syringes, needles, lancets) or (as evidence of vascular disease) a beta-blocker (including combination pills) or a platelet inhibitor (clopidogrel, ticlopidine, dipyridamole, or cilostazol) in the 6-month period before January 1, 2007. In measuring medication use outcomes, we did not consider users of combination atorvastatin-amlodipine (Caduet; Pfizer Inc., New York, New York), because this medication was not subject to the copayment reduction, but we included users of all other combination statin products.

The clopidogrel cohort consisted of patients who filled prescriptions for this drug between January 1, 2006, and December 31, 2007. Because clopidogrel copayments were

reduced for all patients prescribed this drug (i.e., not only those who fulfilled specific clinical criteria), no additional inclusion or exclusion criteria were applied to this cohort.

Patients entered both the statin and clopidogrel cohorts on the dates of their first medication fills after January 1, 2006, and were followed until they died or lost insurance eligibility or the study period ended. Patients who were eligible for copayment reductions for both medication classes appeared in both cohorts.

Outcomes. In both the intervention group and the control group, we measured monthly rates of medication filling before and after the introduction of the new copayment policy for those defined as eligible for reduced copayments. We also measured resource utilization, including coronary events. Resource use consisted of emergency department admissions, hospitalizations, and physician visits for all causes. Major cardiovascular events were defined on the basis of validated diagnosis and procedure codes as hospitalizations for any of the following conditions: acute myocardial infarction (International Classification of Diseases-Ninth Revision [ICD-9], codes 410.x [except 410.x2] as the principal or secondary diagnosis with a length of stay of >3 days and <180 days), unstable angina (ICD-9 codes 411.x as the principal diagnosis), percutaneous coronary intervention (ICD-9 code 36.01, 36.02, 36.05, 36.06, 36.07, or 36.09), and coronary bypass surgery (ICD-9 codes 36.1x and 36.2x; Current Procedural Terminology, Fourth Edition, codes 33510 to 33536, 33545, and 33572).

We assessed the policy change's impact on patient, insurer, and combined patient and insurer spending. Spending was categorized into medical services (i.e., physician visits, emergency department admissions, hospitalizations, and outpatient procedures), prescription drugs, and the combination of these 2 (i.e., total spending) on the basis of the paid amounts appearing in the insurers' claims data. Patient spending on prescription drugs was calculated using the sum of monthly copayments and coinsurance amounts.

Monthly rates of all outcomes were standardized to 30-day intervals by dividing outcome rates by the number of days in the month (or the number of days the patients was eligible in the month) and then multiplying this amount by 30.

Covariates. We assessed several patient characteristics as of the date of cohort entry, including age, sex, income, and race. Data on socioeconomic status and race were obtained by linking ZIP codes of residences with data from the U.S. census, which specified the median income and racial composition of the geographic population associated with each ZIP code. Income and race were dichotomized as being greater or less than the median income or percent of black residents, respectively, for the patients in our cohort. Comorbidities were assessed on the basis of medical service and pharmacy claims from the 12-month period before cohort entry and included coronary artery disease (ICD-9 codes 410.x to 414.x, 429.2, and V45.81), congestive heart failure (ICD-9 codes 428.x), diabetes (ICD-9 codes 250.x), hypertension (ICD-9 codes 401.x to 404.x), Charlson comorbidity score (≥5 or <5), number of hospitalizations (≥4 or <4), and number of prescription medications (≥4 or <4) (14).

Statistical analysis. We began our analyses by plotting monthly medication filling resource use, clinical outcomes, and spending for the intervention and control groups before and after the new policy went into effect. We evaluated whether the policy change was associated with changes in the proportion of eligible patients who filled in a given month using generalized linear models. Our regression models included a constant term, a linear time trend (which measures the pre-intervention slope), a binary indicator for exposure (i.e., intervention vs. control), and a binary indicator for the post-intervention time period. Intervention effects were assessed with the interaction term between exposure and the post-intervention time period parameter.

We then used patient-level segmented regression to quantitatively evaluate whether the benefit design change was associated with changes in resource use. In these models, repeated observations were made on patients in each month. Thus, to control for correlated error terms, we used generalized estimating equations with a first-order autoregressive covariance structure, adjusting for the covariates listed previously. Because of the skewed nature of resource use and spending data, we used a log link function with variances proportional to the mean (i.e., Poisson distributed errors) (15). As a specification check, we also modeled costs with an identity link function and gamma distributed errors. These analyses yielded results very similar to our primary analysis (data not shown). We also evaluated the impact of the copayment policy after including a 3-month transition period for policy adoption, beginning 1 month before and lasting 2 months after January 1, 2007. We also repeated our analyses in those patients who had initiated the statin or clopidogrel therapy before January 1, 2007, to evaluate the impact of the policy only on "prevalent users" rather than those patients who began therapy in response to it. These analyses yielded virtually identical results to those of the primary analyses (data not shown).

Results

The study groups consisted of 2,830 patients who were eligible for copayment reductions (n = 2,051 statin users and n = 779 clopidogrel users) and 49,801 controls (n = 38,174 statin users and n = 11,627 clopidogrel users). The baseline characteristics of these patients are presented in Table 1. Compared with controls, patients in the reduced statin copayment group were older, were more likely to be male, had lower incomes, and were less likely to have hypertension but were similar with regard to other characteristics, including race and the presence of other clinical comorbidities. Differences between the clopidogrel reduced copayment group and controls were more marked: interven-

Table 1 Patient Characteristics

Characteristic	Statin Users			Clopidogrel Users		
	Intervention (n = 2,051)	Control (n = 38,174)	p Value	Intervention (n = 779)	Control (n = 11,627)	p Value
Demographics						
Age (yrs)	58.8 ± 10.1	53.8 ± 7.3	<0.0001	67.5 ± 12.7	54.5 ± 7.0	<0.0001
Women	36.1%	39.8%	0.01	37.6%	28.8%	<0.0001
Income ($)	56,625 ± 21,577	58,263 ± 19,993	<0.0001	54,715 ± 21,886	57,286 ± 19,458	0.0004
Black race	11.5%	11.9%	0.37	10.2%	12.3%	0.004
Comorbid conditions						
Coronary artery disease	26.3%	25.3%	0.29	60.6%	43.8%	<0.0001
Congestive heart failure	1.8%	1.8%	0.86	1.8%	2.4%	0.28
Hypertension	50.0%	59.5%	<0.0001	55.5%	46.4%	<0.0001
Diabetes	36.2%	34.5%	0.12	12.6%	9.9%	0.02
Charlson comorbidity score	1.0 ± 1.3	1.0 ± 1.3	0.72	3.3	3.3	<0.0001
Medication use in prior year	9.0 ± 6.1	9.1 ± 6.6	0.21	12.6 ± 9.2	10.3 ± 9.4	<0.0001
Hospitalizations in prior year	0.2 ± 0.6	0.2 ± 0.5	0.001	0.4 ± 0.7	0.3 ± 0.7	<0.0001
Monthly medication copayments for study class* ($)						
Year before copayment reduction	24.18 ± 21.31	11.80 ± 11.46	<0.0001	17.22 ± 16.74	10.65 ± 10.48	<0.0001
Year after copayment reduction	0.60 ± 3.82	11.95 ± 11.44	<0.0001	8.86 ± 6.97	14.43 ± 13.38	<0.0001
Follow-up time, months	19.7 ± 5.8	18.4 ± 6.3	<0.0001	15.0 ± 7.8	16.5 ± 7.4	<0.0001

Values are mean ± SD or as %. *Statins or clopidogrel as appropriate.

tion patients were older; more likely to be female, to be of white race, and to have coronary artery disease, diabetes, hypertension; and used more medications in the year prior to cohort inclusion but were similar with regard to income status, Charlson score, and the number of past hospitalizations.

In 2006, the year before the intervention began, statin and clopidogrel copayments were higher in the intervention group than in the control group (mean monthly statin copayment $24.18 vs. $11.80, mean monthly clopidogrel copayment $17.22 vs. $10.65) (see Table 1). The policy change produced substantial reductions in copayments in the intervention cohort (mean monthly statin copayment $0.60, mean monthly clopidogrel copayment $8.86). Among controls, monthly copayments increased by $0.15 for statins and by $3.78 for clopidogrel.

Medication use. Rates of monthly statin and clopidogrel filling among intervention and control patients are presented in Figures 1 and 2, respectively. Adjusting for baseline trends, the new copayment policy resulted in an increase in the monthly rate of statin filling of 7.1 percentage points (95% confidence interval [CI]: 5.3 to 8.8 percentage points; $p < 0.001$). Similarly, the rate of clopidogrel filling increased by 5.9 percentage points (95% CI: 3.5 to 8.2 percentage points; $p < 0.001$).

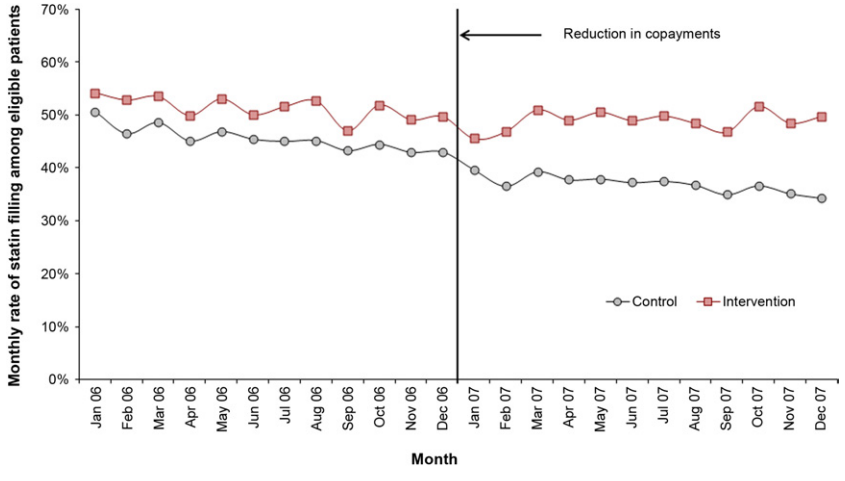

Figure 1 Statin Filling Rates

Statin filling rates before and after copayments were reduced compared with controls.

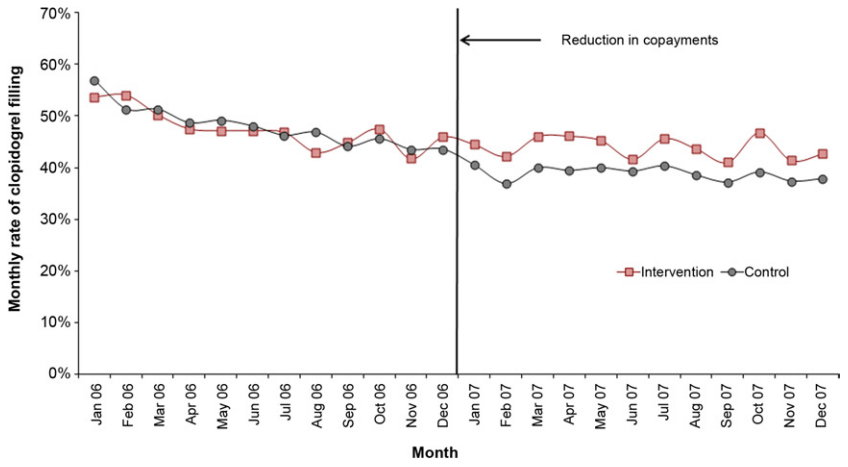

Figure 2 Clopidogrel Filling Rates

Clopidogrel filling rates before and after copayments were reduced compared with controls.

Resource use and clinical outcomes. The impact of lowering copayments on resource utilization and major coronary events is presented in Table 2. Compared with controls, the new policy was associated with statistically significant reductions in rates of physician visits and hospitalizations and emergency department admissions for patients in both study cohorts. For example, rates of physician visits (relative change: statin users 0.80; 95% CI: 0.57 to 0.98; clopidogrel users 0.87; 95% CI: 0.59 to 0.96) decreased with copayment reduction. Eliminating copayments was also associated with reductions in hospitalization or emergency department admission in both cohorts (relative change: statin users 0.90; 95% CI: 0.80 to 0.92; clopidogrel users 0.89; 95% CI: 0.74 to 0.90). Rates of major coronary events or coronary revascularization procedures were not significantly changed (Table 2). Results among the subgroup of patients who had initiated therapy before the start of the new copayment policy were virtually identical.

Spending. Monthly rates of insurer spending for statins and clopidogrel users before and after copayment reduction are shown in Figures 3 and 4, respectively. For patients taking statins, the new copayment policy was associated with significant increases in insurer prescription drug spending (relative change 1.14; 95% CI: 1.10 to 1.19) but no significant changes in insurer medical spending (relative change 1.02; 95% CI: 0.90 to 1.16) (Table 3). Combined insurer pharmacy and medical spending for the statin cohort increased by 8% (relative change 1.08; 95% CI: 1.01 to 1.15). In contrast, patient out-of-pocket spending for prescription drugs and other nondrug services decreased significantly (relative change 0.79; 95% CI: 0.75 to 0.83), and therefore overall, combined insurer and patient spending for drugs and medical services was not significantly changed (relative change 1.03; 95% CI: 0.97 to 1.09). Results among clopidogrel users (Table 3) and the subgroup of patients who had initiated therapy before the start of the new copayment policy (data not shown) were very similar.

Discussion

Programs to enhance cardiovascular medication adherence by strategically reducing patient cost sharing are believed to hold much promise for improving cardiovascular quality in a cost-efficient manner (4,13). In keeping with this, the recently published MI FREEE trial found that eliminating copayments for statins, beta-blockers, and renin-angiotensin system antagonists had beneficial clinical and economic effects among post–myocardial infarction patients (12). And although the existing peer-reviewed research supports the ability of this quality improvement strategy to increase appropriate medication use in a broader range of patients (3,13), the impact of this approach on cardiovascular health services use and

Table 2 Impact of Copayment Reductions on Resource Utilization

Cohort	Impact of Copayment Reduction*	Physician Visits	Hospitalizations or Emergency Department Admissions	Coronary Events or Revascularization
Statin	Relative change in level of resource use (95% CI)	0.80 (0.57–0.98)	0.90 (0.80–0.92)	1.19 (0.22–2.21)
Clopidogrel	Relative change in level of resource use (95% CI)	0.87 (0.59–0.96)	0.89 (0.74–0.90)	1.10 (0.66–2.02)

*Adjusted for age, sex, income, race, coronary artery disease, congestive heart failure, diabetes, hypertension, Charlson comorbidity score, and the number of hospitalizations and prescription medications in the year before cohort entry.

CI = confidence interval.

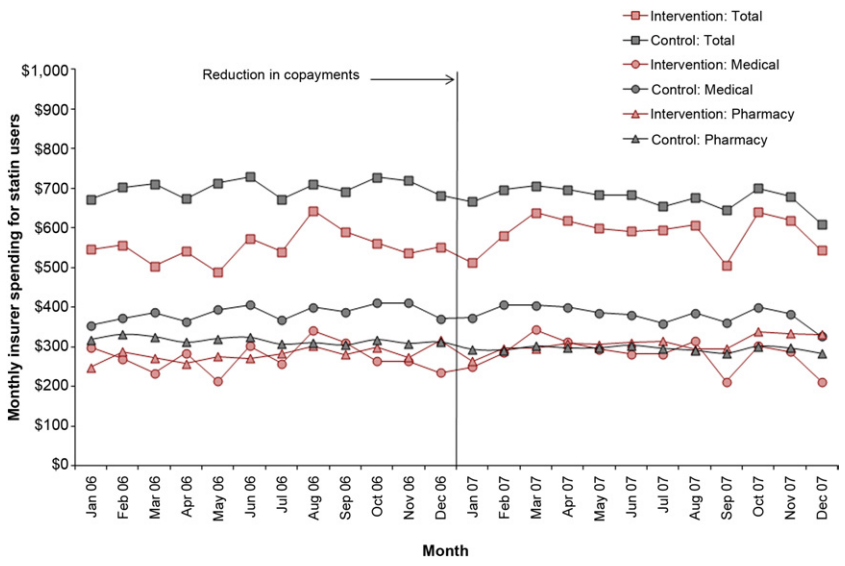

Figure 3 **Insurer Spending for Statin Users**

Insurer pharmacy, medical, and total spending for statin users before and after copayments were reduced compared with controls.

health spending for lower risk groups and for other cardiovascular drugs, specifically clopidogrel, has received limited attention. In our analysis, we found that lowering statin and clopidogrel copayments increased medication filling rates; reduced rates of physician visits, hospitalizations, and emergency department admissions; reduced patient out-of-pocket spending for drugs and other medical services; and was cost neutral with regard to overall health spending, although the reduction did not have a significant impact on rates of vascular events or revascularization.

The hope that copayment reductions for cardiovascular medications will reduce health care consumption and costs has, thus far, been based largely on data from economic models (8,9). Using formal econometric techniques applied to real-world data in the present study, we observed reductions in resource use. In light of the results of MI FREEE, the magnitude of the changes we observed would plausibly be expected from the previously reported modest but significant improvements in adherence resulting from this policy (13). However, we found that these beneficial

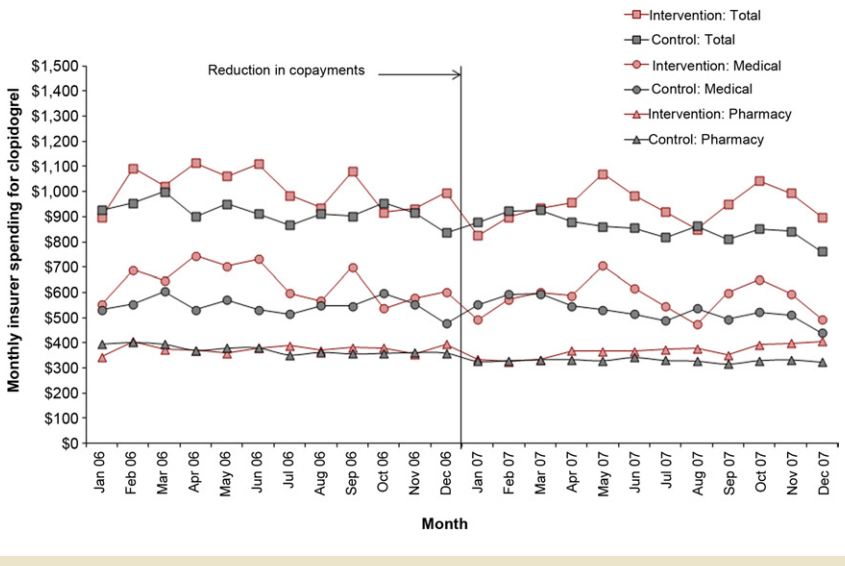

Figure 4 **Insurer Spending for Clopidogrel Users**

Insurer pharmacy, medical, and total spending for clopidogrel users before and after copayments were reduced compared with controls.

Table 3 Impact of Copayment Reductions on Changes in Patient, Insurer, and Combined Pharmacy, Medical, and Total Spending

Cohort	Type*	Pharmacy Spending (95% CI)	Medical Spending (95% CI)	Total Spending (95% CI)
Statin	Insurer	1.14 (1.10–1.19)	1.02 (0.90–1.16)	1.08 (1.01–1.15)
	Patient	0.65 (0.62–0.68)	0.90 (0.83–0.98)	0.79 (0.75–0.83)
	Combined	1.06 (1.02–1.10)	0.99 (0.83–1.18)	1.03 (0.97–1.09)
Clopidogrel	Insurer	0.93 (0.87–1.00)	0.90 (0.78–1.03)	0.96 (0.88–1.05)
	Patient	0.72 (0.67–0.76)	0.76 (0.61–0.94)	0.74 (0.66–0.82)
	Combined	1.03 (0.98–1.08)	1.14 (0.87–1.50)	0.94 (0.87–1.03)

Estimates represent relative spending changes. *Adjusted for age, sex, income, race, coronary artery disease, congestive heart failure, diabetes, hypertension, Charlson comorbidity score, and the number of hospitalizations and prescription medications in the year before cohort entry.
CI = confidence interval.

changes were not associated with an increase or a decrease in combined patient and insurer spending or clinical event rates. This may have been because the policy had only a small effect on absolute event rates, as the clinical impact of modest increases in preventive cardiovascular medication use for lower risk patients may take longer to become evident than the time period we evaluated. The lack of effect may be especially pronounced for patients who became new statin users in response to the reduced copayments, because such patients may be less likely to have an event in the first 12 months of statin therapy. Furthermore, even though clopidogrel may have clinical effects shortly after its discontinuation in patients with acute coronary disease (16), this therapy is often used by lower risk patients who derive less benefit (17). The design of the new policy may have made this particularly likely, because clopidogrel users were not required to meet specific clinical criteria to be eligible for the copayment reduction. Similarly, the statin copayment change targeted patients with coronary artery disease or diabetes, the former of which was assessed on the basis of beta-blocker or antiplatelet use. These agents may be prescribed for noncoronary indications, and thus the policy's lack of clinical benefit could possibly have been due to the inclusion of statin users who were at particularly low clinical risk. Alternatively, as observed in MI FREEE, the lack of a clinical effect may have been attributable to the policy's neutral impact on revascularization procedures, which are sometimes done for discretionary indications (18).

Most coverage changes involve a trade-off between the richness of benefits provided to patients and the associated costs incurred by third-party payers. In this context, concerns about the short-term cost implications may make payers reluctant to reduce patient cost sharing even for therapies such as statins that have ample data demonstrating their long-term cost-effectiveness (3). Our finding that reducing copayments for statins and clopidogrel was cost neutral in the first 12 months of the policy's implementation should be reassuring and may be a sufficiently attractive outcome to promote the greater use of this strategy, especially given that there are few, if any, quality improvement interventions that actually reduce health spending. More important, very consistent with results from MI FREEE, patient out-of-pocket spending decreased by 35% and 28%, respectively, among the statin and clopidogrel patients. This observation, in the context of the policy's overall cost neutrality, suggest that copayment reductions for cardiovascular drugs could be applied more broadly than only to post–myocardial infarction patients.

Study limitations. Our results should be interpreted in light of methodological limitations. First, we performed a retrospective cohort study using time-series methods adjusting for underlying utilization trends in a comparable population for whom copayments were not reduced. This technique is considered the strongest quasi-experimental design (19), and baseline differences in intervention and controls, even with regard to differences in baseline copayments, should not limit our ability to make valid inferences about relative changes in outcomes after copayments were reduced (20). Nevertheless, our analysis is subject to the possibility that the observed improvements in utilization were due to other simultaneously occurring events, of which we were not aware.

Second, our outcome measures relied on administrative claims that do not contain detailed clinical information such as cholesterol levels. Therefore, it is possible that unmeasured differences between intervention and control patients could have contributed to our findings.

Third, our sample size was modest, and we are unable to exclude the possibility that the copayment policy had a small positive or negative effect on the outcomes we evaluated. That said, the upper 95% confidence bounds of our point estimates suggest that any such effects are unlikely to be extremely large. However, it is possible that we underestimated clinical benefits of the copayment policy. Patients in the control population who did not start statin or clopidogrel therapy because of financial barriers would not be included in the control group, and therefore any potentially avoidable clinical events that occurred in these patients would not be captured in the analyses.

Conclusions

Despite these limitations, our study provides high-quality empirical data on the effects of selective copayment reductions for statins and clopidogrel among a lower risk patient cohort than evaluated in recently published clinical trial data. Although these findings do not support the belief that this quality improvement strategy will meaningfully reduce

health care spending, they do suggest overall cost neutrality and beneficial effects for resource use and thus support the reduction of evidence-based medication copayments for a wide range of cardiovascular drugs and patient risk groups.

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REFERENCES

1. Choudhry NK. Promoting persistence: improving adherence through choice of drug class. Circulation 2011;123:1584–6.
2. Chernew ME, Juster IA, Shah M, et al. Evidence that value-based insurance can be effective. Health Aff (Millwood) 2010;29:530–6.
3. Choudhry NK, Rosenthal MB, Milstein A. Assessing the evidence for value-based insurance design. Health Aff (Millwood) 2010;29:1988–94.
4. Patient Protection and Affordable Care Act, HR 3590, § 2713(c) (2010).
5. Fendrick AM, Smith DG, Chernew ME, Shah SN. A benefit-based copay for prescription drugs: patient contribution based on total benefits, not drug acquisition cost. Am J Manag Care 2001;7:861–7.
6. Chernew ME, Shah MR, Wegh A, et al. Impact of decreasing copayments on medication adherence within a disease management environment. Health Aff (Millwood) 2008;27:103–12.
7. Rosen AB, Hamel MB, Weinstein MC, Cutler DM, Fendrick AM, Vijan S. Cost-effectiveness of full medicare coverage of angiotensin-converting enzyme inhibitors for beneficiaries with diabetes. Ann Intern Med 2005;143:89–99.
8. Choudhry NK, Patrick AR, Antman EM, Avorn J, Shrank WH. Cost-effectiveness of providing full drug coverage to increase medication adherence in post-myocardial infarction Medicare beneficiaries. Circulation 2008;117:1261–8.
9. Choudhry NK, Avorn J, Antman EM, Schneeweiss S, Shrank WH. Should patients receive secondary prevention medications for free after a myocardial infarction? An economic analysis. Health Aff (Millwood) 2007;26:186–94.
10. Gibson TB, Mahoney J, Ranghell K, Cherney BJ, McElwee N. Value-based insurance plus disease management increased medication use and produced savings. Health Aff (Millwood) 2011;30:100–8.
11. Gibson TB, Wang S, Kelly E, et al. A value-based insurance design program at a large company boosted medication adherence for employees with chronic illnesses. Health Aff (Millwood) 2011;30:109–17.
12. Choudhry NK, Avorn J, Glynn RJ, et al. Full coverage for preventive medications after myocardial infarction. N Engl J Med 2011;365:2088–97.
13. Choudhry NK, Fischer MA, Avorn J, et al. At Pitney Bowes, value-based insurance design cut copayments and increased drug adherence. Health Aff (Millwood) 2010;29:1995–2001.
14. Schneeweiss S, Seeger JD, Maclure M, Wang PS, Avorn J, Glynn RJ. Performance of comorbidity scores to control for confounding in epidemiologic studies using claims data. Am J Epidemiol 2001;154:854–64.
15. Buntin MB, Zaslavsky AM. Too much ado about two-part models and transformation? Comparing methods of modeling Medicare expenditures. J Health Econ 2004;23:525–42.
16. Ho PM, Peterson ED, Wang L, et al. Incidence of death and acute myocardial infarction associated with stopping clopidogrel after acute coronary syndrome. JAMA 2008;299:532–9.
17. Choudhry NK, Levin R, Avorn J. The economic consequences of non-evidence-based clopidogrel use. Am Heart J 2008;155:904–9.
18. Chan PS, Patel MR, Klein LW, et al. Appropriateness of percutaneous coronary intervention. JAMA 2011;306:53–61.
19. Wagner AK, Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27:299–309.
20. Schneeweiss S, Maclure M, Soumerai SB, Walker AM, Glynn RJ. Quasi-experimental longitudinal designs to evaluate drug benefit policy changes with low policy compliance. J Clin Epidemiol 2002;55:833–41.

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