Care and Treatment of Ambulatory Patients With Diabetes: Evidence-Based Team Care Initiatives

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Upon successful completion of this program, the reader should be able to perform the following:

1. Discuss the prevalence, pathogenesis, secondary complications, and prevention of type 2 diabetes mellitus with a focus on new populations, early identification of warning signs, and modifiable risk factors at prevention and treatment stages.
2. Outline elements of a pharmacist-based, collaborative diabetes self-care education and training plan.
3. Identify physical and clinical requirements involved in establishing a pharmacy-based foot care clinic.
4. Compare currently available professional and site certification or credentialing programs.
5. Describe best practice methods of instituting and maintaining a community pharmacy clinic within a collaborative team setting.

INTRODUCTION AND OVERVIEW
Diabetes as a Health Crisis

Type 2 diabetes mellitus (T2DM), previously known as non–insulin-dependent diabetes, has become a major health crisis in the United States, as diagnoses reach epidemic numbers and as complications nearly double the mortality risk of the diabetic population compared with healthy individuals.

Nearly 8 percent of the U.S. population (26 million adults) has diabetes, primarily T2DM, and approximately two million more are diagnosed each year. In addition, an estimated seven million Americans likely have undiagnosed diabetes. The total cost burden of diabetes is estimated at $174 billion annually, and the severe health impact reduces life expectancy of patients with diabetes by up to 14 years.

T2DM occurs more frequently in people of specific minority ethnicities: African Americans are at 77 percent increased risk and Hispanics are at 66 percent increased risk. Asian, American Indian, and Pacific Islander populations also have greater risks than that of Caucasians. Family history, low physical activity, obesity, and history of gestational diabetes are additional risk factors. Although elderly adults traditionally have a greater risk of diabetes development, and diagnosis after age 45 years was once the most common demographic for disease onset, the diagnosis of T2DM in younger populations is rapidly increasing in the United States—considered by some clinicians as the first response to the obesity epidemic developing in American youth. Childhood T2DM has become so prevalent that nearly half of new-onset diabetes diagnoses in children are T2DM rather than Type 1 diabetes mellitus (formerly, insulin-dependent), the more traditional childhood diagnosis.

In response to the growing epidemic, the American Diabetes Association (ADA) has reissued its recommended standards of care for patients with T2DM, and Healthy People 2020 identified top objectives for curbing the disease course at—or even before—its onset, in efforts to improve the overall health of the aging adult U.S. population. The ADA guidelines for care include emphasis on improving patient understanding of diabetes and on implementing nutritional and physical activity changes that are considered required for effective disease control. Standards of medication management,

reduction of complications, and individualization of treatment plans with health care providers remain essential. Healthy People 2020 recognizes the importance of halting T2DM progression in the United States and includes the ADA-designed prevention goals in its health care planning initiative. Some key Healthy People 2020 objectives to meet these goals are increasing the number of patients who have formal diabetes self-management training and education (DSMT/E), and increasing the number of patients who self-monitor daily, take aspirin daily at least 15 times per month, receive annual specialist examinations for secondary complications, and have glycosylated hemoglobin (Hb A1C, A1C) levels checked at least twice yearly.

Meeting these Healthy People 2020 objectives and the ADA standards ensures that greater numbers of patients with diabetes achieve important clinical endpoints, including lower blood pressure, stable glucose levels, and lipid health. During the 1999–2007 National Health Examination Survey, only 12 percent of patients with diabetes achieved these three clinical endpoints, and only half of patients with diabetes achieved just one endpoint. Addressing patient knowledge and self-motivated action must be encouraged by a participatory health care team to increase treatment adherence and improve historically fragmented care.

Team care by health professionals and pharmacist-driven community clinics both have been shown to significantly improve treatment adherence, frequency of regular blood sugar evaluations and follow-up care, control of secondary complications, and likelihood of patient-implemented lifestyle changes. As certification programs for health professionals develop, reimbursement options improve, and professional guidance standards expand, health care professionals—particularly pharmacists—have increased capabilities and resources on hand to minimize the health toll of T2DM.

Disease Pathophysiology

The primary cause of T2DM is unclear and likely multifactorial; an underlying dysfunction of pancreatic B cells is one likely component. B cells, which release insulin in response to plasma glucose concentrations, can malfunction and stop producing insulin for unknown reasons. Another, perhaps larger, component is the development of insulin resistance, by which insulin is present but is used incorrectly by peripheral cells. As a result, glucose is not broken down for use and instead continues to build in the blood and organs. As plasma glucose levels rise and insulin needs increase, the pancreas becomes desensitized to the presence of glucose and eventually loses the ability to respond to the need for insulin. As the disease progresses, the pancreas stops making insulin at all, causing uncontrolled and damaging hyperglycemia. Thus, insulin levels may be high initially in the disease, when peripheral resistance is only beginning, but become low when insulin secretion slows.

Although a single cause of insulin resistance is not defined, its development is strongly linked to obesity and weight gain, because fatty acids in adipose tissue impair glucose use and because the fat tissue releases damaging cytokines, such as tumor necrosis factor and interleukins, which alter glucose transport throughout the body. The development of insulin resistance coupled with pancreatic B cell impairment and rampant hyperglycemia is traditionally slow, with insidious symptom onset.

Underlying Metabolic Syndrome

A complicating factor of insulin resistance and T2DM is a disorder known as metabolic syndrome. At its simplest, metabolic syndrome is a cluster of risk factors—high glucose, high blood pressure, dyslipidemia, and middle-body obesity—for diabetes and cardiovascular disease. More complex, though, is its connection to the progressive dysfunction of insulin activity. At its first identification in 1998 by the World Health Organization (WHO), insulin resistance was considered an initial cause and a required component of metabolic syndrome. More recently, WHO has eased the insulin resistance requirement while still acknowledging a link among metabolic changes, insulin ineffectiveness, and T2DM.

The National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) defines metabolic syndrome today as a group

of five body changes: increased blood pressure, increased triglycerides, low high-density lipoprotein (HDL), increased plasma glucose, and central obesity. The presence of three of these five markers supports a diagnosis of metabolic syndrome by international standards. The diagnosis of metabolic syndrome is associated with a five-fold increased risk of diabetes development within five to 10 years and a doubled risk of cardiovascular disease in the same time span. Indeed, metabolic syndrome is considered a definite cause of both diabetes and cardiovascular disease. Risks for development of metabolic syndrome include genetic predisposition, environmental factors, low physical activity, increased carbohydrate intake, and obesity, especially viscerally. After meals, glucose is retained longer in fat, especially in abdominal fat, than in muscle, thus prolonging the effect of hyperglycemia on the body of an obese patient.

Despite what seems a straightforward clinical picture, T2DM diagnosis, treatment, and control are complicated by its inextricable link to insulin resistance and the metabolic syndrome. The identification of metabolic syndrome as a precursor to diabetes has broadened the understanding of underlying physical changes occurring before and during diabetes development, but the circular nature of glucose control and metabolic changes in the body precludes a direct cause and effect relationship. Because metabolic syndrome plays such an important role in insulin resistance and T2DM development, early assessment can halt disease progression. Waist circumference, when increased, is an anthropomorphic measure of central obesity and is considered an important preliminary tool to identify the need to evaluate a patient for metabolic syndrome. A particular benefit of this measurement is that waist circumference impact remains standard among men and women of any height. Waist measurement should be taken just after exhalation while the patient is standing and not contracting

abdominal muscles (such as when in conversation with the clinician). The tape measure should ideally be placed halfway between the bottom of the lowest rib and the top of the iliac crest on the hip area. Three measurements should be taken, and the average of the closest two measurements should be representative for screening purposes. However, the precise cutoff waist measure to indicate metabolic syndrome risk is still nonstandardized. For example, the International Diabetes Foundation guidelines suggest that waist measure alone is indicative of metabolic syndrome, and they recommend low cutoffs of 94 cm (37 inches) and 80 cm (31 inches) for men and women, respectively. Conversely, ATP III guidance set in 2001 identifies metabolic syndrome risk at 40 inches (102 cm) and 35 inches (88 cm) for men and women, respectively. WHO identifies 37 inches as a risk indicator for any person as an easy guideline. Recent research suggests that lower cutoffs tend to increase the frequency of correct identification of metabolic syndrome, so clearer standards worldwide are certainly needed for optimal care.

T2DM Signs and Symptoms
Early observed symptoms of hyperglycemia are nondescript and primarily result from osmosis (changing fluid concentrations across cells and vessels) to adapt to the high plasma glucose concentrations. Polydipsia, polyuria, and some polyphagia occur and cause secondary weakness, hypotension, dehydration, and fatigue. Blurred vision, nausea and vomiting, and fungal infections result from excessive glucose, and weight loss can be a sign of extreme hyperglycemia. However, even these symptoms fluctuate as glucose and insulin levels change over time, so the disease can remain undiagnosed for extended periods, even until cardiovascular complications develop as the presenting concern.

Secondary Vascular Complications
Poorly controlled glucose levels and inadequate antidiabetes treatment result in serious vascular damages that have striking morbidity in the diabetic population. The aggressive treatments necessary once these complications develop increase health care costs to patients, providers, and employers or other payers. Additionally, complications drastically reduce quality of life for patients and increase the risk of death. T2DM is the seventh-high-

est cause of death in the United States, most often as a result of secondary complications. Preventing the onset of these complications by stopping T2DM development at early stages, such as when insulin resistance or metabolic syndrome are identified, and by improving early disease control are essential to saving lives of patients with diabetes.

Evaluation Methods

Evaluation of plasma glucose levels is the primary diagnostic and monitoring method. There are three tools are available to clinicians for this purpose: fasting plasma glucose (FPG), oral glucose tolerance testing (OGTT, or two-hour plasma glucose), and the A1C. In practice, random plasma glucose without glucose loading or fasting is often measured and is used to support diagnosis if it is >200 ng/mL.

The two-hour plasma glucose test, or OGTT, is administered to adults as a 75-gram glucose drink after a fasting period of eight to 12 hours, typically in the morning, to observe blood level changes in response to the concentrated glucose intake. Normal results are plasma glucose levels <140 ng/mL, and diabetes is diagnosed with results >200 ng/mL (11.1 mmol/L). The OGTT is sensitive but inconvenient and is not the preferred diagnostic method by the ADA.

FPG, unlike random checks or the OGTT, measures glucose concentrations without any caloric stimuli. The FPG test is the ADA-recommended diagnostic method, because it is easy, cheap, convenient, fast, and patient accepted. Glucose levels for FPG testing are drawn, most often in the morning, after eight to 12 hours of fasting; levels greater than 126 mg/dL (7.0 mmoL/L) are diagnostic for diabetes, and normal levels are less than 100 ng/mL. In practice, an abnormal FPG can be followed by a two-hour OGTT to potentially confirm a diagnosis.

A1C represents an indirect reflection of glucose in the blood by measuring the percentage of hemoglobin in the blood that has been glycosylated, or has been bonded with glucose molecules. A1C differs from direct glucose measures because it reflects past glucose changes in the blood—glucose levels in the body during the eight to 12 weeks prior to testing. Although useful as a diagnostic tool, A1C is even more useful as a predictor of diabetic complications. An A1C of 5.6 percent to as low as 4 percent is considered normal; an A1C greater than 6.5

percent supports a diabetes diagnosis according to 2009 international guidance and should be measured twice a year in healthy, at-risk people. Higher A1C proportionally indicates uncontrolled disease and its vascular morbidities. A1C less than 7 percent is the primary treatment goal and should be measured up to four times annually in patients with diabetes that is poorly controlled. Increasing A1C also reflects medical costs: each 1 percent increase of the A1C over 7 percent significantly increases not only the likelihood of microvascular or nerve damage, but also increasing medication costs.

To involve patients more easily in controlling their A1C and, thus, glucose levels for longer durations, researchers on the A1c-Derived Average Glucose (ADAG) study have recently developed a conversion tool to report A1C percentages to patients as estimated average glucose (eAG) in mg/dL—the same units used for glucose monitor self-care checks. The conversion is recommended by the ADA to simplify information presented to patients. For example, an A1C of 7 percent entered into the equation converts to an eAG of 169 mg/dL, which clearly represents uncontrolled glucose levels to the patient.

All three tests are diagnostic and can be interchanged if necessary for confirmatory testing. One abnormal measure of any test supported by a second abnormal measurement of the same or different test on a separate day warrants a diagnosis of diabetes. Although diagnosis of T2DM is easily made by laboratory glucose evaluations, guidelines for when to check and in whom have become more defined in recent years. Improving the use of lab tools to determine and monitor those at risk of diabetes development will identify patients with T2DM and with risks of DM at early stages, potentially before the onset of symptoms from high glucose levels or complications.

Prediabetes

The importance of being proactive at T2DM detection has already been determined. A

growing population is being identified as having prediabetes, an occurrence of subacute glucose control problems. This is in addition to existing risk factors for diabetes—obesity, family history, gestational diabetes history, low physical activity levels, and certain ethnicities. In 2008, 35 percent of all adults in the United States, and 50 percent of those older than 65 had prediabetes according to random A1C measurements. Prediabetes was initially described in 1997 and was further defined in 2003 as impaired glucose control, a transitory state between normal glucose function and full-blown diabetes. Impaired glucose control is quantified as an FPG of 100 to 125 ng/mL (also, impaired fasting glucose; or as 110 to 125 ng/mL by WHO) or two-hour OGTT results of 140 to 199 ng/dL (also, impaired glucose tolerance). Prediabetes can be identified as an A1C of 5.7 percent to 6.4 percent as well. Prediabetes itself is a risk factor for not only diabetes but also cardiovascular disease, including hypertension and dyslipidemia, and it is likely present in 79 million U.S. adults. Regular screening for prediabetes has no supporting evidence of benefit in clinical trials. Yet early intervention of increased physical activity alone has been documented to decrease the risk of diabetes for long durations by 34 percent in a population of patients with prediabetes. This supports the consideration of more frequent glucose screening in obese patients or those with other specific risk factors for diabetes.

Whom to Test?

Who should be the focus of testing for glucose evaluation? Definitive risk factors for the development of diabetes or prediabetes include the following: a primary relative with T2DM, low physical activity, hypertension of 140/90 mmHg, gestational diabetes history, at-risk ethnicity, high-density lipoprotein (HDL) less than 35 mg/dL, triglycerides greater than 250 mg/dL, history of delivering an infant weighing 9 pounds or greater, insulin resistance diagnosis,

history of cardiovascular disease, or a prior A1C of 5.7 percent or greater.

Testing should be performed in any person with a body mass index (BMI) of 25 mg/m2 or greater (overweight status) and one of the above risk factors. Any adult age 45 or older with an overweight BMI, even without additional risk factors, should be tested as well. Testing should be repeated every three years after normal results. Abnormal results should trigger both a repeat test to confirm a diagnosis of prediabetes or T2DM and immediate interventions. (See Table 1.)

In addition to these regularly scheduled tests, additional glucose measurements and more intensive care are warranted at some clinical breakpoints. These are times of greater complication risk or of excessively poor control. Some common breakpoints include the new onset of secondary complications; new pregnancy in a patient with established diabetes; frequent hypoglycemic episodes; and continually high A1C (eg, >8 percent on separate occasions).

Primary Lifestyle Interventions

Whether a patient is identified with metabolic syndrome, prediabetes, or T2DM with or without cardiovascular disease, immediate and ongoing intervention is essential. "Intensive control" is a new term used to reflect an A1C goal of less than 7 percent for all patients. It involves required lifestyle interventions and consideration of additional early oral treatment—such as metformin—as needed. Encouraging patients with any metabolic dysfunction to change habits significantly improves health and reduces the disease toll. The Diabetes Prevention

Table 1. Breakpoints for Evaluating At-Risk Patients	
When to Test	
Undiagnosed At-Risk Individuals	**Patients With Diabetes At Greater Morbidity Risk**
45 years of age or older with BMI ≥25 mg/m2	New onset secondary complications
Any age with BMI ≥25 mg/m2 and one additional risk factor*	New onset pregnancy
	Frequent hypoglycemia
	Continually high A1C results

*Additional risk factors include a primary relative with diabetes, low physical activity, hypertension, history of gestational diabetes or infant weighing ≥9 pounds at birth, at-risk ethnicity, dyslipidemia, history of cardiovascular disease, or an A1C ≥5.7%.

Program, for example, showed a 58 percent reduction of T2DM diagnoses over three years in people of all ethnicities at risk of diabetes. In the study, weight reduction and increased physical activity together were more successful than metformin alone, which resulted in a 31 percent reduction in a similar patient group. Results from these two behavior changes were especially pronounced in younger populations (between the ages of 25 to 44) and in people with morbid obesity (a BMI 35 mg/m2 or greater), and the preventive effects lasted as long as 10 years—a sufficient duration to reduce cardiovascular morbidity as well.

Clinician guidance for intensive control is highlighted in the ADA and European Association for the Study of Diabetes (EASD) consensus for management, which indicates that, upon diagnosis, exercise and possibly metformin should be started immediately. Behavior changes should be augmented as necessary by oral treatments to maintain an A1C less than 7 percent. If the A1C targets are continually unmet, more aggressive therapy with combinations of oral agents from different drug classes, as well as insulin administration as an option for patients with severe hyperglycemia, should be used to maintain glycemic control. Revising combination therapies according to synergistic benefits and cost-effectiveness must be individualized and ongoing according to the A1C. The actual drug selection is less important than the critical need to maintain a low A1C.

Diabetes self-management education (DSME), a national evidence-based educational standard helps to reduce the stress of diagnosis and management for patients with diabetes and their clinicians. DSME can increase quality of life and reduce costs to patients and payers. DSME is unique in that the program emphasizes psychosocial awareness of the diabetic patient and identifies the need to associate well-being with positive self-management outcomes to ensure success.

Therefore, the best teaching practices for DSME are interactive, not didactic. DSME is not only important at diagnosis for initial coping and for establishing interventions that can incorporate into the patient's life; it is also important throughout care for ongoing support of the disease challenges and newly introduced treatments. Ideally, DSME optimizes ongoing disease control in a trusted partnership and prevents complications to continuously improve quality of life.

COLLABORATIVE MANAGEMENT
Self-Management Requirements for T2DM Control

Patient lifestyle plays a large role in diabetes treatment by maximizing quality of life and minimizing organ system dysfunction from excessive glucose. Simply walking 30 minutes per day and reducing body weight by 7 percent can reduce the risk of developing diabetes by 50 percent or more in people at high risk of T2DM (those with prediabetes). For patients already diagnosed with diabetes, the American Association of Diabetes Educators (AADE) has identified seven self-care behaviors to help patients manage their disease on a daily basis (the AADE7). They are:

1. Healthy eating
2. Being active
3. Monitoring glucose
4. Taking medications
5. Problem solving
6. Reducing risks
7. Healthy coping

The successful T2DM intervention is a triad of self management, lifestyle changes, and proactive medical care involving a collaborative team. AADE7 provides self-care behaviors, and the successful approach to AADE living involves adequate DSME. Implementing DSME in the community pharmacy involves the patient and the pharmacist to reduce costs, improve quality of life, reduce adverse events, and increase adherence. For patients and professionals using AADE7 as a model, DSME education programs can be initiated with a team on five steps: assessment, setting goals, planning programs, implementing programs, and evaluating outcomes, including reduction of A1C, blood pressure, and lipids as well as improvement of adherence.

Patients with diabetes are responsible for 99 percent of their own care, unique among chronic diseases. Therefore, patients with diabetes require maximum amount of skills and information available. Stress the importance

of individual treatment regimens to reduce adverse events. Reinforce medical adherence for blood glucose testing, blood pressure monitoring, and daily aspirin as well as regular foot, eye, and dental care exams. A simple mnemonic for reducing long-term microvascular or macrovascular risks is called the ABCs: **A**1c goal less than 7 percent, **B**lood pressure goal less than 130/80 mmHg, and **C**holesterol goal LDL less than 100 mg/dL. DSME programs can use pharmacists as coaches to provide explanations of ABCs for cardiovascular risk protection, to explain lifestyle changes and why they are important, and to emphasize the importance of medical adherence, regular preventive care, and pharmacy communication for individualization of treatment regimens.

With these steps and other healthy living choices, patients themselves hold the key to reducing morbidity and mortality associated with T2DM and, indeed, T2DM onset itself. Despite prevalent knowledge of this, much of the population is disinclined to make lifestyle changes in an effort to improve health and reduce risk. In fact, people considered at high risk for diabetes are half as likely to change their behaviors as people without risk. Instead, nearly one fifth of people at high risk for developing T2DM in 2011 survey results expressed a preference to taking medications rather than initiating beneficial physical activity and weight loss programs.

If risk awareness is commonplace, what is the reason for rapidly increasing rates of diabetes and the lack of patient self care? Inadequate or inaccessible guided health programs and lack of direct provider care are two possible reasons. Insufficient or lack of knowledge about the large benefits of small change and about the gruesome statistics of T2DM complications also are key factors. Patient initiative must be spurred on by health care providers who have the knowledge to persistently provide easily understood and easily incorporated behavior changes, and these professionals also must ensure that

patients understand the reasons for and the positive results of any change.

Intensive Professional Care
Usual care consists of preventive services with a doctor, medication management with pharmacist communication, and patient education from a nurse. Pharmacists educate, optimize therapy, and increase adherence. Pharmacists can help patients meet AADE7 goals by acting beyond the usual pharmacy care expectations of today. The unique role of pharmacists in providing diabetes care is the teaching of behavior skills combined with the monitoring of patient ability—all while including patients in treatment decisions and lifestyle planning.

At a minimum, pharmacists can teach meter usage, measure ABCs, and review medication use. However, community pharmacists in collaboration with a physician can also implement real-time medication therapy management changes on the basis of a patient's current A1C, blood pressure, and cholesterol measurements directly and with autonomy. Chart reviews and reminder letters to physicians are significantly less effective than pharmacist face-time with the patient for recommendations, medication changes, and test recommendations; similarly, automated clinician reminders are less effective than face-to-face interactions for improving adherence. To institute expanded services, pharmacists must set a goal, communicate regularly with the physician, evaluate end points, and recommend drug changes for continuing control.

In a meta-analysis of such intensive care pharmacist interventions, patient education alone reduced A1C by 0.5 percent. Direct involvement with patients has been associated with blood pressure reductions of 5 mm Hg each and decreases of LDL by 12.9 mg/dL, and direct pharmacist interaction decreases A1C by at least 1 percent; every 1 percent A1C decrease reduced microvascular complications by 35 percent and death by 25 percent. Pharmacist involvement also prevents disease-related hospitalizations and reduces total disease costs by 10 percent to 20 percent. The return on investment for such involvement appears as risk protection within two years, a rapid effect compared with the 10- to 14-year time frame observed to the development of secondary complications.

A successful example of a significant pharmacy-based team intervention for self management is the 1997

Asheville Project, the first documented pharmacy community care program with the pharmacists in addition to a physician or diabetes educator to provide disease management services for 46 patients in North Carolina. In one year, A1C decreased more than 1 percent and costs to patients were reduced by $150/month. Cost savings lasted from 14 months to five years after the intervention was complete. Subsequent diabetes programs continue to build upon the success of the North Carolina project; for example, in the 21st century, when face-to-face drug management was combined with pharmacist-directed preventive care for 30 minutes at least twice a year, more Healthy People 2020 objectives were met than with physician-pharmacist communication alone.

Community Interventions

Team services for T2DM can extend even beyond a nurse, dietician, and pharmacist as medication manager or intensive collaborator. The pharmacist can combine efforts with a podiatrist, optometrist, and dentist to comprise an allied health team that provides a comprehensive self-support care package for diabetes control. Team practices can offer a range of services to the public according to needs; together, the health care professionals must engage patients to reduce information gaps. To support this team care, the pharmacist can verbally encourage daily self foot care, brushing teeth twice daily, monthly oral self exams, and rapid reporting of eye or vision problems. Community programs for individuals; social support for change, especially initiation of physical activity within a group; and campaigns in the community for disease prevention and for obesity control should also be encouraged. Pharmacists with diabetes care services or clinics can bridge the gap and engage otherwise healthy community members to start screenings and referrals for early control.

CONTROLLING VASCULAR COMPLICATIONS IN THE PHARMACY

Secondary complications not only cause the greatest number of deaths attributed to diabetes, but also are the predominant reasons for low quality of life in patients living with the disease. Small-vessel complications in the eye and kidney as well as damage to the peripheral nervous system result in kidney disease, blindness, and nerve and circulatory problems that lead to more than 82,000 lower-limb amputations in the United States each year. Macrovascular (in large blood vessels) damage leads to cardiovascular disease, the cause of death in two thirds of all patients with diabetes as a result of myocardial infarction or stroke.

The mechanism of vascular disease in diabetes is likely two fold, at least. First, oxidative stress from high glucose concentrations causes cell dysfunction via increased amounts of toxic breakdown molecules in cells and tissues and causes glycosylation of proteins to impede functions. Second, small blood vessel leaks from the damaging sugar presence can begin inflammatory cell responses that cause fibrous tissue buildup in vessels and that introduce inflammatory factors like cytokines, which cause continual damage.

Aggressive Prevention of Cardiovascular Morbidity

Rates and Mechanisms of Macrovascular Damage. A profound cause of morbidity of T2DM in the United States, cardiovascular disease is a huge health care burden and causes more than 50 percent of the total diabetes management costs. General risk factors for cardiovascular disease include genetic predisposition, obesity and the resultant inflammatory cytokines released from excessive weight, and the presence of metabolic dysfunction, including T2DM, insulin resistance, or metabolic syndrome. Serious cardiovascular events, such as myocardial infarct or stroke, are predated in patients with diabetes by blood pressure and lipid changes that can be seen as warning signs, requiring aggressive treatment and control to avoid more serious damage.

Cardiovascular Control Goals. Patients and clinicians do not need to wait for a cardiovascular event to initiate prevention strategies. A1C greater than 7 percent is directly proportional to the number of coronary events. Blood pressure control is documented to reduce the risk of serious cardiovascular disease by 50 percent and

the risk of microvascular disease by one third.

A blood pressure goal of 130/80 mmHg in patients with T2DM is supported by studies, because morbidity is associated with hypertension as low as 140/90 mmHg. Reduction of diastolic pressure from 90 to 80 mmHg alone reduces cardiovascular risk by 50 percent. For every 10 mmHg of overall blood pressure (systolic or diastolic), the risk of any type of complication is reduced by 12 percent. Upon evaluation, blood pressure of 130/80 to 139/89 mmHg warrants lifestyle changes for three months and then re-evaluation; blood pressure of 140/90 mmHg or greater, though, warrants lifestyle changes as well as medication of as a primary intervention, and blood pressure at first evaluation of 150/90 mmHg warrants combination drug therapy from the start.

Best Practice Lifestyle Efforts and First-Line Medications. Specific behavioral treatments that should be initiated at the first sign of hypertension include weight loss, increased physical activity, and a healthful diet. Specifically, nutritive efforts include DASH: dietary approaches to stop hypertension (DASH). A DASH-based diet emphasizes lowered sodium intake to 1,500 mg/day, lowered potassium intake, and moderate alcohol intake as means to prevent increasing blood pressure.

Antihypertensive Drug Treatments. Antihypertensive agents are cardioprotective by decreasing blood pressure and by directly reducing heart attack and stroke risk. First-line monotherapy should be an inhibitor of the renin angiotensin system (RAS). Inhibitors of RAS are considered renoprotective antihypertensive therapy and include angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs). Both drug classes similarly reduce microalbuminuria and proteinuria (the latter up to 35 percent) that reflect kidney dysfunction; delay the onset of macroalbuminuria and creatinine impairment; and slow the progression of kidney disease to end-stage renal disease.

ACE inhibitors work by preventing the formation of vasoconstricting angiotensin II. ACE inhibitors have documented protective benefits of reducing heart attack events, decreasing hospitalization rates, and reducing the likelihood of revascularization surgeries. ACE inhibitors save 1 percent of all adults from heart attack mortality and are broadly preventive of cardiovascular mortality in patients with T2DM. In fact, ACE inhibitors, especially at high doses, reduce mortality and decrease cardiovascular disease even without the presence of hypertension or renal complications from diabetes.

Use of ACE inhibitors is specifically linked to reduced mortality from individual cardiovascular events, such as ischemia, heart attack, and stroke, and to reduced occurrences of nonfatal heart attacks. ARBs, which work by preventing the actions of angiotensin II at the receptor itself, significantly reduce blood pressure at least as well as ACE inhibitors when both drugs are compared with placebo. However, ARBs do not yet have the same extensive study support for prevention of individual mortality risks. Currently, ARBs have proven success at reducing composite cardiovascular complications rather than for prevention of a particular mortality risk.

Side effects of both classes of antihypertensives that work in the RAS are typically mild, although ACE inhibitors are associated with a greater number of bothersome side effects than ARBs. Cough, fainting, and high potassium levels are most frequent with ACE inhibitors, and angioedema is possible; high potassium levels and, rarely, angioedema, can occur with ARBs as well. ACE inhibitors remain worthwhile first-line choices because of their proven benefits and because they are more widely available as lower-cost generics, which can increase adherence for some patients. ARBs, though more costly and mostly available only as brand name products, should be considered in patients who experience difficulty with the ACE inhibitor side effects that interfere with adherence. Treatment with drugs from either class requires ongoing monitoring of potassium levels and kidney function.

Antihypertensive treatment can be suboptimal because of inadequate medication review, but evaluating and adjusting antihypertensive medicines regularly each month can reduce cardiovascular accidents and congestive heart failure by 10 percent each in patients with T2DM, and blood pressure control is more cost effective

than treating cardiovascular complications of diabetes. Two drugs are often necessary to maintain blood pressure control over the long term. When initial treatment with an ACE inhibitor or ARB is unsuccessful at maintaining blood pressure goals, combination therapy that still includes an ACE inhibitor or an ARB is warranted. The combination of drugs from both the ACE inhibitor and ARB classes together is not currently indicated and is not recommended on product labeling, in part to prevent additive side effects, such as hypotension, fainting, and kidney problems. Some off-label use of an ACE inhibitor and an ARB has been observed. Most often, a diuretic is a logical second agent instead. A thiazide or loop diuretic should be added according to microalbuminuria presence, glomerular filtration rate (GFR; loop diuretics work better than thiazides at low GFR), and side effect profile tolerance. Alternatively, a calcium channel blocker can be combined with an ACE inhibitor for successful blood pressure control in patients with severe hypertension; this combination effectively controls hypertension and reduces cardiovascular risks but is not as effective as adding a diuretic to prevent kidney dysfunction, because calcium channel blockers do not affect fluid volumes or the RAS. In severe cases, three- or four-drug regimens that include a RAS agent, a diuretic, and additional drugs, such as calcium channel blockers, beta-blockers, or spironolactone, can be prescribed for adequate control.

Aspirin Best Practice Use. In addition to blood pressure control, overall cardiac health should be encouraged. Aspirin, along with other cardiac and diabetic agents like ARBs, ACE inhibitors, fibrates, and thiazolidinediones, reduces inflammatory cytokines from adipose tissue, particularly interleukin 6 and C-reactive protein, to decrease insulin resistance and cardiovascular events. Specifically, using aspirin appears most beneficial at reducing cardiovascular risk in patients with T2DM and concomitant hypertension. Increasing the frequency of aspirin use is one of the newest ADA standards of care that pharmacists can implement, particularly in patients older than 40 or older than 30 and with other risk factors for cardiovascular disease (such as hypertension and obesity). Low-dose aspirin (81 mg) up to 162 mg daily protects the heart and is an important component of cardiac care in patients with diabetes.

Community Pharmacist Clinical Roles. Pharmacists already capably provide consultation to measure glycemic control and blood pressure and to discuss medications. Intensive care agreements allow pharmacists to check blood pressure, evaluate medication efficacy, and adjust the treatment regimen in real time to accommodate uncontrolled hypertension, identify and eliminate medicine adverse effects, and problem solve for patient-voiced concerns about nutrition or supplements that can impact blood pressure levels and drugs. This face-to-face interaction—more a discussion than a directive—with the patient improves adherence to medication regimens, increases disease control as measured by the ABCs, and reduces secondary complications from uncontrolled vascular disease. For example, these pharmacist services can nearly double compliance to initial ACE inhibitor or ARB treatment, thereby delaying the need for additional medication and reducing cardiac risks. The constant presence of a regular pharmacy clinical service provides these benefits to patients not on occasion but on a frequent and recurring basis.

Evaluating Microvascular and Neuropathic Damage in Lower Extremities
The Importance of Proper Foot Self Care. Although foot care by patients with diabetes and their pharmacy providers might not seem intuitive or of great importance when compared with life-threatening cardiovascular risks, lower-limb problems are a frequent complication of diabetes and directly reflect poorly controlled primary disease. Symptoms in lower extremities can occur as an early sign of the onset of T2DM as well, so awareness of foot health by every health professional is essential to total care of patients with or at risk of developing diabetes.

Foot problems resulting from diabetes occur not only from infection that develops in small cuts or cracks in the skin—wounds that do not typically pose problems in healthy populations—but also from small blood vessel

and peripheral nerve damage, when circulation that supplies nerve endings in the limbs becomes impaired from high glucose concentrations. In addition, the poor microvascular circulation increases the risk of lower-limb clotting and compounds the loss of sensation and infection risk in the feet. At least 60 percent of patients with diabetes have some degree of nerve damage that impairs pain sensation, and the greatest at-risk population is patients older than 40 years of age. The circuitous combination of sensory inhibition and vascular inefficiency often results in complicated foot ulcers, or "diabetic foot."

Nearly one-fifth of all patients with diabetes develop foot ulcers, and at least 14 percent of these patients later undergo amputation of a lower extremity in their lifetime—a serious and life-altering morbidity of uncontrolled T2DM. Foot care for all patients with diabetes should be encouraged, but some populations are at even greater risk of foot ulcers and amputations. Any patient with structural foot deformities (bunions), sensation loss, or a history of foot problems should be referred to a podiatrist for ongoing and lifelong preventive care to reduce the likelihood of amputation. Smokers have four times greater risk of lower-extremity problems as a result of microvascular damage, and diabetic patients with a family history of cardiovascular disease or cerebrovascular accidents (strokes) likewise have a greater risk of lower-extremity complications. Additional patients at particular risk of ulcers and amputations include those with diagnosed peripheral neuropathy or peripheral vascular disease (PVD) from any cause and patients with visual impairment or nephropathy requiring dialysis, both of which reflect existing microvascular disease. Patients with uncontrolled disease according to A1C testing results (frequent A1C >8 percent), those with reduced mobility, and those who experience frequent bouts of hyperglycemia are also at great risk of amputation without adequate follow-up care.

Despite the potential severity of microvas-

cular and neurologic foot damage, diabetic foot can be prevented or identified at much earlier stages with aggressive health professional intervention and encouragement of lifestyle modifications. Comprehensive foot care programs that assess risk, educate patients, perform preventive treatment services, and promote rapid specialist referrals have reduced amputations by 45 percent to 85 percent in established community settings.

Baseline Community-Provided Foot Care. The ADA standards of care recommend an annual foot exam for every patient with diabetes, preferably performed by a physician or podiatrist, and they encourage daily foot checks by the patient. A multidisciplinary approach for all patients, particularly patients at high risk of secondary complications, should involve frequent community-based care opportunities. In-person care provides an ideal setting to explain the importance of foot care to patients, to demonstrate what a daily check comprises, and to ensure early identification of potential problems, including early sensation loss or lingering wounds.

Why Pharmacists? Although community pharmacy has focused in the past on guiding orthotic decision making and ordering wound-care supplies, the community pharmacy clinic is perhaps the best location for intensive promotion of foot care regimens to patients with diabetes, especially if a preliminary diabetes clinic is already in effect. Pharmacists are approached by patients seven times more often than physicians and are comfortable translating technical guidelines and directives into usable patient-education language—precisely what patients with diabetes need for improve self care of feet.

Pharmacist-Encouraged Self Care. At a minimum, pharmacists can actively promote self care for diabetic foot prevention by stressing to patients the importance of toenail trimming, foot powder to reduce moisture and prevent fungal infection, and lubricant creams to minimize dry skin and cracking. Counseling about risk aversion includes encouragement of physical activity and good nutrition to ensure adequate circulation in the lower limbs and of smoking cessation. Physical recommendations by a pharmacist include frequent sock changes; avoidance of constricting footwear or stockings; and avoidance of

bare feet to decrease the likelihood of cuts and scrapes. A quick look at the soles of feet each day can identify wounds or sores that result from ill-fitting shoes or stockings before infections or ulcers become established.

Talking points for patient education link early foot damage to serious complications: cramping as a warning sign of clots; calluses and corns as predecessors of more complex blisters and ulcers; and irritated or cracked skin on soles or between the toes as infection risks. Patients should avoid using pads or coverings on blisters, corns, or calluses. Instead, these minor foot problems should trigger an appointment with a podiatrist to evaluate ulcer risk and assess footwear.

Pharmacy Foot Clinics. To introduce pharmacist-guided foot checks in the community setting, pharmacists require a well-lit and private space to discuss self care, to directly observe skin, and to test for vascular or neuropathic abnormalities. Pharmacist examination of the diabetic foot should begin with a visual check of skin integrity to identify dry or moist skin, cuts, and wounds. Some clinics may choose to provide cleansing foot soaks before inspections. Visual identification of foot deformities alone is an indication for specialist referral and fitting for proper footwear. Dry or cracked skin requires counseling about frequent lubrication incorporated into daily self checks. Visual identification of ingrown nails can lead to a nail trimming demonstration: cutting straight across the nail avoids infections, and heat applications can reduce swelling of already ingrown nails to reduce infection risk.

The most efficient method of assessing lower-limb circulation is an examination of pulses in the feet, known as pedal pulses. Absent pedal pulses indicate a problem with circulation that could support a diagnosis of peripheral vascular disease or that could cause nerve damage in the extremities. Reduced sensations in the feet reflect peripheral neuropathy and indicate a loss of the protective detection of pain or irritation from foot wounds. Absent foot sensations provide an opportunity for serious ulcers to develop unnoticed after minor foot damage, which severely increases the likelihood of amputation in a patient with diabetes.

Pharmacist evaluation options for neuropathic foot checks range from simple tool-free tests, such as ankle reflex exams or direct pin prick testing on the feet, to evaluations that use a tuning fork for vibratory percep-

tion or a monofilament thread for sensation identification. All testing options are considered reliable and convenient alternatives to invasive nerve examination. However, the monofilament test is especially preferred, in part because of its ease of use. To perform a monofilament test, a clinician applies pressure with a nylon thread filament (most often a 5.07/10-gauge size) to up to 10 points on the foot sole until the tip of the filament begins to bend. If 10 sites are tested and a patient does not identify the sensation at four or more of the 10 points, peripheral neuropathy should be suspected and subsequently confirmed. Additional testing standards of monofilament use are continually being developed and evaluated for accuracy as well.

The monofilament test alone, similar to other noninvasive nerve examinations, is subject to varied sensitivity and administrator bias; therefore, the ADA recommends performing two tests to improve the accuracy of a neuropathy diagnosis. Any one failed test is a specific indication for an immediate second testing method to confirm loss of sensation; failure on two or more tests indicates peripheral damage and the need for a diagnosis and referral. Conversely, two or more normal results at a single visit indicate peripheral nerve health.

Taken together, the visual exam, pulse evaluation, and nerve testing present a thorough picture of foot health and, by proxy, of diabetes control via the level of observed vascular and nerve complications. All exams should conclude with specific product and action recommendations and a summary of patient-directed regular care behaviors, with a scheduled follow-up time recommended or set.

ACHIEVING CERTIFICATION AND DEVELOPING A CARE PROGRAM

Intensive care beyond usual medication counseling or chart review is of acknowledged importance to care of patients with diabetes. DSME involves health care professionals first as a means of educating patients about self

care. DSME requires a needs assessment, goal identification, patient and clinician education, and evaluation of progress toward goals. The ADA acknowledges the growing and important role of pharmacists in the provision of this expanded care. Their pharmacist standards of practice provide directives for pharmacy diabetes specialists to organize and guide care continuity and to expand upon basic DSME requirements. Pharmacist diabetes educators are encouraged to complete the following procedures:

1. Assessment of lifestyle, current lab and exam results, medications, and patient self-care ability
2. Identification of DSME outcome goals
3. Planning with the patient and team
4. Implementation of the plan with the patient
5. Evaluation of outcomes with lab testing, self care, medication review, and measurable goals
6. Documentation of a full record of care.

Individual Certification. The pharmacist scope of care at minimum includes knowledge of the disease state and comorbidities, maintenance of that knowledge, and involvement in lifestyle counseling and educational strategies. Any pharmacist can extend beyond the basic counseling to become a certified diabetes specialist. Numerous widely available program options that have varied time and financial commitments provide a working knowledge base required for credentialed or certified optimal care and clinic maintenance.

Diabetes specialization offers whole-person, all-encompassing patient care beyond medication therapy management and opens the door for collaborative professional engagement. In addition to existing site-specific professional education programs with Indian Health Services and Veterans Affairs, pharmacists can enroll in residencies and university-based post-secondary structured education on site or online at pharmacy programs such as the University of Texas, University of South Indi-

ana, and Purdue, for example. Board-certified advanced practice specialty in diabetes (BC-ADM) with or without a residency or other certification is available as well from the AADE for registered pharmacists with a graduate degree (such as a PharmD). The exam is offered twice yearly and enables knowledgeable decision making and whole-patient care on both psychosocial and metabolic issue. BC-ADM credentialing emphasizes clinician mentoring, research, and continuous professional development in addition to the comprehensive disease state focus. Certification requires a fee of $900 for non-AADE members and requires 1,000 practical hours in addition to completion of two of five provided continuing education programs. To recertify, clinicians must repeat the fee and educational requirements, and the majority of the completed continuing education performed in the certification interim must relate to advanced disease management.

Options for practicing community pharmacists with any degree (BSPharm or PharmD) include a diabetes specialty continuing education program from APhA that awards a certificate of achievement after completion and a multidisciplinary certified diabetes educator (CDE) credentialing program available from the National Certification Board of Diabetes Educators. (See Table 2.) The APhA certificate program, titled Pharmaceutical Care for Patients With Diabetes, details the role of the pharmacist beyond medication dispensing and into management and patient education, including DSME. The program is recognized nationally as a promoter of pharmacist interventions as part of a health care team. The program cost varies according to grant subsidies and program hosts, ranging from $99 to $350. The standard certificate program is offered directly through APhA as well as through some state pharmacy associations. The material focuses on thorough clinical education about pathophysiology, medication management, and nutrition, and it touches on the roles of pharmacist educators, open communication, and psychosocial patient concerns. Pharmacists who enroll in the program complete a self-study workbook and exam, as well as online activities and case studies, which are followed by a registration-only live-training seminar and a final, post-seminar exam. Any pharmacist completing the ACPE program and scoring at least 70 percent on the exams is awarded a certificate.

The APhA program is an acknowledged introduc-

tory program to the more comprehensive and distinct CDE program administered by the National Certification Board of Diabetes Educators (NCBDE), which focuses on DSME more heavily than on medication management alone. CDE credentialing is available to allied health care professionals who complete the prerequisites and examination. To be eligible for certification, a pharmacist must hold an active license, must have at least two years of professional pharmacy experience, must have completed a minimum of 1,000 hours of DSME-based efforts (40 percent of these within the year directly before examination), and must have completed at least 15 continuing education hours in the two years prior to examination. The CDE exam is offered twice yearly, and applicants must preregister with a $350 fee. Certification, when awarded, is valid for five years; recertification requires an examination or completion of 1,000 documented practical experience hours and 75 hours of diabetes continuing education to demonstrate current disease state awareness and knowledge. Renewal by either method costs $250. For clinicians interested in becoming a CDE, the AADE offers Guidelines for the Practice of Diabetes Education for Practitioners as well as a supplemental companion, Competencies for Diabetes Educators, which identify objectives and skill goals for all ranges of diabetes specialists, from beginners to experts. These knowledge goals encompass the disease state, physiology, and treatments of diabetes; long-term supportive care; teaching skills that enhance self care and behavior change; and business aspects of diabetes specialization.

Pharmacist diabetes educators from any program must maintain knowledge about the disease and comor-

bidities through initial training and continuing education, and they must provide care that includes DSME with lifestyle counseling and educational strategies. Accreditation of a diabetes education program is the gateway for allowing community pharmacies to provide DSME and for receiving reimbursement for these valuable services.

Pharmacy Accreditation. Medicare Part B reimbursement for diabetes training by the pharmacist is limited but expanding. Status as a pharmacist is not enough to establish a community care business model and receive reimbursement by Centers for Medicare and Medicaid Services or many pay-for-performance private insurers, however. To qualify for payment of DSME/T services (Medicare pays for a diabetes *educator* to provide *training*) by a pharmacist, the services must be performed as part of an accredited program billed by the pharmacy. In addition to reimbursement benefits, site accreditation validates the role of the pharmacist as a formal educator. AADE, in addition to providing educational tools for professionals and patients, is one of two organizations that awards accreditation or recognition to pharmacies for clinical care validity and reimbursement. The National Community Pharmacists Association (NCPA) has partnered with AADE to develop DASPA, a program to educate community pharma-

Table 2. Contrasting Diabetes Education Programming		
	Education Program	
	APhA Certificate	**Certified Diabetes Educator Credentialing**
Required advance continuing education hours/renewal hours	0/NA	15 credits within two years prior to examination/75 credits specifically in diabetes topics in place of re-examination
Required advance professional practice hours/renewal hours	1,000/NA	1,000 of DSME (40% in year prior to examination)/1,000 in addition to re-examination
Eligibility	Active pharmacy license, any pharmacy degree	Active allied health professional license and degree, two years professional experience in the field
Costs/renewal costs	$350 maximum, $99 minimum	$350/$250 for either continuing education or re-examination renewal
Program result	One-time certificate of achievement	CDE credentials for 5-year duration

cists about how to implement an accredited diabetes program in their pharmacies. DASPA (Diabetes Accreditation Standards–Practical Applications), is a combined online and live program that introduces program accreditation in combination with introductory management and business aspects of a diabetes clinic. Six online self-directed modules provide and test on essential knowledge about diabetes practices, DSME/T, lifestyle modification recommendations, medications, and common complications. The two-day live program is offered at intervals throughout the year to present the topics of team building, service implementation, billing 101, program establishment, and business marketing.

The DASPA program is designed to equip community pharmacists with the clinical components of providing diabetes education, the business aspects of program management, and the expertise to provide an accredited DSME/T program that meets professional standards. Through DASPA, pharmacists obtain 25 continuing pharmacy education contact hours; upon complication of the program, pharmacists will have the skills needed to implement a successful diabetes education program and pursue individual accreditation.

Importance of Building Community Partnerships. Even before personal certification or site accreditation or recognition occurs and formal clinic planning or needs assessments are underway, community outreach is crucial to establishing a flourishing and vibrant clinic. In fact, the AADE describes an appropriate community care team as containing a credentialed allied health educator and receiving community support to sustain DSME/T in addition to identifying treatment outcome goals. Early interaction with an established patient base and with participatory community leaders will promote the developing pharmacy services; expand the patient base, encourage regular communication and involvement by the pharmacist in the community; and support the

needs assessments and formal steps required to build and maintain a collaborative clinic. The National Diabetes Education Program (NDEP) supports pharmacists and their clinics in these educational and community-building goals by providing clinicians with brochures about diabetes and with activities for patients to complete within their communities.

Steps to Build and Maintain a Clinic Effectively. Establishing a T2DM practice setting requires broad integration of all aspects: experts, patients, community, certification agencies, suppliers, business and reimbursement organizations, and more. Although programs can be fully developed in private before collaborators are approached, establishing a clinic with the support of an existing partnership is likely more timesaving and cost effective as well as more teambuilding.

First, early support from businesses and the patient base can promote interest in collaboration with a primary care physician or practice to establish a pharmacy partnership by demonstrating the need in the area and the positive health and cost benefits to patients, pharmacies, and physicians alike. Fostering trust and communication early in a collaboration sets the stage for success both with nursing and clinical staff and between clerical or administrative professionals, who will inevitably be involved through delegatory roles.

Once a patient base and collaboration are set, identification of possible useful services and the capacities of the existing framework must be defined. For example, identification of guideline goals that are unmet in the current population and the possible methods to engage and treat that population should be delineated. Focusing these needs assessments and the available expert roles will provide patients with the best possible care from the start.

Business plan development, which should be shared with collaborators, early community supporters, and other individuals involved with logistics, identifies the key points succinctly: the clinic purpose, with the ADA standards of care background to support the pharmacist role; applicable collaborative agreements in writing; the physical structure and time allotments, and other physical and temporal expectations; as well as the endpoints, tracking methods, and planned follow-up and billing structures that should be implemented. Finally, the pro-

posed costs and revenue to the clinic and involved professionals, the estimated patient costs spent and saved, and the time commitment and time saved by patients and clinicians alike should be addressed, in particular to accommodate hiring needs, space issues, and the defined scope of all participants.

After the development is thus concluded, the team should market the new clinic to patients and local providers via media, office brochures, physician inservices, and community partnerships. Completing this planning integration fulfills the AADE 2010 standards suggested as the minimum required components of a sustainable diabetes education program. These are: a multi-level team with a credentialed educator and a key coordinator, community support, and identified outcome goals.

To supplement these minimum components, the NDEP suggests and justifies six steps to build a working clinic framework from the business plan: ensure a core leadership for stability and guidance; identify team members and their specific roles; identify the patient population and assess needs; assess resources and clinic needs; develop continuous care systems with a standards of scope, structure, and payment; and evaluate outcomes to adjust care accordingly.

Once a clinic and its team are established, its successful continuation is supported by regular maintenance. Regular promotion of patient quality of life benefits and ease of self care ensures a continuing patient base. Frequent encouragement of community supporters (such as networking partners and suppliers) provides a vital connection to publicity as well as up-to-date supplies and resources. Ongoing, healthy, and structured team communication ensures unfragmented care, prevents any patient from slipping through cracks, and keeps clinician knowledge current through information sharing. Some opportunities include algorithm use, shared real-time e-records, cohesive scheduled meetings, and monthly case rounds.

Aggressive but tactful follow-up for patient preventive care retains existing patients for ongoing care. Examples include prescheduled annual exams, as needed screenings and foot/sugar/hypertension checks, and scheduled phone call reminders.

For professional and lay communication alike, implementation of technology, when available, should be maximized to increase the time available for face-to-face interactions. Automatic reminders as follow-ups to personal phone calls, shared e-records, and electronic reporting tools can keep all team members—including the patients themselves—up to date on patient care.

CONCLUSION

Diabetes is not static, and patients with the disease rely on pharmacists and collaborating health professionals to provide continual care to accommodate their fluctuating needs. Pharmacists caring for people with T2DM must stay at the forefront of knowledge about diabetes care, its treatment goals, and its complications, and they should reach out to related professionals in an attempt to reduce fragmented patient care. By working together to monitor glucose control and morbidities, and by including patients and caregivers as active participants in self-management education and training, pharmacists can not only help patients with diabetes reach outcome goals but also prevent the progression of early metabolic changes into active disease. With the latter, pharmacists can help temper the spreading diabetes epidemic. a℗

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ESSENTIAL RESOURCES BY ORGANIZATION

Every pharmacy diabetes specialist should utilize these important resources to maintain current practice standards and knowledge as well as to provide patients with the most useful tools for and reminders of the importance of self care.

1. American Academy of Diabetes Educators (AADE): Professional resource center
- Main site: www.diabeteseducator.org
- AADE7 handouts: www.diabeteseducator.org/DiabetesEducation/Patient_Resources
- Accrediting and DSME tools: www.diabeteseducator.org/ProfessionalResources/accred/
- Patient-based Web site hub: www.diabetesselfcare.org/self-care-behaviors/overview/

2. National Diabetes Education Program (NDEP): Policies for systems change
- Main site: www.betterdiabetescare.nih.gov
- Patient care and specialist toolbox: www.betterdiabetescare.nih.gov/MAINtoolbox.htm

3. Preventive Care Guidelines
- AHRQ Innovations Exchange: Working Together to Manage Diabetes: www.innovations.ahrq.gov/content.aspx?id=2002, and www.ndep.nih.gov/media/PPODprimer_color.pdf
- Task Force screening guidelines: www.uspreventiveservicestaskforce.org/uspstf/uspsdiab.htm
- AHRQ comparative effective review 18 (cardiac) for professionals: www.ncbi.nlm.nih.gov/books/NBK36476/ and for patients: www.ncbi.nlm.nih.gov/pubmed/21919264

4. American Diabetes Association: Estimated average glucose tools
- Interactive converter: http://professional.diabetes.org/GlucoseCalculator.aspx
- Pharmacy flyer: http://professional.diabetes.org/content/PDF/vnzqcAverage%20Glucose%20flyer.pdf

5. Diabetes Accreditation Standards–Practical Application (DASPA): for site accreditation/educator instruction
- Main site overview: www.ncpanet.org/index.php/daspa

Podiatry Pearls for the Pharmacist

What to Check: sensation (with monofilament or similar test), circulation (with pedal pulses), and physical foot changes (with visual exam for deformities or open wounds/fissures)

Who is at Risk: patients who smoke or who have limited mobility; patients with structural foot deformities, a history of peripheral vascular disease, or a family history of cardiovascular disease or cerebrovascular accident; patients with existing microvascular complications (retinopathy, nephropathy); and patients with highly uncontrolled glucose levels (frequent hyperglycemia, A1C regularly >8 percent)

When to Refer: any foot deformity (eg, bunions, persistent calluses) that requires professional footwear evaluation; any active ulcer or open wound, which might require anti-infective care; any documented sensation loss, which could indicate microvascular damage

Reference Sites: American Family Physician 1998 review, tool instruction, and patient handouts at www.aafp.org/afp/980315ap/armstron.html; American College of Physicians instruction sheet at http://diabetes.acponline.org/custom_resources/tools/using_10g_monofilament.pdf?dbp

Global Outcome and Preventive Care Goals for Patients

ABCs: A1C <7 percent; Blood pressure <130/80 mmHg; and cholesterol goals of HDL >35 mg/dL, LDL <100 mg/dL, and TG <250 mg/dL

Podiatry: Daily foot self checks, frequent as needed professional foot checks, and annual podiatry visits

Glucose control: Twice-daily blood glucose self checks

Allied health: Annual optometry visits and twice-annual dental visits

Lifestyle changes to implement and maintain: Physical activity (walking) 15 min/d; improved nutrition (DASH diet, lower carbs)

CASE 1

G.W. presents at your pharmacy during open hours of a regular diabetes care clinic at your community pharmacy. G.W. is bringing her mother, who is being treated for T2DM, to see you for a regular medication and blood pressure check. During the counseling and education session with her mother, G.W. comments that she had gestational diabetes during her second pregnancy, in her mid-30s, and that her children are now 10 and 12 years old. Given this basic information, how should you respond to G.W. after caring for her mother?

Response 1

Because G.W. has a history of poor glucose control, has a first-degree relative with active T2DM, and is likely near or older than 45 years old, you should recommend that she undergo testing for T2DM. Options for proceeding with an education program for G.W. include the following: weight check to evaluate BMI as a factor in metabolic syndrome; blood pressure measurement to identify possible cardiovascular complications or primary hypertension; waist measurement to identify the need for full evaluation of metabolic syndrome; and an order for a measure of blood glucose (such as a fasting plasma glucose or two-hour tolerance test, or A1C to identify longstanding dysfunction). In addition to these tests, an interactive discussion about the importance of physical activity and nutrition in curbing T2DM onset and progression is warranted in G.W. because of her family and personal history. Emphasis on the profound benefits of walking and reducing salt and carbohydrate intake in particular is beneficial, and awareness of poor foot health as an early sign of uncontrolled diabetes is similarly important. Pending the results of testing, you refer G.W. to a physician for initiation of diabetes team care and/or request a follow-up visit by G.W. to the pharmacy for repeated screening of her metabolic health status.

CASE 2

H.H. is a regular patient at your pharmacy and has been treated for T2DM with oral medications for the past two years. You have recently become a certified diabetes educator, have entered a collaborative practice agreement with a local primary care physician group, and have opened an AADE-accredited diabetes wellness program in your community pharmacy. Today, you are conducting your regular clinical services with foot exam services, and you see H.H. approach. At his physician's suggestion, he agreed to a consultation about medications as well as a blood pressure and glucose check in your clinic. Although his measurements are stable at today's visit, you are aware after reviewing his electronic record from the primary care provider that his A1C is 8 percent. How do you proceed with an education program and foot check?

Response 2

H.H. should be encouraged to participate in DSME, with particular encouragement about long-term glucose control and the prevention of vascular morbidities. By working together with H.H., you can maximize adherence and make rapid adjustments to his current medications as necessary. After H.H. agrees to your offered foot check, you visually examine skin for cracking (and suggestion lubrication as necessary), demonstrate proper toenail trimming (straight across), and check pulses for vascular health/clotting concerns. Finally, you perform a monofilament test to determine nerve sensations in the foot.

CONTINUING EDUCATION QUIZ

Select the correct answer.

1. The prevalence of type 2 diabetes is disproportionately increased in which population(s)?
a. Non-Caucasian ethnicities
b. Moderate alcohol drinkers
c. People with genetic mutations
d. All of the above

2. Healthy People 2020 objectives for managing diabetes in the 21st century include which of the following?
a. Take daily aspirin at least 20 days per month
b. Check A1C at diagnosis
c. Self-monitor daily
d. Two of the above

3. How is type 2 diabetes etiologically linked to insulin resistance?
a. Insulin is used poorly by the peripheral cells to initiate plasma glucose build up.
b. Insulin resistance is highly linked to obesity, especially central obesity.
c. Insulin resistance leads to a net increased insulin production over the long term.
d. B and C

4. Metabolic syndrome is defined as _____.
a. A cluster of risk factors that include overall obesity, increased blood pressure, and increased LDL
b. A cluster of risk factors that include waist obesity, increased blood pressure, and increased TGs
c. A cluster of risk factors that include waist obesity, increased blood pressure, and increased HDL
d. A cluster of risk factors that include overall obesity, increased blood pressure, and decreased LDL

5. Metabolic syndrome was first identified by _____ in _____ and was believed to be the _____ of insulin resistance.
a. WHO, 2000, primary cause
b. WHO, 1998, primary cause
c. WHO, 2000, primary result
d. WHO, 1998, primary result

6. Microvascular complications of diabetes include _____.
a. Stroke
b. Hypertension
c. Diabetic foot
d. All of the above

7. True or false: Microvascular disease causes more mortality than macrovascular disease in patients with type 2 diabetes.
a. True
b. False

8. According to existing research, diabetes often can be prevented in patients with prediabetes by including _____ as a behavior change.
a. Increased physical activity by 15 minutes per day
b. Minimized salt intake entirely
c. Adjustment of the diet to eat more frequent meals
d. Two of the above

9. AADE7 provides guidance strategies for _____.
a. Directives for pharmacist educators
b. Self-care behaviors by patients
c. Daily clinician visits
d. Monthly disease management

10. Intensive care differs from usual care by _____.
a. Collaborating with the community to increase work incentives
b. Collaborating to attend a patient at once as a health care team
c. Involving the pharmacist as a face-to-face health care professional for the patient
d. Involving the pharmacist as a nurse partner

11. Cardiovascular mortality from stroke increases directly in proportion to _____.
a. Increased blood pressure greater than 150/90 mmHg
b. Increased A1C >7 percent
c. Increased retinopathy
d. Two of the above

12. Best practices for vascular care of the diabetic patient include which of the following?
a. Encouraging aspirin use daily to reduce risk of a cardiovascular event
b. Providing foot checks in the clinic to reduce amputation risks
c. Identifying and evaluating outcome goals for optimal glucose control as part of a health care team
d. All of the above

13. Related mechanisms of lower extremity damage include _____.
a. Peripheral nerve impairment from lack of adequate blood flow to the lower limbs
b. Diabetic nephropathy that increases fluid and electrolyte imbalance in the body
c. Poor circulation that increases clotting and impairs wound healing
d. A and C

14. Patients with _____ are at risk of foot ulcers.
a. A1C <6.5 percent
b. Diabetic retinopathy
c. Blood pressure >140/90 mmHg
d. All of the above

15. Pharmacy foot checks involve which of the following?
a. Pin prick test and two other sensory checks
b. Foot massage with acupressure
c. Toenail scrubbing and filing
d. Pedal pulse checks

16. Monofilament foot sensation tests
a. Use nylon thread to check circulation
b. Check sensation at 18 spots on the foot
c. Detect poor sensation in response to filament tip bending with pressure
d. Two of the above

17. DSME represents
a. A method of intensive care for patients alone
b. An educational model for clinician and patient knowledge
c. An educational model for only clinician knowledge
d. A well-rounded program of patient self-instruction

18. ADA standards and scopes for pharmacists include _____.
a. Providing patient training to implement self-care behaviors successfully
b. Providing medication chart reviews monthly
c. Communicating with a prescribing physician every day
d. Providing physical tools to clinic patients for home care

19. DASPA benefits include _____.
a. Medicaid certificate of approval for a clinic
b. Education about program accreditation which is required for reimbursement of services
c. Pharmacist continuing education hours toward program accreditation
d. B and C

20. Maintaining communication for effective clinic continuity of care can be achieved with which of the following?
a. Shared phone lines
b. Shared email announcements
c. Shared paper records that travel with the patient
d. Regular round table meetings focused on active case studies

Care and Treatment of Ambulatory Patients With Diabetes: Evidence-Based Team Care Initiatives

Jan. 2, 2012 (expires Jan. 2, 2015) • Activity Type: Knowledge-based

FREE ONLINE C.E. Pharmacists now have online access to NCPA's C.E. programs through Powered by CECity. By taking this test online—go to the Continuing Education section of the NCPA Web site (www. ncpanet.org) by clicking on "Professional Development" under the Education heading you will receive immediate online test results and certificates of completion at no charge.

To earn continuing education credit: ACPE Program 207-000-12-001-H04-P
A score of 70 percent is required to successfully complete the C.E. quiz. If a passing score is not achieved, one free reexamination is permitted. Statements of credit for mail-in exams will be mailed to you approximately four weeks after the completed program quiz and evaluation has been received by NCPA.

Record your quiz answers and the following information on this form.

☐ NCPA Member   License
　 NCPA Member No. _____   State _____ No. _____
☐ Nonmember   State _____ No. _____

All fields below are required. Mail this form and $7 for manual processing to: NCPA, Attn: Jane Davey; 100 Daingerfield Road Alexandria, VA 22314. Make check payable to NCPA.

_____
Last 4 digits of SSN   MM-DD of birth

_____
Name

_____
Pharmacy name

_____
Address

_____
City   State   ZIP

_____
Phone number (store or home)

_____
Store e-mail (if avail.)   Date quiz taken

Quiz: Shade in your choice

	a	b	c	d	e		a	b	c	d	e
1.	☐	☐	☐	☐	☐	11.	☐	☐	☐	☐	☐
2.	☐	☐	☐	☐	☐	12.	☐	☐	☐	☐	☐
3.	☐	☐	☐	☐	☐	13.	☐	☐	☐	☐	☐
4.	☐	☐	☐	☐	☐	14.	☐	☐	☐	☐	☐
5.	☐	☐	☐	☐	☐	15.	☐	☐	☐	☐	☐
6.	☐	☐	☐	☐	☐	16.	☐	☐	☐	☐	☐
7.	☐	☐	☐	☐	☐	17.	☐	☐	☐	☐	☐
8.	☐	☐	☐	☐	☐	18.	☐	☐	☐	☐	☐
9.	☐	☐	☐	☐	☐	19.	☐	☐	☐	☐	☐
10.	☐	☐	☐	☐	☐	20.	☐	☐	☐	☐	☐

Quiz: Circle your choice

21. Is this program used to meet your mandatory C.E. requirements?
　　a. yes **b.** no

22. Type of pharmacist: **a.** owner **b.** manager **c.** employee

23. Age group: **a.** 21–30 **b.** 31–40 **c.** 41–50 **d.** 51–60 **e.** Over 60

24. Did this article achieve its stated objectives? **a.** yes **b.** no

25. How much of this program can you apply in practice?
　　a. all **b.** some **c.** very little **d.** none

How long did it take you to complete both the reading and the quiz? _____ minutes