

SECTION 3

Value-Based Insurance Design for Diabetes Mellitus: Approaches to Optimal Pharmacoeconomic Implementation

The content in this section is based on a presentation at the roundtable meeting by A. Mark Fendrick, MD

Healthcare Recommended But Undelivered

The principal focus of healthcare reform discussion revolves around reducing the growth of cost. Very little assessment or attention, however, is focused on the quality of healthcare actually delivered relative to basic standards of care. Due to the lack of available analyses concerning the quality of healthcare delivered relative to specific illnesses, injuries, or chronic conditions, there is no perception of a relevant problem within the healthcare system warranting serious concern. In reality, not only does a substantial proportion of standard healthcare go undelivered, but these deficits in adherence to recommended processes for basic care constitute a significant, serious threat to the health of American citizens.⁵⁷

To determine the extent of underutilization of recommended healthcare services, McGlynn et al recently conducted telephone interviews with adults in 12 US metropolitan areas to evaluate performance in 439 quality care indicators across 30 acute and chronic conditions, and preventive care (Figure 3). Overall, participants received approximately 55% of recommended care, with small differences between proportions of received recommended acute care (54%) or care provided for chronic conditions (56%). Patients' adherence to processes involved in treatment ranged from 52% to 59% for screening and follow-up care, respectively. According to medical condition, the percentage of medical care received ranged significantly, from 78.7% for senile cataracts to 10.5% for the treatment of alcohol dependence. Patients with diabetes received approximately 45% of recommended care.⁵⁷

Over 2 years, only 24% of patients with diabetes had their A1C level measured at least 3 times. In another comparable study, only 29% of participants reported having their blood sugar checked within the past year. This lack of recommended glycemic monitoring is highly significant because A1C and blood sugar measurements are required to assess response to therapy, assess response to poor glycemic control, and identify risks of comorbidities early before they become serious complications.

Tight glycemic monitoring and control can significantly reduce complications; in the United Kingdom Prospective Study, microvascular complications were reduced by 25%.⁵⁸

Adherence to Pharmacotherapy

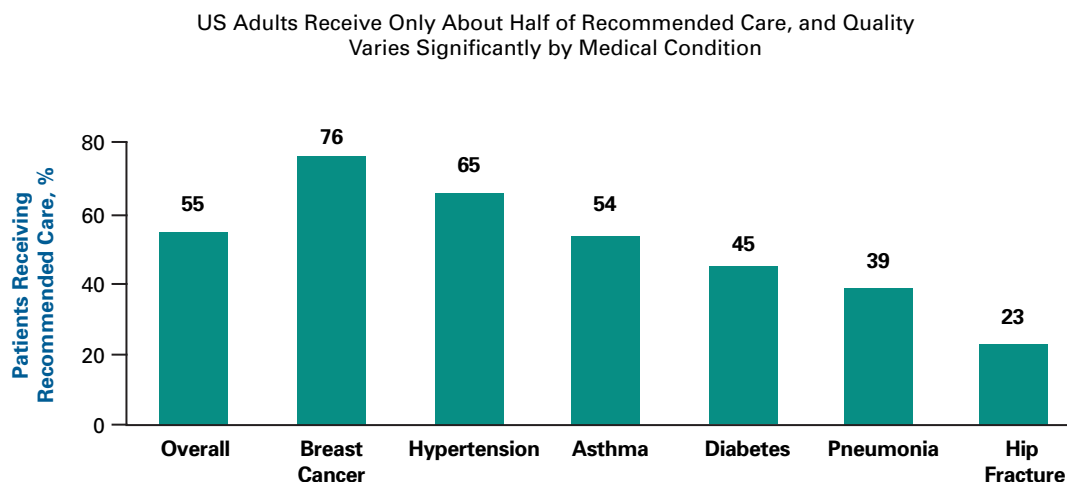
Nonadherence to therapeutic drug regimens is another costly problem that goes relatively unaddressed in healthcare reform discussions. This is also reflected in the literature; in approximately 50 years, there have been only 19 randomized, controlled, intervention studies that measured adherence and clinical outcome for 6 months or longer. However, across diseases, treatments, ages, and chronic disorders, as many as 60% of patients report poor adherence to therapy, with costs estimated at more than \$100 billion annually. It has been demonstrated that 29% to 59% of outpatients do not follow medication regimens as prescribed, and approximately 50% of patients take sufficient doses of medication to produce a therapeutic effect.⁵⁹ The 3 leading reasons that patients report for nonadherence are forgetfulness, managing their own symptoms (ie, taking more or less medication based on how they feel), and schedule disruptions such as traveling.

Strategies to improve adherence have yielded positive yet underwhelmingly moderate effects, with multifactorial interventions comprising cognitive, behavioral, and affective components demonstrating better outcomes than singular interventions. The most predictive factors for relatively high adherence rates include self efficacy, initial adherence, and regimens not requiring multiple behaviors (such as those that cause interruptions to one's schedule). Patients who are 75 years and older are generally less adherent to their treatment regimens; cognitive changes are believed to be responsible for this difference compared with those who are younger.⁵⁹

Cost Sharing and Preventable Reductions in Quality of Care

Numerous interventions discourage the use of more costly

■ **Figure 3.** Percentage of Recommended Healthcare Received in Common Conditions⁵⁷



Adapted from McGlynn EA, et al. *N Engl J Med.* 2003;348(26):2635-2645.

drugs and generally reduce spending; these include (but are not limited to) prior authorization, disease management programs, payment reforms, increasing costs to beneficiaries, and cost-shifting and cost-sharing strategies. The one-size-fits-all approach to cost sharing does not acknowledge that there are real differences in the clinical value of medications among patients; therefore, it lacks the driving forces that direct better-designed plans. Cost-sharing strategies should not create preventable reductions in quality of care. Higher patient copayments should ideally discourage purchase of low-value therapies, while lower copayment costs should encourage the use of higher-value therapies. A growing body of evidence, however, demonstrates that some cost-shifting policies lead to decreases in essential and nonessential care.

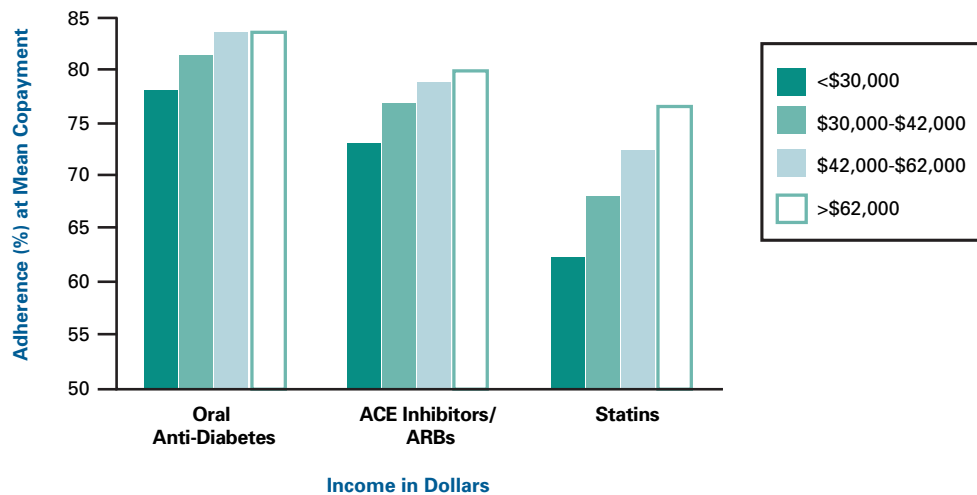
A well-known retrospective US study conducted from 1997 to 2000 sought to determine how cost-sharing changes affected therapeutic utilization of the most common drug classes used in chronic conditions. Pharmacy claims data linked with health plan benefit designs of 30 employers and 52 health plans were examined for 528,569 patients aged 18 to 64 years who were enrolled for up to 4 years. The main outcome measure was member per-year relative change in drug days supplied when copayment cost doubled. Analyses demonstrated that a doubling of copayments was associated with a marked reduction in drug utilization for 8 common chronic disease categories including diabetes (25%), hypercholesterolemia (34%), and hypertension (26%). For patients taking medications for asthma, diabetes, and gastric disorders, there were annual increases in emergency department visits and hospital stays of 17% and

10%, respectively. Patients diagnosed with diabetes reduced their use of diabetes drugs by 23%. Reductions in medications supplied were also noted for nonsteroidal anti-inflammatory drugs (NSAIDs) (45%), antihistamines (44%), antiulcerants (33%), antiasthmatics (32%), and antidepressants (26%). While antihypertensives and antidiabetic drugs demonstrated less price elasticity than medications taken intermittently such as antihistamines and NSAIDs, they were used significantly less with copayment doubling. These patterns raise concern over adverse health consequences associated with elevated price, particularly among diabetics with whom annual days supply decreased by more than 3 months.⁵²

Increased Cost Sharing Results in Socioeconomic Health Disparity

Chernew et al investigated how copayment increases affected adherence in 6 million employer-sponsored health insurance enrollees 18 years and older based on household income (using 2000 census data). Medication use in DM and congestive heart failure (CHF) was investigated. Adherence was measured by the proportion of days a patient had medication available. Results typically indicated an inverse relationship between income and adherence, suggesting that individuals from higher income areas were consistently more adherent to therapeutic regimens than those from lower income areas. Patients in low-income areas (<\$30,000 annually) were more sensitive to elevations in copayments than those in high (>\$62,000 annually) or middle (\$30,000-\$42,000 and \$42,000-\$62,000 annually) income areas, resulting in lower adherence rates (Figure

■ **Figure 4.** Socioeconomic Adherence Disparities in Patients with Diabetes are Affected by Elevations in Copayments⁶⁰



ACE indicates angiotensin-converting enzyme; ARB, angiotensin II receptor blockers. Reprinted with permission from Chernew M, et al. *J Gen Intern Med.* 2008;23(8):1131-1136.

■ **Table 7.** Central Objectives of VBID Health Insurance Programs⁶³

- Achieve greatest possible health impact from medical expenditures
- Create opportunity to restructure health benefits and change orientation of healthcare debate focus from cost to clinical value of services
- Minimize lack of adherence to evidence-based services resulting from across-the-board set cost sharing

Adapted from Fendrick AM. Value Based Insurance Design Landscape Digest. July 1, 2009. National Pharmaceutical Council.

4). For patients with diabetes, the average quarterly adherence rates were 74% for oral antihyperglycemic drugs, 66% for antihyperlipidemic drugs, and 72% for angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs). For patients with CHF, the income-price sensitivity relationship was particularly pronounced. Results suggested that copayment doubling would reduce overall adherence by approximately 2.9% to 5.4%. Also, elevations in copayments may result in further disparities in healthcare outcomes based on socioeconomic factors.⁶⁰

Clinical Optimization Through Cost Containment

Increased cost sharing through elevated copayments creates financial barriers that actually discourage patients from using recommended services. When required to pay more for services, patients purchase less, regardless of whether the intervention is life-saving.⁶¹ In the short term, reduced consumption of certain essential healthcare services and medica-

tions may yield financial savings; however, over the long term, it can result in complications, hospitalizations, and increased utilization.⁶² Taken to the extreme, decreased utilization and savings in prescription drug use encouraged through higher copayments could result in higher overall healthcare costs.⁶³

The healthcare insurance system should provide financial incentives to offset the undesirable decreased use of essential services due to cost shifting. Value-based packages are designed to adjust patients' out-of-pocket costs and clinician reimbursement for specific services based on an assessment of the clinical benefit achieved. Therefore, the more clinically beneficial the therapy is for the patient, the lower the patient's cost share and the higher the clinician's bonus. Peer-reviewed studies and empirical evidence indicate that such value-based insurance design (VBID) can be implemented; although it is not a cure-all for the financial crisis in healthcare, VBID supports cost containment while improving quality of healthcare and promoting a healthier population.⁶²

Synergy of Clinical Efficacy and Fiscal Responsibility

The simplest conceptual identifier of a VBID plan is reflected in its design; such a plan eliminates cost barriers to the acquisition of high-quality drugs and services, raises compliance, and minimizes expensive future costs such as hospitalizations (Table 7). As VBID evolves, it is expected that plan designs will account for individual patient characteristics as well as disease severity, which will impact copayments. Next generation VBID offerings are expected to incorporate wellness programs, disease management, and patient-centered medical homes.⁶³

Approaches to VBID Program Designs

There are 4 distinct program designs based on orientation. A design by *service* eliminates or reduces copayments for a particular drug class or service, such as statin prescriptions and cholesterol tests, regardless of patient diagnosis or any characteristic specific to the individual plan participant. Design by *condition* eliminates or reduces copayments for particular drugs or services associated with a particular disease (eg, diabetes); an example is the University of Michigan Focus on Diabetes Program.⁶⁴ Design by *severity* is essentially like a design by condition program, but high-risk patients are the focus. Finally, design by *disease management participation* eliminates or reduces copayments for drugs or services prescribed for diseases associated with diagnosed patients who participate in relevant disease management programs.⁶³

Recognized Potential Obstacles to VBID

Health plans and insurer groups demonstrate increasing interest in VBID, but some barriers to its acceptance have been identified. For example, short-term pharmacy spending and healthcare utilization will increase through lowered costs for targeted drugs. When copayments are reduced and costs rise, some worry that clinical status will not improve sufficiently within the targeted population to offset the costs of increased benefits utilization. Sophisticated analytics are required to interpret data, identify opportunities, and correlate these findings with high-valued services and specific patient groups who will achieve greater compliance with their use. Also, certain plan members may respond negatively upon learning that other plan members pay less for the same pharmaceutical product or drug. Privacy issues, of course, prohibit the unsanctioned exchange of personal health information, and all patient data and related communications will face compliance with the Health Insurance Portability and Accountability Act. Quantifying clinical and economic return on investment remains in debate, and few studies have assessed the impact of decreased copayments on utilization and adherence. As research progresses, however, matching the correct metric with the correct outcome is critically important. An unintended effect of VBID is that lowered VBID copayments might discourage the use of non-VBID drugs, products, or services for other conditions that might otherwise provide high-value healthcare. Initially, it may be difficult to determine which patients qualify for VBID programs, thereby enabling potential fraud. Elucidating distinctions between qualified and nonqualified patients should become easier as more is learned about high-value service through comparative effectiveness research.⁶⁵

Decreasing Medication Copayment in a VBID Disease Management Model

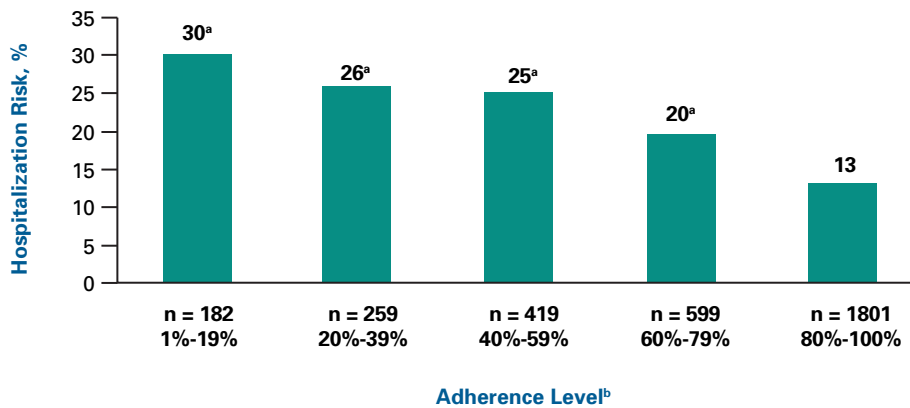
In 2005, a large employer undertook a value-based copayment reduction intervention within its disease management program to estimate reduced copayment effects on adherence.⁶⁶ The same disease management program within another company served as an external control in this large study, which, in part, hoped to replicate the results of the Pitney Bowes study reviewed earlier. Copayment rates were reduced across 5 classes of medications including ACE inhibitors and ARBs, β -blockers, insulin and oral diabetes drugs, statins, and inhaled corticosteroids. By study design, generic copays were reduced from \$5 to \$0 and brand copays by 50% for preferred drugs (from \$25 to \$12.50) and nonpreferred drugs (from \$45 to \$22.50). During execution of the study, weighted average brand and generic copay rates in the intervention group were reduced nearly 40% compared with a 2% increase in the control group copays. Employees and dependent participants were 18 to 64 years of age. The intervention covered 32 clinical conditions and correlated metrics for medical, drug, and lab claims; lab results and clinical recommendations were used to identify opportunities to improve outcomes. Clinicians were notified of the results several times a month through a company program. Eligible participants received a reminder letter on the importance of taking their condition-specific therapies, and a follow-up letter notifying them of their copay reductions. Adherence was measured through a Medication Possession Ratio (MPR).

Results demonstrated marked increases in adherence in the intervention group compared with the control group; in 4 of the 5 medication classes, these differences were significant. Although adherence increased in the corticosteroid group, the difference between the intervention and control group was not significant. Percentage point reductions in nonadherence ranged from 7% to 14%, with diabetes drugs achieving the greatest MPR effect size increase in adherence ($P < .001$).⁶⁶ The diabetes and ACE/ARB models suggested that intervention effects increase over time, and logistic models confirmed the findings of improved adherence as a result of the intervention. Like the Pitney Bowes study, these results demonstrate that VBID-oriented copayment reductions can improve adherence within a disease management context, and that value-based cost sharing initiatives warrant serious consideration in healthcare insurance design.

Medication Adherence Impacts Hospitalization Risk and Cost

Although VBID-oriented copayment adjustment positively affects adherence, it is essential to demonstrate that improved adherence translates directly to healthcare cost savings, which

■ **Figure 5.** Diabetes Hospitalization Risk Decreases as Adherence Increases⁶⁷



^aIndicates significantly higher cost vs the 80%-100% adherence group ($P < .05$); ^bAdherence was defined as the percentage of days during the 1-year analysis period that patients had a supply of 1 or more maintenance medications for the condition.

Reprinted with permission from Sokol MC, et al. *Med Care*. 2005;43(6):521-530.

is the focus of healthcare reform. Sokol et al conducted a 2-year retrospective observational study of 137,277 patients 65 years and younger who were continuously enrolled in prescription drug and medical benefits plans. During the first 12 months of the study, patients were identified by disease through outpatient, emergency department, and inpatient insurance claims. For the remaining 12 months of the study, prescription drug utilization and medical claims were analyzed. The primary outcomes were all-cause and disease-related medical costs, drug costs, and hospitalization risk. These outcomes were modeled at various levels of medication adherence. The targeted chronic medical conditions were 4 of the costliest drivers of pharmaceutical spending: diabetes, hypertension, hypercholesterolemia, and CHF. Patients meeting inclusion criteria for more than 1 condition were included in more than 1 sample population.

Compared with patients at lower adherence levels, patients capable of sustaining adherence at 80% to 100% had significantly less risk of hospitalization than those in lower adherence percentiles, inclusive of all 4 chronic conditions. The decrease in hospitalization risk for patients with diabetes progressed from the lowest to highest adherence percentiles at rates of 30%, 26%, 25%, 20%, and 13%, respectively (Figure 5).⁶⁷ Adherence at higher percentiles was also associated with lower disease-related medical costs for diabetes and hypercholesterolemia. Total healthcare costs for both conditions tended to decrease at higher adherence percentiles regardless of increased drug costs. Most notably, disease-related healthcare costs for diabetes decreased as a function of exposure to diabetes medication (Figure 6). All-cause healthcare costs also decreased for

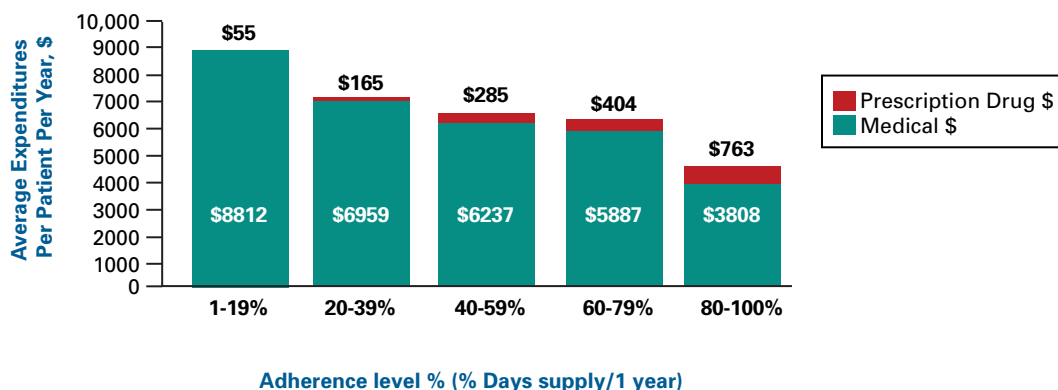
patients as a function of exposure to diabetes medication. For diabetes, hypertension, and hypercholesterolemia, high adherence was associated with lower medical costs; differences were significant for most adherence percentiles.⁶⁷

Sokol and colleagues demonstrated that increased drug utilization driven by adherence to therapeutic regimen and evidence-based disease management guidelines can provide net economic return. These results show the leveraging capability of increased drug costs over total healthcare expenditures within a VBID environment that is both clinically and fiscally sensitive. As more pharmaceutical products become generically available, it is expected that this leveraging power will increase.

Long-Term Outcomes in a Community Pharmacy Diabetes Program

The Asheville Project, a longitudinal cohort study based in 12 community pharmacies in Asheville, NC, assessed the persistence of outcomes for up to 5 years following community-based pharmaceutical care services (PCS) for patients with diabetes.⁶⁸ Participants were city of Asheville employees or the Mission-St. Joseph's Health System. PCS services were spearheaded by community pharmacists who were trained in diabetes care and were reimbursed for cognitive services. Free PCS services included access to a diabetes education center staffed with educators, a home blood glucose monitor, and diabetes drugs and supplies. Participants were able to meet with pharmacists for counseling, establishment, and monitoring of therapeutic goals. Pharmacists performed physical assessments of the skin and feet, and measured weight and blood pressures.

■ **Figure 6.** Higher Adherence Associated with Lower Total Healthcare Costs for Diabetes⁶⁷



Reprinted with permission from Sokol MC, et al. *Med Care*. 2005;43(6):521-530.

■ **Table 8.** Insurance Costs Versus Prescription Costs Over Time⁶⁸

	Year 1 (\$)	Year 2 (\$)	Year 3 (\$)	Year 4 (\$)	Year 5 (\$)
Mean Insurance Cost PPPY Decrease	2704	3609	3908	5480	6502
Mean Total Prescription Cost Increase	656	1487	1932	1942	2188

PPPY indicates paid per patient year.
Adapted from Cranor CW, et al. *J Am Pharm Assoc (Wash)*. 2003;43(2):173-184.

Lipid management was also a key educational intervention, and pharmacist-physician consultation and collaborative therapeutic management played a key role in patient care. Main outcome measures included changes in A1C and lipid levels, and diabetes-related and total medical utilization costs over the course of the study. Optimal clinical outcomes were based on ADA guidelines and economic outcomes were derived from changes in direct medical costs over time. Direct medical costs were defined as amounts paid by the plans for physician and emergency department visits, hospitalizations, laboratory tests, prescription drugs, cognitive PCS, educator’s fees, and copayment waivers.

At every follow-up, mean A1C level improved, with 57.7% to 81.8% of patients demonstrating improvements in A1C levels compared with baseline. Similarly, at every follow-up, the number of patients with an A1C level of 7% or less increased. Mean low-density lipoprotein (LDL-C) and HDL-C profiles also improved at each follow-up visit, with improvements noted in 50.0% to 66.7% of participants. In all follow-up years, costs paid per patient year (PPPY) were less than baseline with more than 50% of participants experiencing a 10% reduction

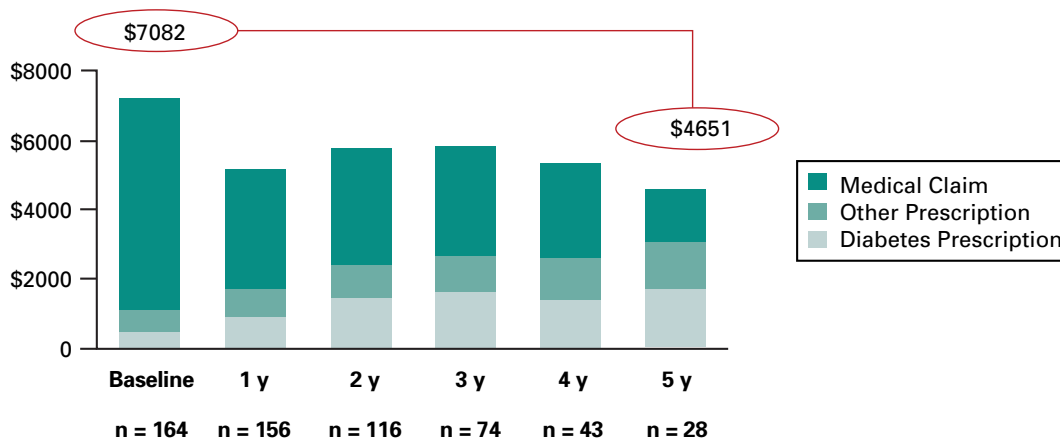
in PPPY amounts in most years. The prescription drug cost trend ran diametrically opposite to PPPY costs, as depicted in **Table 8**. Despite annual increases in prescription drug costs, total direct mean medical costs PPPY compared with baseline decreased every year (\$7,082 at baseline to \$4,651 at year 5) (**Figure 7**). The overall reduction in healthcare costs amounted to approximately 34%.⁶⁸

The Asheville study is one of the few studies to assess the long-term effects of PCS on A1C and lipid levels and direct medical costs. It implemented VBID methodology, and, over a period of 5 years, successfully improved clinical outcomes and reduced costs. Most of the cost savings accrued through cost shifting—from hospitalizations and visits to the emergency department and doctors’ offices to prescription costs. Due to the success of the study, the employers have made it a permanent part of their benefit package.⁶⁸

VBID as a Driver of Healthcare Reform

The intrinsic interests of VBID align with the intentions of healthcare reform. VBID implements healthcare reform cost-saving strategies, such as disease management and wellness

■ **Figure 7.** Overall Reduction of Approximately 34% in Healthcare Costs in the Asheville Project⁶⁸



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programs, comparative effectiveness research, health information technology, payment reforms, and chronic care models. It also eliminates barriers to high-value services including screenings, monitoring, and examinations for disease complications and comorbidities associated with common chronic diseases. These services are required to optimize the pharmacoeconomic outcomes in many costly chronic diseases. While inexorably linked to clinical issues, it is ironic that much of the impetus behind VBID programs comes from Fortune 500 businesses.

After Pitney Bowes, organizations such as Marriot, Procter & Gamble, and Florida Power and Light implemented VBID programs. VBID-related elements have also been incorporated into plans offered by benefit consultants, disease management companies, pharmacy benefit managers, and health plans such as Aetna. Other organizations continue to experiment with VBID-oriented plans. As payers continue to shift increasing costs to patients despite the potential for detrimental outcomes, it is important to evaluate the inherently synergistic strengths of programs that offset adverse clinical effects through aligning therapeutic availability with therapeutic value.⁶⁴

Conclusions

Diabetes continues to present significant clinical and economic challenges across the United States, and it will present as an enormous burden to the world's healthcare systems as nations develop. Many barriers exist to optimal care, some of which manifest from clinical origins; however, others are rooted in economic issues which are as worthy of exploration as clinical issues are of research. New practice and payer models such as VBID have demonstrated the potential to address

optimal clinical care while simultaneously reducing the financial burden on payers. Diabetes, asthma, and hypertension pose a significant and growing threat to world health. Poor management of these and other chronic diseases is largely responsible for the financial strain currently facing the US healthcare system. Further investigation of clinical practice and payer models is required to resolve these interrelated clinical and economic issues.

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