REVIEW ARTICLE

Highlights of the Updated 2016 American Diabetes Association Standards of Medical Care in Diabetes

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Diabetes has become a national epidemic. Nearly 50% of American adults have either prediabetes or diabetes.[1] Further if trends continue, by 2050, 1 in 3 American adults will have overt diabetes.[2] The American Diabetes Association (ADA) publishes annual Standards of Medical Care in Diabetes in the January supplement of Diabetes Care.[3] This review will highlight key features of the Standards of Care and report on changes and new updates to the guidelines.

The ADA has published the Standards of Care since 1989. The Standards cover the spectrum of care, from screening and diagnosis to management and risk reduction. The ADA strives to be transparent in the development of its evidence-based guidelines, following the Institute of Medicine recommendations.

Each year, the ADA's Professional Practice Committee does a systematic MEDLINE search to find new evidence or clarify prior recommendations. This multidiscipline committee also receives feedback from the larger clinical community. The committee assigns each recommendation a rating of A, B, C, or expert opinion E, depending on the quality of evidence.

WHAT IS NEW?

A new section has been added to the Standards, "Obesity Management for the Treatment of Type 2 Diabetes." Recommendations include the comprehensive assessment of weight in diabetes and treatment of overweight/obesity with behavior modification and pharmacotherapy. This section also includes a new table of currently approved medications for the long-term treatment of obesity. Bariatric surgery as a treatment for type 2 diabetes was also added to this section.

To reflect the changing role of technology in the prevention of type 2 diabetes, a recommendation was added encouraging the use of new technology such as apps and text messaging to affect lifestyle modification to prevent diabetes.

A recommendation was made to reflect new evidence that adding ezetimibe to moderate-intensity statin provides additional ardiovascular benefits for select individuals with diabetes and should be considered.

A new recommendation was added to highlight the importance of discussing family planning and effective contraception with women with preexisting diabetes.

WHAT HAS CHANGED?

Diabetes screening recommendations have been clarified. All adults should be screened for type 2 diabetes beginning at age 45 years, regardless of weight. Testing is also recommended for asymptomatic adults of any age who are overweight or obese and who have one or more additional risk factors.

To reflect new evidence on CVD risk among women, the recommendation to consider aspirin therapy in women age >60 years has changed to include women age ≥50 years. A recommendation was also added to address antiplatelet use in patients age <50 years with multiple risk factors.

A1C recommendations for pregnant women with diabetes were changed, from a recommendation of <6.0% to a target of 6.0–6.5%.

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HIGHLIGHTS FROM THE 2016 ADA STANDARDS OF CARE

Screening for diabetes

1. The ADA recommends that all adults age 45 or older be screened for diabetes
2. Younger adults who are overweight or obese (BMI ≥25 kg/m^2 or ≥23 kg/m^2 in Asian Americans) and who have additional risk factors should be screened
3. Screening should be repeated every 3 years if normal
4. Screening should be every year if there is evidence of prediabetes

How should you screen?

1. With fasting plasma glucose (FPG)
2. With A1C
3. With oral glucose tolerance test (OGTT)
4. With random plasma glucose (RPG)

An elevated fasting glucose or A1C should be repeated by another test separated by time to confirm the diagnosis. The addition of the A1C is to allow an additional method of screening as it may be difficult for people to get fasting labs. Point of care A1C machines allow this test to come completed with a simple finger stick.

Prevention of type 2 diabetes

People who are found to have prediabetes (Table 1) should be referred to a program that adheres to the tenants of the National Diabetes Prevention Program (NDPP). The goals of this year-long program are to use group support, problem-based learning and work toward the following goals: lose 7% of body weight, reduce dietary fat and calories, and engage in moderate intensity physical activity for 150 minutes per week. The Diabetes Prevention Program (DPP) demonstrated a 58% reduction in risk of type 2 diabetes in the intervention group, and an even greater reduction in risk of 71% in those ≥60 years.[4] Further, even 10 years after the DPP intervention the risk of developing diabetes is still reduced by 30%.[5] Find a diabetes prevention program near your practice: https://nccd.cdc.gov/DDT_DPRP/Registry.aspx.

Selected medications also have been shown to reduce the progression from prediabetes to diabetes. These include metformin, alpha-glucosidase inhibitors, orlistat and thiazolidinediones. Currently, no medication is FDA-indicated for the prevention of type 2 diabetes.

Diabetes self-management education & support

All people with diabetes should receive comprehensive diabetes self-management education and support (DSME/S).[6] This should be repeated as needed as the disease progresses or as new skills are needed to manage diabetes (such as insulin injection therapy). DSME has been shown to improve clinical outcomes and quality of life in people with diabetes and this education can result in cost savings to the patient and health care system.

Despite the benefit of receiving DSME, only 6.8% of individuals with newly diagnosed type 2 diabetes with private health insurance participated in DSME/S within 12 months of diagnosis.[7] Only 4% of Medicare participants received DSME/S and/or Medical Nutrition Therapy (MNT).[8]

Physical activity

All adults with prediabetes and diabetes should be encouraged to perform at least 150 minutes of moderate intensity physical activity each week. Children with prediabetes and diabetes should perform at least 60 minutes of physical activity per day. This activity should be of at least moderate intensity and can be broken up into smaller segments of time.

Glycemic targets

The decision of the target glucose must be individualized to the patient. Most adults should be treated to an A1C of <7.0%. Younger patients, those newly diagnosed and those without known cardiovascular disease may warrant from a more stringent glucose target. However, patients with advanced complications, long-standing diabetes, multiple comorbidities or those with limited life expectancy are better treated to a less stringent goal to balance the risks and benefits of therapy.

Guidance for how to individualize therapy is provided in Figure 1 *(page 14)*.[9]

TABLE 1:

Diagnostic criteria for diabetes and prediabetes

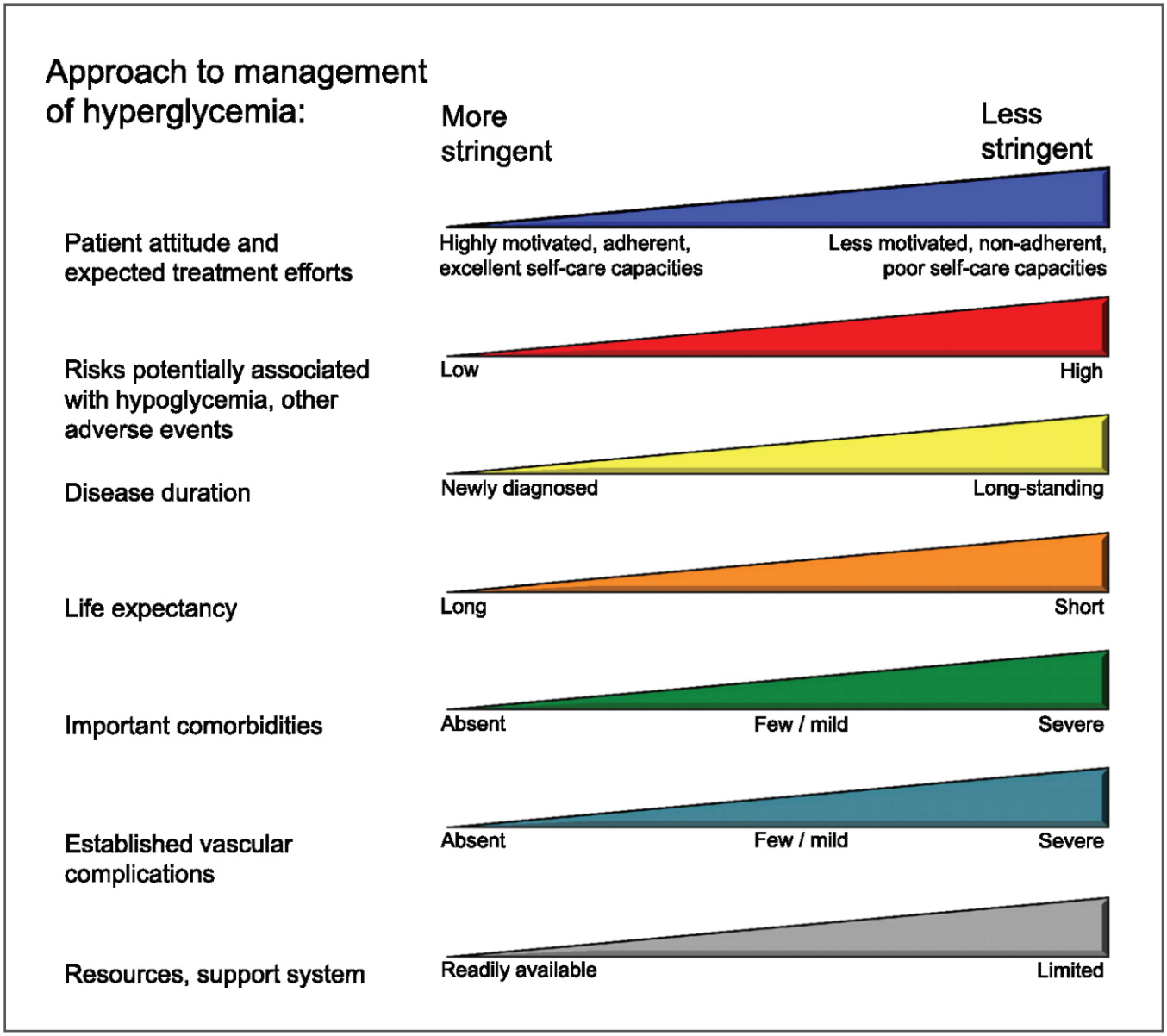
	FPG	A1C	OGTT	RPG
Normal	< 100 mg/dL	< 5.7%	< 140 mg/dL	
Prediabetes	100 - 125 mg/dL	5.7% - 6.4%	> 140 - 199 mg/dL	
Diabetes	≥ 126 mg/dL	≥ 6.5%*	≥ 200 mg/dL*	≥ 200 mg/dL**

*In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing.

**Only diagnostic in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

FIGURE 1:

Guidance for how to individualize therapy.



Depicted are patient and disease factors used to determine optimal A1C targets. Characteristics and predicaments toward the left justify more stringent efforts to lower A1C; those toward the right suggest less stringent efforts. Adapted with permission from Inzucchi et al.9 Reprinted with permission of the American Diabetes Association, Inc. Copyright 2015.

Pharmacologic treatment of type 2 diabetes

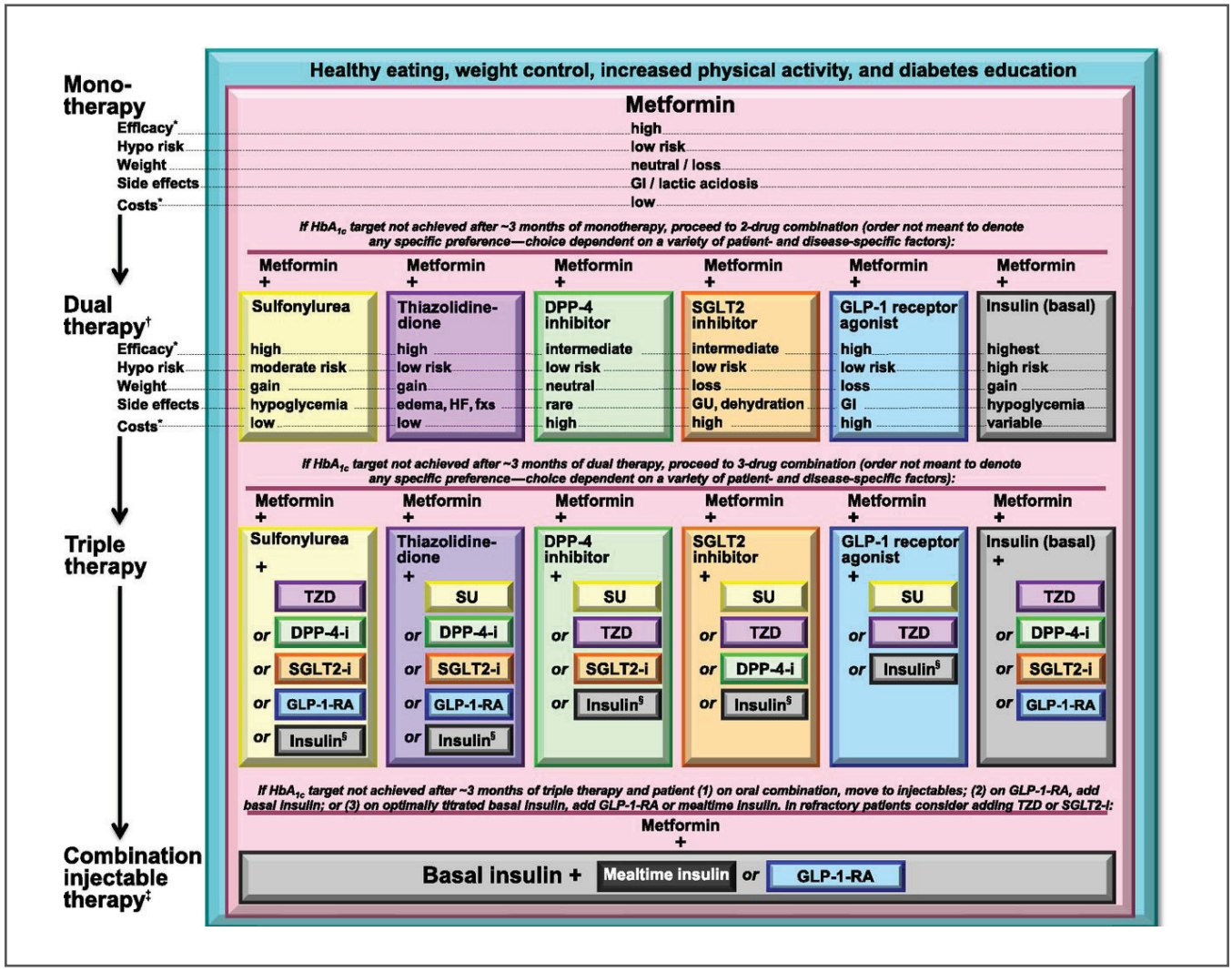
DSME/S and therapeutic lifestyle modification should be prescribed to patients at diagnosis. In addition to lifestyle changes, metformin should be started immediately for all people with type 2 diabetes, as long as it is tolerated and not contraindicated. This medication should be given at the time of diagnosis. Even a delay of 3-6 months after diagnosis can reduce the efficacy and durability of this medication (10). The patient should be evaluated at least every 3 months to see if agreed upon glucose treatment target has been achieved. If not, treatment should be intensified. Many medications are available for treatment, and guidance is available to help the clinician to decide which treatment is most appropriate for each patient.[9] See Figure 2.

Insulin therapy should be considered in patients who present with catabolic symptoms (polyuria, polydipsia and weight loss) or an A1C ≥10%, and in patients who are unable to get control with dual or triple therapy at one year after treatment has started.

Medication cost, potential side effects including hypoglycemia and weight gain, and efficacy are important factors when deciding what treatments are going to be used and avoidance of these side effects is preferred.

FIGURE 2:

Antihyperglycemic therapy in type 2 diabetes: general recommendations



The order in the chart was determined by historical availability and the route of administration, with injectables to the right; it is not meant to denote any specific preference. Potential sequences of antihyperglycemic therapy for patients with type 2 diabetes are displayed, with the usual transition moving vertically from top to bottom (although horizontal movement within therapy stages is also possible, depending on the circumstances). DPP-4-i, DPP-4 inhibitor; fxs, fractures; GI, gastrointestinal; GLP-1-RA, GLP-1 receptor agonist; GU, genitourinary; HF, heart failure; Hypo, hypoglycemia; SGLT2-i, SGLT2 inhibitor; SU, sulfonylurea; TZD, thiazolidinedione. *See ref. 9 for description of efficacy categorization. †Consider starting at this stage when A1C is ≥9% (75 mmol/mol). ‡Consider starting at this stage when blood glucose is ≥300–350 mg/dL (16.7–19.4 mmol/L) and/or A1C is ≥10–12% (86–108 mmol/mol), especially if symptomatic or catabolic features are present, in which case basal insulin + mealtime insulin is the preferred initial regimen. §Usually a basal insulin (NPH, glargine, detemir, degludec). Adapted with permission from Inzucchi et al.[9] Reprinted with permission of the American Diabetes Association, Inc. Copyright 2015.

ASSESSMENT OF HOME GLUCOSE MONITORING

Self-monitoring of blood glucose (SMBG) is a key element to help people evaluate the effectiveness of their treatments (lifestyle and medications).[11] The use of SMBG can be very helpful in medication titration, identification of hypoglycemia, and reinforcement of therapeutic lifestyle behaviors. Studies have supported a relationship between SMBG frequency and improved A1C in type 1 diabetes.

SMBG is especially important in people who are taking insulin and in those who have experienced hypoglycemia. There is not enough evidence to support the optimal frequency of SMBG on those only on oral therapy or therapeutic lifestyle changes.

SMBG requires skills and all people with diabetes should receive education on the use of a glucometer and periodic reassessment of technique. Providers should review the results of SMBG at each assessment to determine the adequacy of treatment and to identify hypoglycemia.

Cardiovascular risk reduction

Atherosclerotic cardiovascular disease (ASCVD) is the (I prefer number 1 or major) cause of death in people with diabetes. People with diabetes should have their cardiovascular risk factors evaluated and managed. Numerous studies have shown the efficacy of controlling individual factors in preventing or slowing ASCVD in people with diabetes. Large benefits are seen when multiple risk factors are addressed simultaneously. There is evidence that measures of 10-year coronary heart disease risk among U.S. adults with diabetes have improved significantly over the past decade, with a decrease in morbidity and mortality.[12, 13, 14]

Blood pressure

Blood pressure should be measured at every clinical appointment. Most people with diabetes should maintain a blood pressure below 140/90 mmHg.[15] If the blood pressure is elevated or if there is evidence of nephropathy (albuminuria or proteinuria), then an ACE inhibitor (ACEI) or angiotensin receptor blocker (ARB) should be started and titrated to the maximum tolerated dose. It is not recommended to start an ACEI or ARB in a person who is normotensive and no nephropathy, as the risks outweigh the benefits. Further, it is not recommended to use an ACEI and ARB concomitantly.

Treatment of dyslipidemia

In addition to intensive lifestyle therapy, statin use is recommended for most people with diabetes age 40 years and older. People who have diabetes age 40 years and older without additional ASCVD risk factors should consider using a moderate-intensity statin. Those people with diabetes age 40-75 years with ASCVD risk factors should consider using a high-intensity statin. Patients age 75 years and older with ASCVD risk factors should consider a moderate- or high-intensity statin. Table 2 provides guidance on statin use and intensity. The addition of ezetimibe to moderate intensity statin therapy has been shown to provide additional cardiovascular benefit compared to moderate intensity statin therapy alone, and may be considered for patients with a recent acute coronary syndrome with an LDL cholesterol ≥ 50mg/dL or in those patients who cannot tolerate high-intensity statin therapy.[16]

Antiplatelet agents

Aspirin therapy (75–162 mg/day) is recommended as a primary prevention strategy in those with type 1 and type 2 diabetes who are at increased cardiovascular risk (10-year risk >10%). However, aspirin should not be recommended for coronary disease prevention for adults with diabetes at low risk (10-year ASCVD risk <5%). Aspirin therapy is well established as a secondary prevention strategy in those with diabetes and a history of ASCVD. In patients with ASCVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. Dual antiplatelet therapy is reasonable for up to a year after an acute coronary syndrome.

Hypoglycemia

Hypoglycemia (≤70 mg/dL) is the rate-limiting step to normalizing glucose. It was previously thought to be a problem mostly for type 1 diabetes, but it is well established that many people with type 2 diabetes experience hypoglycemia. The total number of hypoglycemic episodes are greater from people with type 2 diabetes than type 1 diabetes. Episodes of severe hypoglycemia were associated with mortality in the both the ACCORD and ADVANCE trials.[17-18]

TABLE 2:

Statin intensity in the treatment of ASCVD risk in diabetes

High - intensity statin therapy	Moderate - intensity statin therapy
Lowers LDL by ≥ 50%:	**Lowers LDL by 30% to <50%:**
Atorvastatin 40–80 mg	Atorvastatin 10–20 mg
Rosuvastatin 20–40 mg	Rosuvastatin 5–10 mg
	Simvastatin 20–40 mg
	Pravastatin 40–80 mg
	Lovastatin 40 mg
	Fluvastatin XL 80 mg
	Pitavastatin 2–4 mg

Severe hypoglycemia is defined as hypoglycemia that requires assistance from another person. All patients at risk of severe hypoglycemia should be prescribed glucagon injection and their family/close contacts should be instructed on how to administer glucagon during severe hypoglycemic episodes.

Hypoglycemia may be reversed with administration of rapid acting glucose (15-20 g). Blood glucose reversal should be confirmed with SMBG after fifteen minutes; if hypoglycemia persists, the process should be repeated. Pure glucose is the preferred treatment; however, any form of carbohydrate that contains simple sugars not combined with fat or protein will raise blood glucose quickly (e.g., hard candies instead of a candy bar).

Physicians should assess at each visit if their patient is experiencing hypoglycemia. Patients should be educated on situations that increase their risk of hypoglycemia such as fasting for tests or procedures, alcohol ingestion, during or after exercise, and during sleep. Many patients who experience hypoglycemia may omit or change their treatment plans without the physician's knowledge. Hypoglycemia has substantial negative effects on a person's quality of life.

Repeated episodes of hypoglycemia can lead to hypoglycemia unawareness. Hypoglycemia unawareness is characterized by deficient counterregulatory hormone release and a diminished autonomic response, both of which are risk factors for, and caused by, hypoglycemia. Patients with hypoglycemia unawareness or an episode of severe hypoglycemia should be advised to raise their glycemic targets for at least several weeks to partially reverse hypoglycemia unawareness and reduce the risk of future episodes.

Older adults

Coordination of care and individualization of treatment plans should be considered with respect to changes in functional status and co-existing conditions, such as ASCVD and chronic kidney disease, in older patients with both type 1 and type 2 diabetes. Glycemic goals may be relaxed but hypoglycemia and hyperglycemic complications should be avoided. Lipid-lowering and aspirin therapy should be considered in the context of life expectancy. Hypertension treatment is indicated for nearly all older patients with diabetes. Older adults are a high-priority population for depression screening.[19]

Microvascular complications

Intensive blood glucose and blood pressure control can reduce the risk or slow the progression of microvascular complications.

Nephropathy: There should be annual assessment of urinary albumin (e.g., spot urinary albumin-to-creatinine ratio [UACR]) and estimated glomerular filtration rate (eGFR) in patients with type 1 diabetes with duration of ≥5 years, in all patients with type 2 diabetes, and in all patients with comorbid hypertension. For urinary albumin, two of three specimens collected within a 3 to 6 month period should be abnormal before considering a patient to have developed albuminuria.

For patients with diabetic kidney disease (DKD), dietary protein intake should be 0.8 g/kg body weight per day. ACEIs and ARBs have been shown to slow the decline in GFR in patients with elevated urinary albumin excretion (>30 mg/day). An ACEI or ARB is not recommended for the primary prevention of DKD in patients with diabetes who have normal blood pressure, normal UACR (<30 mg/g), and normal eGFR. Combined use of an ACEI and an ARB should be avoided as it provides no additional benefit for CVD or DKD and has a higher adverse event risk.

Retinopathy

Patients with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after diagnosis of diabetes. Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes. The exams should be repeated annually. If there is no evidence of retinopathy for one or more eye exams, then exams every 2 years may be considered. The presence of retinopathy is not a contraindication to aspirin therapy for cardioprotection, as aspirin does not increase the risk of retinal hemorrhage.

Neuropathy

All patients should be screened for diabetic peripheral neuropathy (DPN) starting at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes and at least annually thereafter. Assessment should include a careful history and 10-gram (g) monofilament testing, and at least one of the following tests: pinprick, temperature, and vibration sensation. Clinicians should screen for signs and symptoms of autonomic neuropathy in patients with more advanced disease. These signs and symptoms can include: resting tachycardia, exercise intolerance, orthostatic hypotension, gastroparesis, constipation, erectile dysfunction, impaired neurovascular function, and autonomic failure in response to hypoglycemia. Control of lipids, smoking, and other lifestyle factors can reduce the progression and development of autonomic neuropathy.

The FDA has approved pregabalin, duloxetine, and tapentadol for the treatment of pain associated with DPN. Tricyclic antidepressants, gabapentin, venlafaxine, carbamazepine, tramadol, and topical capsaisin, although not approved for the treatment of painful DPN, may be effective and considered for the treatment of painful DPN.

Foot Care

An annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations is recommended. The foot examination should begin with inspection and assessment of foot pulses. The exam should seek to identify loss of peripheral sensation (LOPS). The examination should include inspection of the skin, assessment of foot deformities, neurologic assessment including 10-g monofilament testing and pinprick or vibration testing or assessment of ankle reflexes, and vascular assessment including pulses in the legs and feet.

Patients who smoke or have histories of prior lower-extremity complications, a loss of protective sensation, structural abnormalities, or peripheral arterial disease (PAD) should be referred to foot care specialists for ongoing preventive care and lifelong surveillance. Patients should be screened by careful history and physical exam of pulses for PAD. Ankle-brachial index testing (ABI) should be performed in patients with symptoms or signs of PAD. ABI may be considered starting at age 50 and in patients younger than 50 years of age with risk factors.

SUMMARY

The ADA 2016 Standards of Care is a source of high-quality evidence-based recommendations for the care of people with diabetes across the lifespan. Screening for prediabetes is an important priority to identify those at risk for diabetes, as lifestyle intervention is an established preventive strategy with a new emphasis on obesity management. Individualized glycemic targets with attention to hypoglycemia can reduce the risk of diabetes complications. Studies also support evaluation and effective treatment of risk factors to reduce ASCVD in persons with diabetes. The 2016 Abridged Standards of Care can be an important resource for primary care physicians caring for those with diabetes.

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JS has received research support from Sanofi and has served as a consultant to Eli Lilly, Novo Nordisk, Inc., AstraZeneca and GlaxoSmithKline. EJ serves on the Novo Nordisk, Inc. speakers' bureau and is a consultant for Sanofi. NS has served on the advisory panel of AstraZeneca, Lilly, Sanofi, and Teva. KP and FW have no conflicts of interest.

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