

## REVIEW ARTICLE

# Review of Strategies to Enhance Outcomes for Patients with Type 2 Diabetes: Payers' Perspective

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**Background:** Diabetes and its clinical consequences exact a great toll on patients and on society in terms of its effects on morbidity and mortality and its staggering economic impact.

**Objective:** To review various programs and strategies that aim at enhancing adherence to antihyperglycemic therapy and suggest the best approach to improving patient outcomes and reducing healthcare costs.

**Discussion:** Treatment goals for patients with diabetes have been defined, and multiple safe and effective medications are available. Nevertheless, the majority of patients with diabetes fail to achieve treatment goals, because of difficulty with adherence to medication regimens and lifestyle modifications, and because of economic barriers. This article discusses various initiatives developed to improve patient outcomes, including consumer-driven health plans and wellness and prevention programs. Furthermore, economic incentives to patients, such as value-based insurance design, may increase adherence; nevertheless, evidence suggests that such programs alone provide only modest gains. Primary providers in disease management programs can include nurses, case managers, or pharmacists. Supportive interventions across several modalities have been shown to be effective.

**Conclusion:** An approach that uses a combination of strategies designed to impact patients' health-related behaviors across a variety of modalities may help to improve outcomes and reduce costs. Additional novel, innovative interdisciplinary initiatives are necessary to effect meaningful change that can facilitate improved health outcomes for patients with diabetes and maximize cost-effectiveness approaches for payers.



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Diabetes is an important disease state causing significant morbidity and mortality throughout the United States and worldwide. The current obesity epidemic, together with the US aging population, is fueling the rapid increase in diabetes prevalence. A modeling study suggests that by 2020, 15% of adults will have diabetes, and 37% will have prediabetes compared with 12% and 28%, respectively, today.<sup>1</sup> By 2050, approximately 15 new diabetes cases per 1000 people are expected annually. This will result in a diabetes prevalence of between 1 in 5 diagnosed adults and 1 in 3 undiagnosed adults.<sup>1</sup>

Estimates from the Centers for Disease Control and Prevention (CDC) suggest that as of 2007, 23.6 million adults and children in the United States had diabetes; this represented nearly 8% of the US population.<sup>2</sup> In addition, 5.7 million individuals who have diabetes

remain undiagnosed.<sup>2</sup> Currently, type 2 diabetes accounts for at least 95% of diabetes cases.<sup>3</sup> Prediabetic patients with elevated blood glucose levels represent 57 million individuals who are at high risk for progressing to diabetes within 10 years.<sup>3</sup>

## Diabetes Comorbidities

Patients with type 2 diabetes are at increased risk for the development of cardiovascular disorders, including coronary artery disease (CAD) and stroke. The constellation of symptoms that includes insulin resistance and central obesity greatly increases the likelihood of emergence of additional comorbidities.<sup>4</sup> Common comorbidities associated with diabetes include hypertension (Figure 1), hyperglycemia, and dyslipidemia.

Overall, interventions to improve these comorbidities individually result in concurrent improvements in other related clinical parameters. For example, when obese individuals lose weight, insulin resistance is typically diminished, improving blood glucose levels, blood

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**KEY POINTS**

- Patients with type 2 diabetes are at increased risk for cardiovascular disorders, including coronary artery disease, stroke, and peripheral vascular disease.
- The costs for diabetic patients with complications are nearly 3-fold greater than for diabetic patients without complications.
- The complications of diabetes can be prevented or delayed with appropriate glycemic control, disease management, and ongoing monitoring.
- An approach that uses a combination of strategies across a variety of care and payer modalities may provide substantial improvements in patient outcomes and curb the excess costs.
- Payers may need to reexamine how they approach the management of care for patients with diabetes.

imately 2 to 4 times higher than adults without diabetes. And the risk for stroke is 2 to 4 times greater in patients with diabetes compared with those without diabetes.

Macrovascular complications of diabetes include CAD, stroke, and peripheral vascular disease, which can result in ulcers, gangrene, and lower-extremity amputations. Diabetes macrovascular complications associated with larger blood vessels include CVD and stroke, which are responsible for 65% of all deaths in diabetes.<sup>5</sup> Macrovascular complications representing small vascular injuries include diabetic retinopathy and peripheral nerve damage. Neuropathy, renal disease, and ocular damage are among the microvascular complications of diabetes. Diabetes is currently the leading cause of end-stage renal disease.<sup>5</sup>

The complications of diabetes can be prevented or delayed with appropriate glycemic control and ongoing disease management and monitoring. The benefits of good glycemic control have a long-term impact on outcomes. For example, a reduction in hemoglobin (Hb) A<sub>1c</sub> of 1% diminishes the risk for microvascular complications of eye, kidney, and nerve damage by 40%.<sup>1</sup> Each 10-mm Hg reduction in systolic BP reduces diabetes-related complications by 12%, and correction of dyslipidemia may reduce the risk for cardiovascular complications by up to 50%.<sup>1</sup>

**Economic Impact**

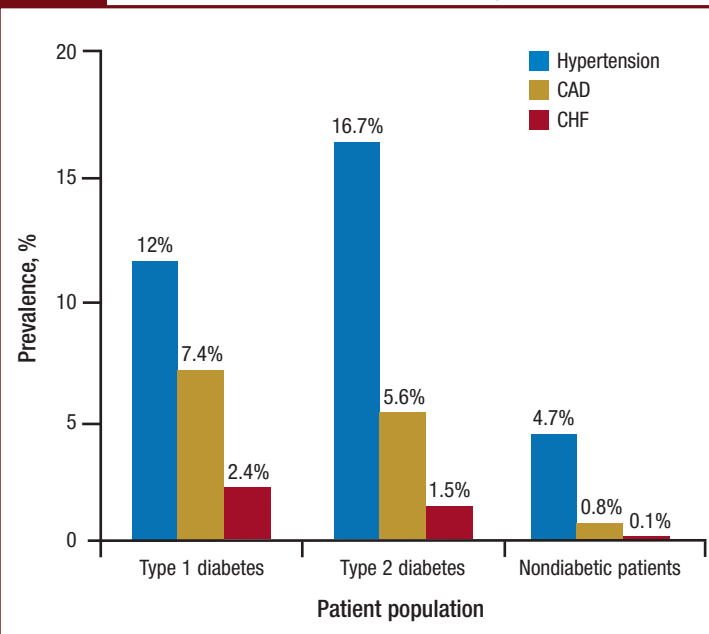
The costs associated with diabetes are staggering. Data released by the CDC in 2007 showed that the total cost of diagnosed diabetes in the United States was \$174 billion, which included \$116 billion of direct medical costs and \$58 billion of indirect costs (ie, disability, work loss, and premature death).<sup>2</sup>

An analysis by UnitedHealth Group indicated that the majority of patients with diabetes are covered by private insurance, but the prevalence of diabetes and prediabetes in Medicare and Medicaid populations is higher than among the privately insured; consequently, these programs carry a disproportionate responsibility for healthcare costs attributed to these conditions.<sup>1</sup>

This analysis included data from a sample of 10 million commercial health plan members, showing that the average annual costs incurred by a patient with diabetes in 2009 was \$11,700 compared with annual costs of \$4400 for a patient without diabetes.<sup>1</sup> Furthermore, the average annual costs incurred by a diabetic patient with complications was \$20,700, which is nearly 3 times that of a diabetic patient without complications (\$7800).<sup>1</sup>

Another analysis demonstrated that even when controlling for specific comorbidities, including hypertension, congestive heart failure, and CAD, patients with diabetes require greater expenditures compared with

**Figure 1** Prevalence of Comorbidities: Diabetes and Cardiovascular Disease in Adults Aged 20-69 Years



CAD indicates coronary artery disease; CHF, chronic heart failure. Reprinted with permission from Fitch K, et al. Value-based insurance designs for diabetes drug therapy: actuarial and implementation considerations. *Milliman Client Report*. December 1, 2008.

pressure (BP) typically decreases, and lipid parameters are improved.

**Clinical Consequences**

Patients with diabetes are at great risk for serious and life-threatening complications.<sup>5</sup> Adults with diabetes have cardiovascular disease (CVD)-related death rates approx-

nondiabetic patients with those conditions.<sup>6</sup> Estimates from the Agency for Healthcare Research and Quality indicate that nearly 25% of hospital spending results from patients with diabetes.<sup>7</sup> In addition, hospital admissions for persons with diabetes cost more than comparable admissions for patients without diabetes.<sup>1</sup>

The optimal management of diabetes requires control of the patient's glucose levels, BP, and lipid levels. However, a relatively low proportion of patients with diabetes actually achieve the treatment goals. Less than 50% of adults with diabetes aged <65 years demonstrate target HbA<sub>1c</sub> levels of <7%, as illustrated in **Table 1**.<sup>8</sup>

Adherence to antihyperglycemic drug therapy is relatively poor, which is an important reason for limited treatment success.<sup>6</sup> A meta-analysis of adherence studies demonstrated a range of adherence between 36% and 93% in retrospective studies, and between 67% and 85% in prospective monitoring studies.<sup>9</sup>

Multiple studies have confirmed that poor adherence to drug therapy is associated with poor glycemic control; similarly, a strong correlation exists between good compliance and adherence to antihyperglycemic medication regimens and glycemic control. One issue that contributes to poor medication adherence is the burden of copayments.<sup>10</sup> With increasing copayments for antihyperglycemic drugs, adherence to prescribed regimens decreases.

**Overview of the Approach to Treatment**

Major medical associations have adopted treatment algorithms and guidelines for the management of patients with diabetes, including the American Diabetes Association, the European Association for the Study of Diabetes, American College of Endocrinology, and the American Association of Clinical Endocrinologists.<sup>11</sup> Although there are differences and distinctions in their recommendations, overall treatment approaches include lifestyle modifications to improve diet, increased physical activity, and smoking cessation.

Virtually all patients with diabetes require pharmacologic therapy, however. In addition to achieving glycemic control with target HbA<sub>1c</sub> levels >7%, medical interventions aim to control BP, correct dyslipidemia, and facilitate weight reduction for patients who are obese or overweight.<sup>1</sup>

Metformin, a biguanide, is generally the first oral antidiabetic medication administered. Metformin is titrated to maximal effect over 1 to 2 months, with the goal of achieving a significant reduction in HbA<sub>1c</sub>. If metformin monotherapy does not achieve an HbA<sub>1c</sub> control level at or near 7%, additional drugs may be added.

Some oral drugs are formulated as combinations (typically with metformin) to enhance compliance with

**Table 1** Control Rates of Blood Glucose, Blood Pressure, and Cholesterol in Patients with Diabetes

	Control rate for patients aged <65 years	Control rate for patients aged ≥65 years
Blood glucose target HbA <sub>1c</sub> <7%	49%	62%
Systolic BP target <130 mm Hg	60%	33%
HDL-C target >40 mg/dL men, >50 mg/dL women	49%	56%
LDL-C target <100 mg/dL	39%	48%

BP indicates blood pressure; HbA<sub>1c</sub>, glycated hemoglobin; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol.

Reprinted with permission from Fitch K, et al. Improved management can help reduce the economic burden of type 2 diabetes: a 20-year actuarial projection. *Milliman Client Report*. April 28, 2010.

multiple-drug combinations. Frequent monitoring is necessary, and clinicians should aggressively modify medication regimens to achieve treatment goals.

Appropriate medication selection requires that physicians be cognizant of all of the potential effects of anti-diabetic medications, beyond their effects on hyperglycemia. For example, the vast majority of patients with type 2 diabetes are overweight or obese, yet the use of many antihyperglycemic medications (ie, insulin, sulfonylureas) results in weight gain. Selection of agents that are weight neutral, or promote weight loss, can offer additional advantages to patients.

Other factors to consider include the effects of different medications on dyslipidemia and BP.<sup>5</sup> The choice of agents may also depend on their effects on beta-cell function. It is estimated that by the time of diagnosis, patients with type 2 diabetes have lost at least 50% of their beta-cells.<sup>12</sup> Preservation of remaining beta-cell function should be a therapeutic priority; weight loss is an important route to this goal. Different antihyperglycemic medications have variable effects on beta-cell function, which should figure in the clinical decision-making.<sup>12</sup>

For example, the thiazolidinediones promote weight gain, but the thiazolidinedione pioglitazone delays beta-cell decline. Agents that promote the release of insulin, including sulfonylureas and the glinides, appear to increase the rate of beta-cell failure. Agents that work

via the incretin pathway, glucagon-like peptide (GLP)-1 analogs and dipeptidyl peptidase (DPP)-4 inhibitors, appear to preserve beta-cell function.<sup>12</sup>

### Unmet Needs

Current treatment approaches remain far from solving the problem of diabetes. This enormous unmet need has driven the development of many novel agents that incorporate innovative technologies and address different metabolic pathways.

At least 3 different classes of agents to stimulate the incretin pathway are being investigated<sup>12</sup>:

- Small-molecule glucose-dependent insulinotropic receptor agonists (GPR119) are in clinical development by at least 3 different companies
- Compounds to stimulate TGR5, which is expressed in enteroendocrine cells of the gut and augments GLP-1 release, are being investigated
- Activators of fatty acid-binding receptors, which potentiate insulin secretion by the pancreas in response to fatty acids, are particularly interesting, because they do not seem to promote beta-cell decline.

Glucokinase activators increase pancreatic beta-cell sensitivity to glucose, thereby promoting insulin secretion and enhancing hepatic handling of glucose; they also promote beta-cell function and survival.<sup>12</sup>

At least 8 companies have glucokinase activators in preclinical or clinical development. Another class of agents under investigation, sodium-glucose transport inhibitors, promotes urinary excretion of glucose; at least 9 of these agents are the subjects of clinical investigation. Several formulations of oral insulin are in development.<sup>12</sup>

### Strategies to Improve Care and Control Costs Disease/Case Management

Disease management programs have long been used to improve outcomes for patients with diabetes. These programs can encompass a wide range of interventions, including patient education, biometric monitoring, reminders for tests and examinations, review of care plans, and patient support programs, all with the goal of supporting treatment adherence.<sup>13</sup>

The Living Well care process, created by the Diabetes Workgroup of Intermountain Healthcare, includes state-of-the-art educational materials for physicians and patients, as well as expert advice to help clinicians with complex treatment decisions.<sup>14</sup> The program also provides multidisciplinary coordination of diabetes care, enhancements to the electronic medical record (EMR), as well as data systems to allow healthcare providers to more readily track their performance.<sup>14</sup>

Highmark, a BlueCross BlueShield health plan in Pennsylvania, evaluated the cost-savings and return on

investment (ROI) of its employee wellness programs, which included smoking cessation, guidance for nutrition and weight management, and stress management.<sup>15</sup> Support was offered via online programs, individual coaching, and classes. Their analysis compared medical claims for participants in the wellness programs with risk-matched employees who did not participate in the wellness programs (N = 1892 for both groups). Although program expenses totaled \$808,403, the savings generated from these programs over 4 years was \$1,335,524, resulting in an ROI of \$1.65 for every dollar spent on the wellness program.<sup>15</sup>

Affinia Group provided economic incentives for patients with diabetes to better manage their disease. Participation in their program resulted in a substantial discount on annual insurance premiums, as well as extra reimbursement for annual healthcare costs and reductions in copays for drugs and provider visits.<sup>14</sup>

Ralston and colleagues implemented a novel web-based collaborative care program.<sup>16</sup> After an initial consultation, participants used online counseling services and medical records were reviewed by a care manager. After adjusting for age, sex, and baseline HbA<sub>1c</sub>, enrollment in this program for 12 months resulted in a significant reduction in HbA<sub>1c</sub> levels. After 1 year, 11% of patients in the usual-care group had HbA<sub>1c</sub> levels <7% compared with 33% of participants in the web-based intervention ( $P = .03$ ).<sup>16</sup>

Another study examined the use of a diabetes management program in a Medicare Advantage population.<sup>13</sup> To be included, these high-risk patients had to have had at least 1 emergency or urgent care visit or 1 hospital admission with a diabetes-related diagnosis in the 12 months before admission. Patients with CAD and diabetes were randomized to the intervention or usual-care group. Patients in the intervention group received educational materials at the beginning of the program and a quarterly newsletter on diabetes.<sup>13</sup>

A critical component of this disease management included periodic telephone calls from a nurse case manager, who called participants every 14 to 30 days for assessment and to provide coaching, education, and reminders about vaccinations, eye and foot examinations, and adherence to prescribed medications. Nurse managers also communicated regularly with patients' physicians to support treatment plans.

This telephone-based intervention was very effective in decreasing diabetes-related inpatient admissions and all-cause medical costs ( $P \leq .05$  vs usual-care group, for both comparisons). The annual all-cause medical costs per member decreased by \$985 in the intervention group and increased by \$4547 ( $P < .05$ ) in the comparison group.

Significant improvements ( $P < .001$ ) were realized in all clinical measures assessed, including HbA<sub>1c</sub>, foot examinations, low-density lipoprotein cholesterol (LDL-C) levels, and the presence of microalbuminuria. Consistent, timely management via telephone by a nurse case manager effectively improved clinical parameters and resulted in cost-savings in patients from a Medicare Advantage population.

### **Pharmacist-Led Intervention**

Approximately 15 years ago, the Asheville Diabetes Care Project was begun.<sup>17,18</sup> This innovative, community-wide disease management program utilized pharmacists to provide critical information and support to enhance outcomes in patients with diabetes in the Asheville, NC, area. The North Carolina Center for Pharmaceutical Care coordinated the project, which included pharmaceutical companies, universities, and hospital-based resources, physicians, and community-based pharmacists. The city of Asheville was the employer and payer; patients included active and retired employees and their families.<sup>17,18</sup>

Once patients were identified, their physicians were notified, and a participating pharmacist was assigned to each patient. Pharmacists met with their designated patients for initial 60-minute counseling sessions and offered guidance and advice to help patients achieve their therapeutic goals: patients understood that their progress would be monitored, their physicians would be informed of their progress, and monthly follow-up visits with the pharmacist were planned. Pharmacists documented patient interactions according to a specified protocol and communicated regularly with referring physicians.<sup>19</sup>

This pharmacist-implemented disease management program offered financial benefits for all stakeholders as well as the potential for improved clinical results.<sup>19</sup> Copays were waived if patients participated in the program with a trained pharmacist. Pharmacists were paid for their interactions with these patients, and the employer incurred lower overall healthcare costs as a result of improved clinical benefits resulting from enhanced diabetes management.<sup>19</sup>

The first clinical outcomes of the Asheville Project were reported after 14 months.<sup>20</sup> At baseline, 33% of patients had HbA<sub>1c</sub> levels between 4.4% and 6.4%; after 14 months, 67% of patients enrolled demonstrated HbA<sub>1c</sub> levels within this range. The mean HbA<sub>1c</sub> of the group improved by 1.4 percentage points. Significant improvements from baseline were observed for high-density lipoprotein cholesterol and LDL-C.<sup>20</sup>

The economic impact of the Asheville Project was evaluated by comparing insurance claims and prescription drug claims for the 12 months before and after the

program initiation date. The total cost of inpatient and outpatient services declined by \$20,246 during 12 months of this program.<sup>20</sup> Although the number of patient-provider interactions increased, inpatient services decreased as outpatient services were increasingly used, leading to decreased costs. This improvement in expenditure includes fees paid to the pharmacists for their intervention, the initial cost of supplying patients with glucose monitors, and charges for the educational program to train participating pharmacists.

The Asheville Project utilized an innovative community-based disease management approach that included pharmacist-patient interactions to provide education and support. With more than 5 years of follow-up, clinical and economic improvements were clear.<sup>21</sup> At each follow-up visit, increasing numbers of patients achieved HbA<sub>1c</sub> levels <7%, and more than 50% demonstrated improvements in dyslipidemia at every measurement. Multivariate analyses revealed that the patients who benefited the most were the ones with the highest baseline HbA<sub>1c</sub> levels and the highest costs at baseline.

Expenditures, which had initially been concentrated on inpatient and outpatient physician services, were increasingly dedicated to prescription medications. Total mean direct medical costs decreased by between \$1200 and \$1872 per patient annually. One employer group noted that employees lost fewer days to sick time annually, resulting in annual increases in productivity of approximately \$18,000.

Individuals enrolled in the Asheville Project were committed to participating in the program. The risk manager for Asheville reported that when individuals did not comply with the disease management program, they were notified that they would no longer receive free medications and healthcare services; that knowledge became "the greatest adherence tool we ever saw."<sup>22</sup>

The program was subsequently expanded to cover other disease areas, including hypertension, dyslipidemia, and asthma; favorable clinical and economic results emerged for all of these conditions.<sup>23</sup> The diabetes program was successfully expanded in 2009 to cover 30 employers in 10 cities. Economic analyses confirmed the benefits of the program: employers saved \$1100 annually on patient healthcare costs on average, and employees typically saved \$600.<sup>24</sup> Another North Carolina company instituted a similar program, which covered about 150 individuals with diabetes. In 3 years, the program resulted in savings of approximately \$5115 per patient.<sup>25</sup>

### **Physician Involvement**

As noted, diabetes and its associated conditions represent a complex constellation that requires proactive, thoughtful clinical intervention. Treatment often re-

quires significant management support and education, and may optimally include medical nutrition therapy, smoking-cessation guidance, as well as other services. A recent web-based survey of 300 primary care physicians and endocrinologists revealed that most physicians feel they are underreimbursed for services they provide to patients with diabetes, resulting in less time spent with each patient.<sup>26</sup> The consequence of this perceived limitation in time prevents physicians from providing comprehensive diabetes care.

Wellmark Blue Cross and Blue Shield, which covers >2 million individuals in Iowa and South Dakota, developed a program to enhance clinical services for patients with diabetes.<sup>27</sup> Wellmark partnered with physicians to design all aspects of the program, including software selection to identify patients who did not meet clinical targets of optimal BP, lipid levels, and glycemic control. Clinicians who achieved high levels of performance, those who utilized EMRs and electronic prescribing, received additional compensation. Overall, Wellmark found that physician-directed quality improvements resulted in better care for patients with diabetes and significant cost-savings. Currently, other payers are reviewing ways to follow the Wellmark model with the goal of achieving similar successful results.

The Physician Consortium for Performance Improvement (PCPI) is an interdisciplinary group convened by the American Medical Association that aims to improve patient health and safety by development and implementation of evidence-based clinical performance measures.<sup>28</sup> The performance measures created focus on outcomes and group-related measures to generate composite information; they also incorporate best practices information and include results from testing projects, and ultimately support patient-centered, appropriate care. Diabetes and hypertension are 2 of the many conditions for which PCPI measure sets exist and are being continually updated and refined. Development of these measure sets is an important vehicle by which physicians can guide provision of coordinated care delivery systems to enhance patient outcomes and utilize economic resources most efficiently.

### **Value-Based Pricing/Risk-Sharing**

Value-based pricing, or risk-sharing, represents a novel approach to reimbursement based on patient outcomes.<sup>29</sup> In the most common type of risk-sharing agreement, the manufacturer assumes the risk of the drug providing benefit to patients. Either the cost of the ineffective drug is refunded to the payer, or an equivalent amount of drug is provided to another patient at no cost. The net effect is that the payer is responsible to pay only for agents that result in improved health outcomes.

Several modifications of this approach have been devised, although details in the literature are few. An antiobesity drug rimonabant was marketed in Sweden according to a finding that it could be cost-effective for patients whose body mass index (BMI) exceeded 35 kg/m<sup>2</sup> or for those with a BMI >28 kg/m<sup>2</sup> plus dyslipidemia or type 2 diabetes. A value-based pricing scheme was developed, but it was in effect only through the end of 2008, and no follow-up details are found in the literature.

Merck and CIGNA developed a novel agreement regarding the use of sitagliptin and a metformin and sitagliptin combination.<sup>29</sup> Merck discounts the cost of these agents to CIGNA with documentation of improved blood glucose control, regardless of whether the improvement results from the use of sitagliptin, the metformin-sitagliptin combination, or other drugs. With this arrangement, Merck actually makes less money per drug used as health outcomes improve, but by placing these products favorably among CIGNA's options for diabetes treatment, increased use of these agents is expected.

An important limitation in understanding the impact of this type of risk-sharing is that, unlike results of controlled clinical trials that are generally widely published, reports of postmarketing outcomes-based approaches, typically based on private agreements between manufacturer and payers, are not often published or disseminated.

### **Value-Based Insurance Design**

Value-based insurance design (VBID) is an innovative approach to benefit planning to reduce long-term healthcare costs while improving health quality.<sup>5,10,30</sup> It involves changing the cost structure for plan participants to promote the use of services or treatments that result in relatively high health benefits and to discourage use of interventions with no or limited health benefits.<sup>6</sup>

Briefly, VBID uses a so-called "clinically sensitive copay structure."<sup>10</sup> Patients with diabetes represent a potentially valuable population within which to study this approach, because previous work has demonstrated relatively poor adherence with antidiabetic drug therapy, and a consistent relationship showing diminished medication adherence with increasing copays.<sup>10</sup> Poor adherence is associated with poor glycemic control. VBID for patients with diabetes aims to increase adherence and treatment compliance by decreasing drug copays.<sup>10</sup>

The Milliman Group performed a modeling experiment to assess 3 different VBID copay tier structures, comparing them with a standard structure in which the copay is \$10 for generic drugs, \$25 for preferred brands, and \$40 for nonpreferred brands (**Table 2**).<sup>6</sup> The options modeled included a plan with no copay for any medica-

tion (\$0/0/0), one in which there was the same copay regardless of preferred status (\$10/10/10), and one that reflects the usual copay structure, although at markedly lower copays (\$0/12.5/30).<sup>6</sup>

The analysis demonstrated that all these VBID plans increased medication adherence as well as costs to the payer. Increased payer costs result from lower copays required from patients with diabetes, as well as from filling of prescriptions by patients who previously were not obtaining their medications.<sup>6</sup> The Milliman report did not further analyze models to predict the cost-savings that might result from improved glycemic control achieved with increased medication adherence after reduction of copays. Results of such modeling exercises would be very informative and could further guide rational program development to enhance outcomes and control costs.

Pitney Bowes implemented a limited VBID program for employees and beneficiaries with diabetes or vascular disease.<sup>30</sup> Copays were eliminated for cholesterol-lowering statins, and copays were reduced for patients who were prescribed the antiplatelet agent clopidogrel for blood-clotting prevention. Results on drug adherence from the Pitney Bowes group were evaluated together with data from comparable patients covered by another plan without VBID.<sup>30</sup>

Eliminating copays for statins promoted stabilization of statin use and encouraged adherence; statin use continued the typical decline in use in the control group. Adherence to statins was 2.8% higher by patients in the Pitney Bowes group than in the control group. Adherence to clopidogrel was stabilized with copay reduction, with 4% higher adherence for Pitney Bowes patients compared with controls. Implementation of this VBID plan for statins and a clot-inhibiting drug resulted in modest improvements in medication adherence.<sup>30</sup>

Nair and colleagues reported on utilization and expenditures in a population of patients with diabetes from a healthcare industry employer.<sup>31</sup> Expenditures and drug prescriptions filled were tracked for a 9-month baseline period and 2 full years after initiation of the program. A total 225 patients with diabetes were continuously enrolled (mean age, 49 years); 52% had dyslipidemia, and 68% had hypertension.<sup>31</sup>

The VBID plan introduced for this study had all diabetes drugs and testing supplies at tier 1; retail copay was \$10 and mail-order copay was \$20. Investigators found a mean increase of 9% for any diabetes-related prescription in year 1, with a smaller increase of 5.5% in year 2. Medication adherence increased between 7% and 8% during year 1, but decreased slightly during the second year of the study. Pharmacy expenditures increased by nearly 50% in both years. Total medical expenditures for

**Table 2** Cost and Adherence Impact of 3 Benefit Designs for Patients with Type 2 Diabetes

Plan	Standard	VBID1	VBID2	VBID3
<b>Copay structure</b>				
Generic/preferred brand/nonpreferred brand, \$	10/25/40	0/12.5/30	0/0/0	10/10/10
<b>Net copayment</b>				
Per patient per month, \$	60	79	102	80
PMPM, \$	2.16	2.82	3.65	2.85
PMPM increment to base, \$	NA	0.67	1.49	0.69
<b>Virtual adherence</b>				
Patients adherent, %	49	60	69	57
Increment to base, %	0	22	41	16

Copays are listed by tier 1/tier 2/tier 3. Model uses data on the actuarial impact of copays. Virtual population is based on a typical employee population.

NA indicates not applicable; PMPM, per member per month; VBID, value-based insurance design.

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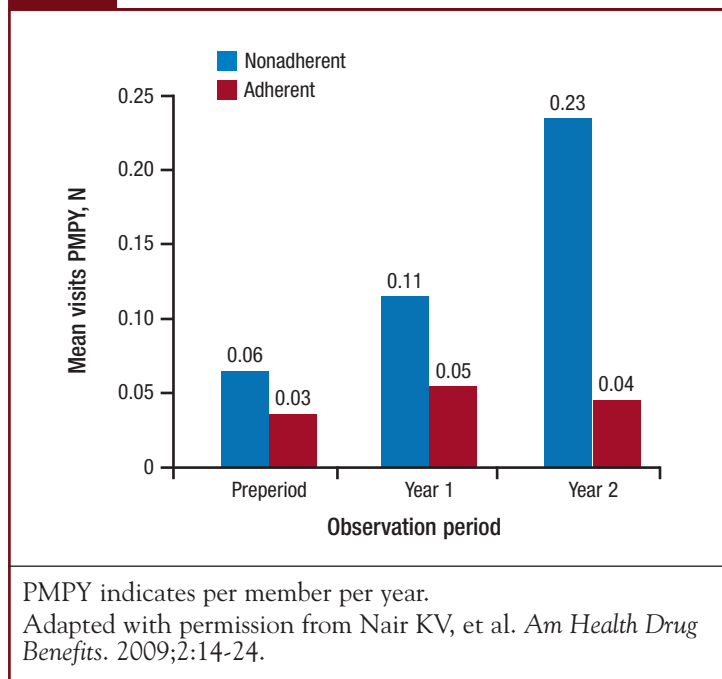
diabetes-related services increased 16% in year 1 and 32% in year 2 from baseline, although these changes were not significant.<sup>31</sup> Of note, emergency department visits decreased in year 1, although expenditures for office visits increased in both years. As shown in **Figure 2**, patients who adhered to drug therapy required far fewer emergency department visits overall.<sup>31</sup>

This analysis indicates that although implementation of VBID by reducing drug copays increases prescription medication adherence, other measures may be necessary to effect the changes that result in meaningful improvements in clinical outcomes. For example, these approaches may include patient and provider education and techniques to aid compliance with treatment, potential components to an integrated disease management program. Furthermore, economic gains resulting in improved adherence to diabetes treatment, with resultant benefits to clinical outcomes, may require a longer-term view.

**Future Directions in Diabetes**

**Interdisciplinary Cooperation, Engagement**

As healthcare-related costs in the United States

**Figure 2 Medication Adherence and Emergency Care Utilization**

have spiraled in an explosive fashion, many stakeholders have actively been seeking creative approaches to maximize the value of healthcare. A diverse array of strategies have been proposed, including consumer-driven health plans, wellness and prevention programs, pay-for-performance initiatives, and use of health information technology to collect, measure, and analyze data. Although economic incentives to patients, such as VBID, may increase adherence, such programs alone seem to provide only modest gains.

An approach that uses a combination of strategies designed to impact patients' health-related behaviors across a variety of modalities may provide a route to substantial improvements both in health outcomes and, ultimately, in health-related expenditures. The Diabetes Ten Cities Challenge used an integrated disease management approach together with elimination of drug copays, educational initiatives, acceptance of evidence-based guidelines, and community-based pharmacist coaching.<sup>32</sup> In a cohort of 573 patients with diabetes, this program demonstrated an average reduction of \$1079 in annual total healthcare costs per patient, and mean HbA<sub>1c</sub> levels decreased from 7.5% to 7.1% ( $P = .002$ ).<sup>32</sup>

Caterpillar's employees with diabetes enrolled in a disease management program that included economic incentives (elimination of copays for medications for diabetes and associated conditions; reduction in annual insurance premiums with participation in health risk

assessment); after 1 year, HbA<sub>1c</sub> levels declined markedly for many participants.<sup>10</sup>

A quality collaborative, the Institute for Clinical Systems Improvement, is sponsored by 6 health plans in Minnesota, including HealthPartners, which covers >1 million individuals.<sup>33</sup> This group defined "optimal diabetes care" for its members; features include BP <130/80 mm Hg, LDL-C <100 mg/dL, HbA<sub>1c</sub> <7%, no tobacco use, and daily aspirin use for individuals aged 41 to 75 years. Minnesota Community Measurement operates a website that tracks patient progress and identifies clinics whose patients successfully achieve optimal diabetes care. Initially, <4% of patients achieved all 5 of these diabetes care goals, but after several years the statewide average indicated that 17.5% of patients with diabetes were receiving optimal care.<sup>33</sup>

In addition to publicly reporting clinical indicators of quality of care, HealthPartners worked with individual employers to provide annual health assessments, devise workplace wellness programs, and institute telephone-based counseling and support services. The innovative, multifaceted approach of HealthPartners provides just one example of creative programming that can be developed to aid in management and provide support to encourage beneficial health behaviors and improve diabetes treatment.

### Potential Cost-Savings: Large-Scale Interventions

Better disease control for patients with diabetes will go far toward improving morbidity and mortality and controlling disease-related expenditures. UnitedHealth Group identified 4 interventions that could ultimately result in a 10-year net savings of up to \$250 billion and up to 10 million fewer individuals with prediabetes or diabetes.

Initiatives to promote weight loss in overweight and obese persons can reduce the incidence of prediabetes and diabetes; modeling studies indicate that a 5% weight loss by overweight or obese individuals could translate into \$45 billion in projected health system cost-savings over a decade.<sup>1</sup>

Reversing prediabetes, preventing disease progression and the ultimate development of complications, is another important goal. Previous trials have shown that adherence to intensive lifestyle interventions can reduce the incidence of diabetes by 58% among prediabetic patients; this could diminish the prevalence of diabetes by 8% and result in cumulative health system cost-savings of up to \$105 billion.<sup>1</sup>

Improving medical compliance by patients with diabetes can reduce complications and improve clinical outcomes, leading to an estimated cost-savings of \$34 billion over 10 years. Intensive lifestyle interventions among patients with diabetes to control overweight and obesity

will further facilitate clinical improvement and may contribute to an additional \$88 billion in cost-savings.

### **Payers' Key Role in Improving Outcomes**

The diabetes population is a medically complex population that requires more aggressive case management and medical intervention. Many payers have implemented innovative approaches to improve health outcomes and per member per month costs for diabetes and at-risk populations. At the same time, payers are limited in how they can effectively engage noncompliant patients with diabetes to change their lifestyle and improve their overall medical care.

With the advent of EMRs and accountable care organizations, payers, physicians, and patients will likely have greater coordination of care, adherence to guidelines, and aligned incentives. Patients and their families will need ongoing case management and monitoring to prevent further progression of the disease and its associated complications. Physicians need the tools and incentives to continue to educate and monitor ongoing treatment planning. Future models must take the successes of prior initiatives and ensure that current and future high-risk patients are engaged into the healthcare system.

Payers in particular may need to reexamine how they approach care of patients with diabetes.<sup>34</sup> The Diabetes Prevention and Control Alliance is a partnership between the CDC, the YMCA, UnitedHealth Group, and Walgreens that aims to reduce the risk of developing diabetes by encouraging lifestyle modifications. Their goals include identification of prediabetic individuals, contacting and screening them, and enrolling them in a program designed to support lifestyle changes. In addition, pharmacists are trained to provide support with regard to diabetes education, medication management, behavioral interventions, and monitoring for complications.

### **Conclusion**

To effect meaningful change, improve health outcomes, and maximize cost-effectiveness, novel programs to engage patients with diabetes should seek to combine educational initiatives; support for lifestyle modifications, including smoking cessation; encouragement of exercise programs; nutritional counseling; health awareness reminders to promote foot and eye examinations; and regular HbA<sub>1c</sub>, lipid, and BP monitoring, together with financial incentives to support patients behaviorally and economically. These wide-ranging interdisciplinary cooperative initiatives may result in improved glycemic control and a reduced risk of the long-term complications of diabetes with their attendant effects on morbidity and mortality.

Diabetes will continue to represent a major and growing source of morbidity, mortality, and spiraling health-care costs. Novel strategies to prevent diabetes, slow the transition from prediabetes to diabetes, and delay disease progression to forestall the development of complications are necessary to improve health outcomes for the increasing numbers of patients affected by these conditions as well as to control related healthcare expenditures. It is clear that these efforts will need to be comprehensive and multidisciplinary, engaging patients, physicians, diabetes educators, nutritionists, care managers, and payers in complex cooperative endeavors. ■

### **Author Disclosure Statement**

*Ms Greenapple reported no conflicts of interest.*

### **References**

1. UnitedHealth Center for Health Reform & Modernization. The united states of diabetes: challenges and opportunities in the decade ahead. Working paper 5, November 2010. [www.unitedhealthgroup.com/hrm/UNH\\_WorkingPaper5.pdf](http://www.unitedhealthgroup.com/hrm/UNH_WorkingPaper5.pdf). Accessed September 1, 2011.
2. Centers for Disease Control and Prevention. National Diabetes Fact Sheet. 2007. [www.cdc.gov/diabetes/pubs/pdf/ndfs\\_2007.pdf](http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf). Accessed August 2, 2010.
3. National Diabetes Information Clearinghouse. Diabetes Prevention Program. <http://diabetes.niddk.nih.gov/dm/pubs/preventionprogram/DPP.pdf>. Accessed August 31, 2011.
4. Long AN, Dagogo-Jack S. Comorbidities of diabetes and hypertension: mechanism and approach to target organ protection. *J Clin Hypertens (Greenwich)*. 2011;13:344-351.
5. American Diabetes Association. Complications of diabetes in the United States. [http://schoolwalk.diabetes.org/swfd/swfd\\_mshs\\_attach.pdf](http://schoolwalk.diabetes.org/swfd/swfd_mshs_attach.pdf). Accessed April 7, 2009.
6. Fitch K, Iwasaki K, Pyenson B. Value-based insurance designs for diabetes drug therapy: actuarial and implementation considerations. *Milliman Client Report*. December 1, 2008. [www.sph.umich.edu/vbidcenter/publications/pdfs/vbid-diabetes-drug-therapy-RR12-01-08.pdf](http://www.sph.umich.edu/vbidcenter/publications/pdfs/vbid-diabetes-drug-therapy-RR12-01-08.pdf). Accessed September 7, 2011.
7. Frazee T, Jiang J, Burgess J. Agency for Healthcare Research and Quality. Hospital stays for patients with diabetes, 2008. Statistical brief #93. August 2010. [www.hcup-us.ahrq.gov/reports/statbriefs/sb93.pdf](http://www.hcup-us.ahrq.gov/reports/statbriefs/sb93.pdf). Accessed September 7, 2011.
8. Koro CE, Bowlin SJ, Bourgeois N, Fedder DO. Glycemic control from 1988 to 2000 among US adults diagnosed with type 2 diabetes: a preliminary report. *Diabetes Care*. 2004;27:17-20.
9. Cramer JA. A systemic review of adherence with medications for diabetes. *Diabetes Care*. 2004;27:1218-1224.
10. Arevalo JD. Perspectives in value-based insurance design for patients with diabetes: assessment and application. *Am Health Drug Benefits*. 2011;4:27-33.
11. Nguyen Q, Nguyen L, Felicetta J. Evaluation and management of diabetes mellitus. *Am Health Drug Benefits*. 2008;1:39-48.
12. Aicher TD, Boyd SA, McVean M, Celeste A. Novel therapeutics and targets for the treatment of diabetes. *Expert Rev Clin Pharmacol*. 2010;3:209-229.
13. Rosenzweig JL, Taitel MS, Norman GK, et al. Diabetes disease management in Medicare Advantage reduces hospitalizations and costs. *Am J Manag Care*. 2010;16:e157-e162.
14. Aggressive diabetes management: evolving paradigms/innovative solutions. Takeda slide set. [www.thechroniccarecollaborative.com/Data/Sites/2/PDFFile/AGGRESSIVE\\_DIABETES\\_MANAGEMENT\\_Evolving\\_Paradigms\\_Innovative\\_Solutions\\_Virtual\\_Conference\\_Slides.pdf](http://www.thechroniccarecollaborative.com/Data/Sites/2/PDFFile/AGGRESSIVE_DIABETES_MANAGEMENT_Evolving_Paradigms_Innovative_Solutions_Virtual_Conference_Slides.pdf). Accessed September 7, 2011.
15. Naydeck BL, Pearson JA, Ozminkowski RJ, et al. The impact of Highmark employee wellness programs on 4-year healthcare costs. *J Occup Environ Med*. 2008;50:146-156.
16. Ralston JD, Hirsch IB, Hoath J, et al. Web-based collaborative care for type 2 diabetes: a pilot randomized trial. *Diabetes Care*. 2009;32:234-239.
17. Kent S. The Asheville Project: walking the tightrope to better health. *Pharmacy Times*. 1998;suppl:9-10.
18. Spillers C. The Asheville Project: using existing resources to prepare pharmacists for an expanded role. *Pharmacy Times*. 1998;suppl:30-31.
19. Bunting B, Horton B. The Asheville Project: taking a fresh look at the pharmacy practice model. *Pharmacy Times*. 1998;suppl:11-18.
20. Cranor CW. Outcomes of the Asheville Diabetes Care Project. *Pharmacy Times*. 1998;suppl:19-25.
21. Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc (Wash)*. 2003;43:173-184.

*Continued*

22. Kertesz L. Copay waiver programs cut health costs, improve productivity. *Business Insurance*. May 10, 2009. [www.businessinsurance.com/article/20090510/ISSUE01/100027603#crit=kertesz](http://www.businessinsurance.com/article/20090510/ISSUE01/100027603#crit=kertesz). Accessed September 7, 2011.
23. Bunting BA, Smith BH, Sutherland SE. The Asheville Project: clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. *J Am Pharm Assoc (2003)*. 2008;48:23-31.
24. Esola L. Asheville, NC, spawns a movement while improving the health of residents. *Business Insurance*. March 14, 2010. [www.businessinsurance.com/article/20100314/ISSUE07/303149993&template=preprint](http://www.businessinsurance.com/article/20100314/ISSUE07/303149993&template=preprint). Accessed September 7, 2011.
25. Wojcik J. Employer sees clear results. *Business Insurance*. April 22, 2007. [www.businessinsurance.com/article/20070422/ISSUE01/100021708&template=printart](http://www.businessinsurance.com/article/20070422/ISSUE01/100021708&template=printart). Accessed September 7, 2011.
26. Pozniak A, Olinger L, Shier V. Physicians' perceptions of reimbursement as a barrier to comprehensive diabetes care. *Am Health Drug Benefits*. 2010;3:31-40.
27. Diamond F. Empowered physicians are key to diabetes program's success. *Manag Care*. 2009;January:44-46. [www.managedcaremag.com/archives/0901/0901.planwatch.html](http://www.managedcaremag.com/archives/0901/0901.planwatch.html). Accessed September 7, 2011.
28. Physician Consortium for Performance Improvement: ahead of the curve. [www.ama-assn.org/resources/doc/cqi/pcpi-brochure.pdf](http://www.ama-assn.org/resources/doc/cqi/pcpi-brochure.pdf). Accessed September 7, 2011.
29. Hunter CA, Glasspool J, Cohen RS, Keskinaslan. A literature review of risk-sharing agreements. *J Korean Acad Managed Care*. 2010;2:1-9.
30. Choudhry NK, Fischer MA, Avorn J, et al. At Pitney Bowes, value-based insurance design cut copayments and increased drug adherence. *Health Aff (Millwood)*. 2010;29:1995-2001.
31. Nair KV, Miller K, Saseen J, et al. Prescription copay reduction program for diabetic employees: impact on medication compliance and healthcare costs and utilization. *Am Health Drug Benefits*. 2009;2:14-24.
32. Fera T, Bluml BM, Ellis WM. Diabetes Ten City Challenge: final economic and clinical results. *J Am Pharm Assoc (2003)*. 2009;49:383-391.
33. Butcher L. Multifaceted diabetes program pays off for HealthPartners. *Manag Care*. 2009;18:36-40.
34. Kuznar W. Payers lead healthcare reform toward prevention of chronic disease. *Am Health Drug Benefits*. 2010;3(suppl 5):S10. [www.ahdbonline.com/sites/default/files/AHDB0410\\_0.pdf](http://www.ahdbonline.com/sites/default/files/AHDB0410_0.pdf). Accessed September 1, 2011.

## STAKEHOLDER PERSPECTIVE

### We Must All Engage in the Diabetes Challenge: A Lifelong Journey, with No Silver Bullet

**MEDICAL/PHARMACY DIRECTORS:** In her article, Ms Greenapple provided an extensive list of successful strategies to go into full battle with the ever-growing type 2 diabetes giant in an effort to produce better outcomes for patients with this disease. So, why is the rate of diabetes continuing to skyrocket? The medical literature is filled with many articles and volumes indicating that good glycemic control is key to diabetes management.

Recommendations from health plans regarding diabetes management start with suggesting to members to change their diet, increase their exercise, and for those who smoke, quit smoking. For the majority of individuals, however, these 3 functions likely represent the most difficult goals to accomplish successfully long-term, with or without diabetes.

After members unsuccessfully attempt these behavioral modifications, the next payer answer is to provide a plethora of pharmacotherapy options for providers to choose from for their patients. These, however, remain just that—a list of options. Payers must become more active in engaging providers to implement more structured diabetes management initiatives. Gone are the days of simply making antidiabetic drugs available at the preferred lowest branded copayment, thereby relieving the payer of any further involvement.

Payer reimbursement for a diabetes office visit and the cost differential of the prescribed drug is just a “paper exercise.” Have we become mere transactions? Our healthcare delivery system deserves more: it hinges on the payer environment. If we are in this diabetes fight together, then we should demand payers to pro-

vide the structured framework necessary to effectively manage diabetes. In this article, Ms Greenapple discusses many examples of innovative payers who took the initiative and developed novel diabetes management programs that led to better outcomes by decreasing hemoglobin (Hb) A<sub>1c</sub>, blood pressure, and lipid levels, as well as weight.

There is no silver bullet to diabetes management, and the onus does not fall entirely on the payer's shoulders. An integrated approach is absolutely necessary: all stakeholders must step up and get engaged for successful management to become sustainable. Perhaps the introduction of accountable care organizations (ACOs) and ACO-like groups will motivate the healthcare community to implement more aggressive diabetes management interventions. Aggressive intervention in the prediabetes population puts a stake in the ground toward reversing the ever-increasing trend of diabetes prevalence in this country. Of course, the ultimate elements of successful diabetes management are patient commitment and accountability.

For health plans not already engaged, this is a grand opportunity to motivate their members, providers, and retail pharmacists to take charge and make a difference. We need a healthier nation, and it starts with aligning all stakeholders. To paraphrase an old saying, the success of diabetes management in reducing weight, HbA<sub>1c</sub> levels, blood pressure, and cholesterol is a lifelong journey, not a destination.

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