

A Randomized Controlled Trial of Co-Payment Elimination: The CHORD Trial

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Hypertension—especially within socioeconomically disadvantaged communities—remains a leading cause of cardiovascular morbidity and mortality in the United States, affecting nearly 50 million Americans.¹ Although there are effective medications to treat hypertension, nearly two-thirds of Americans with the condition have poorly controlled blood pressure.² Lack of adherence to anti-hypertensive medications is considered a critically important factor in blood pressure management. Medication adherence for chronic diseases such as hypertension and hypercholesterolemia is extremely low,^{3,7} limiting the potential for highly efficacious medications to improve population health.

Value-based insurance design (V-BID)—an approach based on the premise that reductions in co-payments will significantly increase the use of beneficial and cost-effective services—is being widely adopted.^{8,9} As part of the Affordable Care Act, elimination of cost sharing for preventive services is being mandated to increase utilization of such services. Although observational studies have shown that increases in co-payments are associated with both decreased medication use and worsened health outcomes,¹⁰⁻¹⁸ the impact of decreasing co-payments seen in observational studies has been more modest¹⁹⁻²⁵ and studies have generally focused exclusively on medication use rather than measured health outcomes. The underlying psychology of how people process changes in payments as losses compared with gains suggests that increases and decreases in co-payments may not be equivalent.²⁶

Only 2 randomized trials examining the relationship between co-payments and health have been published. The first, the RAND Health Insurance Experiment (HIE), was conducted in the 1970s and varied cost sharing for all services, not just those for medications. The second, the recently published Post-Myocardial Infarction Free Rx Event and Economic Evaluation (MI FREEE) study, was a test of co-payment reduction following discharge for myocardial infarction (MI) in an insurer-based intervention.²⁷

ABSTRACT

Objectives: Efforts to improve adherence by reducing co-payments through value-based insurance design are becoming more prevalent despite limited evidence of improved health outcomes. The objective of this study was to determine whether eliminating patient co-payments for blood pressure medications improves blood pressure control.

Study Design: Randomized controlled trial.

Methods: The Collaboration to Reduce Disparities in Hypertension (CHORD) was a randomized controlled trial with 12 months' follow-up conducted among patients from the Philadelphia and Pittsburgh Veterans Administration Medical Centers. We enrolled 479 patients with poorly controlled systolic blood pressure. Participants were randomly assigned to: a) receive reductions in co-payments from \$8 to \$0 per medication per month for each antihypertensive prescription filled, b) a computerized behavioral intervention (CBI), c) both co-pay reduction and CBI, or d) usual care. Our main outcome measure was change in systolic blood pressure from enrollment to 12 months post enrollment. We also measured adherence using the medication possession ratio in a subset of participants.

Results: There were no significant interactions between the co-payment interventions and the CBI interventions. There was no relative difference in the change in medication possession ratio between baseline and 12 months (0.05% and -0.90% in control and incentive groups, respectively; $P = .74$) or in continuous medication gaps of 30, 60, or 90 days. Blood pressure decreased among all participants, but to a similar degree between the financial incentive and control groups. Systolic pressure within the incentive group dropped 13.2 mm Hg versus 15.2 mm Hg for the control group (difference = 2.0; 95% CI, -2.3 to 6.3; $P = .36$). The proportion of patients with blood pressure under control at 12 months was 29.5% in the incentive group versus 33.9% in the control group (odds ratio, 0.8; 95% CI, 0.5-1.3; $P = .36$).

Conclusions: Among patients with poorly controlled blood pressure, financial incentives—as implemented in this trial—that reduced patient cost sharing for blood pressure medications did not improve medication adherence or blood pressure control.

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Take-Away Points

Small rewards that lowered co-payments to \$0 did not improve blood pressure control significantly more than in control-group subjects who simply had blood pressure measured. This may be because of the way in which this program was administered—there were delays in providing rebates for co-payments following prescription filling. The exact nature of the program implementation may have a significant impact on program effectiveness and should be carefully considered in value-based insurance design program design and assessment of impact.

To examine whether reducing co-payments from \$8 to \$0 per medication per month for all antihypertensive medications significantly improves blood pressure control, we conducted a clinic-based, randomized controlled trial of elimination of co-payments among patients with poorly controlled blood pressure at 2 medical centers in Pennsylvania.

METHODS

Study Population

Study participants were drawn from patients at 2 ambulatory clinics in Pennsylvania: the Philadelphia Veterans Affairs Medical Center (PVAMC) and the VA Pittsburgh Healthcare System (VAPitt), with recruitment occurring between March 2005 and July 2007. Eligible patients were 21 years or older, with 1 or more active prescriptions for an antihypertensive medication, systolic blood pressure (SBP) of at least 140 mm Hg (130 mm Hg in patients with diabetes), and those who paid a co-payment for their medications. Exclusion criteria included: participation in another experimental study; markedly shortened life expectancy (due to diagnosis of metastatic cancer, end-stage renal disease on dialysis, New York Heart Association class IV congestive heart failure, or dementia), or atrial fibrillation (because of concerns with accuracy of blood pressure measurement). A total of 479 participants were enrolled (details on enrollment provided in [Figure 1](#)).

Study Protocol

The protocol was approved by the Institutional Review Boards of the PVAMC, VAPitt, and the University of Pennsylvania; all participants provided written informed consent prior to randomization. The study was registered at clinicaltrials.gov as ID # NCT00133068. Participants were randomized to receive 1 of the following: a) a financial incentive equal to their co-payments for all antihypertensive medications that effectively lowered co-payments from \$8 to \$0 per medication per month (note: on January 1, 2006, 9 months after initiation of enrollment, co-payments were raised from \$7 to \$8 per month per Veterans Health Administration Directive 2005-052 and incentives

were adjusted accordingly); b) a computerized behavioral intervention (CBI) that was provided immediately following enrollment and repeated at the 6-month follow-up visit; c) both the financial incentive and the CBI; or d) usual care, which consisted only of their existing medical care.

The CBI was administered at baseline and at 6 months and was designed to help study participants learn the basics about blood pressure control and its impact. Participants watched a video testimonial from a patient who had had multiple strokes due to medication nonadherence and who felt that he had learned the importance of medication adherence from that experience. This helped to improve self-efficacy by reviewing techniques that could be used to enhance adherence. After an initial visit, all participants were requested to return for follow-up blood pressure readings and to complete surveys at 3, 6, 9, and 12 months. The financial reimbursements were paid as soon as study staff received confirmation of prescription fills using either the Veterans Administration's (VA's) computer records, prescription bottles, or receipts.

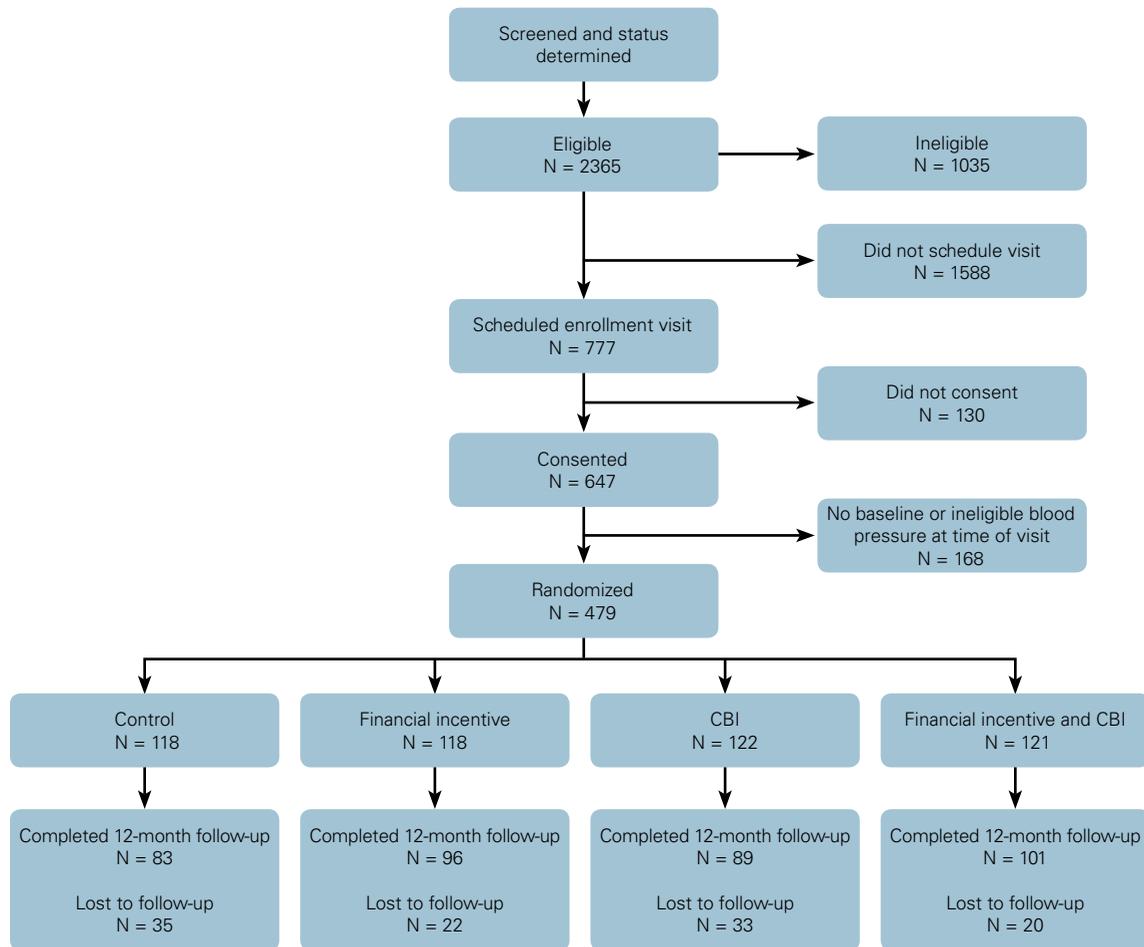
Randomization Procedures

Randomization was carried out using a random number generator and via permuted block randomization with a block size of 4. Randomization was stratified by site, income (<100%, 100%-200%, 200%-300%, and >300% of the federal poverty line [FPL]), and baseline blood pressure (SBP <160 mm Hg or SBP ≥160 mm Hg). Allocation assignments were concealed, with staff unable to access the randomization assignment for each subject until all eligibility criteria were entered into an electronic tracking system and consent forms were completed. Neither staff nor study participants could be blinded due to the nature of the intervention; investigators and analysts, however, remained blinded to intervention assignments until unblinding occurred, in coordination with the Data Safety Monitoring Board, once follow-ups were complete.

Outcome Assessments

The primary outcome variable was change in SBP and diastolic blood pressure (DBP) from enrollment to 12 months post enrollment. Secondary outcome variables included change in SBP and DBP 6 months post enrollment, the percentage of patients with well-controlled blood pressure at 6 and 12 months post enrollment, self-reported medication adherence, and prescription refill data from the VA electronic medical record system. Blood pressure control was

■ **Figure 1.** Flow Diagram of Trial Participation



CBI indicates computer-based intervention.

defined as SBP below 140 mm Hg and DBP below 90 mm Hg for patients without diabetes, and as SBP below 130 mm Hg and DBP below 85 mm Hg for patients with diabetes.

Measurement of blood pressure was done following a standardized protocol using an automated blood pressure cuff (Omron HEM-90R), ensuring that the correct cuff size was used.²⁸ Participants were instructed to relax while seated for 5 minutes before their blood pressure was taken; the patient's arm was supported on a chair or desk and blood pressures were measured 3 times, each reading 2 minutes apart, and averaged, but not revealed to the study participants. Although the study nurses could not be blinded to the randomization due to the need to administer the intervention, the use of an automated blood pressure cuff and a standardized protocol protected against differences in blood pressure measurement.

Medication adherence was measured using self-report based on the Hill-Bone Scale,²⁹ with supplemental assessment using electronic prescription fill records where available. For patients with these records, we calculated the proportion of days covered (number of days with antihypertensive drug supply on hand divided by the number of days in the observation period).³⁰⁻³³ In addition, continuous medication gap measures were calculated as at least 1 continuous episode with no antihypertensive medication for a minimum of 30, 60, or 90 days.³⁴

Study Covariates

Other factors assessed at baseline included height, weight, serum creatinine level, income, health status, health history, medication use, age, gender, and self-reported race or ethnicity. We used information on in-

come and family size to calculate income as a percent of the FPL.

Statistical Analysis

To evaluate the similarity of the treatment groups with respect to baseline covariates, we compared groups using Student's *t* test for continuous variables and χ^2 test for categorical variables, with Fisher's Exact tests used for analyses with 5 or fewer subjects per cell.

Because of the factorial design, we first assessed whether receipt of CBI affected the impact of incentive payments. The trial was designed to test the effects of the 2 interventions individually; we did not assume an interaction but powered the study adequately for individual comparisons of the 3 active arms against control. The primary analysis of the financial incentive began with a formal statistical test of interaction between the incentive and CBI; there was no evidence of this, so we collapsed across the CBI arms to assess the effect of the financial incentive alone.

The primary unadjusted analyses tested the mean differences in the degree of change in SBP and DBP between the incentive and control groups from baseline to 12 months post enrollment using Student's *t* test. We similarly calculated differences in change in SBP and DBP from baseline to 6 months post enrollment. Some participants had missing blood pressure values at 6 and 12 months; we compared baseline data between participants with and without follow-up values. Missing values for 6-month and 12-month SBP and DBP readings were handled using the Markov Chain Monte Carlo multiple imputation method, utilizing 10 imputations after verification that this yielded relative efficiencies of 95% or higher; we also checked that imputed values were within the range of observed values.³⁵ Separate imputation regression models were implemented for SBP and DBP. Unadjusted odds ratios (ORs) for achieving in-control blood pressure were estimated via logistic regression using the imputed data in the same manner. We compared the results using multiply imputed data with models using a baseline observation carried-forward approach and with a last observation carried-forward approach.

We estimated regression coefficients and their 95% confidence intervals (CIs) from an unadjusted linear regression model that incorporated only a factor indicating receipt of incentives versus control. We then compared these with regression coefficients estimated from a model adjusted for the stratification variables (site, high SBP, and income) in all cases using the imputed data.

In addition to prespecified subgroup analyses on race and income, we examined changes in SBP and DBP in subgroups defined by study site, initial SBP (≥ 160 mm Hg

vs < 160 mm Hg), presence of diabetes, and education level (high school/GED or lower, some college or college degree, beyond college). Homogeneity of the association between treatment groups and blood pressure change across subgroups was tested by assessing the significance of appropriate interaction terms included in the linear regression models described above.

The trial was powered to ensure that clinically meaningful differences in SBP of 10 mm Hg and of DBP of 5 mm Hg³⁶⁻³⁸ could be detected in any of the contrasts discussed above, assuming an interaction between the CBI and incentive interventions. We used an alpha of 0.01 to account for multiple comparisons and standard deviations of change in SBP and DBP of 20 and 10, respectively (based on the upper limit of standard deviation directly measured in clinical trials).^{39,40} Based on these estimates, we estimated that we would need 93 subjects per arm to detect the clinically meaningful difference in blood pressures discussed above. Recruitment goals for each arm for this study were increased to 116 subjects to accommodate an estimated 20% loss to follow-up, for a target of 464 subjects.

RESULTS

Study sample characteristics were generally balanced across the arms of the study (Table 1). Average age was 69, with a predominantly male population (97%) that was about 56% white and 42% black. Fifteen percent of the study population had incomes $< 100\%$ of the FPL, 32% between 100% and 200% of the FPL, and the rest fairly evenly divided between the 200%-to-300% FPL and $> 300\%$ FPL ranges. The baseline mean SBP and DBP were 158 and 81 mm Hg, respectively.

Follow-up rates at 12 months were slightly higher among incentive arm participants, with rates of 82.4% and 71.6% for incentive arm and control arm participants, respectively ($P < .01$). Baseline SBP, number of antihypertensive medications, and number of medications overall did not differ between those who were lost to follow-up and those participants for whom we had data at 12 months.

Primary and Secondary Outcomes

Baseline and follow-up medication possession ratio (MPR) values were available for 143 control group participants and 154 incentive group participants. There was no relative difference in the change in MPR between baseline and 12 months (0.05% and -0.90% in the control and incentive groups, respectively; $P = .74$). Changes, as measured by continuous medication gaps of 30 days (OR, 1.0; 95% CI, 0.6-1.7; $P = .98$), 60 days (OR, 1.2; 95% CI, 0.6-2.6,

■ **Table 1. Sociodemographic and Clinical Characteristics of Study Sample**

Variable	Co-Pay Elimination (n = 239)	Control (n = 240)	P
Demographics			
Average age: years (SD)	68.9 (10.4)	68.8 (11.3)	.89
Male: %	98.3	97.1	.36
White: %	55.2	55.8	
Black: %	42.7	42.1	.99
Other race: %	2.1	2.1	
Hispanic ethnicity: %	1.3	2.1	.72
Site			
Philadelphia VA: %	73.6	69.6	
Pittsburgh VA: %	26.4	30.4	.32
Education			
High school graduate or less: %	45.0	52.1	
Some college or college graduate: %	44.1	42.4	.06
Beyond college: %	10.9	5.5	
Income			
<100% FPL: %	15.9	13.8	
100%-200% FPL: %	32.2	30.8	
200%-300% FPL: %	25.5	26.7	.86
>300% FPL: %	26.4	28.8	
Baseline blood pressure			
Systolic blood pressure: mm Hg (SD)	156.5 (15.4)	159.0 (17.9)	.09
Diastolic blood pressure: mm Hg (SD)	80.7 (14.1)	80.3 (13.6)	.77
Medication taking			
% with MPR ≥80%	47.4%	61.5%	.34
No. of antihypertensive medications (SD)	2.5 (1.2)	2.6 (1.3)	.31
No. of medications overall (SD)	4.8 (2.7)	4.7 (2.8)	.78
Comorbidities*			
Diabetes: %	54.8	52.1	.55
Congestive heart failure: %	8.8	12.1	.24
Heart attack or AMI: %	15.5	18.3	.41
Kidney failure: %	2.9	0.8	.11
Stroke: %	8.8	6.7	.38
TIA or mini-stroke: %	10.5	14.2	.22
High cholesterol: %	71.1	68.3	.51
AMI indicates acute myocardial infarction; FPL, federal poverty level; MPR, medication possession ratio; TIA, transient ischemic attack; VA, Veterans Administration. *Subjects may have had multiple comorbidities, thus these percentages do not sum to 100.			

$P = .61$), or 90 days (OR, 0.6; 95% CI, 0.3-1.5; $P = .27$) indicated no detectable differences between the control and incentive groups.

Mean changes in SBP were -12.9 mm Hg (95% CI, -17.4 to -8.4) in the control group, -12.6 (95% CI, -17.0 to -8.3) in the co-payment-reduction group, -17.4 (95% CI, -21.7 to

Table 2. Change in Blood Pressure From Baseline to 12 Months for Co-Pay Elimination Arm (“Incentive Arm”) Compared With Control Arm

Outcome Measures	Co-Pay Elimination (n = 239)	Control (n = 240)	Difference Between Groups (95% CI)	P
Change in blood pressure				
Systolic blood pressure (mm Hg)	-13.2	-15.2	2.0 (-2.3 to 6.3)	.36
Diastolic blood pressure (mm Hg)	-7.0	-7.1	0.1 (-2.5 to 2.7)	.94
	Co-Pay Elimination (n = 239)	Control (n = 240)	Odds Ratio (95% CI)	P
% who reached goal	29.5	33.9	0.8 (0.5-1.3)	.36

-13.0) in the CBI group, and -13.7 (95% CI, -18.0 to -9.4) in the combined co-payment/CBI group. There were no significant interactions between incentive payments and receipt of the CBI with respect to 12-month outcomes ($P = .45$). Therefore, the primary and all subsequent analyses are combined by CBI status to focus on the impact of co-payment reduction on blood pressure and adherence (hereafter comparison of “incentive” vs “control”).

We found no significant difference in SBP and DBP reduction between the incentive and control groups (Table 2). SBP decreased an average of 13.2 mm Hg from baseline to 12 months post enrollment in the incentive group compared with an average of 15.2 mm Hg in the control group ($P = .36$). At the end of 12 months, there were no differences in the proportion of participants with blood pressure in control (29.5% of the incentive group vs 33.9% for the control group (OR, 0.8; 95% CI, 0.5-1.3; $P = .36$). Results of sensitivity analyses in which we assumed that the blood pressure in all patients lost to follow-up was equal to their last measured value or their baseline blood pressure (as opposed to the imputed blood pressure value) were qualitatively similar.

The pattern of changes in blood pressure from baseline to 6 months was similar, with no significant differences observed between the incentive and control group participants (Figure 2). Adjusted estimates of changes in SBP indicated no significant differences between incentive and control groups in the degree of change in blood pressure (Table 3).

Subgroup Analyses

The degree of change in SBP between the incentive and control groups was compared among several subgroups of the populations in the study, including those with MPRs at baseline above and below 80%, those with and without

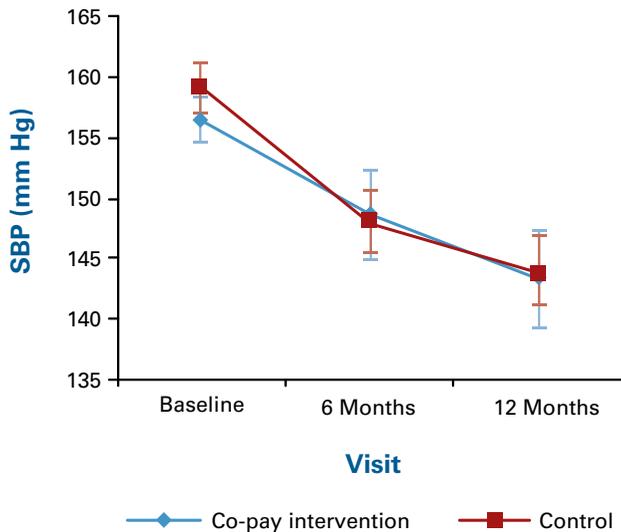
diabetes, those with a baseline SBP above or below 160 mm Hg, and subgroups determined by race, income, and education. There were no statistically significant differences in change in blood pressure between the incentive and control groups 12 months post enrollment in any of the subgroups tested.

DISCUSSION

In a sample of 479 primary care patients with uncontrolled hypertension receiving care at 2 Pennsylvania VA medical centers, we found that a financial incentive that essentially eliminated co-payments for antihypertensive medications had no effect on blood pressure control. To our knowledge, this is the first clinic-based experiment to test the impact of reduced prescription cost sharing while holding constant the level of coverage for other services. The lack of an impact on blood pressure or medication adherence highlights the importance of incentive design in impacting program effectiveness. Previous studies have typically shown small but significant improvements in medication adherence with reduced co-payments.⁴¹ In this case, providing the monetary incentive as a retrospective reimbursement, rather than at the time of purchase of the medications, likely compromised effectiveness. The negative results here highlight the importance of how program design and implementation matter substantially in terms of impact when it comes to incentives (like other programs).

Our findings inform ongoing discussions about value-based insurance design and the national effort to improve patient outcomes through reduction in co-payments for high-value prescription medications.^{9,42} Strategies to modify the degree of patient cost sharing based on the value of the prescriptions provided have garnered extensive publicity

■ **Figure 2.** Change in Systolic Blood Pressure Over Time Comparing the Financial Incentive (co-pay elimination) Intervention and Control Groups



SBP indicates systolic blood pressure.

and are of great interest nationally.^{43,44} Reducing the price of cost-effective treatments or preventive services encourages utilization of highly cost-effective preventive services that could potentially save money by reducing the rate of adverse events from poorly controlled health.^{45,46} Although increases in prescription co-payments have been associated with decreases in medication adherence and increases in poor health outcomes in numerous studies,^{16,18,47,48} previously published studies on co-payment reduction had not examined change in health outcomes until the MI FREEE study, which indicated reductions in the rate of total major vascular events or revascularization without any increase in total healthcare spending from a 6-percentage-point increase in cardiovascular medication adherence.²⁷

The RAND HIE—the most definitive study conducted to date on the relationship between patient cost-sharing and expenditures—found sizable effects of patient cost sharing on healthcare utilization, but more modest effects on health status. Of note, however, among low-income persons with high blood pressure, free care resulted in significant improvements in blood pressure. That study, however, was performed more than 25 years ago when fewer effective medications were available; it also excluded the elderly, was composed of participants who were largely (more than 80%) Caucasian, and included a population with relatively few comorbidities.⁴⁹ Most importantly, the HIE did not isolate the effect of prescription drug cost sharing.^{50,51}

While we did not observe significant improvements in either medication adherence or blood pressure, observational studies of V-BID programs that have lowered co-payments have generally found that adherence, as measured by MPR, increases by an average of about 3 to 5 percentage points on a baseline MPR of 60% to 80%. This means that for every employee who was completely non-adherent (MPR = 0%) who became fully adherent (MPR \geq 80%) there would be 20 to 25 employees who would now receive co-payment reductions but whose adherence did not change.^{19-23,41,52-54}

Reductions in co-payments may have less of an impact on patient outcomes than increases in co-payments, for several reasons. First, increases in co-payments affect utilization among adherent patients, whereas decreases in co-payments are targeted at affecting utilization among nonadherent patients in whom a change in co-payment of a given magnitude is likely to have less impact. Second, increases in co-payments are likely processed as a loss by patients, and behavioral economists have demonstrated that losses are felt much more strongly than equivalent gains.²⁶ Third, co-payment reductions may be a bit like the “dog that didn’t bark.” For a nonadherent patient who doesn’t come to the pharmacy or fill prescriptions, communications about a reduction in co-payments may be largely ignored.

Limitations

There are several limitations to consider. First, because prescriptions for chronic medications within the VA system are typically filled by mail and billed at the end of the month, as opposed to immediately upon filling, our use of post hoc rebates could be partly responsible for the absence of an effect—people tend to have strong present-biased preferences,⁵⁵ making rewards provided in the future less valuable. We had incorporated this method of providing incentives since studies have indicated that unbundling rewards from other payments make the rewards more effective.⁵⁶ Second, patients may be nonadherent for many reasons and the magnitude of the reduction in co-payments may have been too small to induce changes in behavior, though previous work has found co-payment increases as low as \$0.50 to \$1 per prescription (approximately \$2-\$3 adjusting for inflation) in a low-income population can reduce drug utilization.⁵⁷ Third, our study sample was predominantly male veterans from 2 VA hospitals, so the findings may not generalize to women or patients who receive care in the private sector. However, there are no obvious reasons to believe that intervention effectiveness would be different in women. Finally, there may have been contemporaneous efforts to improve

Table 3. Change in Systolic Blood Pressure at 12 Months From Multivariable Models

Group	Parameter	BP Change (95% CI)
Unadjusted model		
Intercept	No Intervention	-15.2 (-18.1 to -12.2)
Study arm	Co-pay Intervention	2.0 (-2.3 to 6.3)
Adjusted for stratification variables		
Intercept	No intervention	-8.5
	Site = Philadelphia VA	-8.5
	SBP at baseline <160 mm Hg Income >300% FPL	(-13.2 to -3.7)
Study arm	Co-pay Intervention	1.6 (-2.4 to 5.6)
Site	Pittsburgh VA	0.9 (-3.9 to 5.6)
SBP at baseline	SBP ≥160	-16.7 (-21.0 to -12.5)
	<100% FPL	-4.5 (-11.1 to 2.1)
	Income	0.4 (-5.3 to 6.2)
	100% to 200% FPL	1.6 (-4.0 to 7.1)
	200% to 300% FPL	1.6 (-4.0 to 7.1)

BP indicates blood pressure; FPL, federal poverty line; SBP, systolic blood pressure; VA, Veterans Administration.

blood pressure control within VA facilities through quality improvement initiatives, and the effectiveness of these efforts may have limited our ability to measure a differential impact on blood pressure of co-payment reduction.

CONCLUSIONS

We found that incentives that effectively eliminated co-payments for high-value medications to treat blood pressure had no impact on blood pressure control. Reducing barriers to high-value care in and of itself makes sense; future studies should examine whether other incentive designs are more successful in improving blood pressure control.

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