

Best Practices in the Care of Type 2 Diabetes: Integrating Clinical Needs With Medical Policy and Practice

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Introduction

It is estimated that about 1 in 4 Americans either has diabetes or is at an increased risk of developing it,¹ and diabetes has been found to be the sixth leading cause of mortality.² Typically associated with such risk factors as older age, obesity, family history, and physical inactivity,³ type 2 diabetes, in particular, can lead to serious medical consequences, including heart disease, hypertension, blindness, and poor circulation, which can contribute to foot complications (individuals with diabetes have an amputation rate that is 10 times higher than that of people without the condition).⁴ Furthermore, almost half of patients with diabetes have glycosylated hemoglobin (A1C) levels that are inadequately controlled (>7%).⁵

In the meantime, the costs to treat diabetes continue to climb. In 2007, total direct and indirect costs were estimated at \$174 billion, of which direct medical costs were estimated at \$116 billion, and indirect costs, such as lost worker productivity, at \$58 billion.⁶

Current treatment guidelines, such as those from the American Diabetes Association⁷ and the National Cholesterol Education Program,⁸ recommend early and aggressive control of glycemia, dyslipidemia, and blood pressure. Specific goals include maintaining A1C levels less than 7%; low-density lipoprotein (LDL) cholesterol less than 100 mg/dL; triglycerides less than 150 mg/dL; high-density lipoprotein (HDL) cholesterol greater than 40 mg/dL; and blood pressure less than 130/80 mm Hg.

Treatment and Management

The first level of treating type 2 diabetes normally involves diet, weight loss, and exercise, but when this proves insufficient, there are many medication options. These include such “older” drugs as the sulfonylureas (eg, glipizide, glyburide, and the newer third-generation gliclazide); meglitinides; biguanides (metformin); thiazolidinediones (the “glitazones,” or insulin sensitizers [eg, pioglitazone, rosiglitazone]); and the less frequently used alpha-glucosidase inhibitors. Newer options include the incretin-based agents (sitagliptin, saxagliptin, and exenatide). Incretin-based therapies have shown possibility in preserving beta-cell function, and their early use may prevent the onset of diabetes in those at risk, or in slowing or even stopping disease progression in patients who already have diabetes.⁹

The use of the above-mentioned therapies in combination has become increasingly common, as evidence has shown combination

Abstract

An estimated 1 in 4 Americans either has diabetes or is at increased risk of developing it in their lifetime. Diabetes is the sixth leading cause of death in America and can often lead to other major medical issues, including heart disease and blindness. Furthering the diabetes dilemma is that almost half of all diabetes patients' glycosylated hemoglobin levels are not controlled properly. There are, however, several programs that have been instituted to help deal with uncontrolled diabetes. It is most likely that a combination of 2 or more of these programs will be necessary for patients to become successful in managing their diabetes in a cost-effective manner. In the short term, costs may rise due to an increase in medications and physician visits, but in the long term these program regimens should offer financial relief from further diabetes complications and hospital visits.

(Am J Manag Care. 2009;15:S263-S268)

For author information and disclosures, see end of text.

therapy to have considerable benefits compared with monotherapy in terms of glycemic control.¹⁰ There are also usually fewer side effects.¹¹ Single-tablet combinations have been shown to improve patients' adherence to therapy as well as often lowering the cost.^{10,11}

Adherence to therapy is a serious barrier to optimal care; half of patients reportedly stay on their medication 6 months or less.¹² Part of this may be due to patients' lack of awareness of the consequences.¹² Physicians have limited time with their patients and cannot properly educate them alone. Other barriers to optimal care involve cost and access to medications. When healthcare systems utilize restrictive formularies or patients' drug copayments are too high, patients are not likely to adhere to their treatment regimen.¹³

Cost-Effective Measures for Optimal Diabetes Care

Several types of programs exist to help meet the clinical needs of diabetes while striving to reach cost-effectiveness goals simultaneously. Some of these programs include value-based health management; care/case and disease management; medication therapy management (MTM); pay-for-performance initiatives; and risk sharing.

Value-Based Health Management. Intended to help control company healthcare costs by targeting employee benefits, value-based health management employs 3 principles: removing barriers such as out-of-pocket costs (copayments are based on an expected clinical benefit from a drug instead of its acquisition cost; therefore, the more beneficial a medication is, the lower its copayment)¹⁴ and limited formulary coverage; the integration of care management (multidisciplinary teams consisting of physicians, pharmacists, nurses, health coaches); and focusing on prevention.¹⁵ Examples of such programs follow.

MHealthy: Focus on Diabetes. The first of its kind in the United States, MHealthy began in July 2006 and is an ongoing, prospective, controlled trial of targeted copayment reductions for underused but valuable diabetes therapies.^{14,16} The trial comprises 2507 employees/dependents with diabetes insured by one large employer (the intervention group),

with a control group of 8637 individuals with diabetes covered by other employers but insured by the same managed care organization. Educational materials emphasizing the importance of adherence to their medications are sent to both groups. Only the intervention group, however, is given copayment reductions for glycemic agents, antihypertensive medications, lipid-lowering agents, antidepressants, and diabetic eye examinations. Medication use and adherence are the primary outcome measures. At the time the trial began, the 3-tiered formulary was as follows: copays of \$7, \$14, and \$24 for generic (tier 1), preferred brand (tier 2), and nonpreferred (tier 3), respectively. These copays have been reduced since the trial's inception to \$0, \$7, and \$18, respectively. The preliminary success of the program has resulted in its being extended an additional 3 years, at which point data will be analyzed completely.

Pitney Bowes. Based on a predictive model showing low medication adherence is associated with increased healthcare costs, the Pitney Bowes company decided to shift all diabetes-related therapies and devices to tier 1 in an effort to decrease their employees' out-of-pocket costs. An outcomes study published in 2005 showed significant increases in medication possession ratio, a 6% decrease in overall claim costs, a 26% decrease in emergency department visits, and a 7% decrease in average overall pharmacy costs for patients with diabetes.¹⁷

The Diabetes Ten City Challenge. Beginning in January 2006, the Diabetes Ten City Challenge currently includes 30 employers and hundreds of pharmacists throughout 10 cities.¹⁸ Employers are able to provide their employees/dependents and retirees with diabetes a voluntary health benefit that waives the copays for diabetes medications and supplies. In addition, patients with diabetes are offered the assistance of at least 1 pharmacist coach possessing specific training in diabetes management. Results of a clinical and economic data analysis that included 573 patients were published earlier this year. Economic outcomes showed the cost of medical claims decreased 8.5%, pharmacy claim costs rose 36.5%, and overall healthcare costs increased 5.32%. Compared with projected costs however, the mean total healthcare cost

per patient per year decreased by \$1079 (7.24%), and healthcare costs for employers and patients were reduced by 18.84% and 21.61%, respectively. The researchers estimated employers and patients averted respective costs of \$278,512 and \$339,875 for the first year of the program. Clinical outcomes showed statistically significant improvements in A1C levels, LDL cholesterol levels, blood pressure, and body mass index.¹⁸

The Asheville Project. Based in Asheville, North Carolina, the Asheville Project is a community-based, pharmaceutical care services program.¹⁹ Employees of 2 companies were offered the same healthcare benefit, in which they were given access to a diabetes education center that employed Certified Diabetes Educators, and incentives such as a home blood glucose monitor and the waiver of copayments for all diabetes medications and supplies. Pharmacists were given specific diabetes training and were reimbursed for cognitive services. They met with patients free of charge to make and keep track of treatment goals and educate them on home glucose meter training and the importance of medication adherence. They also performed such physical assessments as blood pressure monitoring, and weight, feet, and skin evaluations. In one analysis of the Asheville Project, up to 5 years' data were examined, which showed that at patients' follow-up visits, between 57.7% and 81.8% had improved A1C levels compared with baseline, and 24.3% had optimal A1C values (<7%) at their first follow-up visit. Patients also experienced improvements in LDL cholesterol and HDL cholesterol. From an economic standpoint, in the first through fifth follow-up years, the mean insurance cost per person per year decreased by \$2704, \$3609, \$3908, \$5480, and \$6502, respectively. Although mean total prescription costs increased progressively each year (\$656 per person per year for the first year and \$2188 by the fifth), total mean direct medical costs per person per year decreased.¹⁹

The Lancaster County BRIDGE Project. Formed by a small group of businesses in Lancaster County, Pennsylvania, where 8% of the population is affected by diabetes,²⁰ and based on the Asheville Project, features of the BRIDGE Project include monthly, face-to-face meetings between patients and a

trained pharmacist coach, and such incentives as waived or reduced deductibles and copayments for medications, supplies, and laboratory tests.²¹ After the program had been implemented for 1 year, a reduction of \$5800 in healthcare spending per participant was realized, with a total decrease in healthcare costs of 30% (despite an increase of regular healthcare examinations of 34%).

Care/Case and Disease Management Programs.

Care/Case Management. The purpose of care, or case management programs, through assigning a case manager to patients, is to attain optimal wellness, improve coordination of care, and provide cost-effective, nonduplicative services.²² Care management programs associated with diabetes have shown benefit with regard to such process measures as A1C testing rates and patient satisfaction but have not been conclusive with regard to improving blood pressure, glycemic, and lipid control.²³

A large care management program was implemented in 1999 by Kaiser Permanente Northern California and led mainly by more than 150 nurses. The program was designed to treat patients for 3 to 6 months and then place them back into primary care after patients' risk factors for cardiovascular disease had improved and they had demonstrated a willingness to take responsibility in managing their condition.²³ Patients were offered intensive counseling on medication management and adherence as well as diet and lifestyle issues. A recent study of the program sought to determine its effectiveness in the improvement of A1C, LDL cholesterol, systolic blood pressure, medication adherence, and appropriate treatment intensification. The analysis included 3579 patients in the care management program and 3579 patients who were not and served as controls. Results showed statistically significant, although small, differences in favor of patients in the care management program with regard to A1C, LDL cholesterol, and systolic blood pressure levels. Patients in the care management program had A1C levels that were about 0.3% lower than those who were not in the program; patients who began the program with A1C levels of 9% or more experienced reductions of 0.5%; and LDL cholesterol levels were about 3 mg/dL lower for patients in the program. The program was not found to have an effect on medication adherence. Significant

improvements in all cardiovascular risk factors were ultimately found in all of the patients. Study results also showed that patients were likely to remain in the program longer than planned (average length, 8 months) and inclusion criteria were not always adhered to.

Results of a meta-analysis²⁴ that reviewed 66 randomized controlled trials (following patients from 6 to 18 months; with a 13-month median) of case management for type 2 diabetes found a mean reduction in patients' A1C levels of 0.52%, and reductions were particularly noted in situations where case managers could adjust medication without physician approval (mean A1C reduction of 0.80%). The use of a multidisciplinary team was also found to reduce A1C levels 0.37% more than without such teams in place.

Disease Management. Offered by many healthcare systems, disease management programs typically utilize disease registries, clinical guidelines, performance feedback, physician reminders, self-management support for patients, and targeted case management for high-risk patients.²⁵ Generally there are 3 benefits associated with disease management programs: improved quality of life for patients, long-term cost savings arising from the avoidance of complications and a reduction in healthcare system utilization, and gains in workplace productivity.²⁶ Researchers estimated one disease management program offered by HealthPartners would lead to a discounted medical care cost savings per patient with diabetes of approximately \$5345 over 10 years.²⁶

TRIAD (Translating Research into Action for Diabetes) was a study that examined random samples of patients from 63 physician groups within 7 health plans and 4 health plans having individual physician contracts. Researchers gathered information on the use of physician reminders, performance feedback, and structured care management via survey and then measured such processes of care as most recent A1C level, systolic blood pressure, LDL cholesterol level, and several measures of medication use. Results indicated that the use of any 3 strategies was significantly associated with increased retinal screening, nephropathy screening, foot examinations, and measurement of A1C levels. None of the strategies, however, were related to intermediate outcome levels (A1C levels, systolic

blood pressure, LDL cholesterol) or medication management of these outcomes.²⁵

Medication Therapy Management. MTM is a partnership between the pharmacist, other healthcare professionals, and the patient/caregiver to promote the safe and effective use of medications.²⁷

For every dollar spent on pharmacist-provided education for patients with diabetes, a cost savings of \$2 to \$3 is realized, mainly because of a resultant decrease in complications and hospitalizations.¹² Pharmacists see patients more often than their physicians and can help educate patients on diabetes and how to best manage it. MTM programs can help patients reach their treatment goals while avoiding such complications as hypoglycemia.

In one MTM program in Minnesota²⁸ for low-income patients, it was discovered upon checking patients' medical records that 36% of those with diabetes met the state's 5 standards for diabetes care; before MTM was implemented, about 6% of patients had met those standards. After pharmacists began assisting the patients previously not receiving the proper attention, it was believed about \$15,325 were saved annually.

Pay-for-Performance and Risk Sharing. *Pay-for-Performance.* Pay-for-performance programs work by financially rewarding healthcare providers when the quality of their care meets specific guidelines and decreases their reimbursement when it does not.²⁹

To realign incentives around higher quality, Bridges to Excellence was created by a group of employers, physicians, health plans, and patients.³⁰ From Bridges, 2 incentives programs arose: Diabetes Care Link and Physicians Office Link. Through Diabetes Care Link, physicians who have proved to be top performers in diabetes care by receiving recognition through the National Council on Quality Assurance Diabetes Physician Recognition Program³⁰ can earn up to \$200 for each of their patients with diabetes.³¹ These incentives are funded through the realized cost savings of lower healthcare expenses and increased individual productivity that result from higher quality diabetes care. Furthermore, the program estimates a savings of \$350 and a cost of \$175 per patient per year. The focus of the Physician Office Link program is to

encourage the office practice's use of information systems to enhance patient care.³²

However, critics of pay-for-performance for diabetes care say it may have an unintentional and undesirable consequence: a decrease in the availability of healthcare for those patients who need it most.²⁹ A study of more than 12,000 patients who had hypercholesterolemia found that outcomes of care were greatly influenced by the clinical decisions of the patients, regardless of the level of care their physicians had provided²⁹ and were instead affected by such issues as the cost of the drugs and the patients' age and sex. Physicians may be restricted to the formulary set forth by the health insurer, and if the formulary includes only less expensive or less effective drugs, the provider takes on an additional burden to achieve a positive clinical outcome for the patient. Trying to gain approval for nonformulary drugs is often challenging for the physician. There is also a risk of patients being excluded from clinical practices (the more risk associated with patients with diabetes, the less attractive they become to healthcare providers). Furthermore, patients perceived as noncompliant or who do not reach clinical goals quickly enough may find themselves excluded from practices.²⁹

Risk Sharing. In one example of risk sharing, health insurer Cigna and a pharmaceutical manufacturer recently announced that discounts on its diabetes medications would be provided to Cigna's if their members remain compliant on medications—even if members are not taking those made by the sponsoring manufacturer. Also part of the plan, Cigna gave preferred status to 2 of those manufacturer's diabetes drugs to improve access and affordability; in doing so copayments are approximately \$20 to \$25 less than other branded drugs without preferred status.³³

The Use of "Report Cards"

In an effort to motivate physicians to deliver higher quality care, health insurers may issue "report cards" on their performance and make them available to the public. This motivation is thought to come from 2 mechanisms.³⁴ By allowing this information to be made public knowledge, patients, referring physicians, and purchasers of healthcare may more easily select high-quality physicians.

Physicians who are rated may be motivated to compete with other physicians, and any negative feedback would encourage them to improve in the areas needed. Although seemingly logical, the value of physician report cards has not been demonstrated and may in fact lead to unintended consequences, such as physicians avoiding sick patients to improve their scores, encouraging physicians to achieve specific goals for healthcare interventions even in cases where it may not be appropriate for a patient, and disregarding patient preferences and clinical judgment.

Conversely, a new practice may instead involve the physician giving their patients a report card. One physician from Glens Falls, New York, created a report card for his patients with diabetes that evaluated how well they reached specific goals (exercise, cholesterol, weight loss, and A1C), and won a Best Practices Award from the Diabetes Best Practices Web site (www.diabetesbestpractices.com). Additionally, the report cards display laboratory results for patients along with treatment goals and clinical guidelines (those from the National Cholesterol Education Panel and the American Diabetes Association).

Conclusion

The programs discussed throughout this article are not mutually exclusive. Most likely a combination of 2 or more will be necessary to have success in meeting the clinical goals of diabetes in a cost-effective manner while helping patients to adhere to their treatment regimen and attain glycemic control. After program implementation, costs are likely to rise in the short term from an increase in medications, clinician visits, etc, but should ultimately provide cost savings in the long term from reductions in diabetes-related complications and hospitalizations.

Author Affiliation: From the Department of Health, Safety, Security, and Productivity, Navistar, Inc, Warrenville, IL.

Funding Source: Financial support for this work was provided by Merck & Co. Inc.

Author Disclosure: The author reports no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

Authorship Information: Concept and design (WBB); acquisition of data (WBB); analysis and interpretation of data (WBB); drafting of the manuscript (WBB); and critical revision of the manuscript for important intellectual content (WBB).

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