ABSTRACT

Diabetes is a progressive disorder associated with increased mortality, morbidity, and healthcare utilization. Several landmark studies in the past 2 decades have stimulated improved attention to disease control. Despite the availability of best clinical practice guidelines and recommendations, control of disease complications and progression is lacking. Pharmaceutical care services based on clinical guideline recommendations have been shown to improve clinical outcomes and quality of life in patients with diabetes. Pharmacists play an important role in patient education, monitoring, screening, referral, and motivation. Through a collaborative approach, interventions by the multidisciplinary healthcare team can improve management of patients with diabetes. (Adv Stud Pharm. 2008;5(9):280-287)

The prevalence of diabetes continues to increase. Despite enhanced emphasis on glycemic control through evidence-based treatment guidelines, the majority of patients with diabetes are not achieving control of the disease or its comorbidities to accepted goals. The fact that diabetes is often inadequately managed results in poor patient outcomes, costly medical interventions, and higher rates of adverse events requiring hospitalizations. Additionally, patients with diabetes must actively participate in their disease management through physical activity, healthy eating, medication adherence, self-monitoring of blood glucose (SMBG), daily foot inspections, proper oral/dental hygiene, skin care, and perhaps urinary ketone testing and self-injection of insulin. Nonadherence with or misunderstanding of these expectations can lead to poor clinical outcomes. Healthcare costs for patients with diabetes are higher compared to those of matched patients without diabetes, with an estimated $4410 additional employer mean annual per capita cost.

The American Diabetes Association (ADA) has identified that diabetes morbidity can be dramatically reduced by increasing awareness and improving prevention. Additionally, reduced morbidity can improve patient health-related quality of life (HRQOL) and decrease utilization of healthcare resources. Intensive management of diabetes by a multidisciplinary healthcare team appears cost effective while leading to a lower risk of complications. Education by healthcare providers can positively influence behavioral changes in patients with diabetes leading to improved glycemic and metabolic control, and ultimately, reduced morbidity and mortality. Patient education standards have been developed to guide healthcare professionals on how to teach patients and involve caregivers in proper daily care. These national standards are the basis for

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the recognition process of the ADA for diabetes self-management education programs.

Because patients with diabetes visit their pharmacies up to 8 times more frequently than average patients, community pharmacists are well positioned to assist with diabetes management. Pharmacists tend to be more accessible for medication and disease information than physicians. A patient-centered participatory relationship of pharmacists can improve patient satisfaction, adherence, and disease outcomes through education, teaching, monitoring, and motivation.

MANAGING DIABETES

Control of diabetes will lessen the incidence or slow the progression of complications such as foot and leg ulcers, peripheral neuropathy, renal failure, lower extremity amputation, and blindness. Best practice guidelines and recommendations for the management of patients with diabetes are available from several professional organizations (Table). The ADA and the American Association of Clinical Endocrinologists (AACE) each provide comprehensive evidence-based recommendations for the management of patients with diabetes.

Key recommendations from the ADA and AACE focus on aggressive control of glycemia, blood pressure (BP), and dyslipidemia, which the ADA calls the ABCs (A₁c [glycosylated hemoglobin], BP, and Cholesterol) of diabetes. The ADA and AACE general goals for patients with diabetes (excluding special populations—high-risk, pediatric, elderly, or pregnant patients) are identical for BP (130/80 mm Hg) and cholesterol (low-density lipoprotein cholesterol [LDL-C] <100 mg/dL; high-density lipoprotein cholesterol [HDL-C] >40–50 mg/dL; and triglycerides <150 mg/dL). However, to stress its importance in reducing complications, the AACE threshold for glycemic control is lower than that of the ADA (A₁c ≤ 6.5% vs 7%, respectively; preprandial plasma glucose <110 mg/dL vs 70–130 mg/dL, respectively; 2-hour postprandial plasma glucose <140 mg/dL vs 180 mg/dL, respectively). AACE and ADA diabetes management recommendations emphasize lifestyle and nutrition changes, pharmacotherapy interventions, monitoring and

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### Table. Resources for Practice Recommendations Regarding the Management of Patients with Diabetes

<table>
<thead>
<tr>
<th>Organization</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>American College of Endocrinology and the American Association of Clinical Endocrinologists</td>
<td>American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus</td>
</tr>
<tr>
<td>American Diabetes Association</td>
<td>Standards of Medical Care in Diabetes—2008</td>
</tr>
<tr>
<td>American Society of Health-System Pharmacists (ASHP)</td>
<td>ASHP Therapeutic Position Statement on Strict Glycemic Control in Patients with Diabetes</td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention</td>
<td>Strategies for Reducing Morbidity and Mortality from Diabetes Through Health-Care System Interventions and Diabetes Self-Management in Community Settings: A Report on Recommendations of the Task Force on Community Preventive Services</td>
</tr>
<tr>
<td>National Diabetes Education Program</td>
<td>Guiding Principles for Diabetes Care: For Health Care Providers</td>
</tr>
</tbody>
</table>

Data from AACE Diabetes Mellitus Clinical Practice Guidelines Task Force; American Diabetes Association; American Society of Health-System Pharmacists; Centers for Disease Control and Prevention; and National Diabetes Education Program.
screening for complications, multidisciplinary care by healthcare professionals, and patient self-management through education. Recent data strongly indicate that the actual A1c goal for a specific person may need to be set by his or her caregiver within the ranges provided above. This recognition of caregiver involvement focuses attention on the person’s ability and personal coping limitations with intensive care and management.

To assist healthcare professionals in achieving glycemic goals of patients with type 2 diabetes mellitus (DM2), AACE provides Road Maps to direct treatment interventions. Two treatment Road Maps are based on current A1c levels and are individualized for treatment-naive or treated patients. A third Road Map focuses on the prevention of diabetes. In the treatment Road Maps, specific recommendations focus on pharmacotherapy for initiation and adjustment of monotherapy or combination therapy. The treatment

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**Figure 1. AACE Diabetes Road Map to Achieving Glycemic Goals in Treated Patients with DM2**

<table>
<thead>
<tr>
<th>Current A1c%</th>
<th>Current Therapy Intervention</th>
<th>Continuous Titration of Rx (2–3 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;6.5%</td>
<td><strong>Monitor/adjust Rx to maintain ACE Glycemic Goals</strong>*</td>
<td>Monitor/adjust Rx to meet ACE Glycemic Goals*</td>
</tr>
<tr>
<td>6.5%–8.5%</td>
<td><strong>Intensify Lifestyle Modification</strong>&lt;br&gt;Monotherapy: Glinides, SU, AGI, metformin, TZD, DPP-4, premixed insulin preparations, prandial† or basal insulin‡&lt;br&gt;<strong>Initiate Combination Therapy</strong>&lt;br&gt;• Metformin + TZD or AGI&lt;br&gt;• TZD + SU&lt;br&gt;• DPP-4 + metformin or SU&lt;br&gt;• DPP-4 + TZD&lt;br&gt;• Colesevelam = met. SU or insulin&lt;br&gt;• Incretin mimetic + metformin and/or SU&lt;br&gt;Other approved combinations including approved oral agents with insulin†</td>
<td>Monitor/adjust Rx to meet ACE Glycemic Goals*</td>
</tr>
<tr>
<td>&gt;8.5%</td>
<td><strong>Maximize Combination Therapy</strong>&lt;br&gt;Monotherapy or Combination Therapy&lt;br&gt;<strong>Initiate Insulin Therapy (Basal-Bolus)</strong>&lt;br&gt;• Basal‡ + prandial insulin†&lt;br&gt;• Premixed insulin preparations**&lt;br&gt;• Combine with approved oral agents#&lt;br&gt;• Amylin analog†† with prandial insulin†&lt;br&gt;• Add incretin mimetic to patients on SU, TZD, and/or metformin</td>
<td>Monitor/adjust Rx to meet ACE Glycemic Goals*</td>
</tr>
</tbody>
</table>

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*ACE Glycemic Goals<br>
≤ 6.5% A1c<br>≤ 110 mg/dL FPG<br>≤ 110 mg/dL Preprandial<br>≤ 140 mg/dL 2-hr PPG

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1Prandial insulin (rapid-acting insulin analogs available as lispro, aspart, glulisine, or regular insulin) can be added to any therapeutic intervention at any time to address persistent postprandial hyperglycemia; 2Available as glargine and detemir; 3A recent meta-analysis suggests a possible link of rosiglitazone to cardiovascular events; other studies do not confirm or exclude this risk. The FDA has stated “In their entirety, the available data on the risk of myocardial infarction are inconclusive.”; 4Cannot be used in NYHA CHF Class 3 or 4; 5Available as exenatide; 6According to the FDA, rosiglitazone is not recommended with insulin; 7Analog preparations preferred; 8Available as pramlintide.

A1c = glycosylated hemoglobin; AACE = American Association of Clinical Endocrinologists; ACE = American College of Endocrinology; AGI = α-glucosidase inhibitor; CHF = congestive heart failure; DM2 = type 2 diabetes mellitus; DPP-4 = dipeptidyl peptidase-4; FDA = US Food and Drug Administration; FPG = fasting plasma glucose; HDL = high-density lipoprotein; IFG = impaired fasting glucose; IGT = impaired glucose tolerance; MNT = medical nutrition therapy; NYHA = New York Heart Association; OGTT = oral glucose tolerance test; PPG = postprandial glucose; Rx = treatment; SU = sulfonylurea; TZD = thiazolidinedione.

Road Map for treated patients is shown in Figure 1. \(^\text{15}\)

Recently, international expert committees from the United States, Europe, Asia, and Africa have supported reporting \(\text{A1c}\) values along with the calculated estimated average glucose (eAG) level, a more representative and precise measurement of average blood glucose. \(^\text{16}\) The development of a more stable method for \(\text{A1c}\) assay will report values 1.5% to 2% points lower than current \(\text{A1c}\) values, which could lead to errors. Consequently, the eAG value is a mathematical relationship that translates \(\text{A1c}\) into mg/dL or mmol/L, the same units used for blood glucose monitoring. The ADA and European Association for the Study of Diabetes (EASD) encourage incorporating eAG values into laboratory reports. When developing a management plan for patients with DM2, such as the plan shown in Figure 2, the ADA and EASD recommendations for metabolic management (see Figure 1 in article by Vivian A. Fonseca, MD) and for eAG values should be considered.

**The Asheville Project**

The Asheville Project, begun in 1996, is an intent-to-treat pre-post cohort analysis designed to assess the clinical, economic, and humanistic outcomes of employer-funded pharmaceutical care services (PCSs) provided to patients with diabetes insured by 2 local employers in Asheville, North Carolina. \(^\text{2,5}\) Reimbursement for cognitive services was provided to pharmacists in 12 participating community pharmacies without additional personal cost to patients, including waiver of copayments for diabetes drugs and related supplies. \(^\text{2,17}\) PCS consists of access to a diabetes education center staffed by community pharmacists with certificate training in diabetes. Services include patient-customized clinical assessment, diabetes education, SMBG training, adherence information, monitoring, follow-up, and referral. \(^\text{2,17}\) Pharmacists perform physical assessment of patients’ feet, BP, and

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**Figure 2. Summary of PSMP Diabetes: Patient Support and Care Process Flow**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>Patient identified as being “at risk”</strong></td>
</tr>
<tr>
<td>2.</td>
<td><strong>Patient: Understands incentives and provides consent for care</strong></td>
</tr>
<tr>
<td>3.</td>
<td><strong>Point of Care: Enrollment and Initial Visit</strong></td>
</tr>
<tr>
<td>4.</td>
<td><strong>Pharmacist: Reviews program with patient</strong></td>
</tr>
<tr>
<td>5.</td>
<td><strong>Physician: Collaborates to achieve patient goals</strong></td>
</tr>
<tr>
<td>6.</td>
<td><strong>Employer provides patient incentives for self-management</strong></td>
</tr>
<tr>
<td>7.</td>
<td><strong>Patient: Receives education from healthcare team</strong></td>
</tr>
<tr>
<td>8.</td>
<td><strong>Point of Care: Enrollment and Initial Visit</strong></td>
</tr>
<tr>
<td>9.</td>
<td><strong>Pharmacist: Coaches active patient involvement</strong></td>
</tr>
<tr>
<td>10.</td>
<td><strong>Physician: Communicates with pharmacist</strong></td>
</tr>
<tr>
<td>11.</td>
<td><strong>Patient earns Patient Self-Management Credential</strong></td>
</tr>
<tr>
<td>12.</td>
<td><strong>Patient: Maintains targets through active self-management</strong></td>
</tr>
<tr>
<td>13.</td>
<td><strong>Point of Care: Enrollment and Initial Visit</strong></td>
</tr>
<tr>
<td>14.</td>
<td><strong>Pharmacist: Reinforces activities by reviewing</strong></td>
</tr>
<tr>
<td>15.</td>
<td><strong>Physician: Communicates with pharmacist</strong></td>
</tr>
</tbody>
</table>

**PSMP Diabetes** = Patient Self-Management Program for Diabetes. Adapted with permission from Garrett and Bluml. *J Am Pharm Assoc.* 2005;45:130-137. \(^\text{20}\)
Multivariate analysis identified that patients with the highest baseline A₁c values, or at highest risk of morbidity and mortality, benefited most significantly from PCS.³ PCS was also more likely to decrease healthcare costs and the number of provider visits.³ Study limitations prevented determination of the actual relationship of PCS to outcomes assessed. However, thorough documentation of PCS and patient outcomes was recommended to facilitate capturing this relationship.⁵

Short-term outcomes demonstrated a significant increase in the proportion of patients with an improvement in A₁c values to the optimal range.² Although HRQOL remained unchanged, patient satisfaction with PCS improved significantly. Total direct costs of medical care did not increase whereas all-diagnosis medical costs decreased.⁷

Long-term effects on A₁c, lipids, and direct medical costs for up to 5 years following initiation of PCS was assessed, particularly to remove transient improvements that may be observed with short-term assessment.¹⁷ Improvements in A₁c persisted over time, and patients with higher baseline A₁c values were more likely to improve at each follow-up. LDL-C and HDL-C concentrations also improved but not substantially.¹⁷ All-diagnoses mean total amount paid claims decreased at each follow-up year, which was attributed to a shift from insurance claims for emergency care, inpatient care, and physician office visits to claims for prescription medications.¹⁷ Annual employer savings ranged between $1622 and $3356 per patient. Patient-reported self-care, although not a primary focus of the study, improved in all targeted behaviors.¹⁷ Collaboration among physicians, pharmacists, and employers was considered important to the success of this project.¹⁷

Overall, participants revealed satisfaction with their experience in the Asheville Project.¹⁸ Patients deemed education concerning nutrition, SMBG, exercise, use of diabetes-related equipment, and drug interactions as most valuable.¹⁸ Pharmacists and diabetes educators deemed participation and the willingness of patients and healthcare providers as important factors for the success of the program. Although training programs were helpful, healthcare professionals agreed that ongoing learning while working with patients was more valuable.¹⁸ Employers indicated that medical costs and absenteeism were reduced but recommended ongoing data collection to determine financial success.¹⁸ To implement similar programs in other communities, the Asheville Project employers recommend: development of proposals that benefit all participants (ie, patients, pharmacists, physicians, and employers); assessment of the program’s impact on patient health, absenteeism, and overall medical costs; education of invited physicians about program benefits and their role; effective communication among all healthcare provider participants and patients; and designing the program to address variations in patients’ literacy skills.¹⁸

The Diabetes 10-City Challenge

Healthcare advocacy groups and researchers, such as the National Diabetes Education Program (NDEP), the American Pharmacists Association (APhA) Foundation, and the Asheville Project, recognize the importance of patient self-management and employer support in improving health outcomes and decreasing medical costs in diabetes management.¹⁹ Because of the success of the Asheville Project and similar programs on adherence, medical costs, and health outcomes, development of a reproducible model has been championed by the APhA.²⁰ A Patient Self-Management Program for Diabetes (PSMP Diabetes) was designed to align incentives and encourage collaborative care.²⁰ The roles of the employer, physician, pharmacist, and patient are emphasized. As summarized in Figure 2, this model appears to improve health of patients with diabetes, lower medical costs, and improve patient self-management and satisfaction, all of which may be related to increased education, monitoring, support, and empathy from pharmacists.¹³⁰

In 2005, APhA Foundation initiated the Diabetes 10-City Challenge (DTCC) to test the scalability of the PSMP Diabetes model in 10 diverse geographic US sites.¹⁹ This employer-funded, voluntary ongoing project includes aligned incentives, collaborative care interventions, validated patient self-management credentialing, and waived copayments. Compensated pharmacist coaching, evidence-based guidelines, self-management strategies, and patient satisfaction assessment are essential elements of the program objectives. The overall goal of DTCC is to transform the healthcare management of chronic disease.¹⁹ Ongoing assessment of DTCC will include humanistic and clinical outcomes.
Diabetes 10-City Challenge sites include private consultation areas, resources to free pharmacists for PCS, access to the Internet for intervention documentation, and the availability of a trained specialized or certified diabetes management pharmacist coach. The first series of visits focus on assessment of patient knowledge, review of program requirements, patient goals, and medical history. Ongoing visits focus on clinical and self-management credential assessment. Periodic physician office visits include laboratory testing. Patient satisfaction was captured using surveys.

After the first year of implementation, diabetes control improved with mean A1c values reduced from 7.6% to 7.2%. Influenza vaccination, BP recording, lipid profiles, and foot and eye care examinations all improved. More than 97% of patients were very satisfied or satisfied with their care from pharmacists. Economic impact will be assessed at the next reporting phase.

Presently the APhA Foundation is coordinating similar programs in sites throughout the United States. Over 80 employers, public or private, are engaged in projects similar to this model for diabetes care. Pharmacists in these local settings are providing care to people with diabetes, documenting their recommendations, collaborating with other caregivers, and teaching patients and their family members about diabetes care and monitoring. Outcomes data are being collected in each of these sites.

**Role of the Community Pharmacist**

As the activities of pharmacists change from dispensing to clinical functions, the concept of pharmaceutical care has become important for achieving optimal patient outcomes. The ultimate goal of pharmaceutical care is to improve HRQOL through disease control by preventing or arresting the progression of disease. With proper training and continued learning, pharmacists can provide optimal PCS to patients with diabetes. Comprehensive PCS for patients with diabetes should focus on patient screening, assessment, monitoring, referral, and perhaps most importantly, education. Follow-up care and plan adjustment are also important for PCS and must be included.

Patients with diabetes managed by PCSs report improved HRQOL measures, including higher reported impact scores, less worrying about their disease, and improved perception of their health level. Effective communication skills with both patients and other healthcare professionals is critical to optimal PCS. Older patients, in particular, seem to view interpersonal communication (including social conversation) as a mechanism to build trust and improve satisfaction with PCSs. Because many patients with DM2 are older, pharmacists should address cognitive changes associated with aging that may complicate management in some patients (ie, complicated medication regimens and knowledge deficits about complications and comorbidities). However, due to the striking increase of DM2 in young people, pharmacists and all healthcare providers must also develop strategies to teach young people good health habits for successful glycemic control.

**Pharmaceutical Care Services**

Although a survey showed that roughly 66% of patients with diabetes were able to self-report their BP, only 50% knew their A1c value, and only 25% knew their LDL-C level. The NDEP and ADA have developed a campaign to help patients with diabetes understand the ABCs of their disease. Pharmacists can participate in this campaign by helping patients understand ABC goals, motivating patients to discuss the goals with physicians, tracking ABC values, screening for complications associated with ABC levels, and referral to physicians or other healthcare professionals based on ABC levels. PCSs are important to successful control of the ABCs of diabetes.

Patient visits for PCS should include education; review of all medications (especially those for diabetes, hypertension, and dyslipidemia); monitoring and assessment of weight, body mass index, BP, A1c, and lipids; and collaboration with physicians based on assessment. Assessment should include foot care and sensitivity observations, eye examination frequency, and HRQOL evaluations. Specific interventions may include initiating aspirin therapy, administering influenza vaccination, referral for therapeutic shoes, and incentives for participation, such as blood glucose monitors and test strips.

**Patient Education**

Education should focus on improving self-management, eliminating misconceptions of disease, and discussing side effects of medications. Glycemic control is shown to improve with PCSs that include training on SMBG. Poor medication adherence seems to be related to side effects, perception that medications are unhelpful, complex medical regimens,
cost of therapy, confusion about physician instructions, and an asymptomatic state.\textsuperscript{25,26} Medication and self-management adherence may be improved with pharmacist-led individualized interventions that combine education, reminders, feedback, and other support measures.\textsuperscript{26}

Education should include correcting disease and complication misconceptions. Specific topics should include signs and symptoms of hypo- or hyperglycemia and their treatment steps for the individual patient, eye/mouth/dental/foot care and assessment by specific healthcare providers when indicated, nutrition and meal portion control, physical activity, smoking cessation, alcohol moderation or avoidance when indicated, SMBG and ketone testing, drug administration, and carrying medical identification.\textsuperscript{4} Tools for education may include designated patient counseling areas, visual aids, Internet resources, handout materials, teaching models of glucose monitors and devices, food models, and log books to improve adherence and monitoring.\textsuperscript{4,11} Pharmacists should assess the patient's willingness to participate and their anxiety levels, and should adapt education to prevent undue stress to patients.

**Collaborative Approach**

Successful PCS models incorporate evidence-based multicomponent interventions by multidisciplinary teams that focus on monitoring of the ABCs of diabetes and improving quality of care to promote HRQOL.\textsuperscript{4,7,27} A team approach that focuses on patient self-management has been shown to improve glycemic control, cholesterol levels, and BP; decrease foot lesions and retinopathy; and reduce utilization of healthcare resources.\textsuperscript{7} The multidisciplinary approach should be ongoing, proactive, planned, community based, and patient centered.\textsuperscript{7} Team members should consist of physicians, pharmacists, dieticians, physical therapists, nurses, and other allied healthcare professionals as indicated.\textsuperscript{4,7} Pharmacists and other members of the team should develop a list of potential referral practitioners for specific patient needs (eg, ophthalmologists, podiatrists, and dentists). Patients who need a referral can be linked to the practitioner by the pharmacist. Patient education, medical interventions, and psychosocial support are important elements of the team approach.

Since the Centers for Medicare and Medicaid Services (CMS) have now mandated medication therapy management (MTM) for all Part D plans, community pharmacists may have further opportunities to work with managed care organizations to deliver high-quality cost-effective PCS.\textsuperscript{26} CMS has identified diabetes as a target disease state for MTM because of its prevalence and high cost of treatment.\textsuperscript{4} Pharmacists may benefit as a result of becoming well versed in diabetes management programs.

**Conclusions**

Diabetes is a lifelong disease requiring behavioral and coping skills: physical activity; dietary, pharmacologic, and monitoring interventions. Self-management thus comprises a critical element of disease management.\textsuperscript{7} Annual costs have been shown to decrease when A1c, body weight, BP, and lipids are controlled, which could be facilitated through PCSs.\textsuperscript{7} PCSs require the commitment of time and resources, including a dedicated staff, and a shift from dispensing to providing pharmaceutical care.\textsuperscript{4} Through cooperative practice with PCS, diabetes management can be enhanced and patient outcomes improved.

**References**


8. AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of dia-
betes mellitus. *Endocr Pract.* 2007;13(suppl 1):S1-S68.