REVIEW ARTICLE

A Systematic Review of Value-Based Insurance Design in Chronic Diseases

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Objectives

Value-based insurance design (V-BID) is an insurance cost-sharing model in which patients pay less for medications deemed to be of higher value. Our objective was to determine the association between V-BID and medication adherence, clinical outcomes, healthcare utilization, and spending in patients with or at risk for cardiovascular chronic diseases, compared with no differential lowering of drug co-payments.

Study Design

Systematic review.

Methods

We searched PubMed, MEDLINE, EMBASE, CINAHL, Cochrane Controlled Trials Register, Current Controlled Trials, and reference lists of included studies and relevant reviews up to September 2012. Two reviewers independently identified primary research studies with the following study designs: randomized controlled trial, interrupted time series, and controlled before-after studies. Two reviewers independently extracted data and assessed quality.

Results

Ten studies were identified: 1 high-quality randomized controlled trial, 1 interrupted time series analysis, and 8 controlled before-and-after studies. Heterogeneity in study populations and interventions, overall low study quality, and lack of standard error reporting precluded meta-analysis. All reported improvement in medication adherence for medications subject to V-BID, of between 2 and 5 percentage points. Impact on clinical outcomes was unclear, with only 1 study reporting on this, noting no difference in the primary outcome, but a reduction in adverse secondary outcomes with V-BID. Of the four studies that examined the impact of VBID on healthcare expenditures, V-BID tended to increase overall prescription drug spending, though three of the four studies reported similar overall healthcare costs due to decreased non drug medical spending.

Conclusions

V-BID is associated with improved medication adherence but its effects on clinical outcomes, healthcare utilization, and spending remain uncertain.

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Prescription drug costs comprise 10% of all healthcare expenditures in the United States,[1] reaching $263 billion in 2011, and they are projected to rise to nearly $500 billion annually over the next 10 years.[2] Patient co-payments and/or deductibles were established in part to lower costs to the insurer and to reduce inappropriate overconsumption. The amount of cost sharing has traditionally been based on drug acquisition cost, where expensive brand name medications have higher levels of co-payments than less expensive generic drugs.[3] Past studies have shown that patients may reduce drug use in response to cost sharing, but tend to reduce both appropriate and inappropriate therapy,[4,5] indicating that they may not be able to differentiate high- from low-value therapies.[6] This leads to increased medical complications and healthcare utilization[4,7] and higher overall healthcare costs.

Fendrick and colleagues introduced a novel cost sharing design in 2001, initially termed "benefit-based co-pay,"[8] and subsequently renamed "value-based insurance design" (V-BID).[3] The underlying premise is that a drug co-payment is based on the clinical benefit, or value, of that drug rather than its acquisition cost. More specifically, Fendrick and colleagues define V-BID as "decreasing cost sharing for interventions that are known to be effective and increasing cost sharing for those that are not."[9] The goal of the V-BID system is to encourage the use of the most effective drugs, while constraining costs by keeping cost sharing intact for drugs deemed to be of lower value.[6]

Since 2001, numerous private insurers have implemented V-BID for prescription drug coverage. We conducted a systematic review to determine the impact of V-BID on medication adherence, clinical outcomes, and health-system costs in patients with cardiovascular-related chronic diseases, compared with those with usual drug coverage. We defined V-BID as the selective lowering or waiving of drug co-pay-

Take-Away Points

- Value based insurance design for prescription drug coverage improves medication adherence by about 2-5 percentage points for patients with chronic cardiovascular disease.
- The impact of VBID on clinical outcomes and health care expenditures is uncertain due to smaller numbers of studies examining these outcomes, and conflicting results across studies.
- Existing VBID studies are limited by moderate to high risk of bias. There is a need for high quality studies that examine impact of BID not only for medication adherence, but also for clinical outcomes and healthcare expenditures, before widespread implementation of VBID can be recommended.

ments for medications that were deemed to be of high value in the treatment of chronic diseases. Our search focused on cardiovascular (CV)-related chronic diseases, given that long-term medication use (in addition to lifestyle changes) is the mainstay of treatment for these conditions, and that a large body of evidence shows that selected medications are effective in reducing morbidity and mortality. For example, treatment of hypertension reduces the risk of major CV events, with similar benefit seen across many antihypertensive drug classes used.[10] Similarly, intensive glycemic control in diabetes with oral hypoglycemic agents or insulin reduces complications of retinopathy and nephropathy.[11] V-BID is one method by which evidence-based appropriate treatment can be promoted for these diseases.

METHODS

Data Sources and Searches

A study protocol was created that outlined the objectives, eligibility criteria for study inclusion in the systematic review, and plan for data abstraction, synthesis, and quality assessment. We searched the following databases from inception to September 12, 2012: PubMed, MEDLINE, EMBASE, CINAHL, Cochrane Controlled Trials Register, and Current Controlled Trials. Key terms included *hypertension, cardiovascular diseases, stroke, diabetes mellitus, dyslipidemia, cost sharing, deductibles and coinsurance, co-pay,* and *value-based pricing or plan.* The search strategy can be found in the **eAppendix**. The search was limited to English and French language studies, and no limitations were placed on patient characteristics, study duration, or outcome. Reference lists of all included studies and relevant narrative reviews were manually searched.

Study Selection

Using a 2-step process, 2 reviewers (KLT and LB) first independently reviewed all identified abstracts for eligibility, then extracted and reviewed the full-text articles for the abstracts that were thought to meet eligibility criteria, or where there was any uncertainty. Studies published exclusively as abstracts without accompanying full-text articles were not considered. Disagreements were resolved by consensus or with the aid of a third party (BJM). Eligibility criteria were the implementation of V-BID as described above, inclusion of at least a proportion of adults with 1 or more CV-related chronic disease (hypertension, dyslipidemia, diabetes, coronary artery disease, heart failure, or stroke), and 1 or more outcome of interest (medication adherence, clinical outcomes, healthcare utilization, or costs). We included randomized controlled trials (RCTs), nonrandomized controlled trials, interrupted time series (ITS) analyses, and controlled before-and-after studies, based on the Cochrane Effective Practice and Organization of Care Group [EPOC] taxonomy of healthcare policy studies.[12] Studies were excluded if the patient populations were exclusively children or adolescents.

Data Extraction and Quality Assessment

Data were extracted on study characteristics (including funding, inclusion/exclusion criteria, design, and methods), baseline characteristics of the intervention and comparator groups, and primary and secondary outcomes for each study. Two reviewers independently extracted data from all studies fulfilling eligibility criteria; disagreements were resolved by consensus. The quality of included studies was assessed using the Cochrane Collaboration risk of bias tools.[12]

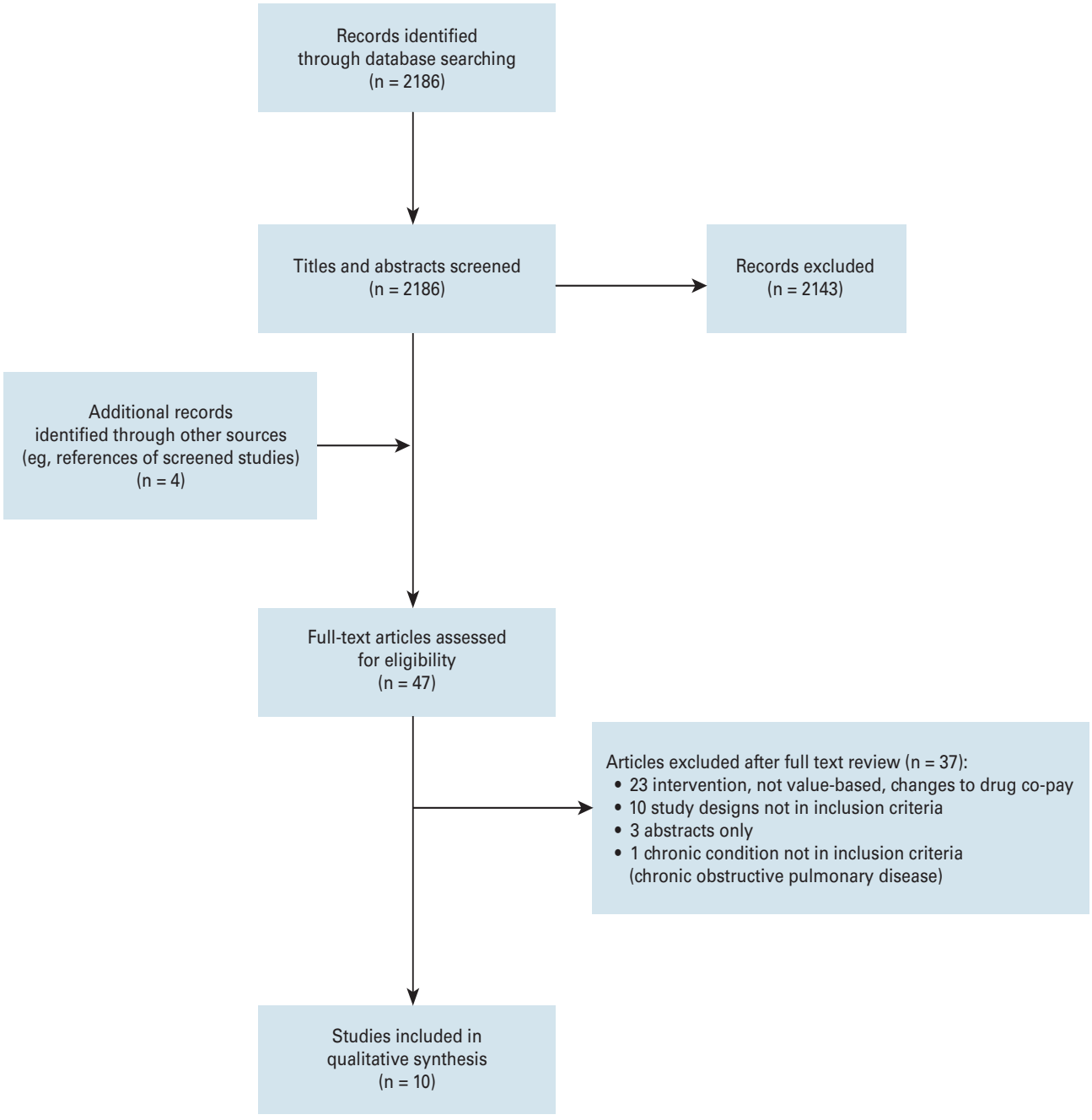
Data Synthesis and Analysis

The significant heterogeneity in study populations and interventions across studies, the overall low quality of the studies, and lack of reported standard error or standard deviation for outcome measurements precluded pooling of results in a meta-analysis. Furthermore, though adherence was reported for all studies, definitions varied slightly among them. Results for each study are summarized individually.

RESULTS

Our search identified 2186 citations, of which 43, along with an additional 4 identified through manual review of reference lists, were included for full-text review (**Figure**).

Figure. Flow Diagram of Study Selection Process



Of those, 10 studies evaluating 9 V-BID interventions met inclusion criteria: 1 randomized controlled trial,[13] 1 interrupted time series study,[14] and 8 controlled before-and-after studies[15-22] (Table 1). All studies were completed in the United States.

Of the 10 studies, 2 studies[13,14] selectively lowered or waived co-payments for CV medications only (antihypertensives and statins); 3 studies[15,19,22] waived co-payments for diabetic medications only, and 5 studies[16-18,20,21] waived co-payments for a combination of both CV and diabetic medications. Two studies[19,22] waived co-payments for brand name drugs only, while the other 8 studies reduced cost-sharing for both generic and brand name drugs.

Six studies[14,16,17,19-21] included disease management co-interventions. Five of these[14,16,17,19,20] introduced V-BID alongside a separate voluntary disease management program[a] while 1 study[21] tied the V-BID intervention to the disease management program; refusal to participate in disease management in this study also precluded patients from participating in V-BID, making it impossible to distinguish whether outcomes could be attributed to V-BID or the disease management intervention in this study. In 3 of the 6 studies[14,16,17,20] with disease management co-interventions, both the intervention and comparison groups could voluntarily participate in disease management programs. Therefore, disease management participation is expected to influence outcomes only if participation rates differed between these 2 groups. Two of these 3 studies[16,17] reported similar disease management participation rates in the V-BID and comparison groups, while the third study[14] did not report participation rates at all. Four of the 6 studies[14,16,17,20] with disease management co-interventions reported only overall results and did not report separate outcomes for participants of disease management programs. A total of 2 studies[15,22] ensured that participating insurance plans in the intervention and control groups did not administer disease management programs simultaneously; and 2 studies[13,18] did not mention the presence or absence of concurrent disease management programs at all.

Quality of Studies

The only randomized controlled trial[13] was rated high quality and the interrupted time series study[14] was rated moderate quality. The remainder of the studies, all controlled before-and-after studies, were considered poor quality (**Table 2**) primarily because of their study designs and their risk of confounding due to concurrent disease management programs for which outcomes were not adjusted.[14,16,21]

Five studies[14,16-18,20] reported significant differences in baseline characteristics (such as age, gender, and baseline medication co-payments) between the intervention and control groups, which were partly addressed in 3 of the 5 studies[17,18,20] through propensity score matching, though this did not entirely eliminate differences across groups in all studies.[18,20] In another study,[21] though the baseline characteristics were similar among groups, the control group was comprised of patients who declined to participate in disease management programs (and therefore were ineligible for V-BID), while the intervention group included patients who agreed to participate in (and therefore also received) V-BID. Five studies[15,16,19-21] also reported statistically significant differences in baseline medication adherence between the intervention and control groups.

Impact on Medication Adherence

All 10 studies reported the impact of V-BID implementation on medication adherence, either on its own (n = 4) or when given in conjunction with disease management (n = 6) (**Table 3**). Baseline adherence (ie, medication possession ratios) across studies was generally in the range of 60% to 80%, though 2 studies[13,19] reported much lower baseline adherence rates of between 30% and 40%. Overall, V-BID was associated with an increase in medication adherence, as measured by medication possession ratio or proportion of days covered, of approximately 2 to 5 percentage points compared with the control group for medications subject to V-BID. In the randomized controlled trial,[13] the increase was 4.4 to 6.2 percentage points across the medications subject to V-BID. Similar outcomes were seen across all studies, with follow-up periods ranging from 3 months[13] to 3 years post V-BID implementation.[19,20] Choudhry and colleagues' interrupted time series study[14] showed that following an immediate improvement in medication adherence in the V-BID group, the rate of decline in adherence was similar between the 2 groups over time.

Absolute increases in medication adherence were also similar between studies that evaluated V-BID only and those that also implemented voluntary disease management programs (Table 3). In the 2 studies[19,21] that reported on the combined effect of disease management and V-BID, medication adherence improved by 2.7 to 6.5 percentage points in patients who received both V-BID and disease management programs. Kim and colleagues[21] added that improvement was seen only if the disease management program was intensive in nature, such as with telephone counseling with a nurse to set goals and care plans, but not when the program consisted only of health education mailings.

Impact on Clinical Outcomes

Only the 1 randomized controlled trial[13] examined the impact of essential drug coverage on clinical outcomes. The trial showed that in patients discharged from the hospital after a myocardial infarction, the rate of first major vascular event or revascularization was similar

[a]Disease management programs consisting of targeted health education mailing, disease workbooks, telephone outreach, and counseling with a nurse to set care plans, periodic monitoring, or any combination of the above.

Table 1. Overview of Included Studies

Primary Author & Accrual Period	Study Design	Study Overview	No. of Patients	F/U (yr)	Outcome(s) Measured: Disease-Specific Outcomes	Outcome(s) Measured: Healthcare Utilization	Outcome(s) Measured: Adherence	Outcome(s) Measured: Cost
Choudhry 2011[13] Study end date Nov 2010	RCT	*Population:* Adults <65 years who were discharged from hospital after an MI *Medications:* ACE inhibitors, ARBs, BBs, statins *Intervention:* Co-pay for included medication classes waived *Comparator:* No change to usual prescription drug coverage, with mean co-pay at study initiation of $13.35 (ACE inhibitors or ARBs), $12.84 (BBs), and $24.92 (statins)	5855	1.1	✓	✘	✓	✓
Choudhry 2010[14] January 1, 2006-December 31, 2007	ITS	*Population:* Adults with diabetes and vascular disease *Medications:* Statins & clopidogrel *Intervention:* Statin cohort: co-pay waived for those with DM or vascular disease [from mean monthly co-pay of $24.18] Clopidogrel cohort: mean monthly co-pay reduced to $8.86 [from $17.22] *Comparator:* Statin cohort: mean monthly co-pay rose to $11.95 [from $11.80] Clopidogrel cohort: mean monthly co-pay rose from $14.43 [from $10.65]	52,631	1	✘	✘	✓	✘
Chang 2010[15] January 2006-December 2007	CBA	*Population:* Adults with diabetes *Medications:* Diabetic medications (biguanides, thiazolidinediones, sulfonylureas, insulin) *Intervention:* Tier 1: Diabetic medication co-pay waived [from $15 per 30-day prescription] Tier 2: Diabetic medication co-pay lowered to $10-$15 [from $30] Tier 3: No change to co-pay of $30-$35 Insulin (average) co-pay waived [from $28] *Comparator:* Tier 1: No change to co-pay of $10 Tier 2: No change to co-pay of $10 Tier 3: No change to co-pay of $35 Insulin (average) co-pay increased to $28 [from $23]	211,062	2	✘	✘	✓	✘
Chernew 2008[16] January 2004-December 2005	CBA	*Population:* Adults aged 18-64 years *Medications:* ACE inhibitors, ARBs, BB,s statins, ICSs *Intervention:* Generic medication co-pay waived [from $5 per prescription] Preferred brand name medication co-pay lowered to $12.50 [from $25] Non-preferred medication co-pay lowered to $22.50 [from $45] *Comparator:* Generic medication co-pay rates decreased to $16.01 [from $16.22] Brand name co-pay rates rose to $30.72 [from $29.72] Both intervention & comparator groups participated in a disease management program	110,152	2	✘	✘	✓	✘

(Continued)

Table 1. Overview of Included Studies *(Continued)*

Primary Author & Accrual Period	Study Design	Study Overview	No. of Patients	F/U (yr)	Outcome(s) Measured: Disease-Specific Outcomes	Outcome(s) Measured: Healthcare Utilization	Outcome(s) Measured: Adherence	Outcome(s) Measured: Cost
Farley 2012[17] January 2007-December 2009	CBA	*Population:* Adults taking at least 1 of the 8 included medications *Medications:* Metformin, thiazide diuretic, ACE inhibitors, ARBs, BBs, CCB, statins, CAIs *Intervention:* Generic medication co-pay waived *Comparator:* No change to generic medication co-pay	1,385,391	2	✘	✘	✓	✘
Maciejewski 2010[18] January 2007-December 2008	CBA	*Population:* Adults taking at least 1 of the 8 included medications *Medications:* Metformin, thiazide diuretic, ACE inhibitors, ARBs, BBs, CCB, statins, CAIs *Intervention:* Generic medication co-pay waived [from average co-pay $10.74-$11.38) *Comparator:* No change to generic medication co-pay	5374-34,439[a]	3	✘	✘	✓	✘
Gibson 2011[19] January 2005-December 2008	CBA	*Population:* Adults <65 years with diabetes. *Medications:* Diabetic medications (insulin, metformin, sulfonylureas, meglitinides, thiazolidinediones, GLP-1 agonists, alpha glucosidase inhibitor, amylin analogue, diazoxide, glucagon emergency kit) *Intervention:* Co-pay for all diabetic medications changed to 10% for all [from tiering system ranging from 10% co-pay for generics to 35% co-pay for non-preferred brand name medications] *Comparator:* 10% co-payment for generic medications. 20% co-payment for preferred brand name medications 35% co-payment for non-preferred brand name medications	4408	4	✘	✘	✓	✓
Gibson 2011[20] January 2004-December 2007	CBA	*Population:* Adults aged 18-64 years with cardiovascular disease, diabetes, or asthma *Medications:* Cardiovascular medications (ACE inhibitors, ARBs, alpha-blockers, BBs, CCBs, diuretics, central alpha-2 agonists, aldosterone receptor blockers); diabetes medications (insulin, oral hypoglycemics) *Intervention:* Retail prescription co-payment 10% [from 20%], mail order prescription co-payment 7.5% [from 10%]; minimum co-payment amount of $10 and maximum of $40; any products made by the study-funding company (Novartis) had no cost sharing before or after policy change *Comparator:* Drug insurance without a value-based design	50,130	4	✘	✘	✘	✓

Continued)

Table 1. Overview of Included Studies *(Continued)*

Primary Author & Accrual Period	Study Design	Study Overview	No. of Patients	F/U (yr)	Outcome(s) Measured: Disease-Specific Outcomes	Healthcare Utilization	Adherence	Cost
Kim[21] April 2007-April 2010	CBA	*Population:* Adults >19 years with CAD, HF, diabetes, or asthma *Medications:* Medications used to treat CAD, HF, diabetes, & asthma *Intervention:* Patients enrolled in disease management program provided with: Tier 1: Retail co-pay $0 (per 30-day prescription)/ mail order co-pay $0 (per 90-day prescription) Tier 2: Retail $8/mail order $20 Tier 3: Retail $25 /mail order $55 Tier 4: Retail 35% ($45 min, $105 max)/ mail order 35% ($90 min, $210 max) *Comparator:* Patients who were eligible for, but did not enroll in, disease management programs were provided with: Tier 1: Retail co-pay $8 (per 30-day prescription)/mail-order co-pay $20 (per 90-day prescription) Tier 2: Retail $25/mail order $55 Tier 3: Retail 35% ($35 min, $40 max)/mail order; 35% ($70 min, $140 max) Tier 4: Retail 35% ($70 min, $140 max)/ mail order; 35% ($140 min, $280 max)	2552	3	✘	✓	✓	✓
Zeng 2010[22] January 2005-December 2007	CBA	*Population:* Adults >18 years with diabetes *Medications:* Diabetes medications (insulin, metformin, sulfonylureas, thiazolidinediones, meglitinides, GLP-1 agonists) *Intervention:* All above diabetes medications moved to tier 1 with $10 co-pay [from tiering system with tier 1 generics with $10 co-pay, tier 2 preferred brand name medications with 30% co-pay, and tier 3 non-preferred brand name medications with 50% co-pay] Average monthly co-payment decreased to $10.10 [from $15.30] *Comparator:* No change to: Tier 1 (generic medications): $10 co-payment Tier 2 (preferred brand name medications): 30% co-payment Tier 3 (non-preferred brand name medications): 50% co-payment	710	3	✘	✘	✓	✘

✓= included in the study
✘ = not included in the study
ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; BB, beta-blocker; CAD, coronary artery disease; CAI, cholesterol absorption inhibitor; CCB, calcium channel blockers; CBA, controlled before-and-after study; F/U, follow-up; GLP-1, glucagon-like peptide-1; HF, heart failure; ICS, inhaled corticosteroid; ITS, interrupted time series analysis; LABA, long-acting beta agonists; MI, myocardial infarction; RCT, randomized controlled trial; SABA, short-acting beta agonist.
[a]Sampling sizes varied across medication classes.

between those with full drug coverage for essential CV medications (angiotensin converting enzyme inhibitors, beta-blockers, and statins) and those with "usual drug coverage" (mean co-payments for the medications of interest ranging between $12.83 and $24.92 depending on the class). However, rates of total major vascular events or revascularization (hazard ratio [HR] 0.89; 95% CI, 0.80-0.99), and first major vascular event (HR 0.86, 95% CI, 0.74-0.99) were significantly lower in the full drug coverage group compared with the usual coverage group.

Table 2. Risk of Bias Summary, by Study

Impact on Health Utilization and Expenditures

One controlled before-and-after study[21] examined changes to healthcare utilization before and after implementation of V-BID, but showed conflicting results, with a reduction in hospitalizations in the high-risk group who participated in V-BID and an intensive disease management program, but an increase in hospitalizations in the low-risk group participating in V-BID and a less intensive disease management program when compared with controls who chose not to participate in either program.

Three of the 4 studies[13,19,21] that examined the impact of V-BID on healthcare expenditures found an increase in prescription drug expenditures overall (Table 4), while the fourth study found no statistically significant difference.[20] As expected, patient-borne prescription drug costs decreased (relative spending 0.70, 95% CI, 0.65-0.75) with V-BID implementation in the randomized trial.[13] Total healthcare spending, including both drug and non-drug expenditures, was similar in the V-BID group compared with the usual care group in 3 studies,[13,19,20] including the randomized trial.[13] In the fourth study,[21] total healthcare

Table 3. Medication Adherence

Study	Medications Included in V-BID	Results	
Studies Excluding or With No Mention of Any Disease Management Co-Interventions (n = 4)			
		Absolute Difference in Medication Adherence Between Intervention Compared With Control Group, in Percentage Points	***P***
Randomized Controlled Trials			
Choudhry 2011[13]	ACE inhibitor or ARB	5.6%	<.001
	Beta-blocker	4.4%	<.001
	Statin	6.2%	<.001
Controlled Before-and-After studies			
Chang 2010[15]	Oral diabetic drugs	5.0%	NR
	Any diabetic drugs	7.2%	NR
	Insulin	9.9%	NR
Maciejewski 2010[18]	ACE inhibitor	3.10%	<.001
	ARB[a]	–0.02%	NS
	Beta-blocker	2.69%	<.001
	Statin	2.56%	<.001
	Metformin	3.69%	<.001
	Calcium channel blocker[a]	1.31%	<.05
	Cholesterol absorption inhibitor	–0.80%	NS
	Thiazide diuretic	3.35%	<.001
		Medication Adherence, Intervention Compared With Control Group	***P***
Zeng 2010[22]	Diabetes medications	OR 1.56 (95% CI, 1.04-2.34)	.03
Studies Including Disease Management Co-Interventions (n = 6)			
		Absolute Difference in Medication Adherence Between Intervention Compared With Control Group, in Percentage Points	***P***
Interrupted Time Series			
Choudhry 2010[14]	Statin	3.1%	<.05
	Clopidogrel	17.0%	<.05
Controlled Before-After Studies			
Chernew 2008[16]	ACE inhibitor or ARB	2.59%	<.001
	Beta-blocker	3.02%	<.001
	Statin	3.39%	<.001
	Diabetes drugs	4.02%	<.001
Farley 2012[17]	ACE inhibitor	4.8%	<.001
	ARB[a]	–0.2%	NS
	Beta blocker	4.3%	<.001
	Statin	2.3%	<.001
	Metformin	5.0%	<.001
	Calcium channel blocker	2.0%	<.001
	Cholesterol absorption inhibitor[a]	0.4%	NS
	Thiazide diuretic	4.5%	<.001
Gibson 2011[19]	***In disease management program***		
	Insulin	2.7%	<.05
	Oral diabetic medications	5.8%	<.01
	All diabetic medications	6.5%	<.01
	Not in disease management program		
	Insulin	0.8%	NS
	Oral diabetic medications	4.1%	NS
	Any diabetic medications	3.6%	NS
Gibson 2011[20]	Diabetes medications (includes insulin)	–0.12%	NS
	Cardiovascular medications	1.99%	<.01
	Any V-BID medications	1.80%	<.01
Kim 2011[21]	***With concurrent nurse counseling***[b]		
	ACE inhibitor or ARB	3.4%	NR
	Beta-blocker	0.5%	NR
	Statin	7.5%	NR
	Oral hypoglycemic	10.1%	NR
	Insulin	3.6%	NR
	With concurrent health education mailings[b]		
	ACE inhibitor or ARBs	1.6%	NR
	Beta-blocker	3.5%	NR
	Statin	5.3%	NR
	Oral hypoglycemics	8.6%	NR
	Insulin	5.4%	NR

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; NR, not reported; NS, not statistically significant; V-BID, value-based insurance design.
[a]No generic option; no difference in co-payments in this medication class between intervention and control groups.
[b]Control group eligible for but not enrolled in any disease management programs which included either nurse counseling or health education mailings.

spending was lower in those patients who participated in V-BID and intensive disease management, but higher in the V-BID and less intensive disease management group compared with those who did not participate in either the V-BID or disease management programs.

DISCUSSION

To our knowledge, this is the first systematic review to examine V-BID. We found 10 studies that evaluated 9 interventions which compared V-BID with no differential lowering of drug co-payments in patients with CV-related chronic diseases. Although V-BID was consistently associated with an increase in medication adherence of 2 to 5 percentage points across all studies, including the sole randomized trial, the evidence of impact of V-BID on clinical outcomes was far more limited, with only 1 study[13] evaluating this. Though this study showed no difference in the primary clinical outcome, there was a decrease in adverse clinical secondary outcomes. Furthermore, the combined role of disease management and V-BID is unclear. Only 2 low-quality studies, at high risk of residual confounding[21] and selection bias,[19,21] reported outcomes separately for patients participating in V-BID and disease management compared with those who chose not to participate in either, allowing assessment of the impact of combining these programs.

Our review reveals a substantial evidence gap on the impact of V-BID on clinical outcomes, health utilization, and healthcare spending, consistent with prior narrative reviews by Choudhry and colleagues[23] and Fairman and Curtiss.[24] One possible reason that V-BID has not resulted in overall cost savings is that an increase in co-payments for low-value medications has not yet been applied together with a decrease in co-payments for high-value medications, as described in the original V-BID model.[8] As a result, any cost savings with V-BID interventions depend on improved medication adherence leading to improved clinical outcomes and resulting in decreased healthcare utilization and medical spending. Melnick and Motheral,[25] using a plausibility calculation method, argued that net cost savings with V-BID is highly unlikely, as large reductions in drug co-payments result only in small increases in medication use (low price elasticity), and that avoidable adverse events due to improved medication adherence are rare.

Despite the limited evidence, approximately 20% of private insurance plans offered by large American employers include V-BID.[24] Moreover, in 2007, 80% of large employers indicated an interest in implementing V-BID over the ensuing 5 years.[23] There has also been substantial US governmental interest and political activity regarding V-BID, and in 2009, the Seniors' Medication Copayment Reduction Act was created, requesting a demonstration program to test V-BID in Medicare beneficiaries.[26] Most recently, the Patient Protection and Affordable Care Act, under Section 2713(a), specifically addresses V-BID, stating "The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs."[27] V-BID need not be limited to drug insurance alone, and could potentially be applied to other health services. In 2010, new regulations in the US required private health insurance plans to cover high-value preventive services that were given a rating of grade A or B by the United States Preventive Services Task Force. This includes breast and colon cancer screening, diabetes screening, and routine vaccinations.[28] There has also been interest in applying V-BID to the areas of diagnostic imaging,[29] gastroenterologic procedures such as endoscopy,[30] and oncology.[31] However, actual implementation and subsequent evaluation of V-BID has yet to extend beyond prescription medications. The limitations in evidence do not seem to substantiate the widespread interest and implementation of V-BID and should be considered experimental.

There were limitations to our review. First, our review evaluated only the impact of V-BID and not whether medications that had their co-payments reduced were correctly classified as "high value" in their respective V-BID programs. As with any systematic review, our study was limited by the quality of the underlying studies. Except for the 1 randomized trial, the literature base in V-BID at the time of our study had a moderate to high risk of bias, specifically in study design (in particular with selection bias) and reporting.[24,32,33] Our focus on CV-related chronic diseases may limit generalizability to other conditions, though medications for these diseases constitute a large proportion of the medications funded by outpatient prescription drug benefit plans. In addition, private insurers implemented V-BID in 9 of the 10 studies, potentially also limiting generalizability of the findings, especially with respect to public drug insurers. Lastly, current studies in V-BID target populations that already have good medication adherence, and this may limit the ability of V-BID to increase compliance.[25] A notable exception was the randomized trial,[13] with a baseline adherence of about 44%, likely because a variety of insurance plan sponsors were included—employer, union, and government insurers—thereby better representing the general population. Further research on the impact of V-BID on clinical and economic outcomes is required, particularly in populations that might benefit most,[23] such as those at highest risk for clinical adverse

Table 4. Healthcare Expenditures[a]

Study	Outcome(s) Measured	Results		
Randomized Controlled Trials		**Relative Spending in Intervention and Control Groups**	***P***	**Summary of Relative Spending in Intervention and Control Groups**
Choudhry 2011[13]	**At minimum 3-month follow-up**			
	Prescription drugs	1.17	.02	⇑[b]
	Non-drug spending	0.90	NS	<=>[c]
	Total spending (prescription drugs + non-drug medical spending)	0.89	NS	<=>
Controlled Before-and-After Studies		**Percentage Point Change in Intervention and Control Groups**	***P***	**Summary of Difference in Spending Between Intervention and Control Groups**
Gibson 2011[19]	**In disease management program at year 3 follow-up**			
	Prescription drugs	21.6%	<.01	⇑
	Medical	–0.2%	NS	<=>
	Total spending (prescription drugs + medical)	8.5%	NS	<=>
	Not in disease management program at year 3 follow-up			
	Prescription drugs	23.2%	NS	<=>
	Medical	–23.5%	NS	<=>
	Total spending (prescription drugs + medical)	–11.8%	NS	<=>
		Percentage Point Change Post V-BID Compared With Pre-V-BID in the Intervention Group	***P***	**Summary of Change in Spending in Intervention Group**
Gibson 2011[20]	**3 years post V-BID implementation**			
	Prescription drugs	16.59%	NS	<=>
	Medical	8.94%	NS	<=>
	Total spending (prescription drugs + medical)	8.40%	NS	<=>
		Control ($ ± standard error)	**Intervention ($ ± standard error)**	***P***	**Summary of Difference in Spending Between Intervention and Control Groups**
Kim 2011[21]	**1.5 years post enrollment, in those who received nurse counseling**				
	Prescription drugs	179 ± 43	666 ± 60	<.001	⇑
	Medical	1289 ± 312	–484 ± 426	=.001	⇓[d]
	Total spending (prescription drugs + medical)	1861 ± 401	44 ± 467	=.003	⇓
	1.5 years post enrollment, in those who received health education mailings				
	Prescription drugs	34 ± 36	286 ± 36	<.001	⇑
	Medical	96 ± 162	849 ± 184	=.002	⇑
	Total spending (prescription drugs + medical)	182 ± 181	1261 ± 199	<.001	⇑

NS indicates not statistically significant; V-BID, value-based insurance design.
[a]Reported as combined costs to the insurer and patient for Choudhry 2011[13], Gibson 2011[19], Gibson 2011[20]. Kim 2011[21] reports costs to the insurer only.
[b]Statistically significant increase.
[c]No statistically significant change.
[d]Statistically significant decrease.

events, those with low baseline compliance, and those facing financial barriers to drug adherence.

If V-BID is expected to lower costs, consideration must be given to increasing cost sharing for low-value medications. The major challenge is in classifying and defining a medication as low value, given that the evidence for services or medications being of low value is far less established than for high-value medications.[34,35] Additional research into this, as well as the most appropriate patient populations to target, is required to inform further use of V-BID,[36] particularly within publicly funded drug formularies.

Value-based insurance design is a novel approach to encourage adherence to high-value medications. Though it appears to be associated with improved medication adherence, the effects on clinical outcomes and overall health utilization and expenditures remain uncertain. Further high-quality research is required before more widespread implementation of V-BID can be encouraged.

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eAppendix: Search Strategy

1. exp Hypertension/
2. exp Cardiovascular Diseases/
3. exp Stroke/
4. exp Diabetes Mellitus/
5. dyslipidemias/ or hyperlipidemias/
6. hyperlipidemias/
7. (copd or heart failure or atherosclerosis or dyslipidemia* or hyperlipidemia* or hypertensi* or heart disease or heart patient* or cardiovascular disease or cardiovascular disorder* or myocardial infarction* or ischemic heart disease or coronary artery disease or heart attack* or (chronic adj10 disease*) or stroke).tw.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. exp *Arthritis/
10. exp *HIV Infections/
11. exp *"Tobacco Use Cessation"/
12. exp *Inflammatory Bowel Diseases/
13. exp *Autoimmune Diseases/
14. (arthritis or arthritic or osteoarthritis or HIV or AIDS or inflammatory bowel* or crohn* or colitis or autoimmune).ti.
15. 9 or 10 or 11 or 12 or 13 or 14
16. 8 not 15
17. limit 16 to (english or french)
18. limit 17 to animals
19. limit 17 to (animals and humans)
20. 18 not 19
21. 17 not 20
22. limit 21 to (case reports or comment or editorial or letter)
23. 21 not 22
24. exp "Cost Sharing"/
25. Insurance, Pharmaceutical Services/
26. exp Fees, Pharmaceutical/
27. exp Insurance Coverage/
28. insurance, health/ or for-profit insurance plans/ or health benefit plans, employee/ or insurance, health, reimbursement/ or exp insurance, pharmaceutical services/ or medicare/ or single-payer system/
29. Insurance, Health, Reimbursement/
30. "Deductibles and Coinsurance"/
31. ((co-pay* or copay* or coverage or insurance or insuring or cap or coinsur* or co-insur* or reimburs* or plan or plans or fees or "cost share" or "cost sharing" or insurance or insuring) adj10 (drug or drugs or medication* or pharmaceutical*)).tw.
32. 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31
33. 23 and 32
34. ((value base* or values base* or valuebase* or valuesbase* or evidence based plan*) adj10 (insur* or plan or plans or scheme* or price or pricing or payment* or reimburs* or copay* or co-pay*)).tw.

35. limit 34 to (english or french)
36. limit 35 to animals
37. limit 35 to (animals and humans)
38. 36 not 37
39. 35 not 38
40. limit 39 to (case reports or comment or editorial or letter)
41. 39 not 40
42. 33 or 41
43. limit 42 to (clinical trial or controlled clinical trial or comparative study or meta analysis or randomized controlled trial)
44. (random* or trial or trials or placebo* or groups).tw.
45. Time Factors/ or cohort studies/
46. time series.tw.
47. (controlled adj3 before adj3 after).tw.
48. 44 or 45 or 46 or 47
49. 42 and 48
50. 43 or 49