Guidelines for Improving the Care of the Older Person with Diabetes Mellitus

California Healthcare Foundation/American Geriatrics Society Panel on Improving Care for Elders with Diabetes

BACKGROUND AND SIGNIFICANCE

Diabetes mellitus (DM) is highly prevalent and increasing in persons aged 65 and older, particularly among racial and ethnic minorities. Estimates have placed the proportion of adults aged 65 to 74 with physician-diagnosed DM at nearly 25% in some ethnic groups. Estimates from the Centers for Disease Control and Prevention indicate that, in 1998, 12.7% of persons aged 70 and older had a diagnosis of DM, up from 11.6% in 1990. There are also large numbers of older adults, almost 11% of the U.S. population aged 60 to 74, with undiagnosed DM.

Older persons with DM have higher rates of premature death, functional disability, and coexisting illnesses such as hypertension, coronary heart disease (CHD), and stroke than do those without DM. Older adults with DM are also at greater risk than other older persons for several common geriatric syndromes, such as depression, cognitive impairment, urinary incontinence, injurious falls, and persistent pain. Although there are numerous evidence-based guidelines for DM, few guidelines are specifically targeted toward the needs of older persons and help clinicians prioritize care for the heterogeneous population of older adults they may see in their practices. Moreover, the main emphasis of most DM guidelines is on intensive blood glucose control and prevention of microvascular complications. Although control of hyperglycemia is important, in older persons with DM, greater reduction in morbidity and mortality may result from control of cardiovascular risk factors than from tight glycemic control. Additionally, little is known about how well providers of health care for older persons with DM adhere to recommendations for the screening and treatment of common geriatric syndromes, such as depression, injurious falls, urinary incontinence, cognitive impairment, chronic pain, and polypharmacy, which are more prevalent with DM and may significantly influence quality of life. Although interventions to reduce the incidence of geriatric syndromes and to ameliorate their symptoms have been studied in general populations of older adults, few studies have focused on the identification and treatment of these common syndromes in older adults with DM. Moreover, because conditions such as cognitive impairment, polypharmacy, and injurious falls may interfere with the provision of appropriate DM care, the identification and management of these syndromes may enhance the effectiveness of DM management for the busy primary care provider.

The purpose of this guideline is to improve the care of older persons with DM by providing a set of evidence-based recommendations that include DM-specific recommendations individualized to persons with DM who are aged 65 and older and recommendations for the screening and detection of geriatric syndromes. Table 1 summarizes the components of care included in the guidelines and the number of randomized controlled trials (RCTs) and systematic evidence reviews that were evaluated for the care recommendations.

IMPORTANCE OF INDIVIDUALIZED GOAL-SETTING IN DIABETES MELLITUS CARE

The goals of DM care in older adults, as in younger persons, include control of hyperglycemia and its symptoms; prevention, evaluation, and treatment of macrovascular and microvascular complications of DM; DM self-management through education; and maintenance or improvement of general health status. Although these goals are similar in older and younger persons, the care of older adults with DM is complicated by their clinical and functional heterogeneity. Some older persons developed DM in middle age and face years of comorbidity; others who are newly diagnosed may have had years of undiagnosed comorbidity or few complications from the disease. Some older adults with DM are frail and have other underlying chronic conditions, substantial DM-related comorbidity, or limited physical or cognitive functioning, but other older persons with DM have little comorbidity and are active. Life expectancies are also highly variable for this population. Clinicians caring for older adults with DM must take this heteroge-

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Table 1. Evidence Evaluated for Each Component of Diabetes Care

<table>
<thead>
<tr>
<th>Component of Care</th>
<th>RCTs</th>
<th>Systematic Reviews or Meta-Analyses</th>
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<tr>
<td>Diabetes recommendations</td>
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<td>Geriatric syndromes screening recommendations</td>
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<tr>
<td>Urinary incontinence</td>
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<td>0</td>
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</tr>
<tr>
<td>Persistent pain</td>
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RCT = randomized controlled trial.

For older persons, whose life expectancy may be shorter than the time needed to benefit from an intervention, a key clinical issue is the expected time horizon for benefit from specific interventions. Clinical trials have demonstrated that approximately 8 years are needed before the benefits of glycemic control are reflected in a reduction in microvascular complications such as diabetic retinopathy or renal disease.18-20 and that only 2 to 3 years are required to see benefits from better control of blood pressure and lipids.21-25 For this reason, this guideline places special emphasis on domains particularly important to the reduction of macrovascular endpoints for persons with DM—blood pressure management, aspirin therapy, and lipid management—for which data from RCTs and systematic reviews provide strong evidence in favor of intensive treatment. It is likely that there is an association between moderate glycemic control and enhancement of wound healing, reduction of symptoms associated with hyperglycemia such as polyuria and fatigue, and possibly maximization of cognitive function. However, the available data suggest that many of these shorter-term benefits may be achieved with less-aggressive glycemic targets than those recommended in most of the national DM guidelines.

Quality of life is another important consideration in caring for older adults with DM. Although several interventions have been found to significantly reduce morbidity and mortality, it is clear that the potential benefits may be associated with reduced quality of life in older adults, particularly for those with chronic conditions. Specifically, complicated, costly, or uncomfortable treatment regimens may result in deleterious side effects, reduction in adherence to recommended therapies, and a decrement in overall well-being. The possible effects on quality of life should be taken into account in any treatment plan.

APPLYING THE EVIDENCE TO THE CARE OF OLDER PATIENTS WITH DIABETES MELLITUS: THE DIFFICULTIES

Solid evidence supports the effectiveness of several components of DM care, including control of glycemia, lipids, and blood pressure; aspirin use; smoking cessation; appropriate eye and foot care; and prevention and management of nephropathy. Nevertheless, very few of the data supporting these interventions were obtained from research studies of older persons. Although it is likely that many guidelines can be generalized to many older adults with DM, intensive management of all these conditions simultaneously may not be feasible for a proportion of older patients, and clinicians may have to prioritize reduction of some risks over others. Moreover, it is clear that there may be some groups of older persons with DM for whom aggressive management of these conditions will not provide the same benefit as observed for younger persons; that is, for some, aggressive management can instead result in harm, such as episodes of hypoglycemia with tight blood sugar control or hypotension with aggressive blood pressure control.

Among the unanswered questions that need to be systematically addressed are: when and how to prioritize interventions targeting blood pressure, glycemia, elevated lipids, and aspirin use, and how to stratify older adults by...
their likelihood of risk or benefit from intensive therapies. For some older persons with DM without significant functional disability, all or most of the guidelines may be appropriate, but for others, frail older adults with DM and a high burden of comorbid conditions, short life expectancy, or significant difficulty adhering to treatment recommendations, choices between therapies may have to be made. Instead of treating these patients by using aggressive target levels for blood pressure, lipids, or glucose, the clinician may instead choose therapeutic goals to enhance quality of life, treating symptoms associated with DM and its related conditions and addressing common geriatric syndromes such as polypharmacy, depression, urinary incontinence, and injurious falls.

RATIONALE FOR THE INCLUSION OF SPECIFIC GERIATRIC SYNDROMES

Six geriatric syndromes were selected for inclusion in these DM guidelines. Syndromes were included if there was population-based evidence that the specific syndrome was more prevalent in persons with DM or, in the absence of clear prevalence estimates, there was a strong pathophysiological reason to believe that persons with DM might be at greater risk for the syndrome or expert consensus that the syndrome should be included. Because of a paucity of RCT evidence supporting screening recommendations in any age group, most of the recommendations to screen for common treatable geriatric syndromes in older persons with DM are based on expert opinion. The guidelines take into consideration the logistical complexity of providing comprehensive care to all older persons with DM by using a window of time that is 3 to 6 months into the initial evaluation. Throughout the guideline, this window is referred to as the “initial evaluation period.”

Polypharmacy

Older adults with DM are at risk for drug side effects and drug-drug and drug-disease interactions. Polypharmacy is a major problem for older adults with DM, who may require several medications to manage glycemia, hyperlipidemia, hypertension, and other associated conditions. In addition, drug therapy for DM and comorbid illness can be costly for some patients. Clinicians should perform a careful review of each medication currently being used by the patient during the initial visit and at each subsequent visit and document whether the patient is taking each medication properly. All drugs identified during the initial review and each new drug prescribed should have clear documentation of the indication in the record, and patients and their caregivers should receive information describing the expected benefits, risks, and potential side effects of each medication.

Depression

Older adults with DM are at increased risk for depression, and there is evidence of underdetection and undertreatment in the primary care setting.26,27 On initial presentation of an older adult with DM, the clinician should assess the patient for symptoms of depression using a single screening question or consider using a standardized screening tool such as the Geriatric Depression Scale, the Beck Depression Inventory, or Zung’s Mood Scale.28-30 If an older adult with DM presents with new-onset or recurrent depression, medications should be evaluated to determine whether any of them are associated with depression. If therapy is initiated, targeted symptoms should be identified and documented in the record.

Cognitive Impairment

Older adults with DM are at increased risk for cognitive impairment.7 Unrecognized cognitive impairment may interfere with the patient’s ability to implement lifestyle modifications and take medications recommended by the clinician. Therefore, it is important that the clinician screen for cognitive impairment during the initial evaluation period and with any change in the patient’s clinical status, particularly if increased difficulty with self-care and self-management is noted. A variety of validated screening tools exist for assessing cognitive impairment. Caregivers can be a valuable source of information as well. Involvement of a caregiver in DM education and management can be critical to the successful management of the cognitively impaired older person with DM.

Urinary Incontinence

Older women with DM are at increased risk for urinary incontinence.31,32 A targeted history and physical examination should be performed, focusing on conditions associated with older age or DM. Examples are polyuria (glycosuria), neurogenic bladder, fecal impaction, prolaphe, cystocele, atrophic vaginitis, vaginal candidiasis, and urinary tract infection, which can cause or exacerbate urinary incontinence.

Injurious Falls

Falls by older adults are associated with high rates of morbidity, mortality, and functional decline.33-36 Older persons with DM are at increased risk for injurious falls.37-39 Possible risk factors for injurious falls in older persons with DM include high rates of frailty and functional disability, visual impairment, peripheral neuropathy, hypoglycemia, and polypharmacy.39,40 Older persons with DM should therefore be screened for their risk for falls and for opportunities to prevent their falling (see the American Geriatrics Society (AGS) guideline for falls prevention in older persons).41

Pain

Older adults with DM are at risk for neuropathic pain, and those with pain are often undertreated.42,43 Older adults with DM should be screened for persistent pain by using a targeted history and physical examination. If there is evidence of persistent pain in an older adult with DM, further evaluation should be performed, appropriate therapy should be offered, and the patient should be monitored, as recommended by the AGS guideline on persistent pain.44

GUIDELINE DEVELOPMENT PROCESS AND METHODS

These guidelines were developed in the following stages: review of existing guidelines and literature on each topic, construction of evidence tables that summarized the data from RCTs on each topic, modification of existing guidelines and development of new guidelines, and review and revision by members of the expert panel. For all domains,
existing evidence and guidelines from sources such as the Cochrane Collaboration, the American Diabetes Association (ADA), the AGS, Assessing Care of Vulnerable Elders, the American Association of Clinical Endocrinologists, and the Adult Treatment Panel III report from the National Cholesterol Education Program were reviewed. Focused searches of the English language literature were performed using PubMed and the references listed in the papers and guidelines reviewed. For most of the topic areas reviewed, limited data that were specific to older adults with DM were found, but for some of the domains under consideration, there were data from studies of older persons or of persons of all ages with DM, and for a number of these, it was reasonable to extrapolate the findings to older adults with DM. Evidence tables (available at http://www.americangeriatrics.org) that summarize data from RCTs were created. Existing guidelines were subsequently modified, and new guidelines were developed on the basis of this literature review. A national advisory panel consisting of general internists, family practitioners, geriatricians, endocrinologists, health services researchers, and certified DM educators, among whom were members of the ADA, the Department of Veterans Affairs, the Centers for Medicare and Medicaid Services, the California Peer Review Organization, the Centers for Disease Control and Prevention, the American Association of Family Practitioners, and the National Institute of Diabetes and Digestive and Kidney Diseases then evaluated the candidate guidelines.

This work was not meant to be an exhaustive review of DM care for the older adult; rather, these guidelines focus on the most important aspects of care for older adults with DM because they differ significantly from or deserve special emphasis in comparison with the care provided to younger persons with DM. Some areas of DM care are beyond the scope of these guidelines and are not addressed in the guidelines. In this document, it is recommended that primary care providers screen older adults with DM for a number of the established geriatric syndromes, but for treatment recommendations, readers are referred to guidelines from the ADA, AGS, and other sources used in these guidelines.

The guidelines were reviewed by the expert panel, who used the ratings for quality and strength of evidence described in Table 2. Some of the guidelines are based on clinical experience and the consensus of members of the expert panel.

THE GUIDELINES

General Guiding Principles for the Care of Older Adults with Diabetes Mellitus

Clinicians should establish, in collaboration with patients or caregivers, specific goals of care or target outcomes for persons with DM. Such targets should be identified and documented for all aspects of care, such as management of hypertension, hyperlipidemia, hyperglycemia, mood disorder if present, and screening and treatment of geriatric syndromes if present. These targets or goals of treatment should be identified and documented in the medical record.

If goals of care are not being met, then the patient should be evaluated for contributing causes. Difficulty with adherence to medications or to lifestyle modification may be a reason that targeted outcomes are not achieved. The clinician should review the feasibility of medication dosing and costs. Efforts should be made to keep care simple and inexpensive through such practices as single daily dosing of drugs (or, when this is not feasible, twice daily dosing). If there is evidence of difficulty with adherence to a regimen that cannot or should not be simplified, a physician, pharmacist, DM educator, or other healthcare practitioner should provide counseling of the patients, family members, and caregivers; aids such as pill-dosing dispensers should be suggested or offered; and efforts should be made to simplify other aspects of care.

If these target outcomes are not being achieved, then clinicians should consider referral to a specialist experienced in the care of older persons. Among the specialists who may assist with the management of these conditions are endocrinologists or diabetologists, geriatricians, hypertension specialists, mental health specialists, DM educators, and nutritionists.

Aspirin

1. The older adult who has DM (and is not on other anticoagulant therapy and does not have any contraindications to aspirin) should be offered daily aspirin therapy, 81 to 325 mg/d. (IB)

Several RCTs have and systematic reviews have shown an association between aspirin use and reduction in

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<td>Evidence from at least one properly designed randomized, controlled trial</td>
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<td>Level II</td>
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<tr>
<td>Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies, from multiple time-series studies, or from dramatic results in uncontrolled experiments</td>
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<tr>
<td>Level III</td>
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<tr>
<td>Evidence from respected authorities, based on clinical experience, descriptive studies, or reports of expert committees</td>
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<th>Strength of Evidence</th>
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<tr>
<td>Good evidence to support the use of a recommendation; clinicians should do this all the time</td>
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<td>B</td>
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<td>Moderate evidence to support the use of a recommendation; clinicians should do this most of the time</td>
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<td>Poor evidence to support or to reject the use of a recommendation; clinicians may or may not follow the recommendation</td>
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<td>E</td>
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<td>Good evidence against the use of a recommendation; clinicians should not do this</td>
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acute myocardial infarction (MI) and other cardiovascular events, as well as reduction in cardiovascular mortality for older adults and persons with DM. The dose of aspirin used in these studies ranges from 75 mg to 325 mg. A meta-analysis found no evidence that a daily dose of 1,000 mg or more was more effective than a 75-mg daily dose.42 (Source guideline: 2, 4, 11)

Smoking
1. The older adult who has DM and smokes should be assessed for willingness to quit and should be offered counseling and pharmacological interventions to assist with smoking cessation. (IIIA)

Approximately 12% of persons with DM aged 65 and older smoke. Of people with DM, smokers have a higher risk than nonsmokers of morbidity and premature death,43 but within 2 to 3 years of smoking cessation, the former smoker’s risk of CHD appears to decline to levels comparable with that of persons who never smoked.44 Although several RCTs and systematic reviews have demonstrated the effectiveness of counseling and pharmacological interventions for smoking cessation in the general population, only two small studies have evaluated smoking cessation programs in persons with DM, with equivocal results.45,46 Nonetheless, the detrimental effects of smoking are clear, and substantial benefit may be obtained through smoking cessation, for older adults and for persons with DM. (Source guideline: 4)

Hypertension

General Recommendations

1. If an older adult has DM and requires medical therapy for hypertension, then the target blood pressure should be less than 140/80 if it is tolerated. (IA) Epidemiologic evidence shows that lowering blood pressure to less than 130/80 may provide further benefit. (IIA)

There is strong evidence from a number of RCTs that drug therapy for blood pressure management reduces cardiovascular events and mortality in middle-aged and older adults. Several studies included large numbers of older participants or persons with DM.22,47-57 In the majority of these studies, target blood pressure levels were less than 140/90 mmHg, but other studies conducted primarily in younger adults found a reduction in cardiovascular endpoints using a target of less than 150/80.48,49 or systolic blood pressure less than 160 mmHg.50 The Appropriate Blood Pressure Control in Diabetes (ABCD) study found that intensive control (blood pressure approximately 128/75) in normotensive patients with type 2 DM slows the progression of diabetic nephropathy and retinopathy.57 (Source guidelines: 2, 4)

Recent evidence comparing classes of antihypertensive medications for persons with DM indicates that many, such as diuretics, angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, and calcium channel blockers, have comparable effectiveness in reducing cardiovascular morbidity and mortality.45,58 There are also data to suggest that angiotensin-receptor blockers (ARBs) have cardiovascular and renal benefit for persons with DM.53

2. Because older adults may have reduced tolerance for blood pressure reduction, hypertension should be treated gradually to avoid complications. (IIIA)

There are no data on the optimal time intervals over which blood pressure should be lowered. Expert consensus suggests that blood pressure in older patients with hypertension should be lowered gradually to avoid complications. An initial goal to lower systolic blood pressure by no more than 20 mmHg is prudent. If that goal is met and well tolerated, then further steps to achieve target blood pressure can be considered as needed. (Source guideline: 4)

3. The older adult who has DM and hypertension should be offered pharmacological and behavioral interventions to lower blood pressure within 3 months if systolic blood pressure is 140 to 160 mmHg or diastolic blood pressure is 90 to 100 mmHg or within 1 month if blood pressure is greater than 160/100 mmHg. (IIIB)

There are no data on the optimal timing for initiation of treatment for hypertension, but expert opinion supports the recommendation that the severity of blood pressure elevation should influence the urgency of initiating therapy. (Source guideline: 11)

Medication

4. The older adult with DM who is on an ACE inhibitor or ARB should have renal function and serum potassium levels monitored within 1 to 2 weeks of initiation of therapy, with each dose increase, and at least yearly. (IIIA)

Although one specific medication for managing blood pressure in older adults with DM is not recommended, special attention should be paid to some commonly used medications. ACE inhibitors have been associated with a reduction in renal function. One RCT found that a moderate dose of ACE inhibitor (i.e., captopril 75 mg/d, enalapril 10 mg/d, or lisinopril 10 mg/d) is significantly associated with the development of hyperkalemia.59 Additionally, a prospective study found a significant increase in serum potassium in patients with type 2 DM on captopril compared with those on other antihypertensive medications,60 and data from several uncontrolled studies suggest that older adults are more susceptible to the reductions in renal function that are related to ACE inhibitors.41 (Source guidelines: 4, 6, 11)

5. The older adult with DM who is prescribed a thiazide or loop diuretic should have electrolytes checked within 1 to 2 weeks of initiation of therapy or of an increase in dosage and at least yearly. (IIIA)

No studies have evaluated the effect of monitoring electrolytes or appropriate monitoring intervals in persons using diuretics. However one RCT found that the use of thiazide diuretics is associated with hypokalemia and ventricular arrhythmias,42 and a case-control study found that hypertensive patients on higher doses of thiazide diuretics have an increased risk of cardiac arrest.43 These data suggest that monitoring of potassium levels at the initiation of therapy and at regular intervals reduces the risk of hypokalemia and its complications. (Source guideline: 11)
Glycemic Control

General Recommendations

1. For older persons, target hemoglobin A1c (A1C) should be individualized. A reasonable goal for A1C in relatively healthy adults with good functional status is 7% or lower. For frail older adults, persons with life expectancy of less than 5 years, and others in whom the risks of intensive glycemic control appear to outweigh the benefits, a less stringent target such as 8% is appropriate. (IIB)

Lowering A1C is one goal of a DM treatment program, but there are no clinical trial data on the macrovascular and microvascular consequences of intensive glycemic control in older adults. Epidemiological analysis of data from the United Kingdom Prospective Diabetes Study (UKPDS), an RCT of persons in late middle age with incident type 2 DM and minimal comorbidity, found a 1% reduction in A1C to be associated with a 37% decline in microvascular complications and a 21% reduction in risk of any endpoint related to DM. Therefore, older adults who are in good health and those who already have microvascular complications are likely to benefit the most from intensive glycemic control.

Nevertheless, the risks of intensive glycemic control, including hypoglycemia, polypharmacy, and drug-drug and drug-disease interactions, may significantly alter the risk-benefit equation. For frail older adults, persons with limited life expectancy, and others in whom the risks of intensive glycemic control appear to outweigh the potential benefits, a less-stringent target than the ADA general recommendation, such as 8.0%, is appropriate.

According to ADA recommendations, the quality of evidence is level I for lowering A1C in younger persons (approximately younger than 65), level II for A1C goal of 7% or less, and level III for applying less stringent goals to some older adults and those with limited life expectancy. (Source guidelines: 2, 4)

Monitoring

2. The older adult who has DM and whose individual targets are not being met should have his or her A1C levels measured at least every 6 months and more frequently, as needed or indicated. For persons with stable A1C over several years, measurement every 12 months may be appropriate. (IIB)

Monitoring blood glucose levels is necessary for enhancing glycemic control. No clinical trials have evaluated the effect on outcomes of routine measurement of A1C in persons with type 2 DM. One RCT conducted in Denmark found that measuring and reporting A1C four times a year in persons with type 1 DM was associated with lower A1C levels and fewer hospitalizations (absolute risk reduction 11%) at 1 year than in persons whose A1C levels were not reported. More-frequent monitoring may be appropriate for persons for whom the achievement of intensive glycemic control is clinically indicated (e.g., symptomatic patients with elevated A1C levels). (Source guidelines: 4, 11)

3. For the older adult with DM, a schedule for self-monitoring of blood glucose should be considered, depending on the individual's functional and cognitive abilities. The schedule should be based on the goals of care, target A1C levels, the potential for modifying therapy, and the individual's risk for hypoglycemia. (IIB)

Self-monitoring of blood glucose is a key component of the management of type 1 DM. Self-monitoring for persons with type 2 DM who are on insulin is recommended on the basis of expert opinion. In a systematic review of 11 studies that evaluated self-monitoring in persons treated with diet or hypoglycemic medications (six randomized trials and five observational studies), only one found an improvement in glycemic control associated with self-monitoring. However, expert opinion strongly suggests that long-term outcomes will be enhanced when self-monitoring is combined with review of blood glucose levels and appropriate adjustment of therapy to attain target levels of glycemic control. In addition, epidemiological evidence suggests that frail older adults with DM are at increased risk for hypoglycemic coma. Expert consensus suggests that self-monitoring may reduce the risk of serious hypoglycemia in older adults with DM who use insulin or oral antidiabetic agents. The optimal frequency and timing of self-monitoring is not known. The ADA recommends that these "should be dictated by the particular needs and goals of the patients" and that frequency should be increased with any modification of therapy. (Source guidelines: 2, 4, 9)

4. The management plan for the older adult with DM who has severe or frequent hypoglycemia should be evaluated; the patient should be offered referral to a DM educator, endocrinologist, or diabetologist; and the patient and any caregivers should have more-frequent contacts with the healthcare team (e.g., physicians, certified DM educators, pharmacists, nurse case manager) while therapy is being readjusted. (IIB)

Epidemiological evidence suggests that frail older adults are at higher risk for serious hypoglycemia than are healthier, more-functional older adults. One small RCT found that automated health assessment calls to patients with follow-up phone calls from a nurse significantly reduced the risk of hypoglycemia in patients with DM on oral antidiabetic medications (adjusted difference in number of symptoms −0.5, P = .001). This study, with a mean age of 56 for participants in the intervention arm, excluded persons aged 75 and older. Older adults with DM who have frequent or severe episodes of hypoglycemia are likely to benefit from more-intensive management to determine the precipitants of hypoglycemia and to attempt to reduce the risk of recurrence. (Source guidelines: 2, 4)

Medications

5. If an older adult is prescribed an oral antidiabetic agent, then chlorpropamide should not be used. (IIA)

Chlorpropamide has a prolonged half-life, particularly in older adults. It is associated with increased risk for hypoglycemia, and this risk increases with age. (Source guideline: 11)
6. Older diabetic men with a serum creatinine of 1.5 mg/dL or greater and older diabetic women with a serum creatinine of 1.4 mg/dL or greater and older diabetic patients of either sex with creatinine clearance that indicates reduced renal function should not use metformin because of the increased risk of lactic acidosis. (IIb)

7. The older adult with DM who receives metformin should have serum creatinine measured at least annually and with any increase in dose, but for individuals aged 80 years or older or those who have reduced muscle mass, a timed urine collection should be obtained for measurement of creatinine clearance. (IIb)

Lactic acidosis, a rare but serious complication of metformin use, is more common in the presence of impaired renal function.77,78 Because aging is associated with reduced renal function, older adults with type 2 DM on metformin should undergo regular monitoring of renal function, and patients with serum creatinine levels above the upper limit of normal for their age should not receive metformin.79 There are no data on the frequency of the timed urine collection. Additionally, metformin should be withheld before initiating radiological studies, and renal function should be reevaluated after such procedures before metformin is reinitiated. (Source guideline: 2)

Lipids

General Recommendations

1. For the older adult with DM who has dyslipidemia, efforts should be made to correct the lipid abnormalities if feasible after overall health status is considered. (IA)

Epidemiological evidence suggests that persons with DM without prior MI have similar elevated risk of MI as persons without DM who have had an MI.24 Persons with DM have high rates of lipid abnormalities that contribute to this cardiovascular risk: high low-density lipoprotein (LDL), low high-density lipoprotein (HDL), and high triglycerides. Evidence supports the use of lipid-lowering agents and therapies to increase HDL in older adults with DM. Several RCTs and meta-analyses have shown that a reduction in LDL cholesterol reduces the risk of cardiovascular events in older adults and persons with DM. The beneficial effects of lowering LDL have been demonstrated with 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (statins).33,80-91 Despite this evidence, there are data to suggest that rates of prescribing of statins in older adults are suboptimal and that, even when they are prescribed, there is poor adherence to these medications.92,93 Data on the effect of HDL and triglyceride levels in older adults with DM are limited. In men with DM (mean age 65) whose primary abnormality is low HDL, the use of fibrates has been found to be associated with an increase in HDL levels, a fall in triglyceride levels, and a reduction in rates of cardiovascular events.94,95 (Source guidelines: 1, 4)

2. When the older adult with DM has an LDL cholesterol level of:
   100 mg/dL or less, lipid status should be rechecked at least every 2 years.

100 to 129 mg/dL, medical nutrition therapy (MNT) and increased physical activity are recommended; lipid status should be checked at least annually, and response to therapy should be monitored. If an LDL of 100 or lower is not achieved in 6 months, then pharmacological therapy should be initiated if feasible.

130 mg/dL or greater, pharmacological therapy is required in addition to lifestyle modification; lipid status should be checked at least annually, and response to therapy should be monitored. (IIb)

The evidence presented in Lipid Recommendation 1 argues for making efforts to lower LDL cholesterol and supports pharmacological interventions (e.g., the use of lipid-lowering agents). Expert opinion supports the selection of specific LDL levels as prompts for specific actions. MNT, enhanced physical activity, and weight loss have also been shown to play a role in improving cardiovascular risk profiles in older adults with DM. Eleven RCTs have evaluated MNT76-103 or MNT and physical activity104-106 in the clinical management of dyslipidemia in older adults with DM.

It is recommended that goals for HDL and triglycerides also be consistent with ADA recommendations of HDL greater than 40 mg/dL and triglycerides lower than 150 mg/dL.67 Older adults with normal or nearly normal LDL cholesterol and low HDL or elevated triglycerides should be offered a fibrate in addition to MNT.

There are no data to support the length of the interval during which lipid levels should be checked. Expert consensus suggests that persons with low-risk lipid values (LDL <100 mg/dL, HDL >40 mg/dL, triglycerides <150 mg/dL) on an initial assessment may have lipids checked every 2 years; persons with moderate or higher-risk lipid levels should have their lipids evaluated at least annually and more frequently if targets are not being met.67 (Source guidelines: 1, 7, 9)

Monitoring

3. The older adult with DM who is newly prescribed niacin or a statin or who has an increase in the current dose of niacin or statin should have alanine aminotransferase level measured within 12 weeks of initiation of the new medication or dose change. (IIb)

4. The older adult with DM who is taking a fibrate should have an annual evaluation of liver enzymes. (IIb)

Data describing the benefit of monitoring liver function for patients using lipid-lowering medications are limited. Clinical trials suggest that the use of statins or fibrates is associated with elevations in liver transaminases in some patients,11 but RCT evidence from studies of persons with type 2 DM found no increase in liver enzymes 12 weeks after initiation of therapy with a statin.107 One RCT comparing older adults (aged 50-70) and younger persons taking niacin, which excluded persons with DM, found no significant difference in frequency of liver function test abnormalities between the two age groups.108

There is no clinical trial evidence supporting the intervals at which monitoring of liver enzymes should occur. (Source guidelines: 1, 12)
Eye Care

1. The older adult who has new-onset DM should have an initial screening dilated-eye examination performed by an eye-care specialist with funduscopy training. (IIb)

Two RCTs have shown that detection and treatment of diabetic retinopathy reduces the progression of diabetic eye disease and visual loss.103,110 Evidence suggests that sensitivity of screening for diabetic retinopathy is highest among eye-care specialists.111,112 (Source guidelines: 2, 4)

2. The older adult who has DM and who is at high risk for eye disease (symptoms of eye disease present; evidence of retinopathy, glaucoma, or cataracts on an initial dilated-eye examination or subsequent examinations during the prior 2 years; A1C ≥8.0%; type 1 DM; or blood pressure ≥140/80) on the prior examination should have a screening dilated-eye examination performed by an eye-care specialist with funduscopy training at least annually. Persons at lower risk may have a dilated-eye examination at least every 2 years. (IIb)

Data from the UKPDS indicates that incidence of retinopathy is associated with, among other things, level of glycemic control over the prior 6 years and higher blood pressure and that the progression of retinopathy is associated with older age, male sex, and hyperglycemia.113 Few patients with type 2 DM without diabetic retinopathy on baseline examination were found to require photocoagulation during the subsequent 3 to 6 years (0.2% and 1.1%, respectively), whereas persons with maculœneurysms in one eye at initial evaluation were found to need photocoagulation at rates of 0.0% and 1.9% at 3 and 6 years, and those with maculœneurysms in both eyes were found to need photocoagulation at rates of 1.2% and 3.6% at 3 and 6 years. Persons with more severe retinopathy required photocoagulation at significantly higher rates, 15.3% and 25.2% at 3 and 6 years. At 12 years, the study reported significant differences in time to photocoagulation between persons with and without diabetic retinopathy at baseline (P < .001).114 Notably, this analysis did not record or examine the prevalence of other common treatable age-related eye disorders, such as glaucoma, cataract, and macular degeneration, which are also more common among persons with DM.

Decision analytic models suggest that screening for diabetic retinopathy is cost-effective. However in persons at low risk for retinopathy, annual screening is not cost-effective in comparison with less-frequent screening intervals.115 There is consensus among experts that data from previous examinations, DM-related considerations, and blood pressure should all be considered when determining the need for photocoagulation. It is important to note that none of the existing decision analytic models for the timing of eye care have taken into consideration the potential health benefits of detecting other age-related vision problems, such as cataract, glaucoma, and uncorrected refractive errors in older adults with DM. (Source guidelines: 2, 4, 11)

Foot Care

The older adult who has DM should have a careful foot examination at least annually to check skin integrity and to determine whether there is bony deformity, loss of sensation, or decreased perfusion and more frequently if there is evidence of any of these findings. (IIIa)

There are no RCT data to support examination of the feet at regular intervals to prevent lower-extremity ulceration or amputation, but a randomized trial of an intervention consisting of patient and provider foot-care education and a team approach to foot care found an increase in rates of foot examinations at routine office visits and a reduction in serious foot lesions (odds ratio (OR) = 0.41, P = .05).116 In addition, several uncontrolled studies have found a reduction in rates of amputation after implementation of comprehensive foot-care programs.117

Regular foot examinations permit identification of diabetic neuropathy and foot lesions and may in turn prevent progression to ulcers and amputation, but there are no data to support the optimal interval for evaluation. Most current recommendations specify that the foot examination should be done at all nonurgent outpatient visits.

Quality of evidence is level II for more frequent examinations for persons at high risk for foot problems and level III for routine annual screening. (Source guidelines: 2, 4).

Nephropathy

1. A test for the presence of microalbumin should be performed at diagnosis in patients with type 2 DM. After the initial screening and in the absence of previously demonstrated macro- or microalbuminuria, a test for the presence of microalbumin should be performed annually. (IIIA) (Source guideline: 4)

Diabetes Mellitus Education

1. Persons with DM, and, if appropriate, family members and caregivers, should be given the following information about hypo- and hyperglycemia at diagnosis, with reassessment and reinforcement periodically as needed:
   (i) precipitating factors
   (ii) prevention
   (iii) symptoms and monitoring
   (iv) treatment
   (v) when to notify a member of the healthcare team. (IA)

RCT evidence from middle-aged and older adults suggests that multidisciplinary interventions that provide education on medication use, monitoring, and recognizing hypo- and hyperglycemia can significantly improve glycemic control.118 (Source guideline: 2)

2. The monitoring technique of the older adult with DM who self-monitors blood glucose levels should be routinely reviewed. (IIIB)

Self-monitoring blood glucose (SMBG) was an important component of two RCTs of education programs for middle-aged and older adults that found improved glycemic control in the intervention arms of the studies.119,120 In addition, one carefully conducted meta-analysis of education programs for adults (younger and older) found SMBG
instruction to have a significant positive effect on adherence to a prescribed regimen (seven studies, effect size = +0.49 (standard deviation (SD) = 0.41)). Finally, one well-conducted RCT found that a single 30-minute session of instruction on SMBG significantly decreased measurement errors in comparison with 30 minutes of self-instruction using the directions included with an SMBG device (P < .01). Nevertheless, there are no clinical trials that evaluate the benefit of reviewing SMBG techniques on DM outcomes. (Source guidelines: 2, 4, 8)

3. The older adult who has DM should be evaluated regularly for level of physical activity and should be informed about the benefits of exercise and available resources for becoming more active. (IA)

Evidence from RCTs indicates that increased physical activity in combination with nutrition education can significantly reduce weight and enhance blood pressure, lipid, and glycemic control. Two of these RCTs dealt specifically with older adults (aged 55 and 60 and older, respectively), but some older persons are too functionally or cognitively impaired to successfully increase their level of physical activity. (Source guidelines: 4)

4. The older adult with DM should be evaluated regularly for diet and nutritional status and, if appropriate, should be offered referral for culturally appropriate MNT and counseled on the content of his or her diet (e.g., intake of high-cholesterol foods and appropriate intake of carbohydrates) and on the potential benefits of weight reduction. (IA)

Eight RCTs have evaluated dietary education or MNT in the clinical management of older adults with DM and found that they can significantly improve weight, blood pressure, lipid levels, and glycemic control. Most of these RCTs focused primarily on middle-aged adults, but one specifically targeted adults aged 65 and older and produced results similar to the others. Data on the effect of weight loss on morbidity and mortality in older adults with DM are limited; thus, weight reduction may not be an appropriate goal in all cases. (Source guidelines: 2, 4)

5. The older adult with DM who is prescribed a new medication and any caregiver should receive education about the purpose of the drug, how to take it, the common side effects, and important adverse reactions, with reassessment and reinforcement periodically as needed. (IIIA)

There is evidence that older persons may receive inadequate information about their medications. Package inserts that accompany prescription medications often do not meet the readability needs of older adults, with many printed on poor quality paper and in small fonts. Furthermore, language and health literacy can be barriers to obtaining vital information about side effects and adverse reactions from package inserts or labels because many are written solely in English or in a form easily misunderstood by patients. In one study, interviews with 325 older adults revealed that 39% could not read their medication labels and 67% did not fully understand the labels. Although trials directly testing the effects of education on new prescriptions are lacking, two RCTs investigated the effect of DM education programs that included education on medication use in middle-aged and older adults and found that the programs had a significant effect on glycemic control. Additionally, a meta-analysis of 153 studies involving adults of various ages indicated that one-on-one interventions significantly improved medication adherence. (Source guideline: 11)

6. The older adult who has DM and any caregiver should receive education about risk factors for foot ulcer and amputation. Physical ability to provide proper foot care should be evaluated, with reassessment and reinforcement periodically as needed. (IB)

Older adults are at higher risk for conditions that may reduce the ability to conduct proper foot surveillance and care (e.g., cognitive impairment, visual impairment, osteoarthritis, and other physical limitations in functioning that prevent movement). One RCT that evaluated a multidisciplinary intervention that included patient education on foot care for middle-aged and older adults (mean age 59) found lower rates of serious foot lesions (OR = 0.41; P = .05). Another RCT found that patients of various ages exposed to an educational program on foot care experienced lower rates of amputation (P = .03) and ulceration (P = .005). (Source guidelines: 2, 4)

Depression

1. The older adult who has DM is at increased risk for major depression and should be screened for depression during the initial evaluation period (first 3 months) and if there is any unexplained decline in clinical status. (IIIA)

On initial presentation of an older adult with DM, the clinician should assess the patient for symptoms of depression using a two-question screen or consider using a standardized screening tool, such as the Geriatric Depression Scale. This tool is available in several languages (http://www.stanford.edu/~yesavage/GDS.html).

Depression is more common in persons with DM and may impede DM self-management. One recent retrospective study found that, controlling for age, sex, and race/ethnicity, older adults with DM were significantly more likely to develop major depression than other older adults and that depressed older adults with DM incurred higher non-mental health costs than those who are not depressed. Older adults have high rates of under-diagnosis and undertreatment of their depressive symptoms, with fewer than 10% of depressed older adults and fewer than 5% of older adults with high levels of depressive symptoms receiving antidepressant medications.

The data on the relationship between screening for depression in the clinical setting and patient outcomes are mixed. One RCT found that middle-aged patients screened with a single question or a longer survey were significantly more likely to recover from depression, but mean improvement in depressive symptoms was not significantly different from the control group. Another partially randomized controlled trial found no improvement in depression in patients aged 70 and older who were screened by office staff before their initial visit. It is important to
note that recent studies have demonstrated poorer outcomes of DM care for patients with unrecognized depression. Therefore, screening and treatment of depression may influence outcomes of DM care in older persons. (Source guideline: 10)

2. The older adult with DM who presents with new-onset or a recurrence of depression should be treated or referred within 2 weeks of presentation, or sooner if the patient is a danger to himself or herself, unless there is documentation that the patient has improved. (IIIB)

There is evidence from two carefully conducted meta-analyses of RCTs that pharmacological and psychological treatment of older adults (aged 55 and older) is effective in reducing depressive symptoms. One systematic review of RCTs shows the same benefit for people with physical illnesses. There are no RCT data on the optimal timing of referral or implementation of treatment in older adults. The quality and strength of evidence is IA for undertaking clinical intervention but IIIB for the timing of referral or treatment. For persons who show evidence of substance abuse or dependence, initiation of therapy for depression may wait until he or she is in a drug- or alcohol-free state. If therapy is initiated, targeted symptoms should be identified and documented in the record. (Source guideline: 11)

3. The older adult who has received therapy for depression should be evaluated for improvement in target symptoms within 6 weeks of the initiation of therapy. (IIIB)

Evaluation of the effectiveness of therapies for depression is critical to managing the disease. Because there is evidence of inadequate treatment once therapy is initiated for depression in older adults, persons who receive therapy for depression should be reassessed to see whether there has been a noticeable improvement in target symptoms, and efforts should be made to modify therapy appropriately. No evidence is available on the optimal time to evaluate treatment effectiveness. Six weeks was identified as the interval for evaluating therapy for depression because antidepressant medications frequently work during this time period. (Source guidelines: 3, 5, 11)

Polypharmacy

1. The older adult who has DM should be advised to maintain an updated medication list for review by the clinician. (IIA)

Older adults with DM are at risk for drug side effects and drug-drug interactions. The availability of an updated medication list that includes nonprescription drugs allows the clinician to evaluate the need for current medications, the potential for drug-drug and drug-disease interactions, and ways to enhance medication adherence.

One RCT found that reviewing a medication list can improve patient care for older adults by significantly decreasing inappropriate prescribing ($P < .001$ at 12 months after initiation of the intervention). (Source guideline: 11)

2. The medication list of an older adult with DM who presents with depression, falls, cognitive impairment, or urinary incontinence should be reviewed. (IIIA)

Epidemiological evidence shows that medications may contribute to or exacerbate geriatric syndromes, alone or through drug-drug or drug-disease interactions. Medications, particularly those with sedating effects, are regularly cited as a risk factor for falls. Medication use is also cited as a potential cause of depression and may complicate its treatment. Many medications (especially sedating medications) have been associated with cognitive impairment (delirium or dementia) in older patients. Urinary incontinence has been linked to some specific medications and to drug-drug interaction and polypharmacy, particularly in women. Finally, adverse drug reactions have been implicated in failure to thrive in older adults, resulting in functional decline, depression, and malnutrition. One RCT found that the withdrawal of psychotropic medications leads to a significant reduction in the risk of falling; therefore, the quality of evidence is IA for falls. (Source guideline: 11)

Cognitive Impairment

1. The clinician should assess the older adult with DM for cognitive impairment using a standardized screening instrument during the initial evaluation period and with any significant decline in clinical status. Increased difficulty with self-care should be considered a change in clinical status. (IIIA)

Diabetes mellitus, particularly type 2, has been associated with decreased cognitive function in older adults, manifested as decreased memory, learning, or verbal skills. Two case-control studies found significant differences in cognitive function between older adults with and without DM using the Mini-Mental State Examination (MMSE), demonstrating that a short formal cognitive assessment like the MMSE can detect impairment in older adults with DM.

One case-control study found that older adults with DM who scored below 24 points on the MMSE are more likely to have been hospitalized in the last year. Therefore, it is important to be aware of a patient's cognitive function when prescribing treatments and to note difficulties with participating in DM self-care that could be an indicator of a change in cognitive status. (Source guideline: 11)

2. If there is evidence of cognitive impairment in an older adult with DM and delirium has been excluded as a cause, then an initial evaluation designed to identify reversible conditions that may potentially cause or exacerbate cognitive impairment should be performed promptly after diagnosis and with any significant change in clinical status. (IIIA)

Recent American Academy of Neurology guidelines recommend screening older adults with evidence of cognitive impairment for depression, vitamin B12 deficiency, and hypothyroidism; structural neuroimaging to identify lesions is also recommended for those recently diagnosed. As noted above, medications can also affect cognitive
function, so a review of the medication list should be performed if there is evidence of cognitive impairment (see Polyparmacy recommendation 2).

Epidemiologic evidence has found that cognitive impairment is associated with DM and that hyperglycemia may be a treatable cause of cognitive impairment. One prospective pre/post study found that older adults with untreated type 2 DM who were treated with an oral hypoglycemic agent for a minimum of 2 weeks (mean fasting glucose before treatment ± standard deviation = 13.8 ± 1.2 mmol/L, mean after treatment = 8.4 ± 0.4 mmol/L) had significantly (P < .05) improved scores on a variety of tests of cognitive function after treatment. A randomized controlled trial found similar results in treated versus untreated older adults with type 2 DM and found an association between treatment of glycemia and improvement in memory and learning, particularly verbal learning. (Source guideline: 11)

Urinary Incontinence

1. The older adult who has DM should be evaluated for symptoms of urinary incontinence during annual screening. (IIIA)

Evidence suggests that women with DM are at higher risk than the general population for urinary incontinence. The risk factors for urinary incontinence that are more common in older adults with DM include polyuria, overflow secondary to neurogenic bladder and autonomic insufficiency, urinary tract infection, candida vaginitis, and fecal impaction due to autonomic insufficiency. Urinary incontinence is commonly unreported by patients and undetected by providers, but its effect may be profound, and it may be associated with social isolation, depression, falls, and fractures. No RCT evidence indicates that routine inquiry about urinary incontinence will result in enhanced detection and treatment or improved outcomes, but evidence from one RCT indicates that using urinary incontinence as a target condition for comprehensive geriatric assessment is associated with reduced functional decline. There is also no evidence in the literature that supports a specific screening interval at which evaluation for urinary incontinence should take place. Although the evidence supporting this recommendation is level III (expert opinion), because of the profound negative effect of underdiagnosis and undertreatment of this condition on quality of life, it is given an importance rating of level A. (Source guideline: 11)

2. If there is evidence of urinary incontinence in the evaluation of an older adult with DM, then an evaluation designed to identify treatable causes of urinary incontinence should be pursued. (IIIB)

Among the reversible or treatable causes of urinary incontinence in older adults in general are urinary tract infection, urine retention, fecal impaction, restricted mobility, and use of certain medications. Other conditions that may contribute to urinary incontinence and are associated with older age and DM include polyuria (glycosuria), neurogenic bladder, prolapse, cystocele, atrophic vaginitis, and vaginal candidiasis. In addition, urinary incontinence itself can be successfully treated in many patients with the use of pharmacological or behavioral interventions. (Source guidelines: 3, 11)

Injurious Falls

1. The older adult who has DM should be asked about falls. (IIIB)

2. If an older adult presents with evidence of falls, the clinician should document a basic falls evaluation, including an assessment of injuries and examination of potentially reversible causes of the falls (e.g., medications, environmental factors). (IIIB)

No RCTs have assessed the efficacy of screening for falls, but evidence from one RCT indicates that using falls as a target condition for comprehensive geriatric assessment is associated with reduced functional decline. Falls frequently go unreported and undetected and may be associated with reversible factors. Five RCTs provide evidence that exercise programs can reduce the rates of falls by older adults. As noted above, psychotropic medications have been associated with falls in epidemiological analyses, and one RCT found that their withdrawal can also lead to a significant reduction in the risk of falling. Interventions involving home visits to assess safety have had mixed results. Two RCTs suggest that home visits can reduce the rate of falls in older people, but six others did not find a significant reduction in falls with home visits. The AGS Guideline for the Prevention of Falls in Older Persons provides further recommendations on this issue. (Source guidelines: 11, 13)

Pain

1. The older adult who has DM should be assessed during the initial evaluation period for evidence of persistent pain. (IIIA)

Older adults with DM are at risk for neuropathic pain, and those with pain are often undertreated. Many older adults are reluctant to report pain unprompted and may remain reluctant even when asked (although using alternative terms, such as aching or discomfort, or other culturally appropriate terminology may be helpful). In many instances, pain can be successfully treated when it is reported. A quantitative systematic review of RCTs of antidepressants or anticonvulsants for the treatment of diabetic neuropathy found both drug classes to be effective in reducing pain associated with the neuropathy. Older adults with DM should be screened for persistent pain by the use of a targeted history and physical examination. If there is evidence of persistent pain in an older adult with DM, further evaluation should be performed, appropriate therapy offered, and patients monitored, as recommended by the AGS guidelines, The Management of Persistent Pain. (Source guidelines: 11, 14)

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SOURCE GUIDELINES

PREVIOUS AGS GUIDELINES:
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