Introduction

The American Diabetes Association (ADA) has been actively involved in the development and dissemination of diabetes care standards, guidelines, and related documents for many years. These statements are published in one or more of the Association’s professional journals. This supplement contains the latest update of the ADA’s major position statement, “Standards of Medical Care in Diabetes,” which contains all of the Association’s key recommendations. In addition, contained herein are selected position statements on certain topics not adequately covered in the “Standards.” ADA hopes that this is a convenient and important resource for all health care professionals who care for people with diabetes.

ADA Clinical Practice Recommendations consist of position statements that represent official ADA opinion as denoted by formal review and approval by the Professional Practice Committee and the Executive Committee of the Board of Directors. Consensus reports and systematic reviews are not official ADA recommendations; however, they are produced under the auspices of the Association by invited experts. These publications may be used by the Professional Practice Committee as source documents to update the “Standards.”

ADA has adopted the following definitions for its clinically related reports.

**ADA position statement.** An official point of view or belief of the ADA. Position statements are issued on scientific or medical issues related to diabetes. They may be authored or unauthored and are published in ADA journals and other scientific/medical publications as appropriate. Position statements must be reviewed and approved by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors. ADA position statements are typically based on a systematic review or other review of published literature. They are reviewed on an annual basis and updated as needed. A list of recent position statements is included on p. e3 of this supplement.

**ADA scientific statement.** A scholarly synopsis of a topic related to diabetes, which may or may not contain clinical or research recommendations. Any recommendations included represent the official point of view or belief of the ADA. Work Group Reports fall into this category. Scientific statements are published in the ADA journals and other scientific/medical publications as appropriate. Scientific statements must be reviewed and approved by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors. A list of recent scientific statements is included on p. e4 of this supplement.

**Systematic review.** A balanced review and analysis of the literature on a scientific or medical topic related to diabetes. Effective January 2010, technical reviews were replaced by systematic reviews, for which a priori search and inclusion/exclusion criteria are developed and published. The systematic review provides a scientific rationale for a position statement and undergoes critical peer review before submission to the Professional Practice Committee for approval. A list of past systematic reviews is included on p. e1 of this supplement.

**Consensus report.** A comprehensive examination by a panel of experts (i.e., consensus panel) of a scientific or medical issue related to diabetes. Effective January 2010, consensus statements were renamed consensus reports. The category may also include task force and expert committee reports. Consensus reports do not have the Association’s name included in the title or subtitle and include a disclaimer in the introduction stating that any recommendations are not ADA position. A consensus report is typically developed immediately following a consensus conference at which presentations are made on the issue under review. The statement represents the panel’s collective analysis, evaluation, and opinion at that point in time based in part on the conference proceedings. The need for a consensus report arises when clinicians or scientists desire guidance on a subject for which the evidence is contradictory or incomplete. Once written by the panel, a consensus report is not subject to subsequent review or approval and does not represent official Association opinion. A list of recent consensus reports is included on p. e2 of this supplement.

**Professional Practice Committee.** The Association’s Professional Practice Committee is responsible for reviewing ADA systematic reviews, scientific statements, and position statements, as well as for overseeing revisions of the latter as needed. Appointment to the Professional Practice Committee is based on excellence in clinical practice and/or research. The committee comprises physicians, diabetes educators, registered dietitians, and others who have expertise in a range of areas, including adult and pediatric endocrinology, epidemiology, and public health, lipid research, hypertension, and preconception and pregnancy care. All members of the Professional Practice Committee are required to disclose potential conflicts of interest (listed on p. S109).

**Grading of scientific evidence.** There has been considerable evolution in the evaluation of scientific evidence and in the development of evidence-based guidelines since the ADA first began publishing practice guidelines. Accordingly, we developed a classification system to grade the quality of scientific evidence supporting ADA recommendations for all new and revised ADA position statements.

Recommendations are assigned ratings of A, B, or C, depending on the quality of evidence (Table 1). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an “A” rating are based on large well-designed clinical trials or well-done meta-analyses.
Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported. The level of evidence supporting a given recommendation is noted either as a heading for a group of recommendations or in parentheses after a given recommendation.

Of course, evidence is only one component of clinical decision making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and, above all, patients' values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by the ADA, may miss some nuances that are important in diabetes care. For example, while there is excellent evidence from clinical trials supporting the importance of achieving multiple risk factor control, the optimal way to achieve this result is less clear. It is difficult to assess each component of such a complex intervention.

ADA will continue to improve and update the Clinical Practice Recommendations to ensure that clinicians, health plans, and policymakers can continue to rely on them as the most authoritative and current guidelines for diabetes care. Our Clinical Practice Recommendations are also available on the Association's website at www.diabetes.org/diabetescare.
Summary of Revisions for the 2013 Clinical Practice Recommendations

Revisions to the Standards of Medical Care in Diabetes—2013

In addition to many small changes related to new evidence since the prior year, and to clarify recommendations, the following sections have undergone more substantive changes:

- Section II.C. Screening for Type 1 Diabetes has been revised to include more specific recommendations.
- Section IV. Prevention/Delay of Type 2 Diabetes has been revised to reflect the importance of screening for and treating other cardiovascular risk factors.
- Section V.C.a. Glucose Monitoring has been revised to highlight the need for patients on intensive insulin regimens to do frequent self-monitoring of blood glucose.
- Section V.D. Pharmacological and Overall Approaches to Treatment has been revised to add a section with more specific recommendations for insulin therapy in type 1 diabetes.
- Section V.F. Diabetes Self-Management Education and Support has been revised to be consistent with the newly revised National Standards for Diabetes Self-Management Education and Support.
- Section V.K. Hypoglycemia has been revised to emphasize the need to assess hypoglycemia and cognitive function when indicated.
- Section V.M. Immunization has been updated to include the new Centers for Disease Control and Prevention (CDC) recommendations for hepatitis B vaccination for people with diabetes.
- Section VI.A.1. Hypertension/Blood Pressure Control has been revised to suggest that the systolic blood pressure goal for many people with diabetes and hypertension should be <140 mmHg, but that lower systolic targets (such as <130 mmHg) may be appropriate for certain individuals, such as younger patients, if it can be achieved without undue treatment burden.
- Section VI.A.2. Dyslipidemia/Lipid Management and Table 10 have been revised to emphasize the importance of statin therapy over particular LDL cholesterol goals in high-risk patients.
- Section VI.B. Nephropathy Screening and Treatment and Table 11 have been revised to highlight increased urinary albumin excretion over the terms micro- and macroalbuminuria, other than when discussion of past studies requires the distinction.
- Section VI.C. Retinopathy Screening and Treatment has been revised to include anti-vascular endothelial growth factor therapy for diabetic macular edema.
- Section IX.A. Diabetes Care in the Hospital has been revised to include a recommendation to consider obtaining an A1C in patients with risk factors for undiagnosed diabetes who exhibit hyperglycemia in the hospital.

Revised Position Statement

- The position statement “Diagnosis and Classification of Diabetes Mellitus” has been revised slightly to add newer information about monogenic forms of diabetes.

Revisions to the National Standards for Diabetes Self-Management Education and Support

- The task force report “National Standards for Diabetes Self-Management Education and Support” represents a major revision completed in 2012.
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Current criteria for the diagnosis of diabetes
- A1C ≥6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the Diabetes Control and Complications Trial (DCCT) assay; or
- fasting plasma glucose (FPG) ≥126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h; or
- 2-h plasma glucose ≥200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water; or
- in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L);
- in the absence of unequivocal hyperglycemia, result should be confirmed by repeat testing.

Testing for diabetes in asymptomatic patients
- Testing to detect type 2 diabetes and prediabetes should be considered in children and adolescents who are overweight and who have two or more additional risk factors for diabetes (see Table 4 of the “Standards of Medical Care in Diabetes—2013”). (E)

Screening for type 2 diabetes in children
- Testing to detect type 2 diabetes and prediabetes should be considered in children and adolescents who are overweight and who have two or more additional risk factors for diabetes (see Table 5 of the “Standards of Medical Care in Diabetes—2013”). (E)

Screening for type 1 diabetes
- Consider referring relatives of those with type 1 diabetes for antibody testing for risk assessment in the setting of a clinical research study. (E)

Detection and diagnosis of gestational diabetes mellitus
- Screen for undiagnosed type 2 diabetes at the first prenatal visit in those with risk factors, using standard diagnostic criteria. (B)
- In pregnant women not previously known to have diabetes, screen for gestational diabetes mellitus (GDM) at 24–28 weeks of gestation, using a 75-g 2-h OGTT and the diagnostic cut points in Table 6 of the “Standards of Medical Care in Diabetes—2013.” (B)
- Screen women with GDM for persistent diabetes at 6–12 weeks postpartum, using the OGTT and nonpregnancy diagnostic criteria. (E)
- Women with a history of GDM should have lifelong screening for the development of diabetes or prediabetes at least every 3 years. (B)
- Women with a history of GDM found to have prediabetes should receive lifestyle interventions or metformin to prevent diabetes. (A)

Prevention/delay of type 2 diabetes
- Patients with impaired glucose tolerance (IGT) (A), impaired fasting glucose (IFG) (E), or an A1C 5.7–6.4% (E) should be referred to an effective ongoing support program targeting weight loss of 7% of body weight and increasing physical activity to at least 150 min/week of moderate activity such as walking.
- Follow-up counseling appears to be important for success. (B)
- Based on the cost-effectiveness of diabetes prevention, such programs should be covered by third-party payers. (B)
- Metformin therapy for prevention of type 2 diabetes may be considered in those with IGT (A), IFG (E), or an A1C 5.7–6.4% (E), especially for those with BMI >35 kg/m², aged <60 years, and women with prior GDM. (A)
- At least annual monitoring for the development of diabetes in those with prediabetes is suggested. (E)
- Screening for and treatment of modifiable risk factors for CVD is suggested. (B)

Glucose monitoring
- Patients on multiple-dose insulin (MDI) or insulin pump therapy should do self-monitoring of blood glucose (SMBG) at least prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving. (B)
- When prescribed as part of a broader educational context, SMBG results may be helpful to guide treatment decisions and/or patient self-management for patients using less frequent insulin injections or noninsulin therapies. (E)
- When prescribing SMBG, ensure that patients receive ongoing instruction and regular evaluation of SMBG technique and SMBG results, as well as their ability to use SMBG data to adjust therapy. (E)
- Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (aged ≥25 years) with type 1 diabetes. (A)
- Although the evidence for A1C lowering is less strong in children, teens, and...
Insulin therapy for type 1 diabetes

**Approaches to treatment**

- **Pharmacological and overall care.**
- **A1C**
  - Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). (E)
  - Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (E)
  - Use of point-of-care testing for A1C provides the opportunity for more timely treatment changes. (E)

**Glycemic goals in adults**

- Lowering A1C to below or around 7% has been shown to reduce microvascular complications of diabetes, and if implemented soon after the diagnosis of diabetes is associated with long-term reduction in macrovascular disease. Therefore, a reasonable A1C goal for many nonpregnant adults is <7%. (B)
- Providers might reasonably suggest more stringent A1C goals (such as <6.5%) for selected individual patients, if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients might include those with short duration of diabetes, long life expectancy, and no significant CVD. (C)
- Less stringent A1C goals (such as <8%) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, and those with long-standing diabetes. (B)

**Pharmacological and overall approaches to treatment**

**Insulin therapy for type 1 diabetes**

- Most people with type 1 diabetes should be educated in how to match prandial insulin dose to carbohydrate intake, premeal blood glucose, and anticipated activity. (E)
- Most people with type 1 diabetes should use insulin analogs to reduce hypoglycemia risk. (A)
- Consider screening those with type 1 diabetes for other autoimmune diseases (thyroid, vitamin B12 deficiency, celiac) as appropriate. (B)

**Pharmacological therapy for hyperglycemia in type 2 diabetes**

- Metformin, if not contraindicated and if tolerated, is the preferred initial pharmacological agent for type 2 diabetes. (A)
- In newly diagnosed type 2 diabetic patients with markedly symptomatic and/or elevated blood glucose levels or A1C, consider insulin therapy, with or without additional agents, from the outset. (E)
- If noninsulin monotherapy at maximal tolerated dose does not achieve or maintain the A1C target over 3–6 months, add a second oral agent, a glucagon-like peptide-1 (GLP-1) receptor agonist, or insulin. (A)
- A patient-centered approach should be used to guide choice of pharmacological agents. Considerations include efficacy, cost, potential side effects, effects on weight, comorbidities, hypoglycemia risk, and patient preferences. (E)
- Due to the progressive nature of type 2 diabetes, insulin therapy is eventually indicated for many patients with type 2 diabetes. (B)

**Medical nutrition therapy**

**General recommendations**

- Individuals who have prediabetes or diabetes should receive individualized medical nutrition therapy (MNT) as needed to achieve treatment goals, preferably provided by a registered diettitian familiar with the components of diabetes MNT. (A)
- Because MNT can result in cost-savings and improved outcomes (B), MNT should be adequately covered by insurance and other payers. (E)

**Energy balance, overweight, and obesity**

- Weight loss is recommended for all overweight or obese individuals who have or are at risk for diabetes. (A)
- For weight loss, either low-carbohydrate, low-fat calorie-restricted, or Mediterranean diets may be effective in the short term (up to 2 years). (A)
- For patients on low-carbohydrate diets, monitor lipid profiles, renal function, and protein intake (in those with nephropathy) and adjust hypoglycemic therapy as needed. (E)
- Physical activity and behavior modification are important components of weight loss programs and are most helpful in maintenance of weight loss. (B)

**Recommendations for primary prevention of type 2 diabetes**

- Among individuals at high risk for developing type 2 diabetes, structured programs that emphasize lifestyle changes that include moderate weight loss (7% body weight) and regular physical activity (150 min/week), with dietary strategies including reduced calories and reduced intake of dietary fat, can reduce the risk for developing diabetes and are therefore recommended. (A)
- Individuals at risk for type 2 diabetes should be encouraged to achieve the U.S. Department of Agriculture (USDA) recommendation for dietary fiber (14 g fiber/1,000 kcal) and foods containing whole grains (one-half of grain intake). (B)
- Individuals at risk for type 2 diabetes should be encouraged to limit their intake of sugar-sweetened beverages (SSBs). (B)

**Recommendations for management of diabetes**

**Macronutrients in diabetes management**

- The mix of carbohydrate, protein, and fat may be adjusted to meet the metabolic goals and individual preferences of the person with diabetes. (C)
- Monitoring carbohydrate, whether by carbohydrate counting, choices, or experience-based estimation, remains a key strategy in achieving glycemic control. (B)
- Saturated fat intake should be <7% of total calories. (B)
- Reducing intake of trans fat lowers LDL cholesterol and increases HDL cholesterol (A); therefore, intake of trans fat should be minimized. (E)

**Other nutrition recommendations**

- If adults with diabetes choose to use alcohol, they should limit intake to a moderate amount (one drink per day or less for adult women and two drinks per day or less for adult men) and...
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should take extra precautions to prevent hypoglycemia. (E)

- Routine supplementation with antioxidants, such as vitamins E and C and carotene, is not advised because of lack of evidence of efficacy and concern related to long-term safety. (A)
- It is recommended that individualized meal planning include optimization of food choices to meet recommended dietary allowance (RDA)/dietary reference intake (DRI) for all micronutrients. (E)

Diabetes self-management education and support
- People with diabetes should receive DSME and diabetes self-management support (DSMS) according to National Standards for Diabetes Self-Management Education and Support when their diabetes is diagnosed and as needed thereafter. (B)
- Effective self-management and quality of life are the key outcomes of DSME and DSMS and should be measured and monitored as part of care. (C)
- DSME and DSMS should address psychosocial issues, since emotional well-being is associated with positive diabetes outcomes. (C)
- DSME and DSMS programs are appropriate venues for people with prediabetes to receive education and support to develop and maintain behaviors that can prevent or delay the onset of diabetes. (C)
- Because DSME and DSMS can result in cost-savings and improved outcomes (B), DSME and DSMS should be adequately reimbursed by third-party payers. (E)

Physical activity
- Adults with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50–70% of maximum heart rate), spread over at least 3 days/week with no more than 2 consecutive days without exercise. (A)
- In the absence of contraindications, adults with type 2 diabetes should be encouraged to perform resistance training at least twice per week. (A)

Psychosocial assessment and care
- It is reasonable to include assessment of the patient’s psychological and social situation as an ongoing part of the medical management of diabetes. (E)
- Psychosocial screening and follow-up may include, but are not limited to, attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, resources (financial, social, and emotional), and psychiatric history. (E)
- Screen for psychosocial problems such as depression and diabetes-related distress, anxiety, eating disorders, and cognitive impairment when self-management is poor. (B)

Hypoglycemia
- Individuals at risk for hypoglycemia should be asked about symptomatic and asymptomatic hypoglycemia at each encounter. (C)
- Glucose (15–20 g) is the preferred treatment for the conscious individual with hypoglycemia, although any form of carbohydrate that contains glucose may be used. If SMBG 15 min after treatment shows continued hypoglycemia, the treatment should be repeated. Once SMBG glucose returns to normal, the individual should consume a meal or snack to prevent recurrence of hypoglycemia. (E)
- Glucagon should be prescribed for all individuals at significant risk of severe hypoglycemia, and caregivers or family members of these individuals should be instructed on its administration. Glucagon administration is not limited to health care professionals. (E)
- Hypoglycemia unawareness or one or more episodes of severe hypoglycemia should trigger re-evaluation of the treatment regimen. (E)
- Insulin-treated patients with hypoglycemia unawareness or an episode of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks, to partially reverse hypoglycemia unawareness, and to reduce risk of future episodes. (A)
- Ongoing assessment of cognitive function is suggested with increased vigilance for hypoglycemia by the clinician, patient, and caregivers if low cognition and/or declining cognition is found. (B)

Bariatric surgery
- Bariatric surgery may be considered for adults with BMI ≥35 kg/m² and type 2 diabetes, especially if the diabetes or associated comorbidities are difficult to control with lifestyle and pharmacological therapy. (B)

Patients with type 2 diabetes who have undergone bariatric surgery need lifelong lifestyle support and medical monitoring. (B)
- Although small trials have shown glycemic benefit of bariatric surgery in patients with type 2 diabetes and BMI 30–35 kg/m², there is currently insufficient evidence to generally recommend surgery in patients with BMI <35 kg/m² outside of a research protocol. (E)
- The long-term benefits, cost-effectiveness, and risks of bariatric surgery in individuals with type 2 diabetes should be studied in well-designed controlled trials with optimal medical and lifestyle therapy as the comparator. (E)

Immunization
- Annually provide an influenza vaccine to all diabetic patients ≥6 months of age. (C)
- Administer pneumococcal polysaccharide vaccine to all diabetic patients ≥2 years of age. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered >5 years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states, such as after transplantation. (C)
- Administer hepatitis B vaccination to unvaccinated adults with diabetes who are aged 19 through 59 years. (C)
- Consider administering hepatitis B vaccination to unvaccinated adults with diabetes who are aged ≥60 years. (C)

Hypertension/blood pressure control

Screening and diagnosis
- Blood pressure should be measured at every routine visit. Patients found to have elevated blood pressure should have blood pressure confirmed on a separate day. (B)

Goals
- People with diabetes and hypertension should be treated to a systolic blood pressure goal of <140 mmHg. (B)
- Lower systolic targets, such as <130 mmHg, may be appropriate for certain individuals, such as younger patients, if it can be achieved without undue treatment burden. (C)
- Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg. (B)
Treatment

- Patients with a blood pressure >120/80 mmHg should be advised on lifestyle changes to reduce blood pressure. (B)
- Patients with confirmed blood pressure ≥140/80 mmHg should, in addition to lifestyle therapy, have prompt initiation and timely subsequent titration of pharmacological therapy to achieve blood pressure goals. (B)
- Lifestyle therapy for elevated blood pressure consists of weight loss, if overweight; Dietary Approaches to Stop Hypertension (DASH)-style dietary pattern including reducing sodium and increasing potassium intake; moderation of alcohol intake; and increased physical activity. (B)
- Pharmacological therapy for patients with diabetes and hypertension should be with a regimen that includes either an ACE inhibitor or an angiotensin receptor blocker (ARB). If one class is not tolerated, the other should be substituted. (C)
- Multiple-drug therapy (two or more agents at maximal doses) is generally required to achieve blood pressure targets. (B)
- Administer one or more antihypertensive medications at bedtime. (A)
- If ACE inhibitors, ARBs, or diuretics are used, serum creatinine/estimated glomerular filtration rate (eGFR) and serum potassium levels should be monitored. (E)
- In pregnant patients with diabetes and chronic hypertension, blood pressure target goals of 110–129/65–79 mmHg are suggested in the interest of long-term maternal health and minimizing impaired fetal growth. ACE inhibitors and ARBs are contraindicated during pregnancy. (E)

Dyslipidemia/lipid management

Screening

- In most adult patients with diabetes, measure fasting lipid profile at least annually. (B)
- In adults with low-risk lipid values (LDL cholesterol <100 mg/dL, HDL cholesterol >50 mg/dL, and triglycerides <150 mg/dL), lipid assessments may be repeated every 2 years. (E)

Treatment recommendations and goals

- Lifestyle modification focusing on the reduction of saturated fat, trans fat, and cholesterol intake; increase of n-3 fatty acids, viscous fiber and plant stanols/sterols; weight loss (if indicated); and increased physical activity should be recommended to improve the lipid profile in patients with diabetes. (A)
- Statin therapy should be added to lifestyle therapy, regardless of baseline lipid levels, for diabetic patients:
  - with overt CVD (A)
  - without CVD who are over the age of 40 years and have one or more other CVD risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (A)
- For lower-risk patients than the above (e.g., without overt CVD and under the age of 40 years), statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains above 100 mg/dL or in those with multiple CVD risk factors. (C)
  - In individuals without overt CVD, the goal is LDL cholesterol <100 mg/dL (2.6 mmol/L). (B)
  - In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dL (1.8 mmol/L), using a high dose of a statin, is an option. (B)
  - If drug-treated patients do not reach the above targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~30–40% from baseline is an alternative therapeutic goal. (B)
- Triglyceride levels <150 mg/dL (1.7 mmol/L) and HDL cholesterol >40 mg/dL (1.0 mmol/L) in men and >50 mg/dL (1.3 mmol/L) in women are desirable. (C). However, LDL cholesterol–targeted statin therapy remains the preferred strategy. (A)
- Combination therapy has been shown to add additional cardiovascular benefit above statin therapy alone and is generally not recommended. (A)
  - Statin therapy is contraindicated in pregnancy. (B)

Antiplatelet agents

- Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men aged >50 years or women aged >60 years who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (C)
  - Aspirin should not be recommended for CVD prevention for adults with diabetes at low CVD risk (10-year CVD risk <5%, such as in men aged <50 years and women aged <60 years with no major additional CVD risk factors), since the potential adverse effects from bleeding is likely offset the potential benefits. (C)
  - If patients in these age-groups with multiple other risk factors (e.g., 10-year risk 5–10%), clinical judgment is required. (E)
  - Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (A)
- For patients with CVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. (B)
- Combination therapy with aspirin (75–162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to a year after an acute coronary syndrome. (B)

Smoking cessation

- Advise all patients not to smoke or use tobacco products. (A)
- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. (B)

Coronary heart disease screening and treatment

Screening

- In asymptomatic patients, routine screening for coronary artery disease (CAD) is not recommended, as it does not improve outcomes as long as CVD risk factors are treated. (A)

Treatment

- In patients with known CVD, consider ACE inhibitor therapy (C) and use aspirin and statin therapy (A) (if not contraindicated) to reduce the risk of cardiovascular events. In patients with a prior myocardial infarction, ß-blockers should be continued for at least 2 years after the event. (B)
  - Avoid thiazolidinedione treatment in patients with symptomatic heart failure. (C)
  - Metformin may be used in patients with stable congestive heart failure (CHF) if renal function is normal. It should be avoided in unstable or hospitalized patients with CHF. (C)

Nephropathy screening and treatment

General recommendations

- To reduce the risk or slow the progression of nephropathy, optimize glucose control. (A)
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- To reduce the risk or slow the progression of nephropathy, optimize blood pressure control. (A)

Screening
- Perform an annual test to assess urine albumin excretion in type 1 diabetic patients with diabetes duration of ≥5 years and in all type 2 diabetic patients starting at diagnosis. (B)
- Measure serum creatinine at least annually in all adults with diabetes regardless of the degree of urine albumin excretion. The serum creatinine should be used to estimate glomerular filtration rate (GFR) and stage the level of chronic kidney disease (CKD), if present. (E)

Treatment
- In the treatment of the nonpregnant patient with modestly elevated (30–299 mg/day) (C) or higher levels (≥300 mg/day) of urinary albumin excretion (A), either ACE inhibitors or ARBs are recommended.
- Reduction of protein intake to 0.8–1.0 g/kg body wt per day in individuals with diabetes and the earlier stages of CKD and to 0.8 g/kg body wt per day in the later stages of CKD may improve measures of renal function (urine albumin excretion rate, GFR) and is recommended. (C)
- When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of increased creatinine or changes in potassium. (E)
- Continued monitoring of urine albumin excretion to assess both response to therapy and progression of disease is reasonable. (E)
- When eGFR is <60 mL/min/1.73 m², evaluate and manage potential complications of CKD. (E)
- Consider referral to a physician experienced in the care of kidney disease for uncertainty about the etiology of kidney disease, difficult management issues, or advanced kidney disease. (B)

Retinopathy screening and treatment

General recommendations
- To reduce the risk or slow the progression of retinopathy, optimize glycemic control. (A)
- To reduce the risk or slow the progression of retinopathy, optimize blood pressure control. (A)

Screening
- Adults and children aged ≥10 years with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes. (B)
- 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. (B)
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. Less frequent exams (every 2–3 years) may be considered following one or more normal eye exams. Examinations will be required more frequently if retinopathy is progressing. (B)
- High-quality fundus photographs can detect most clinically significant diabetic retinopathy. Interpretation of the images should be performed by a trained eye care provider. While retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional. (E)
- Women with pre-existing diabetes who are planning pregnancy or who have become pregnant should have a comprehensive eye examination and be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examination should occur in the first trimester with close follow-up throughout pregnancy and for 1 year postpartum. (B)

Neuropathy screening and treatment
- All patients should be screened for distal symmetric polyneuropathy (DPN) starting at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes and at least annually thereafter, using simple clinical tests. (B)
- Electrophysiological testing is rarely needed, except in situations where the clinical features are atypical. (E)
- Screening for signs and symptoms of cardiovascular autonomic neuropathy (CAN) should be instituted at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes. Special testing is rarely needed and may not affect management or outcomes. (E)
- Medications for the relief of specific symptoms related to painful DPN and autonomic neuropathy are recommended, as they improve the quality of life of the patient. (E)

Foot care
- For all patients with diabetes, perform an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations. The foot examination should include inspection, assessment of foot pulses, and testing for loss of protective sensation (LOPS) (10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold). (B)
- Provide general foot self-care education to all patients with diabetes. (B)
- A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. (B)
- Refer patients who smoke, have LOPS and structural abnormalities, or have a history of prior lower-extremity complications to foot care specialists for ongoing preventive care and lifelong surveillance. (C)
- Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. (C)
Assessment of common comorbid conditions

- For patients with risk factors, signs, or symptoms, consider assessment and treatment for common diabetes-associated conditions (see Table 14 of the “Standards of Medical Care in Diabetes—2013”). (B)

Children and adolescents

- As is the case for all children, children with diabetes or prediabetes should be encouraged to engage in at least 60 min of physical activity each day. (B)

Type 1 diabetes

Glycemic control

- Consider age when setting glycemic goals in children and adolescents with type 1 diabetes. (E)

Screening and management of chronic complications in children and adolescents with type 1 diabetes

Nephropathy

- Annual screening for microalbuminuria, with a random spot urine sample for albumin-to-creatinine ratio (ACR), should be considered once the child is 10 years of age and has had diabetes for 5 years. (B)
- Treatment with an ACE inhibitor, titrated to normalization of albumin excretion, should be considered when elevated ACR is subsequently confirmed on two additional specimens from different days. (E)

Hypertension

- Blood pressure should be measured at each routine visit. Children found to have high-normal blood pressure or hypertension should have blood pressure confirmed on a separate day. (B)
- Initial treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) includes dietary intervention and exercise, aimed at weight control and increased physical activity, if appropriate. If target blood pressure is not reached with 3–6 months of lifestyle intervention, pharmacological treatment should be considered. (E)
- Pharmacological treatment of hypertension (systolic or diastolic blood pressure consistently above the 95th percentile for age, sex, and height or consistently >130/80 mmHg, if 95% exceeds that value) should be considered as soon as the diagnosis is confirmed. (E)
- ACE inhibitors should be considered for the initial treatment of hypertension, following appropriate reproductive counseling due to its potential teratogenic effects. (E)
- The goal of treatment is a blood pressure consistently <130/80 or below the 90th percentile for age, sex, and height, whichever is lower. (E)

Dyslipidemia

Screening

- If there is a family history of hypercholesterolemia or a cardiovascular event before age 55 years, or if family history is unknown, then consider obtaining a fasting lipid profile on children >2 years of age soon after diagnosis (after glucose control has been established). If family history is not of concern, then consider the first lipid screening at puberty (≥10 years of age). For children diagnosed with diabetes at or after puberty, consider obtaining a fasting lipid profile soon after the diagnosis (after glucose control has been established). (E)
- For both age-groups, if lipids are abnormal, annual monitoring is reasonable. If LDL cholesterol values are within the accepted risk levels (<100 mg/dL [2.6 mmol/L]), a lipid profile repeated every 5 years is reasonable. (E)

Treatment

- Initial therapy may consist of optimization of glucose control and MNT using a Step 2 American Heart Association (AHA) diet aimed at a decrease in the amount of saturated fat in the diet. (E)
- After the age of 10 years, the addition of a statin in patients who, after MNT and lifestyle changes, have LDL cholesterol >160 mg/dL (4.1 mmol/L) or LDL cholesterol >130 mg/dL (3.4 mmol/L) and one or more CVD risk factors is reasonable. (E)
- The goal of therapy is an LDL cholesterol value <100 mg/dL (2.6 mmol/L). (E)

Retinopathy

- The first ophthalmologic examination should be obtained once the child is ≥10 years of age and has had diabetes for 3–5 years. (B)
- After the initial examination, annual routine follow-up is generally recommended.

Less frequent examinations may be acceptable on the advice of an eye care professional. (E)

Celiac disease

- Consider screening children with type 1 diabetes for celiac disease by measuring tissue transglutaminase or antigliadin antibodies, with documentation of normal total serum IgA levels, soon after the diagnosis of diabetes. (E)
- Testing should be considered in children with growth failure, failure to gain weight, weight loss, diarrhea, flatulence, abdominal pain, or signs of malabsorption or in children with frequent unexplained hypoglycemia or deterioration in glycemic control. (E)
- Consider referral to a gastroenterologist for evaluation with possible endoscopy and biopsy for confirmation of celiac disease in asymptomatic children with positive antibodies. (E)
- Children with biopsy-confirmed celiac disease should be placed on a gluten-free diet and have consultation with a dietitian experienced in managing both diabetes and celiac disease. (B)

Hypothyroidism

- Consider screening children with type 1 diabetes for thyroid peroxidase and thyroglobulin antibodies soon after diagnosis. (E)
- Measuring thyroid-stimulating hormone (TSH) concentrations soon after diagnosis of type 1 diabetes, after metabolic control has been established, is reasonable. If normal, consider rechecking every 1–2 years, especially if the patient develops symptoms of thyroid dysfunction, thyromegaly, or an abnormal growth rate. (E)

Transition from pediatric to adult care

- As teens transition into emerging adulthood, health care providers and families must recognize their many vulnerabilities (B) and prepare the developing teen, beginning in early to mid adolescence and at least 1 year prior to the transition. (E)
- Both pediatricians and adult health care providers should assist in providing support and links to resources for the teen and emerging adult. (B)

Preconception care

- A1C levels should be as close to normal as possible (<7%) in an individual patient before conception is attempted. (B)
Executive Summary

- Starting at puberty, preconception counseling should be incorporated in the routine diabetes clinic visit for all women of childbearing potential. (C)
- Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (B)
- Medications used by such women should be evaluated prior to conception, since drugs commonly used to treat diabetes and its complications may be contraindicated or not recommended in pregnancy, including statins, ACE inhibitors, ARBs, and most noninsulin therapies. (E)
- Since many pregnancies are unplanned, consider the potential risks and benefits of medications that are contraindicated in pregnancy in all women of childbearing potential and counsel women using such medications accordingly. (E)

Older adults

- Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes care with goals similar to those developed for younger adults. (E)
- Glycemic goals for some older adults might reasonably be relaxed, using individual criteria, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. (E)
- Other cardiovascular risk factors should be treated in older adults with consideration of the time frame of benefit and the individual patient. Treatment of hypertension is indicated in virtually all older adults, and lipid and aspirin therapy may benefit those with life expectancy at least equal to the time frame of primary or secondary prevention trials. (E)
- Screening for diabetes complications should be individualized in older adults, but particular attention should be paid to complications that would lead to functional impairment. (E)

Cystic fibrosis–related diabetes

- Annual screening for cystic fibrosis–related diabetes (CFRD) with OGTT should begin by age 10 years in all patients with cystic fibrosis who do not have CFRD. (B) Use of A1C as a screening test for CFRD is not recommended. (B)
- During a period of stable health, the diagnosis of CFRD can be made in cystic fibrosis patients according to usual glucose criteria. (E)
- Patients with CFRD should be treated with insulin to attain individualized glycemic goals. (A)
- Annual monitoring for complications of diabetes is recommended, beginning 5 years after the diagnosis of CFRD. (E)

Diabetes care in the hospital

- All patients with diabetes admitted to the hospital should have their diabetes clearly identified in the medical record. (E)
- All patients with diabetes should have an order for blood glucose monitoring, with results available to all members of the health care team. (E)
- Goals for blood glucose levels:
  - **Critically ill patients**: Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold of no greater than 180 mg/dL (10 mmol/L). Once insulin therapy is started, a glucose range of 140–180 mg/dL (7.8–10 mmol/L) is recommended for the majority of critically ill patients. (A)
  - More stringent goals, such as 110–140 mg/dL (6.1–7.8 mmol/L) may be appropriate for selected patients, as long as this can be achieved without significant hypoglycemia. (C)
  - Critically ill patients require an intravenous insulin protocol that has demonstrated efficacy and safety in achieving the desired glucose range without increasing risk for severe hypoglycemia. (E)
- **Non–critically ill patients**: There is no clear evidence for specific blood glucose goals. If treated with insulin, the premeal blood glucose targets generally <140 mg/dL (7.8 mmol/L) with random blood glucose <180 mg/dL (10.0 mmol/L) are reasonable, provided these targets can be safely achieved. More stringent targets may be appropriate in stable patients with previous tight glycemic control. Less stringent targets may be appropriate in those with severe comorbidities. (E)
- Scheduled subcutaneous insulin with basal, nutritional, and correction components is the preferred method for achieving and maintaining glucose control in non–critically ill patients. (C)
- Glucose monitoring should be initiated in any patient not known to be diabetic who receives therapy associated with high risk for hyperglycemia, including high-dose glucocorticoid therapy, initiation of enteral or parenteral nutrition, or other medications such as octreotide or immunosuppressive medications. (B). If hyperglycemia is documented and persistent, consider treating such patients to the same glycemic goals as patients with known diabetes. (E)
- A hypoglycemia management protocol should be adopted and implemented by each hospital or hospital system. A plan for preventing and treating hypoglycemia should be established for each patient. Episodes of hypoglycemia in the hospital should be documented in the medical record and tracked. (E)
- Consider obtaining an A1C on patients with diabetes admitted to the hospital if the result of testing in the previous 2–3 months is not available. (E)
- Consider obtaining an A1C in patients with risk factors for undiagnosed diabetes who exhibit hyperglycemia in the hospital. (E)
- Patients with hyperglycemia in the hospital who do not have a prior diagnosis of diabetes should have appropriate plans for follow-up testing and care documented at discharge. (E)

Strategies for improving diabetes care

- Care should be aligned with components of the Chronic Care Model (CCM) to ensure productive interactions between a prepared proactive practice team and an informed activated patient. (A)
- When feasible, care systems should support team-based care, community involvement, patient registries, and embedded decision support tools to meet patient needs. (B)
- Treatment decisions should be timely and based on evidence-based guidelines that are tailored to individual patient preferences, prognoses, and comorbidities. (B)
- A patient-centered communication style should be employed that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers to care. (B)
Diabetes mellitus is a chronic illness that requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of long-term complications. Diabetes care is complex and requires multifactorial risk reduction strategies beyond glycemic control. A large body of evidence exists that supports a range of interventions to improve diabetes outcomes.

These standards of care are intended to provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care. Although individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. Specifically titled sections of the standards address children with diabetes, pregnant women, and people with prediabetes. These standards are not intended to preclude clinical judgment or more extensive evaluation and management of the patient by other specialists as needed. For more detailed information about management of diabetes, refer to references (1–3).

The recommendations included are screening, diagnostic, and therapeutic actions that are known or believed to favorably affect health outcomes of patients with diabetes. A large number of these interventions have been shown to be cost-effective (4). A grading system (Table 1), developed by the American Diabetes Association (ADA) and modeled after existing methods, was utilized to clarify and codify the evidence that forms the basis for the recommendations. The level of evidence that supports each recommendation is listed after each recommendation using the letters A, B, C, or E.

These standards of care are revised annually by the ADA’s multidisciplinary Professional Practice Committee, incorporating new evidence. For the current revision, committee members systematically searched Medline for human studies related to each subsection and published since 1 January 2011. Recommendations (bulleted at the beginning of each subsection and also listed in the “Executive Summary: Standards of Medical Care in Diabetes—2013”) were revised based on new evidence or, in some cases, to clarify the prior recommendation or match the strength of the wording to the strength of the evidence. A table linking the changes in recommendations to new evidence can be reviewed at http://professional.diabetes.org/CPR. As is the case for all position statements, these standards of care were reviewed and approved by the Executive Committee of ADA’s Board of Directors, which includes health care professionals, scientists, and lay people.

Feedback from the larger community was valuable for the 2013 revision of the standards. Readers who wish to comment on the “Standards of Medical Care in Diabetes—2013” are invited to do so at http://professional.diabetes.org/CPR.

Members of the Professional Practice Committee disclose all potential conflicts of interest with industry. These disclosures were discussed at the outset of the standards revision meeting. Members of the committee, their employer, and their disclosed conflicts of interest are listed in the “Professional Practice Committee for the 2013 Clinical Practice Recommendations” table (see p. S109). The ADA funds development of the standards and all its position statements out of its general revenues and does not use industry support for these purposes.

I. CLASSIFICATION AND DIAGNOSIS

A. Classification

The classification of diabetes includes four clinical classes:

- Type 1 diabetes (results from β-cell destruction, usually leading to absolute insulin deficiency)
- Type 2 diabetes (results from a progressive insulin secretory defect on the background of insulin resistance)
- Other specific types of diabetes due to other causes, e.g., genetic defects in β-cell function, genetic defects in insulin action, diseases of the exocrine pancreas (such as cystic fibrosis), and drug- or chemical-induced (such as in the treatment of HIV/AIDS or after organ transplantation)
- Gestational diabetes mellitus (GDM) (diabetes diagnosed during pregnancy that is not clearly overt diabetes)

Some patients cannot be clearly classified as type 1 or type 2 diabetic. Clinical presentation and disease progression vary considerably in both types of diabetes. Occasionally, patients who otherwise have type 2 diabetes may present with ketoacidosis. Similarly, patients with type 1 diabetes may have a late onset and slow (but relentless) progression of disease despite having features of autoimmune disease. Such difficulties in diagnosis may occur in children, adolescents, and adults. The true diagnosis may become more obvious over time.

B. Diagnosis of diabetes

For decades, the diagnosis of diabetes was based on plasma glucose criteria, either the fasting plasma glucose (FPG) or the 2-h value in the 75-g oral glucose tolerance test (OGTT) (5).

In 2009, an International Expert Committee that included representatives of the ADA, the International Diabetes
Position Statement

Table 1—ADA evidence grading system for clinical practice recommendations

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Clear evidence from well-conducted, generalizable RCTs that are adequately powered, including: • Evidence from a well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis Compelling nonexperimental evidence, i.e., “all or none” rule developed by the Centre for Evidence-Based Medicine at the University of Oxford Supportive evidence from well-conducted RCTs that are adequately powered, including: • Evidence from a well-conducted trial at one or more institutions • Evidence from a meta-analysis that incorporated quality ratings in the analysis</td>
</tr>
<tr>
<td>B</td>
<td>Supportive evidence from well-conducted cohort studies • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies Supportive evidence from a well-conducted case-control study</td>
</tr>
<tr>
<td>C</td>
<td>Supportive evidence from poorly controlled or uncontrolled studies • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results • Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) • Evidence from case series or case reports</td>
</tr>
<tr>
<td>E</td>
<td>Conflicting evidence with the weight of evidence supporting the recommendation Expert consensus or clinical experience</td>
</tr>
</tbody>
</table>

Federation (IDF), and the European Association for the Study of Diabetes (EASD) recommended the use of the A1C test to diagnose diabetes, with a threshold of ≥6.5% (6), and the ADA adopted this criterion in 2010 (5). The diagnostic test should be performed using a method that is certified by the NGSP and standardized or traceable to the Diabetes Control and Complications Trial (DCCT) reference assay. Although point-of-care (POC) A1C assays may be NGSP certified, proficiency testing is not mandated for performing the test, so use of these assays for diagnostic purposes could be problematic.

Epidemiological datasets show a similar relationship for A1C to the risk of retinopathy as has been shown for the corresponding FPG and 2-h PG thresholds. The A1C has several advantages to the FPG and OGTT, including greater convenience (since fasting is not required), evidence to suggest greater preanalytical stability, and less day-to-day perturbations during periods of stress and illness. These advantages must be balanced by greater cost, the limited availability of A1C testing in certain regions of the developing world, and the incomplete correlation between A1C and average glucose in certain individuals. In addition, HbA1c levels may vary with patients’ race/ethnicity (7,8). Some have posited that glycation rates differ by race (with, for example, African Americans having higher rates of glycation), but this is controversial. A recent epidemiological study found that, when matched for FPG, African Americans (with and without diabetes) indeed had higher A1C than whites, but also had higher levels of fructosamine and glycated albumin and lower levels of 1,5 anhydroglucitol, suggesting that their glycomic burden (particularly postprandially) may be higher (9). Epidemiological studies forming the framework for recommending use of the A1C to diagnose diabetes have all been in adult populations. Whether the cut point would be the same to diagnose children or adolescents with type 2 diabetes is an area of uncertainty (3,10). A1C inaccurately reflects glycemia with certain anemias and hemoglobinopathies. For patients with an abnormal hemoglobin but normal red cell turnover, such as sickle cell trait, an A1C assay without interference from abnormal hemoglobins should be used (an updated list is available at www.ngsp.org/interf.asp). For conditions with abnormal red cell turnover, such as pregnancy, recent blood loss or transfusion, or some anemias, the diagnosis of diabetes must employ glucose criteria exclusively.

The established glucose criteria for the diagnosis of diabetes (FPG and 2-h PG) remain valid as well (Table 2). Just as there is less than 100% concordance between the FPG and 2-h PG tests, there is no perfect concordance between A1C and either glucose-based test. Analyses of the National Health and Nutrition Examination Survey (NHANES) data indicate that, assuming universal screening of the undiagnosed, the A1C cut point of ≥6.5% identifies one-third fewer cases of undiagnosed diabetes than a fasting glucose cut point of ≥126 mg/dL (7.0 mmol/L) (11), and numerous studies have confirmed that at these cut points the 2-h OGTT value diagnoses more screened people with diabetes (12). However, in practice, a large portion of the diabetic population remains unaware of its condition. Thus, the lower sensitivity of A1C at the designated cut point may well be offset by the test’s greater practicality, and wider application of a more convenient test (A1C) may actually increase the number of diagnoses made.

As with most diagnostic tests, a test result diagnostic of diabetes should be repeated to rule out laboratory error, unless the diagnosis is clear on clinical grounds, such as a patient with a hyperglycemic crisis or classic symptoms of hyperglycemia and a random plasma glucose ≥200 mg/dL. It is preferable that the same test be repeated for confirmation, since there will be a greater likelihood of concurrence in this case. For example, if the A1C is 7.0% and a repeat result is 6.8%, the diagnosis of diabetes is confirmed. However, if two different tests (such as A1C and FPG) are both above the diagnostic thresholds, the diagnosis of diabetes is also confirmed.

On the other hand, if two different tests are available in an individual and the results are discordant, the test whose result is above the diagnostic cut point should be repeated, and the diagnosis is made based on the confirmed test. That is, if a patient meets the diabetes criterion of the A1C (two results ≥6.5%) but not the FPG (<126 mg/dL or 7.0 mmol/L), or vice versa, that person should be considered to have diabetes.

Since there is preanalytical and analytical variability of all the tests, it is also possible that when a test whose result was above the diagnostic threshold is repeated, the second value will be below the diagnostic cut point. This is least likely for A1C, somewhat more likely for FPG, and most likely for the 2-h PG. Barring a laboratory error, such patients are likely to have test results near the margins of the threshold for a diagnosis. The health care professional might opt to
follow the patient closely and repeat the testing in 3–6 months.

The current diagnostic criteria for diabetes are summarized in Table 2.

C. Categories of increased risk for diabetes (prediabetes)

In 1997 and 2003, the Expert Committee on Diagnosis and Classification of Diabetes Mellitus (13,14) recognized an intermediate group of individuals whose glucose levels, although not meeting criteria for diabetes, are nevertheless too high to be considered normal. These persons were defined as having impaired fasting glucose (IFG) (FPG levels 100 mg/dL [5.6 mmol/L] to 125 mg/dL [6.9 mmol/L]) or impaired glucose tolerance (IGT) (2-h values in the OGTT of 140 mg/dL [7.8 mmol/L] to 199 mg/dL [11.0 mmol/L]). It should be noted that the World Health Organization (WHO) and a number of other diabetes organizations define the cutoff for IFG at 110 mg/dL (6.1 mmol/L).

Individuals with IFG and/or IGT have been referred to as having prediabetes, indicating the relatively high risk for the future development of diabetes. IFG and IGT should not be viewed as clinical entities in their own right but rather risk factors for diabetes as well as cardiovascular disease (CVD). IFG and IGT are associated with obesity (especially abdominal or visceral obesity), dyslipidemia with high triglycerides and/or low HDL cholesterol, and hypertension.

As is the case with the glucose measures, several prospective studies that considered the continuum of risk are summarized in Table 2.

Table 2—Criteria for the diagnosis of diabetes

<table>
<thead>
<tr>
<th>Category</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C ≥ 6.5%</td>
<td>The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay. *</td>
</tr>
<tr>
<td>OR</td>
<td>FPG ≥126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h. *</td>
</tr>
<tr>
<td>OR</td>
<td>2-h plasma glucose ≥200 mg/dL (11.1 mmol/L) during an OGTT. The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. *</td>
</tr>
<tr>
<td>OR</td>
<td>In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dL (11.1 mmol/L).</td>
</tr>
</tbody>
</table>

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

A1C 5.7–6.4% as identifying individuals with prediabetes.

Table 3—Categories of increased risk for diabetes (prediabetes)*

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>FPG 100 mg/dL (5.6 mmol/L) to 125 mg/dL (6.9 mmol/L) (IFG)</td>
<td>OR</td>
</tr>
<tr>
<td>OR</td>
<td>2-h plasma glucose in the 75-g OGTT 140 mg/dL (7.8 mmol/L) to 199 mg/dL (11.0 mmol/L) (IGT)</td>
</tr>
<tr>
<td>OR</td>
<td>A1C 5.7–6.4%</td>
</tr>
</tbody>
</table>

*For all three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at higher ends of the range.

For many illnesses, there is a major distinction between screening and diagnostic testing. However, for diabetes, the same tests would be used for “screening” as for diagnosis. Diabetes may be identified anywhere along a spectrum of clinical scenarios ranging from a seemingly low-risk individual who has high suspicion of diabetes, to the symptomatic patient. The discussion herein is primarily framed as testing for diabetes in those without symptoms. The same assays used for testing for diabetes will also detect individuals with prediabetes.

A. Testing for type 2 diabetes and risk of future diabetes in adults

Prediabetes and diabetes meet established criteria for conditions in which early detection is appropriate. Both conditions are common, increasing in prevalence, and impose significant public health burdens. There is a long presymptomatic phase before the diagnosis of type 2 diabetes is usually made. Relatively simple tests are available to detect preclinical disease. Additionally, the duration of glycemic burden is a strong predictor of adverse outcomes, and effective interventions exist to prevent progression of prediabetes to diabetes (see Section IV) and to reduce risk of complications of diabetes (see Section VI).

Type 2 diabetes is frequently not diagnosed until complications appear, and approximately one-fourth of all people with diabetes in the U.S. may be undiagnosed. The effectiveness of early identification of prediabetes and diabetes through mass testing of asymptomatic individuals has not been proven definitively, and rigorous trials to provide such proof are unlikely to occur. In a large randomized controlled trial (RCT) in Europe, general practice patients between the ages of 40–69 years were screened for diabetes and...
then randomly assigned by practice to routine care of diabetes or intensive treat-
ment of multiple risk factors. After 5.5
years of follow-up, CVD risk factors were
modestly but significantly more improved
with intensive treatment. Incidence of first
CVD event and mortality rates were not
significantly different between groups
(18). This study would seem to add sup-
port for early routine screening-detected
diabetes, as risk factor control was excel-
rent even in the routine treatment arm
and both groups had lower event rates
than predicted. The absence of a control
unscreened arm limits the ability to defi-
nitely prove that screening impacts out-
comes. Mathematical modeling studies
suggest that screening independent of risk
factors beginning at age 30 years or age
45 years is highly cost-effective
(<$11,000 per quality-adjusted life-
year gained) (19).

Recommendations for testing for di-
abetes in asymptomatic, undiagnosed
adults are listed in Table 4. Testing
should be considered in adults of any age
with BMI ≥25 kg/m2 and one or more of
the known risk factors for diabetes. In ad-
dition to the listed risk factors, certain med-
ications, such as glucocorticoids and
antipsychotics (20), are known to in-
crease the risk of type 2 diabetes. There
is compelling evidence that lower BMI cut
points suggest diabetes risk in some racial
and ethnic groups. In a large multiethnic
cohort study, for an equivalent incidence
rate of diabetes conferred by a BMI of 30
kg/m2 in whites, the BMI cutoff value was
24 kg/m2 in South Asians, 25 kg/m2 in
Chinese, and 26 kg/m2 in African Ameri-
cans (21). Disparities in screening rates,
not explainable by insurance status, are
highlighted by evidence that despite much
higher prevalence of type 2 diabe-
tes, non-Caucasians in an insured popu-
lation are no more likely than Caucasians
to be screened for diabetes (22). Because
age is a major risk factor for diabetes, test-
ing of those without other risk factors
should begin no later than age 45 years.

The A1C, FPG, or the 2-h OGTT are
appropriate for testing. It should be noted
that the tests do not necessarily detect
diabetes in the same individuals. The
efficacy of interventions for primary pre-
vention of type 2 diabetes (23–29) has
primarily been demonstrated among indi-
viduals with IGT, not for individuals
with isolated IFG or for individuals
with specific A1C levels.

The appropriate interval between
tests is not known (30). The rationale
for the 3-year interval is that false nega-
tives will be repeated before substantial
time elapses, and there is little likelihood
that an individual will develop significant
complications of diabetes within 3 years
of a negative test result. In the modeling
study, repeat screening every 3 or 5 years
was cost-effective (19).

Because of the need for follow-up and
discussion of abnormal results, testing
should be carried out within the health
care setting. Community screening outside
a health care setting is not recommended
because people with positive tests may not
seek, or have access to, appropriate follow-up
testing and care. Conversely, there may be
failure to ensure appropriate repeat testing
for individuals who test negative. Commu-
nity screening may also be poorly targeted; i.
. . , it may fail to reach the groups most at risk
and inappropriately test those at low risk (the
worried well) or even those already diag-
nosed.

B. Screening for type 2 diabetes
in children
Recommendations

• Testing to detect type 2 diabetes and
prediabetes should be considered in chil-
dren and adolescents who are overweight
and who have two or more additional
risk factors for diabetes (Table 5) (E)

The incidence of type 2 diabetes in
adolescents has increased dramatically in
the last decade, especially in minority
cohorts (31), although the disease
remains rare in the general pediatric pop-
ulation (32). Consistent with recom-
endations for adults, children and
adolescents at increased risk for the presence
of type 2 diabetes should be tested within the health care
setting (33). The recommendations of the ADA consensus statement “Type 2
Diabetes in Children and Adolescents,”
with some modifications, are sum-
mmarized in Table 5.

C. Screening for type 1 diabetes
Recommendations

• Consider referring relatives of those
with type 1 diabetes for antibody test-
ing for risk assessment in the setting
of a clinical research study (E)

Generally, people with type 1 diabetes
present with acute symptoms of diabetes
and markedly elevated blood glucose
levels, and some cases are diagnosed with
life-threatening ketoacidosis. Evidence
from several studies suggests that mea-
surement of islet autoantibodies in rela-
tives of those with type 1 diabetes
distinguishes individuals who are at risk for
developing type 1 diabetes. Such testing,
coupled with education about symptoms
of diabetes and follow-up in an observa-
tional clinical study, may allow earlier
identification of onset of type 1 diabetes
and lessen presentation with ketoacidosis
at time of diagnosis. This testing may be
appropriate in those who have relatives
with type 1 diabetes, in the context of

Table 4—Criteria for testing for diabetes in asymptomatic adult individuals

<table>
<thead>
<tr>
<th>1.</th>
<th>Testing should be considered in all adults who are overweight (BMI ≥25 kg/m2*) and have additional risk factors:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• physical inactivity</td>
<td></td>
</tr>
<tr>
<td>• first-degree relative with diabetes</td>
<td></td>
</tr>
<tr>
<td>• high-risk race/ethnicity (e.g., African American, Latino, Native American, Asian American, Pacific Islander)</td>
<td></td>
</tr>
<tr>
<td>• women who delivered a baby weighing &gt;9 lb or were diagnosed with GDM</td>
<td></td>
</tr>
<tr>
<td>• hypertension (≥140/90 mmHg or on therapy for hypertension)</td>
<td></td>
</tr>
<tr>
<td>• HDL cholesterol level &lt;35 mg/dL (0.90 mmol/L) and/or a triglyceride level &gt;250 mg/dL (2.82 mmol/L)</td>
<td></td>
</tr>
<tr>
<td>• women with polycystic ovary syndrome</td>
<td></td>
</tr>
<tr>
<td>• A1C ≥5.7%, IGT, or IFG on previous testing</td>
<td></td>
</tr>
<tr>
<td>• other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)</td>
<td></td>
</tr>
<tr>
<td>• history of CVD</td>
<td></td>
</tr>
</tbody>
</table>

| 2. | In the absence of the above criteria, testing for diabetes should begin at age 45 years. |

| 3. | If results are normal, testing should be repeated at least at 3-year intervals, with consideration of more frequent testing depending on initial results (e.g., those with prediabetes should be tested yearly) and risk status. |

*At-risk BMI may be lower in some ethnic groups.
Table 5—Testing for type 2 diabetes in asymptomatic children*

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Frequency: every 3 years</th>
<th>Age of initiation: age 10 years or at onset of puberty, if puberty occurs at a younger age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overweight (BMI &gt;85th percentile for age and sex, weight for height &gt;85th percentile, or weight &gt;120% of ideal for height)</td>
<td>(B)</td>
<td></td>
</tr>
<tr>
<td>Plus any two of the following risk factors:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family history of type 2 diabetes in first- or second-degree relative</td>
<td>(B)</td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity (Native American, African American, Latino, Asian American, Pacific Islander)</td>
<td>(B)</td>
<td></td>
</tr>
<tr>
<td>Signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome, or small-for-gestational-age birth weight)</td>
<td>(B)</td>
<td></td>
</tr>
<tr>
<td>Maternal history of diabetes or GDM during the child’s gestation</td>
<td>(B)</td>
<td></td>
</tr>
</tbody>
</table>

*Persons aged 18 years and younger.

Table 6—Screening for and diagnosis of GDM

Perform a 75-g OGTT, with plasma glucose measurement fasting and at 1 and 2 h, at 24–28 weeks of gestation in women not previously diagnosed with overt diabetes. The OGTT should be performed in the morning after an overnight fast of at least 8 h. The diagnosis of GDM is made when any of the following plasma glucose values are exceeded:

- Fasting: ≥92 mg/dL (5.1 mmol/L)
- 1 h: ≥180 mg/dL (10.0 mmol/L)
- 2 h: ≥153 mg/dL (8.5 mmol/L)

For many years, GDM was defined as any degree of glucose intolerance with onset or first recognition during pregnancy, whether or not the condition persisted after pregnancy, and not excluding the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy. This definition facilitated a uniform strategy for detection and classification of GDM, but its limitations were recognized for many years. As the ongoing epidemic of obesity and diabetes has led to more type 2 diabetes in women of childbearing age, the number of pregnant women with undiagnosed type 2 diabetes has increased. Because of this, it is reasonable to screen women with risk factors for type 2 diabetes (Table 4) for diabetes at their initial prenatal visit, using standard diagnostic criteria (Table 2). Women with diabetes found at this visit should receive a diagnosis of overt, not gestational, diabetes.

GDM carries risks for the mother and neonate. The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study (37), a large-scale (~25,000 pregnant women) multinational epidemiological study, demonstrated that risk of adverse maternal, fetal, and neonatal outcomes continuously increased as a function of maternal glycaemia at 24–28 weeks, even within ranges previously considered normal for pregnancy. For most complications, there was no threshold for risk. These results have led to careful reconsideration of the diagnostic criteria for GDM. After deliberations in 2008–2009, the International Association of Diabetes and Pregnancy Study Groups (IADPSG), an international consensus group with representatives from multiple obstetrical and diabetes organizations, including ADA, developed revised recommendations for diagnosing GDM. The group recommended that all women not known to have prior diabetes undergo a 75-g OGTT at 24–28 weeks of gestation. Additionally, the group developed diagnostic cut points for the fasting, 1-h, and 2-h plasma glucose measurements that conveyed an odds ratio for adverse outcomes of at least 1.75 compared with women with the mean glucose levels in the HAPO study. Current screening and diagnostic strategies, based on the IADPSG statement (38), are outlined in Table 6.

These new criteria will significantly increase the prevalence of GDM, primarily because only one abnormal value, not two, is sufficient to make the diagnosis. The ADA recognizes the anticipated significant increase in the incidence of GDM diagnosed by these criteria and is sensitive to concerns about the “medicalization” of pregnancies previously categorized as normal. These diagnostic criteria changes are being made in the context of worrisome worldwide increases in obesity and diabetes rates, with the intent of optimizing gestational outcomes for women and their babies.

Admittedly, there are few data from randomized clinical trials regarding therapeutic interventions in women who will now be diagnosed with GDM based on only one blood glucose value above the
Position Statement

IV. PREVENTION/Delay of Type 2 Diabetes

Recommendations
- Patients with IGT (A), IFG (E), or an A1C of 5.7–6.4% (E) should be referred to an effective ongoing support program targeting weight loss of 7% of body weight and increasing physical activity to at least 150 min/week of moderate activity such as walking.
- Follow-up counseling appears to be important for success. (B)
- Based on the cost-effectiveness of diabetes prevention, such programs should be covered by third-party payers. (B)
- Metformin therapy for prevention of type 2 diabetes may be considered in those with IGT (A), IFG (E), or an A1C of 5.7–6.4% (E), especially for those with BMI >35 kg/m², aged <60 years, and women with prior GDM. (A)
- At least annual monitoring for the development of diabetes in those with prediabetes is suggested. (E)
- Screening for and treatment of modifiable risk factors for CVD is suggested. (B)

RCTs have shown that individuals at high risk for developing type 2 diabetes (those with IFG, IGT, or both) can significantly decrease the rate of onset of diabetes with particular interventions (23–29). These include intensive lifestyle modification programs that have been shown to be very effective (~58% reduction after 3 years) and use of the pharmacological agents metformin, α-glucosidase inhibitors, orlistat, and thiazolidinediones, each of which has been shown to decrease incident diabetes to various degrees. Follow-up of all three large studies of lifestyle intervention has shown sustained reduction in the rate of conversion to type 2 diabetes, with 43% reduction at 20 years in the Da Qing study (47), 43% reduction at 7 years in the Finnish Diabetes Prevention Study (DPYS) (48), and 34% reduction at 10 years in the U.S. Diabetes Prevention Program Outcomes Study (DPPOS) (49). A cost-effectiveness model suggested that lifestyle interventions as delivered in the DPP are cost-effective (50), and actual cost data from the DPP and DPPOS confirm that lifestyle interventions are highly cost-effective (51). Group delivery of the DPP intervention in community settings has the potential to be significantly less expensive while still achieving similar weight loss (52).

Based on the results of clinical trials and the known risks of progression of prediabetes to diabetes, persons with an A1C of 5.7–6.4%, IGT, or IFG should be counseled on lifestyle changes with goals similar to those of the DPP (7% weight loss and moderate physical activity of at least 150 min/week). Regarding drug therapy for diabetes prevention, metformin has a strong evidence base and demonstrated long-term safety (53). For other drugs, issues of cost, side effects, and lack of persistence of effect in some studies (54) require consideration. Metformin was less effective than lifestyle modification in the DPP and DPPOS, but may be cost-saving over a 10-year period (51). It was as effective as lifestyle modification in participants with a BMI of at least 35 kg/m², but not significantly better than placebo than those over age 60 years (23). In women in the DPP with a history of GDM, metformin and intensive lifestyle modification led to an equivalent 50% reduction in the risk of diabetes (55). Metformin therefore might reasonably be recommended for very high-risk individuals (those with a history of GDM, the very obese, and/or those with more severe or progressive hyperglycemia).

People with prediabetes often have other cardiovascular risk factors, such as obesity, hypertension, and dyslipidemia. Assessing and treating these risk factors is an important aspect of reducing cardiometabolic risk. In the DPP and DPPOS, cardiovascular event rates have been very low, perhaps due to appropriate management of cardiovascular risk factors in all arms of the study (56).

V. Diabetes Care

A. Initial evaluation
A complete medical evaluation should be performed to classify the diabetes, detect the presence of diabetes complications, review previous treatment and risk factor control in patients with established diabetes, assist in formulating a management plan, and provide a basis for continuing care. Laboratory tests appropriate to the evaluation of each patient’s medical condition should be performed. A focus on the components of comprehensive care (Table 7) will assist the health care team to ensure optimal management of the patient with diabetes.

B. Management
People with diabetes should receive medical care from a team that may include physicians, nurse practitioners, physician’s assistants, nurses, dietitians, pharmacists, and mental health professionals with
Table 7—Components of the comprehensive diabetes evaluation

Medical history
- Age and characteristics of onset of diabetes (e.g., DKA, asymptomatic laboratory finding)
- Eating patterns, physical activity habits, nutritional status, and weight history, growth and development in children and adolescents
- Diabetes education history
- Review of previous treatment regimens and response to therapy (A1C records)
- Current treatment of diabetes, including medications, medication adherence and barriers thereto, meal plan, physical activity patterns, and readiness for behavior change
- Results of glucose monitoring and patient’s use of data
- DKA frequency, severity, and cause
- Hypoglycemic episodes
- Hypoglycemia awareness
- Any severe hypoglycemia: frequency and cause
- History of diabetes-related complications
- Microvascular: retinopathy, nephropathy, neuropathy (sensory, including history of foot lesions; autonomic, including sexual dysfunction and gastroparesis)
- Macrovascular: CHD, cerebrovascular disease, and PAD
- Other: psychosocial problems*, dental disease*

Physical examination
- Height, weight, BMI
- Blood pressure determination, including orthostatic measurements when indicated
- Fundoscopic examination*
- Thyroid palpation
- Skin examination (for acanthosis nigricans and insulin injection sites)
- Comprehensive foot examination
  - Inspection
  - Palpation of dorsalis pedis and posterior tibial pulses
  - Presence/absence of patellar and Achilles reflexes
  - Determination of proprioception, vibration, and monofilament sensation

Laboratory evaluation
- A1C, if results not available within past 2–3 months
  - If not performed/available within past year
  - Fasting lipid profile, including total, LDL and HDL cholesterol and triglycerides
  - Liver function tests
  - Test for urine albumin excretion with spot urine albumin-to-creatinine ratio
  - Serum creatinine and calculated GFR
  - TSH in type 1 diabetes, dyslipidemia or women over age 50 years

Referrals
- Eye care professional for annual dilated eye exam
- Family planning for women of reproductive age
- Registered dietitian for MNT
- DSME
- Dentist for comprehensive periodontal examination
- Mental health professional, if needed

*See appropriate referrals for these categories.

Expertise and a special interest in diabetes. It is essential in this collaborative and integrated team approach that individuals with diabetes assume an active role in their care.

The management plan should be formulated as a collaborative therapeutic alliance among the patient and family, the physician, and other members of the health care team. A variety of strategies and techniques should be used to provide adequate education and development of problem-solving skills in the various aspects of diabetes management. Implementation of the management plan requires that the goals and treatment plan are individualized and take patient preferences into account. The management plan should recognize diabetes self-management education (DSME) and ongoing diabetes support as an integral component of care. In developing the plan, consideration should be given to the patient’s age, school or work schedule and conditions, physical activity, eating patterns, social situation and cultural factors, and presence of complications of diabetes or other medical conditions.

C. Glycemic control

1. Assessment of glycemic control

Two primary techniques are available for health providers and patients to assess the effectiveness of the management plan on glycemic control: patient self-monitoring of blood glucose (SMBG) or interstitial glucose, and A1C.

a. Glucose monitoring

Recommendations
- Patients on multiple-dose insulin (MDI) or insulin pump therapy should do SMBG at least prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving. (B)
- When prescribed as part of a broader educational context, SMBG results may be helpful to guide treatment decisions and/or patient self-management for patients using less frequent insulin injections or noninsulin therapies. (E)
- When prescribing SMBG, ensure that patients receive ongoing instruction and regular evaluation of SMBG technique and SMBG results, as well as their ability to use SMBG data to adjust therapy. (E)
- Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (aged ≥25 years) with type 1 diabetes. (A)
- Although the evidence for A1C lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. (C)
- CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. (E)

Major clinical trials of insulin-treated patients that demonstrated the benefits of intensive glycemic control on diabetes complications have included SMBG as part of multifactorial interventions, suggesting that SMBG is a component of effective therapy. SMBG allows patients to evaluate their individual response to
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therapy and assess whether glycemic targets are being achieved. Results of SMBG can be useful in preventing hypoglycemia and adjusting medications (particularly prandial insulin doses), medical nutrition therapy (MNT), and physical activity.

The frequency and timing of SMBG should be dictated by the particular needs and goals of the patient. SMBG is especially important for patients treated with insulin to monitor for and prevent asymptomatic hypoglycemia and hyperglycemia. Most patients with type 1 diabetes and others on intensive insulin regimens (MDI or insulin pump therapy) should do SMBG at least prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, alter treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving. For many patients, this will require testing 6–8 times daily, although individual needs may be greater. Although there are few rigorous studies, a database study of almost 27,000 children and adolescents with type 1 diabetes showed that, after adjustment for multiple confounders, increased daily frequency of SMBG was significantly associated with lower A1C (~0.2% per additional test per day, leveling off at five tests per day) and with fewer acute complications (57). The optimal frequency of SMBG for patients on non-intensive regimens, such as those with type 2 diabetes on basal insulin, is not known, although a number of studies have used fasting SMBG for patient or provider titration of the basal insulin dose.

The evidence base for SMBG for patients with type 2 diabetes on noninsulin therapy is somewhat mixed. Several randomized trials have called into question the clinical utility and cost-effectiveness of routine SMBG in non–insulin-treated patients (58–60). A recent meta-analysis suggested that SMBG reduced A1C by 0.25% at 6 months (61), while a Cochrane review concluded that the overall effect of SMBG in such patients is small up to 6 months after initiation and subsides after 12 months (62).

Because the accuracy of SMBG is instrument and user dependent (63), it is important to evaluate each patient’s monitoring technique, both initially and at regular intervals thereafter. Optimal use of SMBG requires proper review and interpretation of the data, both by the patient and provider. Among patients who checked their blood glucose at least once daily, many reported taking no action when results were high or low (64). In one study of insulin-naive patients with suboptimal initial glycemic control, use of structured SMBG (a paper tool to collect and interpret 7-point SMBG profiles over 3 days at least quarterly) reduced A1C by 0.3% more than in an active control group (65). Patients should be taught how to use SMBG data to adjust food intake, exercise, or pharmacological therapy to achieve specific goals, and the ongoing need for and frequency of SMBG should be re-evaluated at each routine visit.

Real-time CGM through the measurement of interstitial glucose (which correlates well with plasma glucose) is available. These sensors require calibration with SMBG, and the latter are still recommended for making acute treatment decisions. CGM devices have alarms for hypoglycemic and hyperglycemic excursions. A 26-week randomized trial of 322 type 1 diabetic patients showed that adults aged ≥25 years using intensive insulin therapy and CGM experienced a 0.5% reduction in A1C (from ~7.6 to 7.1%) compared with usual intensive insulin therapy with SMBG (66). Sensor use in children, teens, and adults to age 24 years did not result in significant A1C lowering, and there was no significant difference in hypoglycemia in any group. Importantly, the greatest predictor of A1C lowering in this study for all age-groups was frequency of sensor use, which was lower in younger age-groups. In a smaller RCT of 129 adults and children with base-line A1C <7.0%, outcomes combining AIC and hypoglycemia favored the group utilizing CGM, suggesting that CGM is also beneficial for individuals with type 1 diabetes who have already achieved excellent control (67).

A trial comparing CGM plus insulin pump to SMBG plus multiple injections of insulin in adults and children with type 1 diabetes showed significantly greater improvements in AIC with ‘sensor-augmented pump’ therapy (68,69), but this trial did not isolate the effect of CGM itself. Overall, meta-analyses suggest that compared with SMBG, CGM lowers A1C by ~0.26% (70). Altogether, these data suggest that, in appropriately selected patients who are motivated to wear it most of the time, CGM reduces A1C. The technology may be particularly useful in those with hypoglycemia unawareness and/or frequent episodes of hypoglycemia, although studies as yet have not shown significant reductions in severe hypoglycemia (70). CGM forms the underpinning for the development of pumps that suspend insulin delivery when hypoglycemia is developing and for the burgeoning work on ‘artificial pancreas’ systems.

b. A1C

Recommendations

- Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). (E)
- Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (E)
- Use of POC testing for A1C provides the opportunity for more timely treatment changes. (E)

Because A1C is thought to reflect average glycemia over several months (63) and has strong predictive value for diabetes complications (71,72), A1C testing should be performed routinely in all patients with diabetes, at initial assessment and then as part of continuing care. Measurement approximately every 3 months determines whether patient’s glycemic targets have been reached and maintained. For any individual patient, the frequency of A1C testing should be dependent on the clinical situation, the treatment regimen used, and the judgment of the clinician. Some patients with stable glycemia well within target may do well with testing only twice per year, while unstable or highly intensively managed patients (e.g., pregnant type 1 diabetic women) may be tested more frequently than every 3 months. The availability of the A1C result at the time that the patient is seen (POC testing) has been reported in small studies to result in increased intensification of therapy and improvement in glycemic control (73,74). However, two recent systematic reviews and meta-analyses found no significant difference in A1C between POC and laboratory A1C usage (75,76).

The A1C test is subject to certain limitations. Conditions that affect erythrocyte turnover (hemolysis, blood loss) and hemoglobin variants must be considered, particularly when the A1C result does not correlate with the patient’s clinical situation (63). In addition, A1C does not provide a measure of glycemic variability or hypoglycemia. For patients prone to glycemic variability (especially type 1 diabetic patients or type 2 diabetic patients with severe insulin deficiency), glycemic control is best judged by the combination of results of self-monitoring and the A1C. The A1C may also serve as a check on the accuracy of the patient’s meter (or the patient’s reported SMBG.
results) and the adequacy of the SMBG testing schedule.

Table 8 contains the correlation between A1C levels and mean plasma glucose levels based on data from the international A1C-Derived Average Glucose (ADAG) trial utilizing frequent SMBG and CGM in 507 adults (83% Caucasian with type 1, type 2, and no diabetes (77)). The ADA and the American Association for Clinical Chemistry have determined that the correlation ($r = 0.92$) is strong enough to justify reporting both an A1C result and an estimated average glucose (eAG) result when a clinician orders the A1C test. The table in pre-2009 versions of the “Standards of Medical Care in Diabetes” describing the correlation between A1C and mean glucose was derived from relatively sparse data (one 7-point profile over 1 day per A1C reading) in the primarily Caucasian type 1 diabetic participants in the DCCT (78).

Clinicians should note that the numbers in the table are now different, as they are based on ~2,800 readings per A1C in the ADAG trial. In the ADAG trial, there were no significant differences among racial and ethnic groups in the regression lines between A1C and mean glucose, although there was a trend toward a difference between African/African American participants and Caucasian ones. A small study comparing A1C to CGM data in type 1 diabetic children found a highly statistically significant correlation between A1C and mean blood glucose, although the correlation ($r = 0.7$) was significantly lower than in the ADAG trial (79).

### Table 8—Correlation of A1C with average glucose

<table>
<thead>
<tr>
<th>A1C (%)</th>
<th>Mean plasma glucose (mg/dL)</th>
<th>Mean plasma glucose (mmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>126</td>
<td>7.0</td>
</tr>
<tr>
<td>7</td>
<td>154</td>
<td>8.6</td>
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<td>8</td>
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<td>9</td>
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<td>11.8</td>
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<td>240</td>
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<tr>
<td>11</td>
<td>269</td>
<td>14.9</td>
</tr>
<tr>
<td>12</td>
<td>298</td>
<td>16.5</td>
</tr>
</tbody>
</table>

These estimates are based on ADAG data of ~2,700 glucose measurements over 3 months per A1C measurement in 507 adults with type 1, type 2, and no diabetes. The correlation between A1C and average glucose was 0.92 (ref. 77). A calculator for converting A1C results into eAG, in either mg/dL or mmol/L, is available at http://professional.diabetes.org/eAG.

There are significant differences in how A1C relates to average glucose in children or in African American patients is an area for further study. For the time being, the question has not led to different recommendations about testing A1C or to different interpretations of the clinical meaning of given levels of A1C in those populations.

For patients in whom A1C/eAG and measured blood glucose appear discrepant, clinicians should consider the possibilities of hemoglobinopathy or altered red cell turnover, and the options of more frequent and/or different timing of SMBG or use of CGM. Other measures of chronic glycemia such as fructosamine are available, but their linkage to average glucose and their prognostic significance are not as clear as is the case for A1C.

### 2. Glycemic goals in adults

#### Recommendations

- Lowering A1C to below or around 7% has shown to reduce microvascular complications of diabetes and if implemented soon after the diagnosis of diabetes is associated with long-term reduction in macrovascular disease. Therefore, a reasonable A1C goal for many nonpregnant adults is <7%.
- Providers might reasonably suggest more stringent A1C goals (such as <6.5%) for selected individual patients, if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients might include those with short duration of diabetes, long life expectancy, and no significant CVD.
- Less stringent A1C goals (such as <8%) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, and those with long-standing diabetes in whom the general goal is difficult to attain despite DSME, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin.

Hyperglycemia defines diabetes, and glycemic control is fundamental to the management of diabetes. The DCCT (71), a prospective RCT of intensive versus standard glycemic control in patients with relatively recently diagnosed type 1 diabetes, showed definitively that improved glycemic control is associated with significantly decreased rates of microvascular (retinopathy and nephropathy) and neuropathic complications. Follow-up of the DCCT cohorts in the Epidemiology of Diabetes Interventions and Complications (EDIC) study (80,81) demonstrated persistence of these microvascular benefits in previously intensively treated subjects, even though their glycemic control approximated that of previous standard arm subjects during follow-up.

The Kumamoto Study (82) and UK Prospective Diabetes Study (UKPDS) (83,84) confirmed that intensive glycemic control was associated with significantly decreased rates of microvascular and neuropathic complications in patients with type 2 diabetes. Long-term follow-up of the UKPDS cohorts showed persistence of the effect of early glycemic control on most microvascular complications (85).

Subsequent trials in patients with more long-standing type 2 diabetes, designed primarily to look at the role of intensive glycemic control on cardiovascular outcomes, also confirmed a benefit, although more modest, on onset or progression of microvascular complications. The Veterans Affairs Diabetes Trial (VADT) showed significant reductions in albuminuria with intensive (achieved median A1C 6.9%) compared with standard glycemic control, but no difference in retinopathy and neuropathy (86,87). The Action in Diabetes and Vascular Disease: Preterax and DiaMicon MR Controlled Evaluation (ADVANCE) study of intensive versus standard glycemic control in type 2 diabetes found a statistically significant reduction in albuminuria, but not in neuropathy or retinopathy, with an A1C target of <6.5% (achieved median A1C 6.3%) compared with standard therapy achieving a median A1C of 7.0% (88). Analyses from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial have shown lower rates of onset or progression of early-stage microvascular complications in the intensive glycemic control arm compared with the standard arm (89,90).

Epidemiological analyses of the DCCT and UKPDS (71,72) demonstrate a curvilinear relationship between A1C and microvascular complications. Such analyses suggest that, on a population level, the greatest number of complications will be averted by taking patients from very poor control to fair or good control. These analyses also suggest that further lowering of A1C from 7 to 6% is associated with further reduction in the risk of microvascular complications, albeit the absolute risk...
reductions become much smaller. Given the substantially increased risk of hypoglycemia (particularly in those with type 1 diabetes, but also in the recent type 2 diabetes trials), the concerning mortality findings in the ACCORD trial (91), and the relatively much greater effort required to achieve near-normoglycemia, the risks of lower glycemic targets may outweigh the potential benefits on microvascular complications on a population level. However, selected individual patients, especially those with little comorbidity and long life expectancy (who may reap the benefits of further lowering of glycemia below 7%), may, based on provider judgment and patient preferences, adopt more intensive glycemic targets (e.g., an A1C target <6.5%) as long as significant hypoglycemia does not become a barrier.

CVD, a more common cause of death in populations with diabetes than microvascular complications, is less clearly impacted by levels of hyperglycemia or the intensity of glycemic control. In the DCCT, there was a trend toward lower risk of CVD events with intensive control, and in 9-year post-DCCT follow-up of the EDIC cohort participants previously randomized to the intensive arm had a significant 57% reduction in the risk of nonfatal myocardial infarction (MI), stroke, or CVD death compared with those previously in the standard arm (92). The benefit of intensive glycemic control in this type 1 diabetic cohort has recently been shown to persist for several decades (93).

In type 2 diabetes, there is evidence that more intensive treatment of glycemia in newly diagnosed patients may reduce long-term CVD rates. During the UKPDS trial, there was a 16% reduction in cardiovascular events (combined fatal or nonfatal MI and sudden death) in the intensive glycemic control arm that did not reach statistical significance (P = 0.052), and there was no suggestion of benefit on other CVD outcomes such as stroke. However, after 10 years of follow-up, those originally randomized to intensive glycemic control had significant long-term reductions in MI (15% with sultolnurea or insulin as initial pharmacotherapy, 33% with metformin as initial pharmacotherapy) and in all-cause mortality (13% and 27%, respectively) (85).

Three more recent large trials (ACCORD, ADVANCE, and VADT) suggested no significant reduction in CVD outcomes with intensive glycemic control in participants who had more advanced type 2 diabetes than UKPDS participants. All three of these trials were conducted in participants with more long-standing diabetes (mean duration 8–11 years) and either known CVD or multiple cardiovascular risk factors. Details of these three studies are reviewed extensively in an ADA position statement (94).

The ACCORD study enrolled participants with either known CVD or two or more major cardiovascular risk factors and randomized them to intensive glycemic control (goal A1C <6%) or standard glycemic control (goal A1C 7–8%). The glycemic control comparison was halted early due to the finding of an increased rate of mortality in the intensive arm compared with the standard arm (1.41% vs. 1.14% per year; HR 1.22; 95% CI 1.01–1.46), with a similar increase in cardiovascular deaths. This increase in mortality in the intensive glycemic control arm was seen in all prespecified patient subgroups. The primary outcome of ACCORD (nonfatal MI, nonfatal stroke, or cardiovascular death) was nonsignificantly lower in the intensive glycemic control group due to a reduction in nonfatal MI, both when the glycemic control comparison was halted and all participants transitioned to the standard glycemic control intervention (91), and at completion of the planned follow-up (95).

Exploratory analyses of the mortality findings of ACCORD (evaluating variables including weight gain, use of any specific drug or drug combination, and hypoglycemia) were reportedly unable to identify a clear explanation for the excess mortality in the intensive arm (91). The ACCORD investigators subsequently published additional epidemiological analyses showing no increase in mortality in the intensive arm participants who achieved A1C levels below 7% nor in those who lowered their A1C quickly after trial enrollment. In fact, although there was no A1C level at which intensive arm participants had significantly lower mortality than standard arm participants, the highest risk for mortality was observed in intensive arm participants with the highest A1C levels (96).

The role of hypoglycemia in the excess mortality findings was also complex. Severe hypoglycemia was significantly more likely in participants randomized to the intensive glycemic control arm. However, excess mortality in the intensive versus standard arms was only significant for participants with no severe hypoglycemia, and not for those with one or more episodes. Severe hypoglycemia was associated with excess mortality in either arm, but the association was stronger in those randomized to the standard glycemic control arm (97). Unlike the case with the DCCT trial, where lower achieved A1C levels were related to significantly increased rates of severe hypoglycemia, in ACCORD every 1% decline in A1C from baseline to 4 months into the trial was associated with a significant decrease in the rate of severe hypoglycemia in both arms (96).

The primary outcome of ADVANCE was a combination of microvascular events (nephropathy and retinopathy) and major adverse cardiovascular events (MI, stroke, and cardiovascular death). Intensive glycemic control (to a goal A1C <6.5% vs. treatment to local standards) significantly reduced the primary end point. However, this was due to a significant reduction in the microvascular outcome, primarily development of macroalbuminuria, with no significant reduction in the macrovascular outcome. There was no difference in overall or cardiovascular mortality between the intensive compared with the standard glycemic control arms (88).

The VADT randomized participants with type 2 diabetes uncontrolled on insulin or maximal-dose oral agents (median entry A1C 9.4%) to a strategy of intensive glycemic control (goal A1C <6.0%) or standard glycemic control, with a planned A1C separation of at least 1.5%. The primary outcome of the VADT was a composite of CVD events. The cumulative primary outcome was nonsignificantly lower in the intensive arm (86). An ancillary study of the VADT demonstrated that intensive glycemic control significantly reduced the primary CVD outcome in individuals with less atherosclerosis at baseline (assessed by coronary calcium) but not in persons with more extensive baseline atherosclerosis (98). A post hoc analysis showed a complex relationship between duration of diabetes before glycemic intensification and mortality: mortality in the intensive vs. standard glycemic control arm was inversely related to duration of diabetes at the time of study enrollment. Those with diabetes duration less than 15 years had a mortality benefit in the intensive arm, while those with duration of 20 years or more had higher mortality in the intensive arm (99).

The evidence for a cardiovascular benefit of intensive glycemic control primarily rests on long-term follow-up of study cohorts treated early in the course of type
the potential risks of intensive glycemic group analyses of the VADT suggest that mortality without known CVD at baseline (HR 0.84, 95% CI 0.74–0.94) (100). Conversely, the mortality findings in ACCORD and subgroup analyses of the VADT suggest that the potential risks of intensive glycemic control may outweigh its benefits in some patients, such as those with very long duration of diabetes, known history of severe hypoglycemia, advanced atherosclerosis, and advanced age/frailty. Certainly, providers should be vigilant in preventing severe hypoglycemia in patients with advanced disease and should not aggressively attempt to achieve near-normal A1C levels in patients in whom such a target cannot be safely and reasonably easily achieved. Severe or frequent hypoglycemia is an absolute indication for the modification of treatment regimens, including setting higher glycomic goals. Many factors, including patient preferences, should be taken into account when developing a patient’s individualized goals (101).

Recommended glycomic goals for many nonpregnant adults are shown in Table 9. The recommendations are based on those for A1C values, with listed blood glucose levels that appear to correlate with achievement of an A1C of <7%.

The issue of pre- versus postprandial SMBG targets is complex (102). Elevated postchallenge (2-h OGTT) glucose values have been associated with increased cardiovascular risk independent of FPG in some epidemiological studies. In diabetic subjects, some surrogate measures of vascular pathology, such as endothelial dysfunction, are negatively affected by postprandial hyperglycemia (103). It is clear that postprandial hyperglycemia, like preprandial hyperglycemia, contributes to elevated A1C levels, with its relative contribution being higher at A1C levels that are closer to 7%. However, outcome studies have clearly shown A1C to be the primary predictor of complications, and landmark glycomic control trials such as the DCCT and UKPDS relied overwhelmingly on preprandial SMBG. Additionally, an RCT in patients with known CVD found no CVD benefit if insulin regimens targeting postprandial glucose compared with those targeting preprandial glucose (104). A reasonable recommendation for postprandial testing and targets is that for individuals who have premeal glucose values within target but have A1C values above target, monitoring postprandial plasma glucose (PPG) 1–2 h after the start of the meal and treatment aimed at reducing PPG values to <180 mg/dL may help lower A1C.

Glycomic goals for children are provided in Section VIII A.1a. As regards goals for glycomic control for women with GDM, recommendations from the Fifth International Workshop-Conference on Gestational Diabetes Mellitus (105) were to target maternal capillary glucose concentrations of:

- preprandial: ≤95 mg/dL (5.3 mmol/L), and either:
- 1-h postmeal: ≤140 mg/dL (7.8 mmol/L) or
- 2-h postmeal: ≤120 mg/dL (6.7 mmol/L)

For women with pre-existing type 1 or type 2 diabetes who become pregnant, a recent consensus statement (106) recommended the following as optimal glycomic goals, if they can be achieved without excessive hypoglycemia:

- premeal, bedtime, and overnight glucose 60–99 mg/dL (3.3–5.4 mmol/L)
- peak postprandial glucose 100–129 mg/dL (5.4–7.1 mmol/L)
- A1C <6.0%.

D. Pharmacological and overall approaches to treatment

1. Insulin therapy for type 1 diabetes

Recommendations

- Most people with type 1 diabetes should be treated with MDI injections (three to four injections per day of basal and prandial insulin) or continuous subcutaneous insulin infusion (CSII). (A)
- Most people with type 1 diabetes should be educated in how to match prandial insulin dose to carbohydrate intake, premeal blood glucose, and anticipated activity. (E)
- Most people with type 1 diabetes should use insulin analogs to reduce hypoglycemia risk. (A)
- Consider screening those with type 1 diabetes for other autoimmune diseases (thyroid, vitamin B12 deficiency, celiac) as appropriate. (B)

The DCCT clearly showed that intensive insulin therapy (three or more injections per day of insulin, CSII, or insulin pump therapy) was a key part of improved glycaemia and better outcomes (71,92). At the time of the study, therapy was carried out with short- and intermediate-acting human insulins. Despite better microvascular outcomes, intensive insulin therapy was associated with a high rate in severe hypoglycemia (62 episodes per 100 patient-years of therapy). Since the time of the DCCT, a number of rapid-acting and long-acting insulin analogs have been developed. These analogs are associated with less hypoglycemia with equal A1C lowering in type 1 diabetes (107,108).

Recommended therapy for type 1 diabetes consists of the following components:
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1) use of MDI injections (three to four injections per day of basal and prandial insulin) or CSII therapy; 2) matching of prandial insulin to carbohydrate intake, premeal blood glucose, and anticipated activity; and 3) for most patients (especially if hypoglycemia is a problem), use of insulin analogs. There are excellent reviews available that guide the initiation and management of insulin therapy to achieve desired glycemic goals (107,109,110). Although most studies of MDI versus pump therapy have been small and of short duration, a systematic review and meta-analysis concluded that there were no systematic differences in A1C or rates of severe hypoglycemia in children and adults between the two forms of intensive insulin therapy (70).

Because of the increased frequency of other autoimmune diseases in type 1 diabetes, screening for thyroid dysfunction, vitamin B12 deficiency, or celiac disease should be considered based on signs and symptoms. Periodic screening in absence of symptoms has been recommended, but the effectiveness and optimal frequency are unclear.

2. Pharmacological therapy for hyperglycemia in type 2 diabetes

Recommendations

- Metformin, if not contraindicated and if tolerated, is the preferred initial pharmacological agent for type 2 diabetes (A).
- In newly diagnosed type 2 diabetic patients with markedly symptomatic and/or elevated blood glucose levels or A1C, consider insulin therapy, with or without additional agents, from the outset. (E)
- If noninsulin monotherapy at maximal tolerated dose does not achieve or maintain the A1C target over 3–6 months, add a second oral agent, a glucagon-like peptide-1 (GLP-1) receptor agonist, or insulin. (A)
- A patient-centered approach should be used to guide choice of pharmacological agents. Considerations include efficacy, cost, potential side effects, effects on weight, comorbidities, hypoglycemia risk, and patient preferences. (E)
- Due to the progressive nature of type 2 diabetes, insulin therapy is eventually indicated for many patients with type 2 diabetes. (B)

The ADA and EASD have recently partnered on guidance for individualization of use of medication classes and combinations in patients with type 2 diabetes (111). This 2012 position statement is less prescriptive than prior algorithms and discusses advantages and disadvantages of the available medication classes and considerations for their use. A patient-centered approach is stressed, taking into account patient preferences, cost and potential side effects of each class, effects on body weight, and hypoglycemia risk. The position statement reaffirms metformin as the preferred initial agent, barring contraindication or intolerance, either in addition to lifestyle counseling and support for weight loss and exercise, or when lifestyle efforts alone have not achieved or maintained glycemic goals. Metformin has a long-standing evidence base for efficacy and safety, is inexpensive, and may reduce risk of cardiovascular events (85). When metformin fails to achieve or maintain glycemic goals, another agent should be added. Although there are a number of trials comparing dual therapy to metformin alone, few directly compare drugs as add-on therapy. Comparative effectiveness meta-analyses (112) suggest that overall each new class of noninsulin agents added to initial therapy lowers A1C around 0.9–1.1%.

Many patients with type 2 diabetes eventually benefit from insulin therapy. The progressive nature of type 2 diabetes and its therapies should regularly be explained in a matter-of-fact manner to patients, avoiding using insulin as a threat or describing it as a failure or punishment. Providing patients with an algorithm for self-titration of insulin doses based on SMBG results improves glycemic control in type 2 diabetic patients initiating insulin (113). For more details on pharmacotherapy for hyperglycemia in type 2 diabetes, including a table of information about currently approved classes of medications for treating hyperglycemia in type 2 diabetes, readers are referred to the ADA-EASD position statement (111).

E. MNT

General recommendations

- Individuals who have prediabetes or diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of diabetes MNT. (A)
- Because MNT can result in cost-savings and improved outcomes (B), MNT should be adequately covered by insurance and other payers. (E)

Energy balance, overweight, and obesity

- Weight loss is recommended for all overweight or obese individuals who have or are at risk for diabetes. (A)
- For weight loss, either low-carbohydrate, low-fat calorie-restricted, or Mediterranean diets may be effective in the short-term (up to 2 years). (A)
- For patients on low-carbohydrate diets, monitor lipid profiles, renal function, and protein intake (in those with nephropathy) and adjust hypoglycemic therapy as needed. (E)
- Physical activity and behavior modification are important components of weight loss programs and are most helpful in maintenance of weight loss. (B)

Recommendations for primary prevention of type 2 diabetes

- Among individuals at high risk for developing type 2 diabetes, structured programs that emphasize lifestyle changes that include moderate weight loss (7% body weight) and regular physical activity (150 min/week), with dietary strategies including reduced calories and reduced intake of dietary fat, can reduce the risk for developing diabetes and are therefore recommended. (A)
- Individuals at risk for type 2 diabetes should be encouraged to achieve the U.S. Department of Agriculture (USDA) recommendation for dietary fiber (14 g fiber/1,000 kcal) and foods containing whole grains (one-half of grain intake). (B)
- Individuals at risk for type 2 diabetes should be encouraged to limit their intake of sugar-sweetened beverages (SSBs). (B)

Recommendations for management of diabetes

Macronutrients in diabetes management

- The mix of carbohydrate, protein, and fat may be adjusted to meet the metabolic goals and individual preferences of the person with diabetes. (C)
- Monitoring carbohydrate, whether by carbohydrate counting, choices, or experience-based estimation, remains a key strategy in achieving glycemic control. (B)
- Saturated fat intake should be <7% of total calories. (B)
- Reducing intake of trans fat lowers LDL cholesterol and increases HDL cholesterol (A), therefore, intake of trans fat should be minimized. (E)
Other nutrition recommendations

- If adults with diabetes choose to use alcohol, they should limit intake to a moderate amount (one drink per day or less for adult women and two drinks per day or less for adult men) and should take extra precautions to prevent hypoglycemia. (E)
- Routine supplementation with antioxidants, such as vitamins E and C and carotene, is not advised because of lack of evidence of efficacy and concern related to long-term safety. (A)
- It is recommended that individualized meal planning include optimization of food choices to meet recommended dietary allowance (RDA)/dietary reference intake (DRI) for all micronutrients. (E)

MNT is an integral component of diabetes prevention, management, and self-management education. In addition to its role in preventing and controlling diabetes, the ADA recognizes the importance of nutrition as an essential component of an overall healthy lifestyle. A full review of the evidence regarding nutrition in preventing and controlling diabetes and its complications and additional nutrition-related recommendations can be found in the ADA position statement “Nutrition Recommendations and Interventions for Diabetes” (114), which is being updated as of 2013. Achieving nutrition-related goals requires a coordinated team effort that includes the active involvement of the person with prediabetes or diabetes. Because of the complexity of nutrition issues, it is recommended that a registered diettian who is knowledgeable and skilled in implementing nutrition therapy into diabetes management and education be the team member who provides MNT.

Clinical trials/outcome studies of MNT have reported decreases in A1C at 3–6 months ranging from 0.25 to 2.9% with higher reductions seen in type 2 diabetes of shorter duration. Multiple studies have demonstrated sustained improvements in A1C at 12 months and longer when a registered diettian provided follow-up visits ranging from monthly to 3 sessions per year (115–122). Studies in nondiabetic individuals suggest that MNT reduces LDL cholesterol by 15–25 mg/dL up to 16% (123) and support a role for lifestyle modification in treating hypertension (123,124).

Although the importance of weight loss for overweight and obese individuals is well documented, an optimal macronutrient distribution and dietary pattern of weight loss diets has not been established. A systematic review of 80 weight loss studies of ≥1-year duration demonstrated that moderate weight loss achieved through diet alone, diet and exercise, and meal replacements can be achieved and maintained (4.8–8% weight loss at 12 months) (125). Both low-fat low-carbohydrate and Mediterranean style eating patterns have been shown to promote weight loss with similar results after 1 to 2 years of follow-up (126–129). A meta-analysis showed that at 6 months, low-carbohydrate diets were associated with greater improvements in triglyceride and HDL cholesterol concentrations than low-fat diets; however, LDL cholesterol was significantly higher on the low-carbohydrate diets (130).

Because of the effects of obesity on insulin resistance, weight loss is an important therapeutic objective for overweight or obese individuals who are at risk for diabetes (131). The multifactorial intensive lifestyle intervention used in the DPP, which included reduced intake of fat and calories, led to weight loss averaging 7% at 6 months and maintenance of 3% weight loss at 3 years, associated with a 58% reduction in incidence of type 2 diabetes (23). An RCT looking at high-risk individuals in Spain showed that the Mediterranean dietary pattern reduced the incidence of diabetes in the absence of weight loss by 52% compared with the low-fat control group (132).

Although our society abounds with examples of high-calorie nutrient-poor foods, large increases in the consumption of SSFs have coincided with the epidemics of obesity and type 2 diabetes. In a meta-analysis of eight prospective cohort studies (n = 310,819), a diet high in consumption of SSFs was associated with the development of type 2 diabetes (n = 15,043). Individuals in the highest versus lowest quartile of SSB intake had a 26% greater risk of developing diabetes (133).

For individuals with type 2 diabetes, studies have demonstrated that moderate weight loss (5% of body weight) is associated with decreased insulin resistance, improved measures of glycemia and lipemia, and reduced blood pressure (134); longer-term studies (≥52 weeks) showed mixed effects on A1C in adults with type 2 diabetes (135–137), and in some studies results were confounded by pharmacological weight loss therapy. Look AHEAD (Action for Health in Diabetes) is a large clinical trial designed to determine whether long-term weight loss will improve glycemia and prevent cardiovascular events in subjects with type 2 diabetes. One-year results of the intensive lifestyle intervention in this trial show an average 8.6% weight loss, significant reduction of A1C, and reduction in several CVD risk factors (138), with benefits sustained at 4 years (139). At the time this article was going to press, the Look AHEAD trial was halted early, after 11 years of follow-up, because there was no significant difference in the primary cardiovascular outcome between the weight loss and standard care group (http://www.nih.gov/news/health/oct2012/niddk-19.htm). Multiple cardiovascular risk factors were improved with weight loss, and those participants on average were on fewer medications to achieve these improvements.

Although numerous studies have attempted to identify the optimal mix of macronutrients for meal plans of people with diabetes, a recent systematic review (140) confirms that there is no most effective mix that applies broadly, and that macronutrient proportions should be individualized. It must be clearly recognized that regardless of the macronutrient mix, total caloric intake must be appropriate to weight management goal. Further, individualization of the macronutrient composition will depend on the metabolic status of the patient (e.g., lipid profile, renal function) and/or food preferences. A variety of dietary meal patterns are likely effective in managing diabetes including Mediterranean-style, plant-based (vegan or vegetarian), low-fat and lower-carbohydrate eating patterns (127,141–143).

It should be noted that the RDA for digestible carbohydrate is 130 g/day and is based on providing adequate glucose as the required fuel for the central nervous system without reliance on glucose production from ingested protein or fat. Although brain fuel needs can be met on lower carbohydrate diets, long-term metabolic effects of very low-carbohydrate diets are unclear and such diets eliminate many foods that are important sources of energy, fiber, vitamins, and minerals and are important in dietary palatability (144).

Saturated and trans fatty acids are the principal dietary determinants of plasma LDL cholesterol. There is a lack of evidence on the effects of specific fatty acids on people with diabetes, so the recommended goals are consistent with those for individuals with CVD (123,145).

Reimbursement for MNT
MNT, when delivered by a registered diettian according to nutrition practice guidelines, is reimbursed as part of the
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Medicare program as overseen by the Centers for Medicare and Medicaid Services (CMS), as well as many health insurance plans.

F. Diabetes self-management education and support

Recommendations

- People with diabetes should receive Diabetes Self-Management Education and Support (DSME) according to National Standards for Diabetes Self-Management Education and Support when their diabetes is diagnosed and as needed thereafter. (B)
- Effective self-management and quality of life are the key outcomes of DSME and DSMS and should be measured and monitored as part of care. (C)
- DSME and DSMS should address psychosocial issues, since emotional well-being is associated with positive diabetes outcomes. (C)
- DSME and DSMS programs are appropriate venues for people with prediabetes to receive education and support to develop and maintain behaviors that can prevent or delay the onset of diabetes. (C)
- Because DSME and DSMS can result in cost-savings and improved outcomes (B), DSME and DSMS should be adequately reimbursed by third-party payers. (E)

Current best practice of DSME is a skill-based approach that focuses on helping those with diabetes make informed self-management choices. DSME has changed from a didactic approach focusing on providing information to more theoretically based empowerment models that focus on helping those with diabetes make informed self-management decisions. Care of diabetes has shifted to an approach that is more patient centered and places the person with diabetes and his or her family at the center of the care model working in collaboration with health care professionals. Patient-centered care is respectful of and responsive to individual patient preferences, needs, and values and ensures that patient values guide all decision making (154).

Evidence for the benefits of DSME and DSMS

Multiple studies have found that DSME is associated with improved diabetes knowledge and improved self-care behavior (146), improved clinical outcomes such as lower A1C (147, 148, 150, 151, 153–158), lower self-reported weight (146), improved quality of life (149, 156, 159), healthy coping (160), and lower costs (161). Better outcomes were reported for DSME interventions that were longer and included follow-up support (DSMS) (146, 162–165), that were culturally (166, 167) and age appropriate (168, 169) and were tailored to individual needs and preferences, and that addressed psychosocial issues and incorporated behavioral strategies (146, 150, 170, 171). Both individual and group approaches have been found effective (172, 173). There is growing evidence for the role of community health workers and peer health coaches (174–180) and lay leaders (181) in delivering DSME and DSMS in conjunction with the core team (182).

Diabetes education is associated with increased use of primary and preventive services (161, 183) and lower use of acute, inpatient hospital services (161). Patients who participate in diabetes education are more likely to follow best practice treatment recommendations, particularly among the Medicare population, and have lower Medicare and commercial claim costs (184, 185).

The National Standards for Diabetes Self-Management Education and Support

The National Standards for Diabetes Self-Management Education and Support are designed to define quality DSME and DSMS and to assist diabetes educators in a variety of settings to provide evidence-based education and self-management support (152). The standards, recently updated, are reviewed and updated every 5 years by a task force representing key organizations involved in the field of diabetes education and care.

DSME and DSMS providers and people with prediabetes

The new standards for DSME and DSMS also apply to the education and support of people with prediabetes. Currently, there are significant barriers to the provision of education and support to those with pre-diabetes. However, the strategies for supporting successful behavior change and the healthy behaviors recommended for people with prediabetes are largely identical to those for people with diabetes. As barriers to care are overcome, providers of DSME and DSMS, given their training and experience, are particularly well equipped to assist people with prediabetes in developing and maintaining behaviors that can prevent or delay the onset of diabetes (152, 186).

Reimbursement for DSME and DSMS

DSME, when provided by a program that meets national standards for DSME and is recognized by the ADA or other approval bodies, is reimbursed as part of the Medicare program as overseen by the CMS. DSME is also covered by most health insurance plans. Although DSMS has been shown to be instrumental for improving outcomes, as described in the “Evidence for the benefits of DSME and DSMS,” and can be provided in formats such as phone calls and via telehealth, it currently has limited reimbursement as face-to-face visits included as follow-up to DSME.

G. Physical activity

Recommendations

- Adults with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50–70% of maximum heart rate), spread over at least 3 days/week with no more than two consecutive days without exercise. (A)
- In the absence of contraindications, adults with type 2 diabetes should be encouraged to perform resistance training at least twice per week. (A)

Exercise is an important part of the diabetes management plan. Regular exercise has been shown to improve blood
glucose control, reduce cardiovascular risk factors, contribute to weight loss, and improve well-being. Furthermore, regular exercise may prevent type 2 diabetes in high-risk individuals (23–25). Structured exercise interventions of at least 8 weeks duration have been shown to lower A1C by an average of 0.66% in people with type 2 diabetes, even with no significant change in BMI (187). Higher levels of exercise intensity are associated with greater improvements in A1C and in fitness (188). A joint position statement of the ADA and the American College of Sports Medicine (ACSM) summarizes the evidence for the benefits of exercise in people with type 2 diabetes (189).

**Frequency and type of exercise**

The U.S. Department of Health and Human Services’ Physical Activity Guidelines for Americans (190) suggest that adults over age 18 years do 150 min/week of moderate-intensity, or 75 min/week of vigorous aerobic physical activity, or an equivalent combination of the two. In addition, the guidelines suggest that adults also do muscle-strengthening activities that involve all major muscle groups ≥2 days/week. The guidelines suggest that adults over age 65 years, or those with disabilities, follow the adult guidelines if possible or (if this is not possible) be as physically active as they are able. Studies included in the meta-analysis of effects of exercise interventions on glycemic control (187) had a mean number of sessions per week of 3.4, with a mean of 49 min per session. The DPP lifestyle intervention, which included 150 min/week of moderate-intensity exercise, had a beneficial effect on glycemia in those with prediabetes. Therefore, it seems reasonable to recommend that people with diabetes try to follow the physical activity guidelines for the general population.

Progressive resistance exercise improves insulin sensitivity in older men with type 2 diabetes to the same or even a greater extent as aerobic exercise (191). Clinical trials have provided strong evidence for the A1C lowering value of resistance training in older adults with type 2 diabetes (192,193) and for an additive benefit of combined aerobic and resistance exercise in adults with type 2 diabetes (194,195). In the absence of contraindications, patients with type 2 diabetes should be encouraged to do at least two weekly sessions of resistance exercise (exercise with free weights or weight machines), with each session consisting of at least one set of five or more different resistance exercises involving the large muscle groups (189).

**Evaluation of the diabetic patient before recommending an exercise program**

Prior guidelines suggested that before recommending a program of physical activity, the provider should assess patients with multiple cardiovascular risk factors for coronary artery disease (CAD). As discussed more fully in Section VI.A.5, the area of screening asymptomatic diabetic patients for CAD remains unclear, and a recent ADA consensus statement on this issue concluded that routine screening is not recommended (196). Providers should use clinical judgment in this area. Certainly, high-risk patients should be encouraged to start with short periods of low-intensity exercise and increase the intensity and duration slowly.

Providers should assess patients for conditions that might contraindicate certain types of exercise or predispose to injury, such as uncontrolled hypertension, severe autonomic neuropathy, severe peripheral neuropathy or history of foot lesions, and unstable proliferative retinopathy. The patient’s age and previous physical activity level should be considered.

**Exercise in the presence of nonoptimal glycemic control**

**Hyperglycemia.** When people with type 1 diabetes are deprived of insulin for 12–48 h and are ketogenic, exercise can worsen hyperglycemia and ketosis (197); therefore, vigorous activity should be avoided in the presence of ketosis. However, it is not necessary to postpone exercise based simply on hyperglycemia, provided the patient feels well and urine and/or blood ketones are negative.

**Hypoglycemia.** In individuals taking insulin and/or insulin secretagogues, physical activity can cause hypoglycemia if medication dose or carbohydrate consumption is not altered. For individuals on these therapies, added carbohydrate should be ingested if pre-exercise glucose levels are <100 mg/dL (5.6 mmol/L). Hypoglycemia is rare in diabetic individuals who are not treated with insulin or insulin secretagogues, and no preventive measures for hypoglycemia are usually advised in these cases.

**Exercise in the presence of specific long-term complications of diabetes**

**Retinopathy.** In the presence of proliferative diabetic retinopathy (PDR) or severe non-PDR (NPDR), vigorous aerobic or resistance exercise may be contraindicated because of the risk of triggering vitreous hemorrhage or retinal detachment (198).

**Peripheral neuropathy.** Decreased pain sensation in the extremities results in increased risk of skin breakdown and infection and of Charcot joint destruction. Prior recommendations have advised non–weight-bearing exercise for patients with severe peripheral neuropathy. However, studies have shown that moderate-intensity walking may not lead to increased risk of foot ulcers or ulceration in those with peripheral neuropathy (199). All individuals with peripheral neuropathy should wear proper footwear and examine their feet daily to detect lesions early. Anyone with a foot injury or open sore should be restricted to non–weight-bearing activities.

**Autonomic neuropathy.** Autonomic neuropathy can increase the risk of exercise-induced injury or adverse event through decreased cardiac responsiveness to exercise, postural hypotension, impaired thermoregulation, impaired night vision due to impaired papillary reaction, and unpredictable carbohydrate delivery from gastroparesis predisposing to hypoglycemia (200). Autonomic neuropathy is also strongly associated with CVD in people with diabetes (201,202). People with diabetic autonomic neuropathy should undergo cardiac investigation before beginning physical activity more intense than that to which they are accustomed.

**Albuminuria and nephropathy.** Physical activity can acutely increase urinary protein excretion. However, there is no evidence that vigorous exercise increases the rate of progression of diabetic kidney disease, and there is likely no need for any specific exercise restrictions for people with diabetic kidney disease (203).

**H. Psychosocial assessment and care Recommendations**

- It is reasonable to include assessment of the patient’s psychological and social situation as an ongoing part of the medical management of diabetes. (E)
- Psychosocial screening and follow-up may include, but is not limited to, attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, resources (financial, social, and emotional), and psychiatric history. (E)
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- Screen for psychosocial problems such as depression and diabetes-related distress, anxiety, eating disorders, and cognitive impairment when self-management is poor. (B)

It is important to establish that emotional well-being is part of diabetes care and self-management. Psychological and social problems can impair the individual’s (204–207) or family’s ability to carry out diabetes care tasks and therefore compromise health status. There are opportunities for the clinician to assess psychosocial status in a timely and efficient manner so that referral for appropriate services can be accomplished. A systematic review and meta-analysis showed that psychosocial interventions modestly but significantly improved A1C (standardized mean difference –0.29%) and mental health outcomes. However, there was a limited association between the effects on A1C and mental health, and no intervention characteristics predicted benefit on both outcomes (208).

Key opportunities for screening of psychosocial status occur at diagnosis, during regularly scheduled management visits, during hospitalizations, at discovery of complications, or when problems with glucose control, quality of life, or adherence are identified. Patients are likely to exhibit psychological vulnerability at diagnosis and when their medical status changes (e.g., the end of the honeymoon period), when the need for intensified treatment is evident, and when complications are discovered (206).

Depression affects about 20–25% of people with diabetes (207) and increases the risk for MI and post-MI (209,210) and all-cause (211) mortality. Other issues known to impact self-management and health outcomes include but are not limited to attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, diabetes-related distress (212,213), resources (financial, social, and emotional) (214), and psychiatric history (215–217). Screening tools are available for a number of these areas (170). Indications for referral to a mental health specialist familiar with diabetes management may include gross disregard for the medical regimen (by self or others) (217), depression, possibility of self-harm, debilitating anxiety (alone or with depression), indications of an eating disorder (218), or cognitive functioning that significantly impairs judgment. It is preferable to incorporate psychological assessment and treatment into routine care rather than waiting for identification of a specific problem or deterioration in psychological status (170). Although the clinician may not feel qualified to treat psychological problems (219), utilizing the patient-provider relationship as a foundation can increase the likelihood that the patient will accept referral for other services. Collaborative care interventions and using a team approach have demonstrated efficacy in diabetes and depression (220,221).

I. When treatment goals are not met

For a variety of reasons, some people with diabetes and their health care providers do not achieve the desired goals of treatment (Table 9). Rethinking the treatment regimen may require assessment of barriers including income, health literacy, diabetes distress, depression, and competing demands, including those related to family responsibilities and dynamics. Other strategies may include culturally appropriate and enhanced DSME and DSMS, co-management with a diabetes team, referral to a medical social worker for assistance with insurance coverage, or change in pharmacological therapy. Initiation of or increase in SMBG, utilization of CGM, frequent contact with the patient, or referral to a mental health professional or physician with special expertise in diabetes may be useful.

J. Intercurrent illness

The stress of illness, trauma, and/or surgery frequently aggravates glycemic control and may precipitate diabetic ketoacidosis (DKA) or nonketotic hyperosmolar state—life-threatening conditions that require immediate medical care to prevent complications and death. Any condition leading to deterioration in glycemic control necessitates more frequent monitoring of blood glucose and (in ketosis-prone patients) urine or blood ketones. Marked hyperglycemia requires temporary adjustment of the treatment program and, if accompanied by ketosis, vomiting, or alteration in level of consciousness, immediate interaction with the diabetes care team. The patient treated with noninsulin therapies or MNT alone may temporarily require insulin. Adequate fluid and caloric intake must be assured. Infection or dehydration is more likely to necessitate hospitalization of the person with diabetes than the person without diabetes.

The hospitalized patient should be treated by a physician with expertise in the management of diabetes. For further information on management of patients with hyperglycemia in the hospital, see Section IX.A. For further information on management of diabetes and their health care providers do not achieve the desired goals of treatment (Table 9). Rethinking the treatment regimen may require assessment of barriers including income, health literacy, diabetes distress, depression, and competing demands, including those related to family responsibilities and dynamics. Other strategies may include culturally appropriate and enhanced DSME and DSMS, co-management with a diabetes team, referral to a medical social worker for assistance with insurance coverage, or change in pharmacological therapy. Initiation of or increase in SMBG, utilization of CGM, frequent contact with the patient, or referral to a mental health professional or physician with special expertise in diabetes may be useful.

K. Hypoglycemia

Recommendations

- Individuals at risk for hypoglycemia should be asked about symptomatic and asymptomatic hypoglycemia at each encounter. (C)
- Glucose (15–20 g) is the preferred treatment for the conscious individual with hypoglycemia, although any form of carbohydrate that contains glucose may be used. If SMBG 15 min after treatment shows continued hypoglycemia, the treatment should be repeated. Once SMBG glucose returns to normal, the individual should consume a meal or snack to prevent recurrence of hypoglycemia (E).
- Glucagon should be prescribed for all individuals at significant risk of severe hypoglycemia, and caregivers or family members of these individuals should be instructed on its administration. Glucagon administration is not limited to health care professionals. (E)
- Hypoglycemia unawareness or one or more episodes of severe hypoglycemia should trigger re-evaluation of the treatment regimen. (E)
- Insulin-treated patients with hypoglycemia unawareness or an episode of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks, to partially reverse hypoglycemia unawareness, and to reduce risk of future episodes. (A)
- Ongoing assessment of cognitive function is suggested with increased vigilance for hypoglycemia by the clinician, patient, and caregivers if low cognition and/or declining cognition is found. (B)

Hypoglycemia is the leading limiting factor in the glycemic management of type 1 and insulin-treated type 2 diabetes (223). Mild hypoglycemia may be inconvenient or frightening to patients with diabetes, and more severe hypoglycemia can cause acute harm to the person with diabetes or others, if it causes falls, motor vehicle accidents, or loss of consciousness.
Oral carbohydrate due to confusion or individual requires the assistance of an...

...glicemia unless further food is ingested.

Ongoing activity of insulin or insulin secretion with hypoglycemia (225). Evidence from the DCCT/EDIC trial, which involved younger adults and adolescents with type 1 diabetes, suggested no association of frequency of severe hypoglycemia with cognitive decline (226). As discussed in the Section VIII A.1.a, a few studies have suggested that severe hypoglycemia in very young children is associated with mild impairments in cognitive function.

As described in the Section V.b.2, severe hypoglycemia was associated with mortality in participants in both the standard and intensive glycemia arms of the ACCORD trial, but the relationships with achieved A1C and treatment intensity were not straightforward. An association of severe hypoglycemia with mortality was also found in the ADVANCE trial (227), but its association with other outcomes such as pulmonary and skin disorders raises the question of whether severe hypoglycemia is a marker for a sicker patient, rather than a cause of mortality. An association of self-reported severe hypoglycemia with 5-year mortality has also been reported in clinical practice (228). At the time this statement went to press, the ADA and The Endocrine Society were finalizing a Hypoglycemia Work Group report, where the causes of and associations with hypoglycemia are discussed in depth.

Treatment of hypoglycemia (plasma glucose <70 mg/dL) requires ingestion of glucose- or carbohydrate-containing foods. The acute glycemic response correlates better with the glucose content than with the carbohydrate content of the food. Although pure glucose is the preferred treatment, any form of carbohydrate that contains glucose will raise blood glucose. Added fat may retard and then prolong the acute glycemic response. Ongoing activity of insulin or insulin secretagogues may lead to recurrence of hypoglycemia unless further food is ingested after recovery.

Severe hypoglycemia (where the individual requires the assistance of another person and cannot be treated with oral carbohydrate due to confusion or unconsciousness) should be treated using emergency glucagon kits, which require a prescription. Those in close contact with, or having custodial care of, people with hypoglycemia-prone diabetes (family members, roommates, school personnel, child care providers, correctional institution staff, or coworkers) should be instructed in use of such kits. An individual does not need to be a health care professional to safely administer glucagon. Care should be taken to ensure that unexpired glucagon kits are available.

Prevention of hypoglycemia is a critical component of diabetes management. Particularly for insulin-treated patients, SMBG and, for some patients, CGM to detect incipient hypoglycemia and assess adequacy of treatment are a key component of safe therapy. Patients should understand situations that increase their risk of hypoglycemia, such as when fasting for tests or procedures, during or after intense exercise, and during sleep and that increase the risk of harm to self or others from hypoglycemia, such as with driving. Teaching people with diabetes to balance insulin use, carbohydrate intake, and exercise is a necessary but not always sufficient strategy for prevention. In type 1 diabetes and severely insulin-deficient type 2 diabetes, the syndrome of hypoglycemia unawareness, or hypoglycemia-associated autonomic failure, can severely compromise stringent diabetes control and quality of life. The deficient counter-regulatory hormone release and autonomic responses in this syndrome are both risk factors for, and caused by, hypoglycemia. A corollary to this “vicious cycle” is that several weeks of avoidance of hypoglycemia has been demonstrated to improve counter-regulation and awareness to some extent in many patients (229). Hence, patients with one or more episodes of severe hypoglycemia may benefit from at least short-term relaxation of glycemic targets.

**L. Bariatric surgery**

**Recommendations**

- Bariatric surgery may be considered for adults with BMI ≥35 kg/m^2^ and type 2 diabetes, especially if the diabetes or associated comorbidities are difficult to control with lifestyle and pharmacological therapy. (B)
- Patients with type 2 diabetes who have undergone bariatric surgery need lifelong lifestyle support and medical monitoring. (B)
- Although small trials have shown glycemic benefit of bariatric surgery in patients with type 2 diabetes and BMI 30–35 kg/m^2^, there is currently insufficient evidence to generally recommend surgery in patients with BMI <35 kg/m^2^ outside of a research protocol. (E)
- The long-term benefits, cost-effectiveness, and risks of bariatric surgery in individuals with type 2 diabetes should be studied in well-designed controlled trials with optimal medical and lifestyle therapy as the comparator. (E)

Gastric reduction surgery, either gastric banding or procedures that involve bypassing, transposing, or resecting sections of the small intestine, when part of a comprehensive team approach, can be an effective weight loss treatment for severe obesity, and national guidelines support its consideration for people with type 2 diabetes who have BMI of 33 kg/m^2^ or greater. Bariatric surgery has been shown to lead to near- or complete normalization of glycemia in ~40–95% of patients with type 2 diabetes, depending on the study and the surgical procedure (230–232). A meta-analysis of studies of bariatric surgery involving 3,188 patients with diabetes reported that 78% had remission of diabetes (normalization of blood glucose levels in the absence of medications) and that the remission rates were sustained in studies that had follow-up exceeding 2 years (233). Remission rates tend to be lower with procedures that only constrict the stomach and higher with those that bypass portions of the small intestine. Additionally, there is a suggestion that intestinal bypass procedures may have glycemic effects that are independent of their effects on weight, perhaps involving the incretin axis.

There is also evidence for diabetes remission in subjects who are less obese. One randomized trial compared adjustable gastric banding to “best available” medical and lifestyle therapy in subjects with type 2 diabetes and BMI 30–40 kg/m^2^ (234). Overall, 73% of surgically treated patients achieved “remission” of their diabetes compared with 13% of those treated medically. The latter group lost only 1.7% of body weight, suggesting that their therapy was not optimal. Overall the trial had 60 subjects, and only 13 had a BMI under 35 kg/m^2^, making it difficult to generalize these results widely to diabetic patients who are less severely obese or with longer duration of diabetes.
In a recent nonrandomized study of 66 people with BMI of 30–35 kg/m², 88% of participants had remission of their type 2 diabetes up to 6 years after surgery (235).

Bariatric surgery is costly in the short-term and has some risks. Rates of morbidity and mortality directly related to the surgery have been reduced considerably in recent years, with 30-day mortality rates now 0.28%, similar to those of laparoscopic cholecystectomy (236). Longer-term concerns include vitamin and mineral deficiencies, osteoporosis, and rare but often severe hypoglycemia from insulin hypersecretion. Cohort studies attempting to match subjects suggest that the procedure may reduce longer-term mortality rates (237). Recent retrospective analyses and modeling studies suggest that these procedures may be cost-effective, when one considers reduction in subsequent health care costs (238–240).

Some caution about the benefits of bariatric surgery might come from recent studies. Propensity score–adjusted analyses of older severely obese patients with high baseline mortality in Veterans Affairs Medical Centers found that the use of bariatric surgery was not associated with decreased mortality compared with usual care during a mean 6.7 years of follow-up (241). A study that followed patients who had undergone laparoscopic adjustable gastric banding (LAGB) for 12 years found that 60% were satisfied with the procedure. Nearly one out of three patients experienced band erosion, and almost half required removal of their bands. The authors’ conclusion was that “LAGB appears to result in relatively poor long-term outcomes” (242). Studies of the mechanisms of glycemie improvement and long-term benefits and risks of bariatric surgery in individuals with type 2 diabetes, especially those who are not severely obese, will require well-designed clinical trials, with optimal medical and lifestyle therapy of diabetes and cardiovascular risk factors as the comparator.

M. Immunization

Recommendations

- Annually provide an influenza vaccine to all diabetic patients ≥6 months of age. (C)
- Administer pneumococcal polysaccharide vaccine to all diabetic patients ≥2 years of age. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered ≥5 years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states, such as after transplantation. (C)
- Administer hepatitis B vaccination to unvaccinated adults with diabetes who are aged 19 through 59 years. (C)
- Consider administering hepatitis B vaccination to unvaccinated adults with diabetes who are aged ≥60 years. (C)

Influenza and pneumonia are common, preventable infectious diseases associated with high mortality and morbidity in the elderly and in people with chronic diseases. Though there are limited studies reporting the morbidity and mortality of influenza and pneumococcal pneumonia specifically in people with diabetes, observational studies of patients with a variety of chronic illnesses, including diabetes, show that these conditions are associated with an increase in hospitalizations for influenza and its complications. People with diabetes may be at increased risk of the bacteremic form of pneumococcal infection and have been reported to have a high risk of nosocomial bacteremia, which has a mortality rate as high as 50% (243).

Safe and effective vaccines are available that can greatly reduce the risk of serious complications from these diseases (244,245). In a case-control series, influenza vaccine was shown to reduce diabetes-related hospital admission by as much as 79% during flu epidemics (244). There is sufficient evidence to support that people with diabetes have appropriate serological and clinical responses to these vaccinations. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices recommends influenza and pneumococcal vaccines for all individuals with diabetes (http://www.cdc.gov/vaccines/recs/).

Late in 2012, the Advisory Committee on Immunization Practices of the CDC recommended that all previously unvaccinated adults with diabetes aged 19 through 59 years be vaccinated against hepatitis B virus (HBV) as soon as possible after a diagnosis of diabetes is made and that vaccination be considered for those aged ≥60 years, after assessing risk and likelihood of an adequate immune response (246). At least 29 outbreaks of HBV in long-term care facilities and hospitals have been reported to the CDC, with the majority involving adults with diabetes receiving “assisted blood glucose monitoring,” in which such monitoring is done by a health care professional with responsibility for more than one patient. HBV is highly transmissible and stable for long periods of time on surfaces such as fencing devices and blood glucose meters, even when no blood is visible. Blood sufficient to transmit the virus has also been found in the reservoirs of insulin pens, resulting in warnings against sharing such devices between patients.

The CDC analyses suggest that, excluding persons with HBV-related risk behaviors, acute HBV infection is about twice as high among adults with diabetes aged ≥23 years compared with adults without diabetes. Seroprevalence of antibody to HBV core antigen, suggesting past or current infection, is 60% higher among adults with diabetes than those without, and there is some evidence that diabetes imparts a higher HBV case fatality rate. The age differentiation in the recommendations stems from CDC economic models suggesting that vaccination of adults with diabetes who were aged 20–59 years would cost an estimated $75,000 per quality-adjusted life-year saved, while cost per quality-adjusted life-year saved increased significantly at higher ages. In addition to competing causes of mortality in older adults, the immune response to the vaccine declines with age (246).

These new recommendations regarding HBV vaccinations serve as a reminder to clinicians that children and adults with diabetes need a number of vaccinations, both those specifically indicated because of diabetes as well as those recommended for the general population (http://www.cdc.gov/vaccines/recs/).

VI. PREVENTION AND MANAGEMENT OF DIABETES COMPLICATIONS

A. CVD

CVD is the major cause of morbidity and mortality for individuals with diabetes and the largest contributor to the direct and indirect costs of diabetes. The common conditions coexisting with type 2 diabetes (e.g., hypertension and dyslipidemia) are clear risk factors for CVD, and diabetes itself confers independent risk. Numerous studies have shown the efficacy of controlling individual cardiovascular risk factors in preventing or slowing CVD in
people with diabetes. Large benefits are seen when multiple risk factors are addressed globally (247,248). There is evidence that measures of 10-year coronary heart disease (CHD) risk among U.S. adults with diabetes have improved significantly over the past decade (249).

1. Hypertension/blood pressure control

Recommendations

Screening and diagnosis

- Blood pressure should be measured at every routine visit. Patients found to have elevated blood pressure should have blood pressure confirmed on a separate day. (B)

Goals

- People with diabetes and hypertension should be treated to a systolic blood pressure goal of <140 mmHg. (B)
- Lower systolic targets, such as <130 mmHg, may be appropriate for certain individuals, such as younger patients, if it can be achieved without undue treatment burden. (C)
- Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg. (B)

Treatment

- Patients with a blood pressure >120/80 mmHg should be advised on lifestyle changes to reduce blood pressure. (B)
- Patients with confirmed blood pressure ≥140/80 mmHg should, in addition to lifestyle therapy, have prompt initiation and timely subsequent titration of pharmacological therapy to achieve blood pressure goals. (B)
- Lifestyle therapy for elevated blood pressure consists of weight loss, if overweight. Dietary Approaches to Stop Hypertension (DASH)-style dietary pattern including reducing sodium and increasing potassium intake; moderation of alcohol intake; and increased physical activity. (B)
- Pharmacological therapy for patients with diabetes and hypertension should be with a regimen that includes either an ACE inhibitor or an angiotensin receptor blocker (ARB). If one class is not tolerated, the other should be substituted. (C)
- Multiple-drug therapy (two or more agents at maximal doses) is generally required to achieve blood pressure targets. (B)
- Administer one or more antihypertensive medications at bedtime. (A)
- If ACE inhibitors, ARBs, or diuretics are used, serum creatinine/estimated glomerular filtration rate (eGFR) and serum potassium levels should be monitored. (E)
- In pregnant patients with diabetes and chronic hypertension, blood pressure target goals of 110–129/65–79 mmHg are suggested in the interest of long-term maternal health and minimizing impaired fetal growth. ACE inhibitors and ARBs are contraindicated during pregnancy. (E)

Hypertension is a common comorbidity of diabetes, affecting the majority of patients, with prevalence depending on type of diabetes, age, obesity, and ethnicity. Hypertension is a major risk factor for both CVD and microvascular complications. In type 1 diabetes, hypertension is often the result of underlying nephropathy, while in type 2 diabetes it usually coexists with other cardiometabolic risk factors.

Screening and diagnosis

Measurement of blood pressure in the office should be done by a trained individual and follow the guidelines established for nondiabetic individuals: measurement in the seated position, with feet on the floor and arm supported at heart level, after 5 min of rest. Cuff size should be appropriate for the upper arm circumference. Elevated values should be confirmed on a separate day.

Home blood pressure self-monitoring and 24-h ambulatory blood pressure monitoring may provide additional evidence of "white coat" and masked hypertension and other discrepancies between office and "true" blood pressure. Studies in nondiabetic populations found that home measurements may better correlate with CVD risk than office measurements (250,251). However, the preponderance of the evidence of benefits of treatment of hypertension in people with diabetes is based on office measurements.

Treatment goals

Epidemiological analyses show that blood pressure >115/75 mmHg is associated with increased cardiovascular event rates and mortality in individuals with diabetes (252–254) and that systolic blood pressure above 120 mmHg predicts long-term end-stage renal disease (ESRD). Randomized clinical trials have demonstrated the benefit (reduction of CHD events, stroke, and nephropathy) of lowering blood pressure to <140 mmHg systolic and <80 mmHg diastolic in individuals with diabetes (252,255–257). The evidence for benefits from lower systolic blood pressure targets is, however, limited.

The ACCORD trial examined whether blood pressure lowering to systolic blood pressure <120 mmHg provides greater cardiovascular protection than a systolic blood pressure level of 130–140 mmHg in patients with type 2 diabetes at high risk for CVD (258). The blood pressure achieved in the intensive group was 119/64 mmHg and in the standard group 133/70 mmHg; the goals were attained with an average of 3.4 medications per participant in the intensive group and 2.1 in the standard therapy group. The hazard ratio for the primary end point (nonfatal MI, nonfatal stroke, and CVD death) in the intensive group was 0.88 (95% CI 0.73–1.06, P = 0.20). Of the prespecified secondary end points, only stroke and nonfatal stroke were statistically significantly reduced by intensive blood pressure treatment, with a hazard ratio of 0.99 (95% CI 0.99–0.99, P = 0.01) and 0.63 (95% CI 0.41–0.96, P = 0.03), respectively. Absolute stroke event rates were low; the number needed to treat to prevent one stroke over the course of 5 years with intensive blood pressure management is 89. Serious adverse event rates (including syncope and hyperkalemia) were higher with intensive targets (3.3% vs. 1.3%, P = 0.001). Rates of albuminuria were reduced with more intensive blood pressure goals, but there were no differences in renal function in this 5-year trial (and in fact more adverse events related to reduced eGFR with more intensive goals) nor in other microvascular complications.

Other recent randomized trial data include those of the ADVANCE trial in which treatment with an ACE inhibitor and a thiazide-type diuretic reduced the rate of death but not the composite macrovascular outcome. However, the ADVANCE trial had no specified targets for the randomized comparison, and the mean systolic blood pressure in the intensive group (135 mmHg) was not as low as the mean systolic blood pressure even in the ACCORD standard-therapy group (259). Post hoc analysis of achieved blood pressure in several hypertension treatment trials has suggested no benefit of lower achieved systolic blood pressure. As an example, among 6,400 patients with diabetes and CAD enrolled in one trial, “tight control” (achieved systolic
blood pressure <130 mmHg) was not associated with improved cardiovascular outcomes compared with “usual care” (achieved systolic blood pressure 130–140 mmHg) (260). Similar findings emerged from an analysis of another trial, but additionally those with achieved systolic blood pressure (<115 mmHg) had increased rates of CVD events (though lower rates of stroke) (261).

Observational data, including those derived from clinical trials, may be inappropriate to use for defining blood pressure targets since sicker patients may have low blood pressure or, conversely, healthier or more adherent patients may achieve goals more readily. A recent meta-analysis of randomized trials of adults with type 2 diabetes comparing prespecified blood pressure targets found no significant reduction in mortality or nonfatal MI. There was a statistically significant 35% relative reduction in stroke, but the absolute risk reduction was only 1% (262). Other outcomes, such as indicators of microvascular complications, were not examined. Another meta-analysis that included both trials comparing blood pressure goals and trials comparing treatment strategies concluded that a systolic treatment goal of 130–135 mmHg was acceptable. With goals <130 mmHg, there were greater reductions in stroke, a 10% reduction in mortality, but no reduction of other CVD events and increased rates of serious adverse events. Systolic blood pressure <130 mmHg was associated with reduced onset and progression of albuminuria. However, there was heterogeneity in the measure, rates of more advanced renal disease outcomes were not affected, and there were no significant changes in retinopathy or neuropathy (263).

This change in the “default” systolic blood pressure target is not meant to downplay the importance of treating hypertension in patients with diabetes or to imply that lower targets than <140 mmHg are generally inappropriate. The clear body of evidence that systolic blood pressure over 140 mmHg is harmful suggests that clinicians should promptly initiate and titrate therapy in an ongoing fashion to achieve and maintain systolic blood pressure below 140 mmHg in virtually all patients. Additionally, patients with long life expectancy (in whom there may be renal benefits from long-term stricter blood pressure control) or those in whom stroke risk is a concern might, as part of shared decision making, appropriately have lower systolic targets such as <130 mmHg. This would especially be the case if this can be achieved with fewer drugs and without side effects of therapy.

Treatment strategies
Although there are no well-controlled studies of diet and exercise in the treatment of elevated blood pressure or hypertension in individuals with diabetes, the DASH study in nondiabetic individuals has shown antihypertensive effects similar to pharmacological monotherapy. Lifestyle therapy consists of reducing sodium intake (to below 1,500 mg/day) and excess body weight, increasing consumption of fruits, vegetables (8–10 servings per day), and low-fat dairy products (2–3 servings per day); avoiding excessive alcohol consumption (no more than two servings per day for men and no more than one serving per day for women) (264); and increasing activity levels (252). These nonpharmacological strategies may also positively affect glycemia and lipid control and as a result should be encouraged in those with even mildly elevated blood pressure. Their effects on cardiovascular events have not been established. Nonpharmacological therapy is reasonable in diabetic individuals with mildly elevated blood pressure (systolic blood pressure >120 mmHg or diastolic blood pressure >80 mmHg). If the blood pressure is confirmed to be ≥140 mmHg systolic and/or ≥80 mmHg diastolic, pharmacological therapy should be initiated along with nonpharmacological therapy (252).

Lowering of blood pressure with regimens based on a variety of antihypertensive drugs, including ACE inhibitors, ARBs, β-blockers, diuretics, and calcium channel blockers, has been shown to be effective in reducing cardiovascular events. Several studies suggested that ACE inhibitors may be superior to dihydropyridine calcium channel blockers in reducing cardiovascular events (265–267). However, a variety of other studies have shown no specific advantage to ACE inhibitors as initial treatment of hypertension in the general hypertensive population, but rather an advantage on cardiovascular outcomes of initial therapy with low-dose thiazide diuretics (252,268,269).

In people with diabetes, inhibitors of the renin-angiotensin system (RAS) may have unique advantages for initial or early therapy of hypertension. In a nonhypertension trial of high-risk individuals, including a large subset with diabetes, an ACE inhibitor reduced CVD outcomes (270). In patients with congestive heart failure (CHF), including diabetic subgroups, ARBs have been shown to reduce major CVD outcomes (271–274), and in type 2 diabetic patients with significant nephropathy, ARBs were superior to calcium channel blockers for reducing heart failure (275). Though evidence for distinct advantages of RAS inhibitors on CVD outcomes in diabetes remains conflicting (255,269), the high CVD risks associated with diabetes, and the high prevalence of undiagnosed CVD, may still favor recommendations for their use as first-line hypertension therapy in people with diabetes (252).

Recently, the blood pressure arm of the ADVANCE trial demonstrated that routine administration of a fixed combination of the ACE inhibitor perindopril and the diuretic indapamide significantly reduced combined microvascular and macrovascular outcomes, as well as CVD and total mortality. The improved outcomes could also have been due to lower achieved blood pressure in the perindopril-indapamide arm (259). Another trial showed a decrease in morbidity and mortality in those receiving benazepril and amlodipine compared with benazepril and hydrochlorothiazide (HCTZ). The compelling benefits of RAS inhibitors in diabetic patients with albuminuria or renal insufficiency provide additional rationale for use of these agents (see Section VI B). If needed to achieve blood pressure targets, amlodipine, HCTZ, or chlorothalidone can be added. If eGFR is <30 mL/min/m², a loop diuretic rather than HCTZ or chlorothalidone should be prescribed. Titration of and/or addition of further blood pressure medications should be made in timely fashion to overcome clinical inertia in achieving blood pressure targets.

Evidence is emerging that health information technology can be used safely and effectively as a tool to enable attainment of blood pressure goals. Using a telemonitoring intervention to direct titrations of antihypertensive medications between medical office visits has been demonstrated to have a profound impact on systolic blood pressure control (276).

An important caveat is that most patients with hypertension require multiple-drug therapy to reach treatment goals (252). Identifying and addressing barriers to medication adherence (such as cost and side effects) should routinely
Treatment recommendations and goals

In adults with low-risk lipid values (LDL cholesterol <100 mg/dL, HDL cholesterol >50 mg/dL, and triglycerides <150 mg/dL), lipid assessments may be recommended every 2 years. (E)

Treatment recommendations and goals

- Lifestyle modification focusing on the reduction of saturated fat, trans fat, and cholesterol intake; increase of n-3 fatty acids, viscous fiber, and plant stanols/sterols; weight loss (if indicated); and increased physical activity should be recommended to improve the lipid profile in patients with diabetes. (A)
- Statin therapy should be added to lifestyle therapy, regardless of baseline lipid levels, for diabetic patients:
  - with overt CVD (A)
  - without CVD who are over the age of 40 years and have one or more other CVD risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria) (A)
  - For lower-risk patients than the above (e.g., without overt CVD and under the age of 40 years), statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains above 100 mg/dL or in those with multiple CVD risk factors. (C)
- In individuals without overt CVD, the goal is LDL cholesterol <100 mg/dL (2.6 mmol/L). (B)
- In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dL (1.8 mmol/L), using a high dose of a statin, is an option. (B)
- If drug-treated patients do not reach the above targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~30–40% from baseline is an alternative therapeutic goal. (B)
- Triglycerides levels <150 mg/dL (1.7 mmol/L) and HDL cholesterol >40 mg/dL (1.0 mmol/L) in men and >50 mg/dL (1.3 mmol/L) in women are desirable (C). However, LDL cholesterol–targeted statin therapy remains the preferred strategy. (A)
- Combination therapy has been shown not to provide additional cardiovascular benefit above statin therapy alone and is not generally recommended. (A)
- Statin therapy is contraindicated in pregnancy. (B)

Evidence for benefits of lipid-lowering therapy

Patients with type 2 diabetes have an increased prevalence of lipid abnormalities, contributing to their high risk of CVD. Multiple clinical trials demonstrated significant effects of pharmacological (primarily statin) therapy on CVD outcomes in subjects with diabetes (286,287) showed significant primary and secondary prevention of CVD events +/- CHD deaths in diabetic populations. Meta-analyses including data from over 18,000 patients with diabetes from 14 randomized trials of statin therapy, followed for a mean of 4.3 years, demonstrate a 9% proportional reduction in all-cause mortality and 13% reduction in vascular mortality, for each mmol/L reduction in LDL cholesterol (288). As is the case in non-diabetic individuals, absolute reductions in "hard" CVD outcomes (CHD death and nonfatal MI) are greatest in people with high baseline CVD risk (known CVD and/or very high LDL cholesterol levels), but overall the benefits of statin therapy in people with diabetes at moderate or high risk for CVD are convincing.

There is an increased risk of incident diabetes with statin use (289,290), which may be limited to those with risk factors for diabetes. These patients may benefit additionally from diabetes screening when on statin therapy. In an analysis of one of the initial studies suggesting that statins are linked to risk of diabetes, the cardiovascular event rate reduction with statins outweighed the risk of incident diabetes even for patients at highest risk for diabetes. The absolute risk increase was small (over 5 years of follow-up, 1.2% of participants on placebo developed diabetes and 1.5% on rosuvastatin) (291). The relative risk-benefit ratio favoring statins is further supported by meta-analysis of individual data of over 170,000 persons from 27 randomized trials. This demonstrated that individuals at low risk of vascular disease, including those undergoing primary prevention, received benefits from statins that included reductions in major vascular events and vascular death without increase in incidence of cancer or deaths from other causes (280).

Low levels of HDL cholesterol, often associated with elevated triglyceride levels, are the most prevalent pattern of dyslipidemia in persons with type 2 diabetes. However, the evidence base for drugs that target these lipid fractions is significantly less robust than that for statin therapy (292). Nicotinic acid has been shown to reduce CVD outcomes (293), although the study was done in a nondiabetic cohort. Gemfibrozil has been shown to decrease rates of CVD events in subjects without diabetes (294,295) and in the diabetic subgroup of one of the larger trials (294). However, in a large trial specific to diabetic patients, fenofibrate failed to reduce overall cardiovascular outcomes (296).

Combination therapy, with a statin and a fibrate or statin and niacin, may be efficacious for treatment for all three lipid fractions, but this combination is associated with an increased risk for abnormal transaminase levels, myositis, or rhabdomyolysis. The risk of rhabdomyolysis is higher with higher doses of statins and with renal insufficiency and seems to be lower when statins are combined with fenofibrate or gemfibrozil (297). In the ACCORD study, the combination of
Dyslipidemia treatment and target lipid levels

For most patients with diabetes, the first priority of dyslipidemia therapy (unless severe hypertriglyceridemia with risk of pancreatitis is the immediate issue) is to lower LDL cholesterol to a target goal of <100 mg/dL (2.60 mmol/L) (300). Lifestyle intervention, including MNT, increased physical activity, weight loss, and smoking cessation, may allow some patients to reach lipid goals. Nutrition intervention should be tailored according to each patient’s age, type of diabetes, pharmacological treatment, lipid levels, and other medical conditions and should focus on the reduction of saturated fat, cholesterol, and trans unsaturated fat intake and increases in n-3 fatty acids, viscous fiber (such as in oats, legumes, citrus), and plant stanol/sterols. Glycemic control can also beneficially modify plasma lipid levels, particularly in patients with very high triglycerides and poor glycemic control.

In those with clinical CVD or over age 40 years with other CVD risk factors, pharmacological treatment should be added to lifestyle therapy regardless of baseline lipid levels. Statins are the drugs of choice for LDL cholesterol lowering and cardioprotection. In patients other than those described above, statin treatment should be considered if there is an inadequate LDL cholesterol response to lifestyle modifications and improved glucose control, or if the patient has increased cardiovascular risk (e.g., multiple cardiovascular risk factors or long duration of diabetes). Very little clinical trial evidence exists for type 2 diabetic patients under the age 40 years, or for type 1 diabetic patients of any age. In the Heart Protection Study (lower age limit 40 years), the subgroup of ~600 patients with type 1 diabetes had a reduction in risk proportionately similar to that of patients with type 2 diabetes, although not statistically significant (282). Although the data are not definitive, consideration should be given to similar lipid-lowering goals in type 1 diabetic patients as in type 2 diabetic patients, particularly if they have other cardiovascular risk factors.

Alternative lipoprotein goals

Virtually all trials of statins and CVD outcome tested specific doses of statins against placebo, other doses of statin, or other statins, rather than aiming for specific LDL cholesterol goals (301). Placebo-controlled trials generally achieved LDL cholesterol reductions of 30–40% from baseline. Hence, LDL cholesterol lowering of this magnitude is an acceptable outcome for patients who cannot reach LDL cholesterol goals due to severe baseline elevations in LDL cholesterol and/or intolerance of maximal, or any, statin doses. Additionally for those with baseline LDL cholesterol minimally above 100 mg/dL, prescribing statin therapy to lower LDL cholesterol about 30–40% from baseline is probably more effective than prescribing just enough to get LDL cholesterol slightly below 100 mg/dL.

Clinical trials in high-risk patients, such as those with acute coronary syndromes or previous cardiovascular events (302–304), have demonstrated that more aggressive therapy with high doses of statins to achieve an LDL cholesterol of <70 mg/dL led to a significant reduction in further events. Therefore, a reduction in LDL cholesterol to a goal of <70 mg/dL is an option in very high-risk diabetic patients with overt CVD (305). Some experts recommend a greater focus on non–HDLC cholesterol, apolipoprotein B (apoB), or lipoprotein particle measurements to assess residual CVD risk in statin-treated patients who are likely to have small LDL particles, such as people with diabetes (306), but it is unclear whether clinical management would change with these measurements.

In individual patients, LDL cholesterol lowering with statins is highly variable, and this variable response is poorly understood (307). Reduction of CVD events with statins correlates very closely with LDL cholesterol lowering (279). If initial attempts to prescribe a statin leads to side effects, clinicians should attempt to find a dose or alternative statin that the patient can tolerate. There is evidence for significant LDL cholesterol lowering from even extremely low, less than daily, statin doses (308). When maximally tolerated doses of statins fail to significantly lower LDL cholesterol (<30% reduction from the patient’s baseline), there is no strong evidence that combination therapy should be used to achieve additional LDL cholesterol lowering. Niacin, fenofibrate, ezetimibe, and bile acid sequestrants all offer additional LDL cholesterol lowering to statins alone, but without evidence that such combination therapy for LDL cholesterol lowering provides a significant increment in CVD risk reduction over statin therapy alone.

Treatment of other lipoprotein fractions or targets

Hypertriglyceridemia should be addressed with dietary and lifestyle changes. Severe hypertriglyceridemia (>1,000 mg/dL) may warrant immediate pharmacological therapy (fibrin acid derivative, niacin, or fish oil) to reduce the risk of acute pancreatitis. In the absence of severe hypertriglyceridemia, therapy targeting HDL cholesterol or triglycerides lacks the strong evidence base of statin therapy. If the HDL cholesterol is <40 mg/dL and the LDL cholesterol is between 100 and 129 mg/dL, a fibrate or niacin might be used, especially if a patient is intolerant to statins. Niacin is the most effective drug for raising HDL cholesterol. It can significantly increase blood glucose at high doses, but at modest doses (750–2,000 mg/day) significant improvements in LDL cholesterol, HDL cholesterol, and triglyceride levels are accompanied by only modest changes in glucose that are generally amenable to adjustment of diabetes therapy (299,309,310).

Table 10 summarizes common treatment goals for A1C, blood pressure, and LDL cholesterol.

3. Antiplatelet agents

Recommendations

• Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes
at increased cardiovascular risk (10-year risk >10%). This includes most men aged >50 years or women aged >60 years who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (C)

- Aspirin should not be recommended for CVD prevention for adults with diabetes at low CVD risk (10-year CVD risk <5%), such as in men aged <50 years and women aged <60 years with no major additional CVD risk factors), since the potential adverse effects from bleeding likely offset the potential benefits. (C)

- In patients in these age-groups with multiple other risk factors (e.g., 10-year risk 5-10%), clinical judgment is required. (E)

- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (A)

- For patients with CVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. (B)

- Combination therapy with aspirin (75–162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to a year after an acute coronary syndrome. (B)

Aspirin has been shown to be effective in reducing cardiovascular morbidity and mortality in high-risk patients with previous MI or stroke (secondary prevention). Its net benefit in primary prevention among patients with no previous cardiovascular events is more controversial, both for patients with and without a history of diabetes (311). Two recent RCTs of aspirin in patients with diabetes failed to show a significant reduction in CVD end points, raising further questions about the efficacy of aspirin for primary prevention in people with diabetes (312,313). The Antithrombotic Trialists’ (ATT) collaborators recently published an individual patient-level meta-analysis of the six large trials of aspirin for primary prevention in the general population. These trials collectively enrolled over 95,000 participants, including almost 4,000 with diabetes. Overall, they found that aspirin reduced the risk of vascular events by 12% (RR 0.88, 95% CI 0.82–0.94). The largest reduction was for nonfatal MI with little effect on CHD death (RR 0.95, 95% CI 0.78–1.15) or total stroke. There was some evidence of a difference in aspirin effect by sex. Aspirin significantly reduced CVD events in men but not in women. Conversely, aspirin had no effect on stroke in men but significantly reduced stroke in women. Notably, sex differences in aspirin’s effects have not been observed in studies of secondary prevention (311). In the six trials examined by the ATT collaborators, the effects of aspirin on major vascular events were similar for patients with or without diabetes: RR 0.88 (95% CI 0.67–1.15) and 0.87 (95% CI 0.79–0.96), respectively. The confidence interval was wider for those with diabetes because of their smaller number.

Based on the currently available evidence, aspirin appears to have a modest effect on ischemic vascular events with the absolute decrease in events depending on the underlying CVD risk. The main adverse effects appear to be an increased risk of gastrointestinal bleeding. The excess risk may be as high as 1–5 per 1,000 per year in real-world settings. In adults with CVD risk greater than 1% per year, the number of CVD events prevented will be similar to or greater than the number of episodes of bleeding induced, although these complications do not have equal effects on long-term health (314).

In 2010, a position statement of the ADA, the American Heart Association (AHA), and the American College of Cardiology Foundation (ACCF) updated prior joint recommendations for primary prevention (315). Low-dose (75–162 mg/day) aspirin use for primary prevention is reasonable for adults with diabetes and no previous history of vascular disease who are at increased CVD risk (10-year risk of CVD events over 10%) and who are not at increased risk for bleeding. This generally includes most men over age 50 years and women over age 60 years who also have one or more of the following major risk factors: 1) smoking, 2) hypertension, 3) dyslipidemia, 4) family history of premature CVD, and 5) albuminuria.

However, aspirin is no longer recommended for those at low CVD risk (women under age 60 years and men under age 50 years with no major CVD risk factors; 10-year CVD risk under 5%) as the low benefit is likely to be outweighed by the risks of significant bleeding. Clinical judgment should be used for those at intermediate risk (younger patients with one or more risk factors, or older patients with no risk factors; those with 10-year CVD risk of 5–10%) until further research is available. Use of aspirin in patients under the age of 21 years is contraindicated due to the associated risk of Reye syndrome.

Average daily dosages used in most clinical trials involving patients with diabetes ranged from 50 to 650 mg but were mostly in the range of 100 to 325 mg/day. There is little evidence to support any specific dose, but using the lowest possible dosage may help reduce side effects (316). In the U.S., the most common low dose tablet is 81 mg. Although platelets from patients with diabetes have altered function, it is unclear what, if any, impact that finding has on the required dose of aspirin for cardioprotective effects in the patient with diabetes. Many alternate pathways for platelet activation exist that are independent of thromboxane A 2 and thus not sensitive to the effects of aspirin (317). Therefore, while “aspirin resistance” appears higher in the diabetic patients when measured by a variety of ex vivo and in vitro methods (platelet aggregometry, measurement of thromboxane B 2), these observations alone are insufficient to empirically recommend higher doses of aspirin be used in the diabetic patient at this time.

Table 10—Summary of recommendations for glycemic, blood pressure, and lipid control for most adults with diabetes

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C</td>
<td>&lt;7.0%*</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>&lt;140/80 mmHg**</td>
</tr>
<tr>
<td>Lipids</td>
<td></td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>&lt;100 mg/dl (&lt;2.6 mmol/L)†</td>
</tr>
<tr>
<td>Statins</td>
<td>therapy for those with history of MI or age over 40 + other risk factors</td>
</tr>
</tbody>
</table>

*More or less stringent glycemic goals may be appropriate for individual patients. Goals should be individualized based on duration of diabetes, age/life expectancy, comorbid conditions, known CVD or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations.

**Based on patient characteristics and response to therapy, lower systolic blood pressure targets may be appropriate. In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/L), using a high dose of a statin, is an option.
4. Smoking cessation

**Recommendations**
- Advise all patients not to smoke or use tobacco products. (A)
- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. (B)

A large body of evidence from epidemiological, case-control, and cohort studies provides convincing documentation of the causal link between cigarette smoking and health risks. Much of the work documenting the impact of smoking on health did not separately discuss results on subsets of individuals with diabetes, but suggests that the identified risks are at least equivalent to those found in the general population. Other studies of individuals with diabetes consistently demonstrate that smokers have a heightened risk of CVD, premature death, and increased rate of microvascular complications of diabetes. Smoking may have a role in the development of type 2 diabetes. One study in smokers with newly diagnosed type 2 diabetes found that smoking cessation was associated with amelioration of metabolic parameters and reduced blood pressure and albuminuria at 1 year (319).

The routine and thorough assessment of tobacco use is important as a means of preventing smoking or encouraging cessation. A number of large randomized clinical trials have demonstrated the efficacy and cost-effectiveness of brief counseling in smoking cessation, including the use of quitlines, in the reduction of tobacco use. For the patient motivated to quit, the addition of pharmacological therapy to counseling is more effective than either treatment alone. Special considerations should include assessment of level of nicotine dependence, which is associated with difficulty in quitting and relapse (320).

5. CHD screening and treatment

**Recommendations**
- In asymptomatic patients, routine screening for CAD is not recommended, as it does not improve outcomes as long as CVD risk factors are treated. (A)

**Screening**
- In patients with known CVD, consider ACE inhibitor therapy (C) and use aspirin and statin therapy (A) (if not contraindicated) to reduce the risk of cardiovascular events. In patients with a prior MI, β-blockers should be continued for at least 2 years after the event. (B)
- Avoid thiazolidinedione treatment in patients with symptomatic heart failure. (C)
- Metformin may be used in patients with stable CHF if renal function is normal. It should be avoided in unstable or hospitalized patients with CHF. (C)

Screening for CAD is reviewed in a recently updated consensus statement (196). To identify the presence of CAD in diabetic patients without clear or suggestive symptoms, a risk factor–based approach to the initial diagnostic evaluation and subsequent follow-up has intuitive appeal. However, recent studies concluded that using this approach fails to identify which patients with type 2 diabetes will have silent ischemia on screening tests (201,321).

**Treatment**
- In patients with known CVD, consider ACE inhibitor therapy (C) and use aspirin and statin therapy (A) (if not contraindicated) to reduce the risk of cardiovascular events. In patients with a prior MI, β-blockers should be continued for at least 2 years after the event. (B)
- Avoid thiazolidinedione treatment in patients with symptomatic heart failure. (C)
- Metformin may be used in patients with stable CHF if renal function is normal. It should be avoided in unstable or hospitalized patients with CHF. (C)

Although asymptomatic diabetic patients found to have a higher coronary disease burden have more future cardiac events (326–328), the role of these tests beyond risk stratification is not clear. Their routine use leads to radiation exposure and may result in unnecessary invasive testing such as coronary angiography and revascularization procedures. The ultimate balance of benefit, cost, and risks of such an approach in asymptomatic patients remains controversial, particularly in the modern setting of aggressive CVD risk factor control.

In all patients with diabetes, cardiovascular risk factors should be assessed at least annually. These risk factors include dyslipidemia, hypertension, smoking, a positive family history of premature coronary disease, and the presence of micro- or macroalbuminuria. Abnormal risk factors should be treated as described elsewhere in these guidelines. Patients at increased CHD risk should receive aspirin and a statin, and ACE inhibitor or ARB therapy if hypertensive, unless there are contraindications to a particular drug class.

Although clear benefit exists for ACE inhibitor and ARB therapy in patients with nephropathy or hypertension, the benefits in patients with CVD in the absence of these conditions are less clear, especially when LDL cholesterol is consistently controlled (329,330).

B. Nephropathy screening and treatment

**Recommendations**

**General recommendations**
- To reduce the risk or slow the progression of nephropathy, optimize glucose control. (A)
- To reduce the risk or slow the progression of nephropathy, optimize blood pressure control. (A)

**Screening**
- Perform an annual test to assess urine albumin excretion in type 1 diabetic patients with diabetes duration of ≥5 years and in all type 2 diabetic patients starting at diagnosis. (B)
- Measure serum creatinine at least annually in all adults with diabetes regardless of the degree of urine albumin excretion. The serum creatinine should be used to estimate GFR and stage the level of chronic kidney disease (CKD), if present. (E)

**Treatment**
- In the treatment of the nonpregnant patient with modestly elevated (30–299
mg/day) (C) or higher levels (≥300 mg/day) of urinary albumin excretion (A), either ACE inhibitors or ARBs are recommended.

- Reduction of protein intake to 0.8–1.0 g/kg body wt per day in individuals with diabetes and the earlier stages of CKD and to 0.8 g/kg body wt per day in the later stages of CKD may improve measures of renal function (urine albumin excretion rate, GFR) and is recommended. (C)

- When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of increased creatinine or changes in potassium. (E)

- Continued monitoring of urine albumin excretion to assess both response to therapy and progression of disease is reasonable. (E)

- When eGFR <60 mL/min/1.73 m², evaluate and manage potential complications of CKD. (E)

- Consider referral to a physician experienced in the care of kidney disease for uncertainty about the etiology of kidney disease, difficult management issues, or advanced kidney disease. (B)

Diabetic nephropathy occurs in 20–40% of patients with diabetes and is the single leading cause of ESRD. Persistent albuminuria in the range of 30–299 mg/24 h (historically called microalbuminuria) has been shown to be the earliest stage of diabetic nephropathy in type 1 diabetes and a marker for development of nephropathy in type 2 diabetes. It is also a well-established marker of increased CVD risk (331,332). Patients with microalbuminuria who progress to more significant levels (≥300 mg/24 h, historically called macroalbuminuria) are likely to progress to ESRD (333,334). However, a number of interventions have been demonstrated to reduce the risk and slow the progression of renal disease.

Intensive diabetes management with the goal of achieving near-normoglycemia has been shown in large prospective randomized studies to delay the onset and progression of increased urinary albumin excretion in patients with type 1 (335,336) and type 2 (83,84,88,89) diabetes. The UKPDS provided strong evidence that control of blood pressure can reduce the development of nephropathy (255). In addition, large prospective randomized studies in patients with type 1 diabetes have demonstrated that achievement of lower levels of systolic blood pressure (<140 mmHg) resulting from treatment using ACE inhibitors provides a selective benefit over other antihypertensive drug classes in delaying the progression of increased urinary albumin excretion and can slow the decline in GFR in patients with higher levels of albuminuria (337–339). In type 2 diabetes with hypertension and normoalbuminuria, RAS inhibition has been demonstrated to delay onset of microalbuminuria (340,341). In the latter study, there was an unexpected higher rate of fatal cardiovascular events with olmesartan among patients with preexisting CHD.

ACE inhibitors have been shown to reduce major CVD outcomes (i.e., MI, stroke, death) in patients with diabetes (270), thus further supporting the use of these agents in patients with albuminuria, a CVD risk factor. ARBs do not prevent onset of albuminuria in normotensive patients with type 1 or type 2 diabetes (342,343); however, ARBs have been shown to reduce the rate of progression from micro- to macroalbuminuria as well as ESRD in patients with type 2 diabetes (344–346). Some evidence suggests that ARBs have a smaller magnitude of rise in potassium compared with ACE inhibitors in people with nephropathy (347,348). Combinations of drugs that block the renin-angiotensin-aldosterone system (e.g., an ACE inhibitor plus an ARB, a mineralocorticoid antagonist, or a direct renin inhibitor) provide additional lowering of albuminuria (349–352). However, such combinations have been found to provide no additional cardiovascular benefit and have higher adverse event rates (353), and their effects on major renal outcomes have not yet been proven.

Other drugs, such as diuretics, calcium channel blockers, and β-blockers, should be used as additional therapy to further lower blood pressure in patients already treated with ACE inhibitors or ARBs (275), or as alternate therapy in the rare individual unable to tolerate ACE inhibitors or ARBs.

Studies in patients with varying stages of nephropathy have shown that protein restriction of dietary protein helps slow the progression of albuminuria, GFR decline, and occurrence of ESRD (354–357), although more recent studies have provided conflicting results (140). Dietary protein restriction might be considered particularly in patients whose nephropathy seems to be progressing despite optimal glucose and blood pressure control and use of ACE inhibitor and/or ARBs (357).

Assessment of albuminuria status and renal function

Screening for increased urinary albumin excretion can be performed by measurement of the albumin-to-creatinine ratio in a random spot collection, 24-h or timed collections are more burdensome and add little to prediction or accuracy (358,359). Measurement of a spot urine for albumin only, whether by immunoassay or by using a dipstick test specific for microalbumin, without simultaneously measuring urine creatinine, is somewhat less expensive but susceptible to false-negative and false-positive determinations as a result of variation in urine concentration due to hydration and other factors.

Abnormalities of albumin excretion and the linkage between albumin-to-creatinine ratio and 24-h albumin excretion are defined in Table 11. Because of variability in urinary albumin excretion, two of three specimens collected within a 3- to 6-month period should be abnormal before considering a patient to have developed increased urinary albumin excretion or had a progression in albuminuria. Exercise within 24 h, infection, fever, CHF, marked hyperglycemia, and marked hypertension may elevate urinary albumin excretion over baseline values.

Information on presence of abnormal urine albumin excretion in addition to level of GFR may be used to stage CKD. The National Kidney Foundation classification (Table 12) is primarily based on GFR levels and therefore differs from other systems, in which staging is based primarily on urinary albumin excretion (360). Studies have found decreased GFR in the absence of increased urine albumin excretion in a substantial percentage of adults with diabetes (361). Serum creatinine should therefore be measured at least annually in all adults with

Table 11—Definitions of abnormalities in albumin excretion

<table>
<thead>
<tr>
<th>Category</th>
<th>Spot collection (µg/mg creatinine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;30</td>
</tr>
<tr>
<td>Increased urinary albumin excretion*</td>
<td>≥30</td>
</tr>
</tbody>
</table>

*Historically, ratios between 30 and 299 have been called microalbuminuria and those ≥300 or greater have been called macroalbuminuria (or clinical albuminuria).
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diabetes, regardless of the degree of urine albumin excretion.

Serum creatinine should be used to estimate GFR and to stage the level of CKD, if present. eGFR is commonly reported by laboratories or can be estimated using formulae such as the Modification of Diet in Renal Disease (MDRD) study equation (362). Recent reports have indicated that the MDRD is more accurate for the diagnosis and stratification of CKD in patients with diabetes than the Cockcroft-Gault formula (363). GFR calculators are available at http://www.nkdep.nih.gov.

The role of continued annual quantitative assessment of albumin excretion after diagnosis of albuminuria and institution of ACE inhibitor or ARB therapy and blood pressure control is unclear. Continued surveillance can assess both response to therapy and progression of disease. Some suggest that reducing albuminuria to the normal (<30 mg/g) or near-normal range may improve renal and cardiovascular prognosis, but this approach has not been formally evaluated in prospective trials.

Complications of kidney disease correlate with level of kidney function. When the eGFR is <60 mL/min/1.73 m², screening for complications of CKD is indicated (Table 13). Early vaccination against hepatitis B is indicated in patients likely to progress to end-stage kidney disease.

Consider referral to a physician experienced in the care of kidney disease when there is uncertainty about the etiology of kidney disease (heavy proteinuria, active urine sediment, absence of retinopathy, rapid decline in GFR, resistant hypertension). Other triggers for referral may include difficult management issues (anemia, secondary hyperparathyroidism, metabolic bone disease, or electrolyte disturbance) or advanced kidney disease. The threshold for referral may vary depending on the frequency with which a provider encounters diabetic patients with significant kidney disease. Consultation with a nephrologist when stage 4 CKD develops has been found to reduce cost, improve quality of care, and keep people off dialysis longer (364). However, nonrenal specialists should not delay educating their patients about the progressive nature of diabetic kidney disease, the renal preservation benefits of aggressive treatment of blood pressure, blood glucose, and hyperlipidemia, and the potential need for renal replacement therapy.

C. Retinopathy screening and treatment

Recommendations

General recommendations

- To reduce the risk or slow the progression of retinopathy, optimize glycemic control. (A)
- To reduce the risk or slow the progression of retinopathy, optimize blood pressure control. (A)

Screening

- Adults and children aged ≥10 years with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes. (B)
- 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. (B)
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. Less frequent exams (every 2–3 years) may be considered following one or more normal eye exams. Examinations will be required more frequently if retinopathy is progressing. (B)
- High-quality fundus photographs can detect most clinically significant diabetic retinopathy. Interpretation of the images should be performed by a trained eye care provider. While retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional. (E)
- Women with pre-existing diabetes who are planning pregnancy or who have become pregnant should have a comprehensive eye examination and be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examination should occur in the first trimester with close follow-up throughout pregnancy and for 1 year postpartum. (B)

Treatment

- Promptly refer patients with any level of macular edema, severe NPDR, or any PDR to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy. (A)
- Laser photocoagulation therapy is indicated to reduce the risk of vision loss in patients with high-risk PDR, clinically significant macular edema, and in some cases of severe NPDR. (A)
- Anti-vascular endothelial growth factor (VEGF) therapy is indicated for diabetic macular edema. (A)
- The presence of retinopathy is not a contraindication to aspirin therapy for cardioprotection, as this therapy does not increase the risk of retinal hemorrhage. (A)

Diabetic retinopathy is a highly specific vascular complication of both type 1 and type 2 diabetes, with prevalence strongly related to the duration of diabetes. Diabetic retinopathy is the most frequent cause of new cases of blindness among adults aged 20–74 years. Glaucoma, cataracts, and other disorders of the eye occur earlier and more frequently in people with diabetes.

In addition to duration of diabetes, other factors that increase the risk of, or are associated with, retinopathy include chronic hyperglycemia (365), nephropathy (366), and hypertension (367). Intensive diabetes management with the goal of achieving near-normoglycemia has been shown in large prospective randomized studies to prevent and/or delay the onset and progression of diabetic retinopathy (71,83,84,90). Lowering blood pressure has been shown to decrease the progression of retinopathy (255), although tight targets (systolic <120 mmHg) do not impart additional benefit (90). Several case series and a controlled prospective study suggest that pregnancy

Table 12—Stages of CKD

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
<th>GFR (mL/min/1.73 m² body surface area)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kidney damage* with normal or increased GFR</td>
<td>≥90</td>
</tr>
<tr>
<td>2</td>
<td>Kidney damage* with mildly decreased GFR</td>
<td>60–89</td>
</tr>
<tr>
<td>3</td>
<td>Moderately decreased GFR</td>
<td>30–59</td>
</tr>
<tr>
<td>4</td>
<td>Severely decreased GFR</td>
<td>13–29</td>
</tr>
<tr>
<td>5</td>
<td>Kidney failure</td>
<td>&lt;15 or dialysis</td>
</tr>
</tbody>
</table>

*Kidney damage defined as abnormalities on pathological, urine, blood, or imaging tests. Adapted from ref. 359.
in type 1 diabetic patients may aggravate retinopathy (368,369), laser photocoagulation surgery can minimize this risk (369).

One of the main motivations for screening for diabetic retinopathy is the long-established efficacy of laser photocoagulation surgery in preventing visual loss. Two large trials, the Diabetic Retinopathy Study (DRS) in patients with PDR and the Early Treatment Diabetic Retinopathy Study (ETDRS) in patients with macular edema, provide the strongest support for the therapeutic benefits of photocoagulation surgery. The DRS (370) showed that panretinal photocoagulation surgery reduced the risk of severe vision loss from PDR from 15.9% in untreated eyes to 6.4% in treated eyes, with greatest risk-benefit ratio in those with baseline disease (disc neovascularization or vitreous hemorrhage).

The ETDRS (371) established the benefit of focal laser photocoagulation surgery in eyes with macular edema, particularly those with clinically significant macular edema, with reduction of doubling of the visual angle (e.g., 20/50 to 20/100) from 20% in untreated eyes to 8% in treated eyes. The ETDRS also verified the benefits of panretinal photocoagulation for high-risk PDR and in older-onset patients with severe NPDR or less-than-high-risk PDR.

Laser photocoagulation surgery in both trials was beneficial in reducing the risk of further visual loss, but generally not beneficial in reversing already diminished acuity. Recombinant monoclonal neutralizing antibody to VEGF is a newly approved therapy that improves vision and reduces the need for laser photocoagulation in patients with macular edema (372). Other emerging therapies for retinopathy include sustained intravitreal delivery of fluocinolone (373) and the possibility of prevention with fenofibrate (374,375).

The preventive effects of therapy and the fact that patients with PDR or macular edema may be asymptomatic provide strong support for a screening program to detect diabetic retinopathy. As retinopathy is estimated to take at least 5 years to develop after the onset of hyperglycemia, patients with type 1 diabetes should have an initial dilated and comprehensive eye examination within 5 years after the onset of diabetes. Patients with type 2 diabetes, who generally have had years of undiagnosed diabetes and who have a significant risk of prevalent diabetic retinopathy at time of diabetes diagnosis, should have an initial dilated and comprehensive eye examination soon after diagnosis. Examinations should be performed by an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management. Subsequent examinations for type 1 and type 2 diabetic patients are generally repeated annually. Less frequent exams (every 2–3 years) may be cost effective after one or more normal eye exams, and in a population with well-controlled type 2 diabetes there was essentially no risk of development of significant retinopathy with a 3-year interval after a normal examination (376). Examinations will be required more frequently if retinopathy is progressing (377).

The use of retinal photography with remote reading by experts has great potential in areas where qualified eye care professionals are not available and may also enhance efficiency and reduce costs when the expertise of ophthalmologists can be utilized for more complex examinations and for therapy (378). In-person exams are still necessary when the photos are unacceptable and for follow-up of abnormalities detected. Photos are not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional. Results of eye examinations should be documented and transmitted to the referring health care professional.

D. Neuropathy screening and treatment

**Recommendations**

- All patients should be screened for distal symmetric polyneuropathy (DPN) starting at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes and at least annually thereafter, using simple clinical tests. (B)
- Electrophysiological testing is rarely needed, except in situations where the clinical features are atypical. (E)
- Screening for signs and symptoms of cardiovascular autonomic neuropathy (CAN) should be instituted at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes. Special testing is rarely needed and may not affect management or outcomes. (E)
- Medications for the relief of specific symptoms related to painful DPN and autonomic neuropathy are recommended, as they improve the quality of life of the patient. (E)

The diabetic neuropathies are heterogeneous with diverse clinical manifestations. They may be focal or diffuse. Most common among the neuropathies are chronic sensorimotor DPN and autonomic neuropathy. Although DPN is a diagnosis of exclusion, complex investigations to exclude other conditions are rarely needed.

The early recognition and appropriate management of neuropathy in the patient with diabetes is important for a number of reasons: 1) nondiabetic

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**Table 13—Management of CKD in diabetes**

<table>
<thead>
<tr>
<th>GFR</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients 45–60</td>
<td>Yearly measurement of creatinine, urinary albumin excretion, potassium</td>
</tr>
<tr>
<td></td>
<td>Referral to nephrology if possibility for nondiabetic kidney disease exists (duration of type 1 diabetes &lt;10 years, heavy proteinuria, abnormal findings on renal ultrasound, resistant hypertension, rapid fall in GFR, or active urinary sediment on ultrasound)</td>
</tr>
<tr>
<td></td>
<td>Consider need for dose adjustment of medications</td>
</tr>
<tr>
<td></td>
<td>Monitor eGFR every 6 months</td>
</tr>
<tr>
<td></td>
<td>Monitor electrolytes, bicarbonate, hemoglobin, calcium, phosphorus, parathyroid hormone at least yearly</td>
</tr>
<tr>
<td></td>
<td>Assure vitamin D sufficiency</td>
</tr>
<tr>
<td></td>
<td>Consider bone density testing</td>
</tr>
<tr>
<td></td>
<td>Referral for dietary counseling</td>
</tr>
<tr>
<td>30–44</td>
<td>Monitor eGFR every 3 months</td>
</tr>
<tr>
<td></td>
<td>Monitor electrolytes, bicarbonate, calcium, phosphorus, parathyroid hormone, hemoglobin, albumin, weight every 3–6 months</td>
</tr>
<tr>
<td>&lt;30</td>
<td>Consider need for dose adjustment of medications</td>
</tr>
<tr>
<td></td>
<td>Referral to nephrologist</td>
</tr>
</tbody>
</table>

Adapted from http://www.kidney.org/professionals/KDOQI/guideline_diabetes/
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some societies have developed guidelines for screening for CAN, the benefits of sophisticated testing beyond risk stratification are not clear (384).

Gastrointestinal neuropathies (e.g., esophageal enteropathy, gastroparesis, constipation, diarrhea, fecal incontinence) are common, and any section of the gastrointestinal tract may be affected. Gastroparesis should be suspected in individuals with erratic glucose control or with upper gastrointestinal symptoms without other identified cause. Evaluation of solid-phase gastric emptying using double-isotope scintigraphy may be done if symptoms are suggestive, but test results often correlate poorly with symptoms. Constipation is the most common lower-gastrointestinal symptom but can alternate with episodes of diarrhea.

Diabetic autonomic neuropathy is also associated with genitourinary tract disturbances. In men, diabetic autonomic neuropathy may cause erectile dysfunction and/or retrograde ejaculation. Evaluation of bladder dysfunction should be performed for individuals with diabetes who have recurrent urinary tract infections, pyelonephritis, incontinence, or a palpable bladder.

**Symptomatic treatments DPN.** The first step in management of patients with DPN should be to aim for stable and optimal glycemic control. Although controlled trial evidence is lacking, several observational studies suggest that neuropathic symptoms improve not only with optimization of control, but also with the avoidance of extreme blood glucose fluctuations. Patients with painful DPN may benefit from pharmacological treatment of their symptoms: many agents have confirmed or probable efficacy confirmed in systematic reviews of RCTs (379), with several U.S. Food and Drug Administration (FDA)-approved for the management of painful DPN.

**Treatment of autonomic neuropathy.** Gastroparesis symptoms may improve with dietary changes and prokinetic agents such as metoclopramide or erythromycin. Treatments for erectile dysfunction may include phosphodiesterase type 5 inhibitors, intracorporeal or intraurethral prostaglandins, vacuum devices, or penile prostheses. Interventions for other manifestations of autonomic neuropathy are described in the ADA statement on neuropathy (380). As with DPN treatments, these interventions do not change the underlying pathology and natural history of the disease process, but may have a positive impact on the quality of life of the patient.

**E. Foot care**

**Recommendations**

- For all patients with diabetes, perform an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations. The foot examination should include inspection, assessment of foot pulses, and testing for loss of protective sensation (LOPS) (10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold). (B)
- Provide general foot self-care education to all patients with diabetes. (B)
- A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. (B)
- Refer patients who smoke, have LOPS and structural abnormalities, or have history of prior lower-extremity complications to foot care specialists for ongoing preventive care and lifelong surveillance. (C)
- Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. (C)
- Refer patients with significant claudication or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options. (C)

Amputation and foot ulceration, consequences of diabetic neuropathy and/or PAD, are common and major causes of morbidity and disability in people with diabetes. Early recognition and management of risk factors can prevent or delay adverse outcomes.

The risk of ulcers or amputations is increased in people who have the following risk factors:

- Previous amputation
- Past foot ulcer history
- Peripheral neuropathy
- Foot deformity
- Peripheral vascular disease
- Visual impairment

**Diabetic autonomic neuropathy.** The symptoms and signs of autonomic dysfunction should be elicited carefully during the history and physical examination. Major clinical manifestations of diabetic autonomic neuropathy include resting tachycardia, exercise intolerance, orthostatic hypotension, constipation, gastroparesis, erectile dysfunction, sudomotor dysfunction, impaired neurovascular function, and, potentially, autonomic failure in response to hypoglycemia (383).

CAN, a CVD risk factor (93), is the most studied and clinically important form of diabetic autonomic neuropathy. CAN may be indicated by resting tachycardia (>100 bpm), orthostasis (a fall in systolic blood pressure >20 mmHg upon standing without an appropriate heart rate response); it is also associated with increased cardiac event rates. Although

**Diagnosis of neuropathy DPN.** Patients with diabetes should be screened annually for DPN using tests such as pinprick sensation, vibration perception (using a 128-Hz tuning fork), 10-g monofilament pressure sensation at the distal plantar aspect of both great toes and metatarsal joints, and assessment of ankle reflexes. Combinations of more than one test have >87% sensitivity in detecting DPN. Loss of 10-g monofilament perception and reduced vibration perception predict foot ulcers (380). Importantly, in patients with neuropathy, particularly when severe, causes other than diabetes should always be considered, such as neurotoxic medications, heavy metal poisoning, alcohol abuse, vitamin B12 deficiency (especially in those taking metformin for prolonged periods (381), renal disease, chronic inflammatory demyelinating neuropathy, inherited neuropathies, and vasculitis (382).

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Diabetic nephropathy (especially patients on dialysis)
Poor glycemic control
Cigarette smoking

Many studies have been published proposing a range of tests that might usefully identify patients at risk for foot ulceration, creating confusion among practitioners as to which screening tests should be adopted in clinical practice. An ADA task force was therefore assembled in 2008 to concisely summarize recent literature in this area and then recommend what should be included in the comprehensive foot exam for adult patients with diabetes. Their recommendations are summarized below, but clinicians should refer to the task force report (385) for further details and practical descriptions of how to perform components of the comprehensive foot examination.

At least annually, all adults with diabetes should undergo a comprehensive foot examination to identify high-risk conditions. Clinicians should ask about history of previous foot ulceration or amputation, neuropathic or peripheral vascular symptoms, impaired vision, tobacco use, and foot care practices. A general inspection of skin integrity and musculoskeletal deformities should be done in a well-lit room. Vascular assessment would include inspection and assessment of pedal pulses.

The neurologic exam recommended is designed to identify LOPS rather than early neuropathy. The clinical examination to identify LOPS is simple and requires no expensive equipment. Five simple clinical tests (use of a 10-g monofilament, vibration testing using a 128-Hz tuning fork, tests of pinprick sensation, ankle reflex assessment, and testing vibration perception threshold with a biothesiometer), each with evidence from well-conducted prospective clinical cohort studies, are considered useful in the diagnosis of LOPS in the diabetic foot. The task force agrees that any of the five tests listed could be used by clinicians to identify LOPS, although ideally two of these should be regularly performed during the screening exam—normally the 10-g monofilament and one other test. One or more abnormal tests would suggest LOPS, while at least two normal tests (and no abnormal test) would rule out LOPS. The last test listed, vibration assessment using a biothesiometer or similar instrument, is widely used in the U.S.; however, identification of the patient with LOPS can easily be carried out without this or other expensive equipment.

Initial screening for PAD should include a history for claudication and an assessment of the pedal pulses. A diagnostic ABI should be performed in any patient with symptoms of PAD. Due to the high estimated prevalence of PAD in patients with diabetes and the fact that many patients with PAD are asymptomatic, an ADA consensus statement on PAD (386) suggested that a screening ABI be performed in patients over 50 years of age and be considered in patients under 50 years of age who have other PAD risk factors (e.g., smoking, hypertension, hyperlipidemia, or duration of diabetes >10 years). Refer patients with significant symptoms or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options (386).

Patients with diabetes and high-risk foot conditions should be educated regarding their risk factors and appropriate management. Patients at risk should understand the implications of the loss of protective sensation, the importance of foot monitoring on a daily basis, the proper care of the foot, including nail and skin care, and the selection of appropriate footwear. Patients with LOPS should be educated on ways to substitute other sensory modalities (hand palpation, visual inspection) for surveillance of early foot problems. The patients’ understanding of these issues and their physical ability to conduct proper foot surveillance and care should be assessed. Patients with visual difficulties, physical constraints preventing movement, or cognitive problems that impair their ability to assess the condition of the foot and to institute appropriate responses will need other people, such as family members, to assist in their care.

People with neuropathy or evidence of increased plantar pressure (e.g., erythema, warmth, callus, or measured pressure) may be adequately managed with well-fitted walking shoes or athletic shoes that cushion the feet and redistribute pressure. Callus can be debrided with a scalpel by a foot care specialist or other health professional with experience and training in foot care. People with bony deformities (e.g., hammer toes, prominent metatarsal heads, bunions) may need extra-wide or -depth shoes. People with extreme bony deformities (e.g., Charcot foot) who cannot be accommodated with commercial therapeutic footwear may need custom-molded shoes.

Foot ulcers and wound care may require care by a podiatrist, orthopedic or vascular surgeon, or rehabilitation specialist experienced in the management of individuals with diabetes. Guidelines for treatment of diabetic foot ulcers have recently been updated (387).

VII. ASSESSMENT OF COMMON COMORBID CONDITIONS

Recommendations

- For patients with risk factors, signs or symptoms, consider assessment and treatment for common diabetes-associated conditions (see Table 14). (B)

In addition to the commonly appreciated comorbidities of obesity, hypertension, and dyslipidemia, diabetes is also associated with other diseases or conditions at rates higher than those of age-matched people without diabetes. A few of the more common comorbidities are described herein and listed in Table 14.

Hearing impairment

Hearing impairment, both high frequency and low/mid frequency, is more common in people with diabetes, perhaps due to neuropathy and/or vascular disease. In an NHANES analysis, hearing impairment was about twice as great in people with diabetes compared with those without, after adjusting for age and other risk factors for hearing impairment (388).

Controlling for age, race, and other demographic factors, high frequency loss in those with diabetes was significantly associated with history of CHD and with peripheral neuropathy, while low/mid frequency loss was associated with low HDL cholesterol and with poor reported health status (389).

Table 14—Common comorbidities for which increased risk is associated with diabetes

<table>
<thead>
<tr>
<th>Condition</th>
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<tbody>
<tr>
<td>Hearing impairment</td>
</tr>
<tr>
<td>Obstructive sleep apnea</td>
</tr>
<tr>
<td>Fatty liver disease</td>
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<tr>
<td>Low testosterone in men</td>
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<tr>
<td>Periodontal disease</td>
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<tr>
<td>Certain cancers</td>
</tr>
<tr>
<td>Fractures</td>
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<tr>
<td>Cognitive impairment</td>
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<tr>
<td>Depression</td>
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</tbody>
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Position Statement
Position Statement

Obstructive sleep apnea
Age-adjusted rates of obstructive sleep apnea, a risk factor for CVD, are significantly higher (4- to 10-fold) with obesity, especially with central obesity, in men and women (390). The prevalence in general populations with type 2 diabetes may be up to 23% (391), and in obese participants enrolled in the Look AHEAD trial exceeded 80% (392). Treatment of sleep apnea significantly improves quality of life and blood pressure control. The evidence for a treatment effect on glycemic control is mixed (393).

Fatty liver disease
Unexplained elevation of hepatic transaminase concentrations is significantly associated with higher BMI, waist circumference, triglycerides, and fasting insulin, and with lower HDL cholesterol. Type 2 diabetes and hypertension are independently associated with transaminase elevations in women (394). In a prospective analysis, diabetes was significantly associated with incident nonalcoholic chronic liver disease and with hepatocellular carcinoma (395). Interventions that improve metabolic abnormalities in patients with diabetes (weight loss, glycemic control, treatment with specific drugs for hyperglycemia or dyslipidemia) are also beneficial for fatty liver disease (396).

Low testosterone in men
Mean levels of testosterone are lower in men with diabetes compared with age-matched men without diabetes, but obesity is a major confounder (397). The issue of treatment in asymptomatic men is controversial. The evidence for effects of testosterone replacement on outcomes is mixed, and recent guidelines suggest that screening and treatment of men without symptoms are not recommended (398).

Periodontal disease
Periodontal disease is more severe, but not necessarily more prevalent, in patients with diabetes than those without (399). Numerous studies have suggested associations with poor glycemic control, nephropathy, and CVD, but most studies are highly confounded. A comprehensive assessment, and treatment of identified disease, is indicated in patients with diabetes, but the evidence that periodontal disease treatment improves glycemic control is mixed. A meta-analysis reported a significant 0.47% improvement in A1C, but noted multiple problems with the quality of the published studies included in the analysis (400). Several high-quality RCTs have not shown a significant effect (401).

Cancer
Diabetes (possibly only type 2 diabetes) is associated with increased risk of cancers of the liver, pancreas, endometrium, colon/rectum, breast, and bladder (402). The association may result from shared risk factors between type 2 diabetes and cancer (obesity, age, and physical inactivity) but may also be due to hyperinsulinemia or hyperglycemia (401,403). Patients with diabetes should be encouraged to undergo recommended age- and sex-appropriate cancer screenings and to reduce their modifiable cancer risk factors (obesity, smoking, and physical inactivity).

Fractures
Age-matched hip fracture risk is significantly increased in both type 1 (summary RR 6.3) and type 2 diabetes (summary RR 1.7) in both sexes (404). Type 1 diabetes is associated with osteoporosis, but in type 2 diabetes an increased risk of hip fracture is seen despite higher bone mineral density (BMD) (405). One study showed that prevalent vertebral fractures were significantly more common in men and women with type 2 diabetes, but were not associated with BMD (406). In three large observational studies of older adults, femoral neck BMD T-score and the WHO fracture risk algorithm (FRAX) score were associated with hip and nonspine fracture, although fracture risk was higher in diabetic patients compared with participants without diabetes for a given T-score and age or for a given FRAX score risk (407). It is appropriate to assess fracture history and risk factors in older patients with diabetes and recommend BMD testing if appropriate for the patient’s age and sex. For at-risk patients, it is reasonable to consider standard primary or secondary prevention strategies (reduce risk factors for falls, ensure adequate calcium and vitamin D intake, avoid use of medications that lower BMD, such as glucocorticoids), and to consider pharmacotherapy for high-risk patients. For patients with type 2 diabetes with fracture risk factors, avoiding use of thiazolidinediones is warranted.

Cognitive impairment
Diabetes is associated with significantly increased risk of cognitive decline, a greater rate of cognitive decline, and increased risk of dementia (408,409). In a 15-year prospective study of a community-dwelling people over the age of 60 years, the presence of diabetes at baseline significantly increased the age- and sex-adjusted incidence of all-cause dementia, Alzheimer disease, and vascular dementia compared with rates in those with normal glucose tolerance (410). In a substudy of the ACCORD study, there were no differences in cognitive outcomes between intensive and standard glycemic control, although there was significantly less of a decrement in total brain volume by magnetic resonance imaging in participants in the intensive arm (411). The effects of hyperglycemia and insulin on the brain are areas of intense research interest.

Depression
As discussed in Section V H, depression is highly prevalent in people with diabetes and is associated with worse outcomes.

VIII. DIABETES CARE IN SPECIFIC POPULATIONS

A. Children and adolescents

Recommendations
• As is the case for all children, children with diabetes or prediabetes should be encouraged to engage in at least 60 min of physical activity each day. (B)

1. Type 1 diabetes
Three-quarters of all cases of type 1 diabetes are diagnosed in individuals <18 years of age. It is appropriate to consider the unique aspects of care and management of children and adolescents with type 1 diabetes. Children with diabetes differ from adults in many respects, including changes in insulin sensitivity related to sexual maturity and physical growth, ability to provide self-care, supervision in child care and school, and unique neurologic vulnerability to hypoglycemia and DKA. Attention to such issues as family dynamics, developmental stages, and physiological differences related to sexual maturity are all essential in developing and implementing an optimal diabetes regimen. Although recommendations for children and adolescents are less likely to be based on clinical trial evidence, expert opinion and a review of available and relevant experimental data are summarized in the ADA statement on care of children and adolescents with type 1 diabetes (412).

Ideally, the care of a child or adolescent with type 1 diabetes should be provided by a multidisciplinary team of specialists trained in the care of children
with pediatric diabetes. At the very least, education of the child and family should be provided by health care providers trained and experienced in childhood diabetes and sensitive to the challenges posed by diabetes in this age-group. It is essential that DSME, MNT, and psychological support be provided at the time of diagnosis and regularly thereafter by individuals experienced with the educational, nutritional, behavioral, and emotional needs of the growing child and family. It is expected that the balance between adult supervision and self-care should be defined and that it will evolve with physical, psychological, and emotional maturity.

a. Glycemic control

Recommendations

- Consider age when setting glycemic goals in children and adolescents with type 1 diabetes. (E)

While current standards for diabetes management reflect the need to lower glucose as safely possible, special consideration should be given to the unique risks of hypoglycemia in young children. Glycemic goals may need to be modified to take into account the fact that most children <6 or 7 years of age have a form of “hypoglycemic unawareness,” including immaturity and a relative inability to recognize and respond to hypoglycemic symptoms, placing them at greater risk for severe hypoglycemia and its sequelae. In addition, and unlike the case in type 1 diabetic adults, young children below the age of 5 years may be at risk for permanent cognitive impairment after episodes of severe hypoglycemia (413–415). Furthermore, the DCCT demonstrated that near-normalization of blood glucose levels was more difficult to achieve in adolescents than adults. Nevertheless, the increased frequency of use of basal-bolus regimens and insulin pumps in youth from infancy through adolescence has been associated with more children reaching ADA blood glucose targets (416,417) in those families in which both parents and the child with diabetes participate jointly to perform the required diabetes-related tasks. Furthermore, recent studies documenting neurocognitive sequelae of hyperglycemia in children provide another compelling motivation for achieving glycemic targets (418,419).

In selecting glycemic goals, the benefits on long-term health outcomes of achieving a lower A1C should be balanced against the risks of hypoglycemia and the developmental burdens of intensive regimens in children and youth. Age-specific glycemic and A1C goals are presented in Table 15.

b. Screening and management of chronic complications in children and adolescents with type 1 diabetes

i. Nephropathy

Recommendations

- Annual screening for microalbuminuria, with a random spot urine sample for albumin-to-creatinine ratio, should be considered once the child is 10 years of age and has had diabetes for 5 years. (B)
- Treatment with an ACE inhibitor, titrated to normalization of albumin excretion, should be considered when elevated albumin-to-creatinine ratio is subsequently confirmed on two additional specimens from different days. (E)

ii. Hypertension

Recommendations

- Blood pressure should be measured at each routine visit. Children found to have high-normal blood pressure or hypertension should have blood pressure confirmed on a separate day. (B)
- Initial treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) includes dietary intervention and exercise, aimed at weight control and increased physical activity, if appropriate. If target blood pressure is not reached with 3–6 months of lifestyle intervention, pharmacological treatment should be considered. (E)
- Pharmacological treatment of hypertension (systolic or diastolic blood pressure consistently above the 95th percentile for age, sex, and height or consistently >130/80 mmHg, if 95% exceeds that value) should be considered as soon as the diagnosis is confirmed. (E)
- ACE inhibitors should be considered for the initial treatment of hypertension, following appropriate reproductive counseling due to its potential teratogenic effects. (E)
- The goal of treatment is a blood pressure consistently <130/80 or below the 90th percentile for age, sex, and height, whichever is lower. (E)

It is important that blood pressure measurements are determined correctly, using the appropriate size cuff, and with the child seated and relaxed. Hypertension should be confirmed on at least three separate days. Normal blood pressure levels for age, sex, and height and appropriate methods for determinations are available online at www.nhlbi.nih.gov/health/prof/heart/hbp/hbp_ped.pdf.

iii. Dyslipidemia

Recommendations

Screening

- If there is a family history of hypercholesterolemia or a cardiovascular event before age 55 years, or if family history is unknown, then consider obtaining a fasting lipid profile on children >2 years of age soon after diagnosis (after glucose control has been established). If family history is not of concern, then consider the first lipid screening at puberty (≥10 years of age). For children diagnosed with diabetes at or after puberty, consider obtaining a fasting lipid profile soon after the diagnosis (after glucose control has been established). (E)
- For both age-groups, if lipids are abnormal, annual monitoring is reasonable. If LDL cholesterol values are within the accepted risk levels (<100 mg/dL [2.6 mmol/L]), a lipid profile repeated every 5 years is reasonable. (E)

Treatment

- Initial therapy may consist of optimization of glucose control and MNT using a Step 2 AHA diet aimed at a decrease in the amount of saturated fat in the diet. (E)
- After the age of 10 years, the addition of a statin in patients who, after MNT and lifestyle changes, have LDL cholesterol >160 mg/dL (4.1 mmol/L), or LDL cholesterol >130 mg/dL (3.4 mmol/L) and one or more CVD risk factors, is reasonable. (E)
- The goal of therapy is an LDL cholesterol value <100 mg/dL (2.6 mmol/L). (E)

People diagnosed with type 1 diabetes in childhood have a high risk of early subclinical (420–422) and clinical (423) CVD. Although intervention data are lacking, the AHA categorizes children with type 1 diabetes in the highest tier for cardiovascular risk and recommends both lifestyle and pharmacological treatment for those with elevated LDL cholesterol levels (424,425). Initial therapy should be with a Step 2 AHA diet, which restricts saturated fat to 7% of total calories and restricts dietary cholesterol to 200 mg/day. Data from randomized clinical trials in children as young as 7 months of age indicate that this diet is safe and...
iv. Retinopathy

Recommendations

- The first ophthalmologic examination should be obtained once the child is ≥10 years of age and has had diabetes for 3–5 years. (B)
- After the initial examination, annual routine follow-up is generally recommended. Less frequent examinations may be acceptable on the advice of an eye care professional. (E)

Although retinopathy (like albuminuria) most commonly occurs after the onset of puberty and after 5–10 years of diabetes duration (431), it has been reported in prepubertal children and with diabetes duration of only 1–2 years. Referrals should be made to eye care professionals with expertise in diabetic retinopathy, an understanding of the risk for retinopathy in the pediatric population, and experience in counseling the pediatric patient and family on the importance of early prevention/intervention.

v. Celiac disease

Recommendations

- Consider screening children with type 1 diabetes for celiac disease by measuring tissue transglutaminase or antiendomysial antibodies, with documentation of normal total serum IgA levels, soon after the diagnosis of diabetes. (E)
- Testing should be considered in children with growth failure, failure to gain weight, weight loss, diarrhea, flatulence, abdominal pain, or signs of malabsorption or in children with frequent unexplained hypoglycemia or deterioration in glycemic control. (E)
- Consider referral to a gastroenterologist for evaluation with possible endoscopy and biopsy for confirmation of celiac disease in asymptomatic children with positive antibodies. (E)
- Children with biopsy-confirmed celiac disease should be placed on a gluten-free diet and have consultation with a dietitian experienced in managing both diabetes and celiac disease. (B)

Celiac disease is an immune-mediated disorder that occurs with increased frequency in patients with type 1 diabetes (1–10% of individuals compared with 0.3–1% in the general population) (432,433). Symptoms of celiac disease include diarrhea, weight loss, pain, growth failure, abdominal pain, chronic fatigue, malnutrition due to malabsorption, and other gastrointestinal problems, and unexplained hypoglycemia or erratic blood glucose concentrations.

Screening for celiac disease includes measuring serum levels of tissue transglutaminase or antiendomysial antibodies, then small bowel biopsy in antibody-positive children. Recent European guidelines on screening for celiac disease in children (not specific to children with type 1 diabetes) suggested that biopsy might not be necessary in symptomatic children with positive antibodies, as long as further testing such as genetic or HLA testing was supportive, but that asymptomatic but at-risk children should have biopsies (434). One small study that included children with and without type 1 diabetes suggested that antibody-positive but biopsy-negative children were similar clinically to those who were biopsy positive and that biopsy-negative children had benefits from a gluten-free diet but worsening on a usual diet (435). Because this study was small and because children with type 1 diabetes already need to follow a careful diet, it is difficult to advocate for not confirming the diagnosis by biopsy before recommending a lifelong gluten-free diet, especially in asymptomatic children. In symptomatic children with type 1 diabetes and celiac...
disease, gluten-free diets reduce symptoms and rates of hypoglycemia (436).

vi. Hypothyroidism

Recommendations
- Consider screening children with type 1 diabetes for thyroid peroxidase and thyroglobulin antibodies soon after diagnosis. (E)
- Measuring thyroid-stimulating hormone (TSH) concentrations soon after diagnosis of type 1 diabetes, after metabolic control has been established, is reasonable. If normal, consider rechecking every 1–2 years, especially if the patient develops symptoms of thyroid dysfunction, thyromegaly, or an abnormal growth rate. (E)

Autoimmune thyroid disease is the most common autoimmune disorder associated with diabetes, occurring in 17–30% of patients with type 1 diabetes (437). About one-quarter of type 1 diabetic children have thyroid autoantibodies at the time of diagnosis of their diabetes (438), and the presence of thyroid autoantibodies is predictive of thyroid dysfunction, generally hypothyroidism but less commonly hyperthyroidism (439). Subclinical hypothyroidism may be associated with increased risk of symptomatic hypoglycemia (440) and with reduced linear growth (441). Hyperthyroidism alters glucose metabolism, potentially resulting in deterioration of metabolic control.

c. Self-management

No matter how sound the medical regimen, it can only be as good as the ability of the family and/or individual to implement it. Family involvement in diabetes remains an important component of optimal diabetes management throughout childhood and adolescence. Health care providers who care for children and adolescents, therefore, must be capable of evaluating the educational, behavioral, emotional, and psychosocial factors that impact implementation of a treatment plan and must work with the individual and family to overcome barriers or redefine goals as appropriate.

d. School and day care

Since a sizable portion of a child’s day is spent in school, close communication with and cooperation of school or day care personnel is essential for optimal diabetes management, safety, and maximal academic opportunities. See the ADA position statement on diabetes care in the school and day care setting (442) for further discussion.

e. Transition from pediatric to adult care

Recommendations
- As teens transition into emerging adulthood, health care providers and families must recognize their many vulnerabilities (B) and prepare the developing teen, beginning in early to mid adolescence and at least 1 year prior to the transition. (E)
- Both pediatricians and adult health care providers should assist in providing support and links to resources for the teen and emerging adult. (B)

Care and close supervision of diabetes management is increasingly shifted from parents and other older adults throughout childhood and adolescence. However, the shift from pediatric to adult health care providers often occurs very abruptly as the older teen enters the next developmental stage referred to as emerging adulthood (443), a critical period for young people who have diabetes; during this period of major life transitions, youth begin to move out of their parents’ home and must become more fully responsible for their diabetes care including the many aspects of self-management, making medical appointments, and financing health care once they are no longer covered under their parents’ health insurance (444,445). In addition to lapses in health care, this is also a period of deterioration in glycemic control, increased occurrence of acute complications, psycho-social-emotional-behavioral issues, and emergence of chronic complications (444,447).

Though scientific evidence continues to be limited, it is clear that early and ongoing attention be given to comprehensive and coordinated planning for seamless transition of all youth from pediatric to adult health care (444,445). A comprehensive discussion regarding the challenges faced during this period, including specific recommendations, is found in the ADA position statement “Diabetes Care for Emerging Adults: Recommendations for Transition From Pediatric to Adult Diabetes Care Systems” (445).

The National Diabetes Education Program (NDEP) has materials available to facilitate the transition process (http://ndep.nih.gov/transitions/), and The Endocrine Society (in collaboration with the ADA and other organizations has developed transition tools for clinicians and youth/families (http://www.endo-society.org/clinicalpractice/transition_of_care.cfm).

2. Type 2 diabetes

The incidence of type 2 diabetes in adolescents is increasing, especially in ethnic minority populations (31). Distinction between type 1 and type 2 diabetes in children can be difficult, since the prevalence of overweight in children continues to rise and since autoantigens and ketosis may be present in a substantial number of patients with features of type 2 diabetes (including obesity and acanthosis nigricans). Such a distinction at the time of diagnosis is critical because treatment regimens, educational approaches, and dietary counsel will differ markedly between the two diagnoses.

Type 2 diabetes has a significant incidence of comorbidities already present at the time of diagnosis (448). It is recommended that blood pressure measurement, a fasting lipid profile, microalbuminuria assessment, and dilated eye examination be performed at the time of diagnosis. Thereafter, screening guidelines and treatment recommendations for hypertension, dyslipidemia, microalbuminuria, and retinopathy in youth with type 2 diabetes are similar to those for youth with type 1 diabetes. Additional problems that may need to be addressed include polycystic ovarian disease and the various comorbidities associated with pediatric obesity such as sleep apnea, hepatic steatosis, orthopedic complications, and psychosocial concerns. The ADA consensus statement on this subject (33) provides guidance on the prevention, screening, and treatment of type 2 diabetes and its comorbidities in young people.

3. Monogenic diabetes syndromes

Monogenic forms of diabetes (neonatal diabetes or maturity-onset diabetes of the young) represent a small fraction of children with diabetes (<5%), but the ready availability of commercial genetic testing is now enabling a true genetic diagnosis with increasing frequency. It is important to correctly diagnose one of the monogenic forms of diabetes, as these children may be incorrectly diagnosed with type 1 or type 2 diabetes, leading to nonoptimal treatment regimens and delays in diagnosing other family members.

The diagnosis of monogenic diabetes should be considered in the following settings: diabetes diagnosed within the first 6 months of life; in children with strong family history of diabetes but without typical features of type 2 diabetes.
Position Statement

Vital studies indicate that the risk of serious morbidity in infants of mothers with type 1 and type 2 diabetes. Observational studies such as the Diabetes in early pregnancy, including statins, ACE inhibitors, ARBs, and most noninsulin therapies. (E)

Since many pregnancies are unplanned, the potential risks and benefits of medications that are contraindicated in pregnancy in all women of childbearing potential. (C)

Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (B)

Medications used by such women should be evaluated prior to conception, since drugs commonly used to treat diabetes and its complications may be contraindicated or not recommended in pregnancy, including statins, ACE inhibitors, ARBs, and most noninsulin therapies. (E)

Since many pregnancies are unplanned, the potential risks and benefits of medications that are contraindicated in pregnancy in all women of childbearing potential and counsel women using such medications accordingly. (E)

Major congenital malformations remain the leading cause of mortality and serious morbidity in infants of mothers with type 1 and type 2 diabetes. Observational studies indicate that the risk of malformations increases continuously with increasing maternal glycemia during the first 6–8 weeks of gestation, as defined by first-trimester A1C concentrations. There is no threshold for A1C values below which risk disappears entirely. However, malformation rates above the 1–2% background rate of nondiabetic pregnancies appear to be limited to pregnancies in which first-trimester A1C concentrations are >2% above the normal range for a nondiabetic pregnant woman.

Preconception care of diabetes appears to reduce the risk of congenital malformations. Five randomized studies compared rates of major malformations in infants between women who participated in preconception diabetes care programs and women who initiated intensive diabetes management after they were already pregnant. The preconception care programs were multidisciplinary and designed to train patients in diabetes self-management with diet, intensified insulin therapy, and SMBG. Goals were set to achieve normal blood glucose concentrations, and >80% of subjects achieved normal A1C concentrations before they became pregnant. In all five studies, the incidence of major congenital malformations in women who participated in preconception care (range 1.0–1.7% of infants) was much lower than the incidence in women who did not participate (range 1.4–10.9% of infants) (106). One limitation of these studies is that participation in preconception care was self-selected rather than randomized. Thus, it is impossible to be certain that the lower malformation rates resulted fully from improved diabetes care. Nonetheless, the evidence supports the concept that malformations can be reduced or prevented by careful management of diabetes before pregnancy.

Planned pregnancies greatly facilitate preconception diabetes care. Unfortunately, nearly two-thirds of pregnancies in women with diabetes are unplanned, leading to a persistent excess of malformations in infants of diabetic mothers. To minimize the occurrence of these devastating malformations, standard care for all women with diabetes who have childbearing potential, beginning at the onset of puberty or at diagnosis, should include 1) education about the risk of malformations associated with unplanned pregnancies and poor metabolic control and 2) use of effective contraception at all times, unless the patient has good metabolic control and is actively trying to conceive.

Women contemplating pregnancy need to be seen frequently by a multidisciplinary team experienced in the management of diabetes before and during pregnancy. The goals of preconception care are to 1) involve and empower the patient in the management of her diabetes, 2) achieve the lowest A1C test results possible without excessive hypoglycemia, 3) assure effective contraception until stable and acceptable glycemia is achieved, and 4) identify, evaluate, and treat long-term diabetes complications such as retinopathy, nephropathy, neuropathy, hypertension, and CHD (106).

Among the drugs commonly used in the treatment of patients with diabetes, a number may be relatively or absolutely contraindicated during pregnancy. Statins are category X (contraindicated for use in pregnancy) and should be discontinued before conception, as should ACE inhibitors (450). ARBs are category C (risk cannot be ruled out) in the first trimester but category D (positive evidence of risk) in later pregnancy and should generally be discontinued before pregnancy. Since many pregnancies are unplanned, health care professionals caring for any woman of childbearing potential should consider the potential risks and benefits of medications that are contraindicated in pregnancy. Women using medications such as statins or ACE inhibitors need ongoing family planning counseling. Among the oral antidiabetic agents, metformin and acarbose are classified as category B (no evidence of risk in humans) and all others as category C. Potential risks and benefits of oral antidiabetic agents in the preconception period must be carefully weighed, recognizing that data are insufficient to establish the safety of these agents in pregnancy.

For further discussion of preconception care, see the ADA’s consensus statement on pre-existing diabetes and pregnancy (106) and the position statement (451) on this subject.

C. Older adults

Recommendations

- Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes care with goals similar to those developed for younger adults. (E)
- Glycemic goals for some older adults might reasonably be relaxed, using individual criteria, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. (E)
- Other cardiovascular risk factors should be treated in older adults with consideration of the time frame of benefit and the individual patient. Treatment of hypertension is indicated in virtually all older adults, and lipid and aspirin therapy may benefit those with life expectancy at least equal to the time frame of primary or secondary prevention trials. (E)
- Screening for diabetes complications should be individualized in older adults, but particular attention should be paid to complications that would lead to functional impairment. (E)
Diabetes is an important health condition for the aging population, at least 20% of patients over the age of 65 years have diabetes, and this number can be expected to grow rapidly in the coming decades. Older individuals with diabetes have higher rates of premature death, functional disability, and coexisting illnesses such as hypertension, CHD, and stroke than those without diabetes. Older adults with diabetes are also at greater risk than other older adults for several common geriatric syndromes, such as polypharmacy, depression, cognitive impairment, urinary incontinence, injurious falls, and persistent pain.

A consensus report on diabetes and older adults (452) influenced the following discussion and recommendations. The care of older adults with diabetes is complicated by their clinical and functional heterogeneity. Some older individuals developed diabetes years earlier and may have significant complications; others are newly diagnosed who have had years of undiagnosed diabetes with resultant complications or may have truly recent-onset disease and few or no complications. Some older adults with diabetes are frail and have other underlying chronic conditions, substantial diabetes-related comorbidity, or limited physical or cognitive functioning. Other older individuals with diabetes have little comorbidity and are active. Life expectancies are highly variable for this population, but often longer than clinicians realize. Providers caring for older adults with diabetes must take this heterogeneity into consideration when setting and prioritizing treatment goals.

There are few long-term studies in older adults demonstrating the benefits of intensive glycemic, blood pressure, and lipid control. Patients who can be expected to live long enough to reap the benefits of long-term intensive diabetes management, who have good cognitive and functional function, and who choose to do so via shared decision making may be treated using therapeutic interventions and goals similar to those for younger adults with diabetes. As with all patients, DSME and ongoing DSMS are vital components of diabetes care for older adults and their caregivers.

For patients with advanced diabetes complications, life-limiting comorbid illness, or substantial cognitive or functional impairment, it is reasonable to set less intensive glycemic target goals. These patients are less likely to benefit from reducing the risk of microvascular complications and more likely to suffer serious adverse effects from hypoglycemia. However, patients with poorly controlled diabetes may be subject to acute complications of diabetes, including dehydration, poor wound healing, and hyperglycemic hyperosmolar coma. Glycemic goals at a minimum should avoid these consequences.

Although control of hyperglycemia may be important in older individuals with diabetes, greater reductions in morbidity and mortality may result from control of other cardiovascular risk factors rather than from tight glycemic control alone. There is strong evidence from clinical trials of the value of treating hypertension in the elderly (453,454). There is less evidence for lipid-lowering and aspirin therapy, although the benefits of these interventions for primary and secondary prevention are likely to apply to other adults whose life expectancies equal or exceed the time frames seen in clinical trials.

Special care is required in prescribing and monitoring pharmacological therapy in older adults. Costs may be a significant factor, especially since older adults tend to be on many medications. Metformin may be contraindicated because of renal insufficiency or significant heart failure. Thiazolidinediones, if used at all, should be used very cautiously in those with, or at risk for, CHF and have also been associated with fractures. Sulfonylureas, other insulin secretagogues, and insulin can cause hypoglycemia. Insulin use requires that patients or caregivers have good visual and motor skills and cognitive ability. Dipeptidyl peptidase 4 (DPP-4) inhibitors have few side effects, but their costs may be a barrier to some older patients; the latter is also the case for GLP-1 agonists.

Screening for diabetes complications in older adults also should be individualized. Particular attention should be paid to complications that can develop over short periods of time and/or that would significantly impair functional status, such as visual and lower-extremity complications.

D. Cystic fibrosis–related diabetes

- Annual screening for cystic fibrosis–related diabetes (CFRD) with OGTT should begin by age 10 years in all patients with cystic fibrosis who do not have CFRD (B). Use of A1C as a screening test for CFRD is not recommended. (B)
- During a period of stable health, the diagnosis of CFRD can be made in cystic fibrosis patients according to usual glucose criteria. (E)
- Patients with CFRD should be treated with insulin to attain individualized glycemic goals. (A)
- Annual monitoring for complications of diabetes is recommended, beginning 5 years after the diagnosis of CFRD. (E)

CFRD is the most common comorbidity in persons with cystic fibrosis, occurring in about 20% of adolescents and 40–50% of adults. The additional diagnosis of diabetes in this population is associated with worse nutritional status, more severe inflammatory lung disease, and greater mortality from respiratory failure. Insulin insufficiency related to partial fibrotic destruction of the islet mass is the primary defect in CFRD. Genetically determined function of the remaining β-cells and insulin resistance associated with infection and inflammation may also play a role. Encouraging new data suggest that early detection and aggressive insulin therapy have narrowed the gap in mortality between cystic fibrosis patients with and without diabetes and have eliminated the sex difference in mortality (455).

Recommendations for the clinical management of CFRD can be found in the recent ADA position statement on this topic (456).

IX. DIABETES CARE IN SPECIFIC SETTINGS

A. Diabetes care in the hospital

- All patients with diabetes admitted to the hospital should have their diabetes clearly identified in the medical record. (E)
- All patients with diabetes should have an order for blood glucose monitoring, with results available to all members of the health care team. (E)
- Goals for blood glucose levels:
  - Critically ill patients: Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold of no greater than 180 mg/dL (10 mmol/L). Once insulin therapy is started, a glucose range of 140–180 mg/dL (7.8–10 mmol/L) is recommended for the majority of critically ill patients. (A)
  - More stringent goals, such as 110–140 mg/dL (6.1–7.8 mmol/L) may be
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appropriate for selected patients, as long as this can be achieved without significant hypoglycemia. (C)
• Critically ill patients require an intravenous insulin protocol that has demonstrated efficacy and safety in achieving the desired glucose range without increasing risk for severe hypoglycemia. (E)
• Non-critically ill patients: There is no clear evidence for specific blood glucose goals. If treated with insulin, the pre-meal blood glucose targets generally <140 mg/dL (7.8 mmol/L) with random blood glucose <180 mg/dL (10.0 mmol/L) are reasonable, provided these targets can be safely achieved. More stringent targets may be appropriate in stable patients with previous tight glycemic control. Less stringent targets may be appropriate in those with severe comorbidities. (E)
• Scheduled subcutaneous insulin with basal, nutritional, and correction components is the preferred method for achieving and maintaining glucose control in non-critically ill patients. (C)
• Glucose monitoring should be initiated in any patient not known to be diabetic who receives therapy associated with high risk for hyperglycemia, including high-dose glucocorticoid therapy, initiation of enteral or parenteral nutrition, or other medications such as octreotide or immunosuppressive medications. (B)
If hyperglycemia is documented and persistent, consider treating such patients to the same glycemic goals as patients with known diabetes. (E)
• A hypoglycemia management protocol should be adopted and implemented by each hospital or hospital system. A plan for preventing and treating hypoglycemia should be established for each patient. Episodes of hypoglycemia in the hospital should be documented in the medical record and tracked. (E)
• Consider obtaining an A1C on patients with diabetes admitted to the hospital if the result of testing in the previous 2–3 months is not available. (E)
• Consider obtaining an A1C in patients with risk factors for undiagnosed diabetes who exhibit hyperglycemia in the hospital. (E)
• Patients with hyperglycemia in the hospital who do not have a prior diagnosis of diabetes should have appropriate plans for follow-up testing and care documented at discharge. (E)

Hyperglycemia in the hospital can represent previously known diabetes, previously undiagnosed diabetes, or hospital-related hyperglycemia (fasting blood glucose $\geq$126 mg/dL or random blood glucose $\geq$200 mg/dL occurring during the hospitalization that reverts to normal after hospital discharge). The difficulty distinguishing between the second and third categories during the hospitalization may be overcome by measuring an A1C in undiagnosed patients with hyperglycemia, as long as conditions interfering with A1C utility (hemolysis, blood transfusion) have not occurred. The management of hyperglycemia in the hospital has often been considered secondary in importance to the condition that prompted admission (457). However, a body of literature now supports targeted glucose control in the hospital setting for potential improved clinical outcomes. Hyperglycemia in the hospital may result from stress, decomposition of type 1 or type 2 or other forms of diabetes, and/or may be iatrogenic due to withholding of antihyperglycemic medications or administration of hyperglycemia-provoking agents such as glucocorticoids or vasoconstrictors.

There is substantial observational evidence linking hyperglycemia in hospitalized patients to poor outcomes. Cohort studies as well as a few early RCTs suggested that intensive treatment of hyperglycemia improved hospital outcomes (457–459). In general, these studies were heterogeneous in terms of patient population, blood glucose targets and insulin protocols used, provision of nutritional support, and the proportion of patients receiving insulin, which limits the ability to make meaningful comparisons among them. Recent trials in critically ill patients have failed to show a significant improvement in mortality with intensive glycemic control (460,461) or have even shown increased mortality risk (462). Moreover, these recent RCTs have highlighted the risk of severe hyperglycemia resulting from such efforts (460–465).

The largest study to date, NICE-SUGAR (Normoglycaemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation), a multicenter, multinational RCT, compared the effect of intensive glycemic control (target 81–108 mg/dL, mean blood glucose attained 115 mg/dL) to standard glycemic control (target 144–180 mg/dL, mean blood glucose attained 144 mg/dL) on outcomes among 6,104 critically ill participants, almost all of whom required mechanical ventilation (462). Ninety-day mortality was significantly higher in the intensive versus the conventional group in both surgical and medical patients, as was mortality from cardiovascular causes. Severe hypoglycemia was also more common in the intensively treated group (6.8% vs. 0.5%, P < 0.001). The precise reason for the increased mortality in the tightly controlled group is unknown. The results of this study lie in stark contrast to a famous 2001 single-center study that reported a 42% relative reduction in intensive care unit (ICU) mortality in critically ill surgical patients treated to a target blood glucose of 80–110 mg/dL (458). Importantly, the control group in NICE-SUGAR had reasonably good blood glucose management, maintained at a mean glucose of 144 mg/dL, only 29 mg/dL above the intensively managed patients. Accordingly, this study’s findings do not disprove the notion that glycemic control in the ICU is important. However, they do strongly suggest that it may not be necessary to target blood glucose values <140 mg/dL and that a highly stringent target of <110 mg/dL may actually be dangerous.

In a recent meta-analysis of 26 trials (N = 13,567), which included the NICE-SUGAR data, the pooled RR of death with intensive insulin therapy was 0.93 as compared with conventional therapy (95% CI 0.83–1.04) (465). Approximately half of these trials reported hypoglycemia, with a pooled RR of intensive therapy of 6.0 (95% CI 4.5–8.0). The specific ICU setting influenced the findings, with patients in surgical ICUs appearing to benefit from intensive insulin therapy (RR 0.63, 95% CI 0.44–0.91), whereas those in other medical and mixed critical care settings did not. It was concluded that, overall, intensive insulin therapy increased the risk of hypoglycemia but provided no overall benefit on mortality in the critically ill, although a possible mortality benefit to patients admitted to the surgical ICU was suggested.

1. Glycemic targets in hospitalized patients

Definition of glucose abnormalities in the hospital setting
Hyperglycemia in the hospital has been defined as any blood glucose >140 mg/dL (7.8 mmol/L). Levels that are significantly and persistently above this may require treatment in hospitalized patients. A1C values >6.5% suggest, in undiagnosed
patients, that diabetes preceded hospitalization (466). Hypoglycemia has been defined as any blood glucose <70 mg/dL (3.9 mmol/L). This is the standard definition in outpatients and correlates with the initial threshold for the release of counter-regulatory hormones. Severe hypoglycemia in hospitalized patients has been defined by many as <40 mg/dL (2.2 mmol/L), although this is lower than the ~50 mg/dL (2.8 mmol/L) level at which cognitive impairment begins in normal individuals (467). As with hyperglycemia, hypoglycemia among inpatients is also associated with adverse short- and long-term outcomes. Early recognition and treatment of mild to moderate hypoglycemia (40–69 mg/dL [2.2–3.8 mmol/L]) can prevent deterioration to a more severe episode with potential adverse sequela (468).

**Critically ill patients**

Based on the weight of the available evidence, for the majority of critically ill patients in the ICU setting, insulin infusion should be used to control hyperglycemia, with a starting threshold of no higher than 180 mg/dL (10.0 mmol/L). Once intravenous insulin is started, the glucose level should be maintained between 140 and 180 mg/dL (7.8 and 10.0 mmol/L). Greater benefit maybe realized at the lower end of this range. Although strong evidence is lacking, somewhat lower glucose targets may be appropriate in selected patients. One small study suggested that medical intensive care unit (MICU) patients treated to targets of 120–140 mg/dL had less negative nitrogen balance than those treated to higher targets (469). However, targets <110 mg/dL (6.1 mmol/L) are not recommended. Use of insulin infusion protocols with demonstrated safety and efficacy, resulting in low rates of hypoglycemia, are highly recommended (468).

**Non–critically ill patients**

With no prospective RCT data to inform specific glycemic targets in non–critically ill patients, recommendations are based on clinical experience and judgment (470). For the majority of non–critically ill patients treated with insulin, premeal glucose targets should generally be <140 mg/dL (7.8 mmol/L) with random blood glucose <180 mg/dL (10.0 mmol/L), as long as these targets can be safely achieved. To avoid hypoglycemia, consideration should be given to reassessing the insulin regimen if blood glucose levels fall below 100 mg/dL (5.6 mmol/L). Modification of the regimen is required when blood glucose values are <70 mg/dL (3.9 mmol/L), unless the event is easily explained by other factors (such as a missed meal). There is some evidence that systematic attention to hyperglycemia in the emergency room leads to better glycemic control in the hospital for those subsequently admitted (471).

Occasional patients with a prior history of successful tight glycemic control in the outpatient setting who are clinically stable may be maintained with a glucose range below the above cut points. Conversely, higher glucose ranges may be acceptable in terminally ill patients or in patients with severe comorbidities, as well as in those in patient care settings where frequent glucose monitoring or close nursing supervision is not feasible.

Clinical judgment, combined with ongoing assessment of the patient’s clinical status, including changes in the trajectory of glycemic measures, the severity of illness, nutritional status, or concurrent use of medications that might affect glucose levels (e.g., steroids, octreotide), must be incorporated into the day-to-day decisions regarding insulin dosing (468).

**2. Antihyperglycemic agents in hospitalized patients**

In the hospital setting, insulin therapy is the preferred method of glycemic control in majority of clinical situations (468). In the ICU, intravenous infusion is the preferred route of insulin administration. When the patient is transitioned off intravenous insulin to subcutaneous therapy, precautions should be taken to prevent hyperglycemia escape (472,473). Outside of critical care units, scheduled subcutaneous insulin that delivers basal, nutritional, and correction (supplemental) components is preferred. Typical dosing schemes are based on body weight, with some evidence that patients with renal insufficiency should be treated with lower doses (474). Prolonged therapy with sliding-scale insulin (SSI) as the sole regimen is ineffective in the majority of patients, increases risk of both hyperglycemia and hypoglycemia, and has recently been shown in a randomized trial to be associated with adverse outcomes in general surgery patients with type 2 diabetes (475). SSI is potentially dangerous in type 1 diabetes (468). The reader is referred to several recent publications and reviews that describe currently available insulin preparations and protocols and provide guidance in use of insulin therapy in specific clinical settings including parental nutrition (476), enteral tube feedings and with high dose glucocorticoid therapy (468).

There are no data on the safety and efficacy of oral agents and injectable noninsulin therapies such as GLP-1 analogs and pramlintide in the hospital. They are generally considered to have a limited role in the management of hyperglycemia in conjunction with acute illness. Continuation of these agents may be appropriate in selected stable patients who are expected to consume meals at regular intervals, and they may be initiated or resumed in anticipation of discharge once the patient is clinically stable. Specific caution is required with metformin, due to the possibility that a contraindication may develop during the hospitalization, such as renal insufficiency, unstable hemodynamic status, or need for an imaging study that requires a radio-contrast dye.

**3. Preventing hypoglycemia**

In the hospital, multiple risk factors for hypoglycemia are present. Patients with or without diabetes may experience hyperglycemia in the hospital in association with altered nutritional state, heart failure, renal or liver disease, malignancy, infection, or sepsis. Additional triggering events leading to iatrogenic hyperglycemia include sudden reduction of corticosteroid dose, altered ability of the patient to report symptoms, reduction of oral intake, emesis, new NPO status, inappropriate timing of short- or rapid-acting insulin in relation to meals, reduction of rate of administration of intravenous dextrose, and unexpected interruption of enteral feedings or parenteral nutrition. Despite the preventable nature of many inpatient episodes of hypoglycemia, institutions are more likely to have nursing protocols for the treatment of hypoglycemia than for its prevention. Tracking such episodes and analyzing their causes are important quality-improvement activities (468).

**4. Diabetes care providers in the hospital**

Inpatient diabetes management may be effectively championed and/or provided by primary care physicians, endocrinologists, intensivists, or hospitalists. Involvement of appropriately trained specialists or specialty teams may reduce length of stay, improve glycemic control, and improve outcomes (468). In the care of diabetes, implementation of standardized
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order sets for scheduled and correction
doctrine insulin may reduce reliance on
sliding-scale management. As hospitals
move to comply with “meaningful use”
regulations for electronic health records,
as mandated by the Health Information
Technology Act, efforts should be made
to assure that all components of struc
tured insulin order sets are incorporated
into electronic insulin order sets (477,478).

A team approach is needed to estab-
lish hospital pathways. To achieve glyce-
mic targets associated with improved
hospital outcomes, hospitals will need
multidisciplinary support to develop insu-
lin management protocols that effect-
tively and safely enable achievement of
glycemic targets (479).

5. Self-management in the hospital
Self-management of diabetes in the hos-
pital may be appropriate for competent
adult patients who have a stable level of
consciousness, have reasonably stable
daily insulin requirements, successfully
conduct self-management of diabetes at
home, have physical skills needed to
successfully self-administer insulin and
perform SMBG, have adequate oral in-
take, and are proficient in carbohydrate
counting, use of multiple daily insulin
injections or insulin pump therapy, and
sick-day management. The patient and
physician, in consultation with nursing
staff, must agree that patient self-
management is appropriate under the
conditions of hospitalization.

Patients who use CSII pump therapy
in the outpatient setting can be candidates
for diabetes self-management in the hos-
pital, provided that they have the mental
and physical capacity to do so (468). A
hospital policy and procedures delineat-
ing inpatient guidelines for CSII therapy
are advisable, and availability of hospital
personnel with expertise in CSII therapy
is essential. It is important that nursing
personnel document basal rates and bolus
doses taken on a regular basis (at least
daily).

6. MNT in the hospital
The goals of MNT are to optimize glyce-
mic control, to provide adequate calories
to meet metabolic demands, and to
create a discharge plan for follow-up
care (457,480). The ADA does not en-
dorse any single meal plan or specified
percentages of macronutrients, and the
term “ADA diet” should no longer be
used. Current nutrition recommenda-
tions advise individualization based on
treatment goals, physiological parame-
ters, and medication usage. Consistent
carbohydrate meal plans are preferred
by many hospitals because they facilitate
matching the prandial insulin dose to the
amount of carbohydrate consumed (481).

Because of the complexity of nutrition is-
sues in the hospital, a registered dietitian,
knowledgeable and skilled in MNT,
should serve as an inpatient team mem-
ber. The dietitian is responsible for inte-
grating information about the patient’s
clinical condition, eating, and lifestyle
habits and for establishing treatment
goals in order to determine a realistic
plan for nutrition therapy (482,483).

7. Bedside blood glucose monitoring
POC blood glucose monitoring per-
formed at the bedside is used to guide
insulin dosing. In the patient who is
receiving nutrition, the timing of glucose
monitoring should match carbohydrate
exposure. In the patient who is not re-
ceiving nutrition, glucose monitoring is
performed every 4 to 6 h (484,485). More
frequent blood glucose testing ranging
from every 30 min to every 2 h is required
for patients on intravenous insulin infusions.

Safety standards should be estab-
lished for blood glucose monitoring pro-
hibiting sharing of finger-stick lancing
devices, lancets, needles, and meters to
reduce the risk of transmission of blood
borne diseases. Shared lancing devices carry
essentially the same risk as is conferred from
sharing of syringes and needles (486).

Accuracy of blood glucose measure-
ments using POC meters has limitations
that must be considered. Although the
FDA allows a +/- 20% error for blood
glucose meters, questions about the ap-
propriateness of these criteria have been
raised (388). Glucose measures differ sig-
nificantly between plasma and whole
blood, terms that are often used inter-
changeably and can lead to misinter-
pretation. Most commercially available
capillary blood glucose meters introduce a
correction factor of ~1.12 to report a
“plasma-adjusted” value (487).

Significant discrepancies between capillary, venous, and arterial plasma
samples have been observed in patients
with low or high hemoglobin concentra-
tions, hypoperfusion, and the presence
of interfering substances particularly
malse, as contained in immunoglobu-
mins (488). Analytical variability has been
described with several POC meters (489).

Increasingly newer generation POC blood
glucose meters correct for variation in
hematocrit and for interfering substances.

Any glucose result that does not correlate
with the patient’s status should be con-
ﬁrmed through conventional laboratory
sampling of plasma glucose. The FDA
has become increasingly concerned about
the use of POC blood glucose meters in
the hospital and is presently reviewing
matters related to their use.

8. Discharge planning and DSME
Transition from the acute care setting is a
high-risk time for all patients, not just those
with diabetes or new hyperglycemia.
Although there is an extensive literature
concerning safe transition within and
from the hospital, little of it is speciﬁc to
diabetes (490). It is important to remember
that diabetes discharge planning is not a
separate entity, but is part of an overall dis-
charge plan. As such, discharge planning
begins at admission to the hospital and is
updated as projected patient needs change.

Inpatients may be discharged to vari-
ed settings, including home (with or
without visiting nurse services), assisted
living, rehabilitation, or skilled nursing
facilities. The latter two sites are generally
staffed by health professionals, so diabe-
tes discharge planning will be limited to
communication of medication and diet
orders. For the patient who is discharged
to assisted living or to home, the optimal
program will need to consider the type
and severity of diabetes, the effects of the
patient’s illness on blood glucose levels,
and the capacities and desires of the pa-
tient. Smooth transition to outpatient care
should be ensured. The Agency for Health-
care Research and Quality (AHRQ) recom-
mends that at a minimum, discharge plans
include the following:

- Medication reconciliation: The pa-
tient’s medications must be cross-
checked to ensure that no chronic
medications were stopped and to en-
sure the safety of new prescriptions.
- Whenever possible, prescriptions for
new or changed medication should be
filled and reviewed with the patient and
family at or before discharge.
- Structured discharge communication:
Information on medication changes,
pending tests and studies, and follow-up
needs must be accurately and promptly
communicated to outpatient physicians.
- Discharge summaries should be trans-
mitted to the primary physician as soon
as possible after discharge.
- Appointment keeping behavior is en-
hanced when the inpatient team
Teaching diabetes self-management to patients in hospitals is a challenging task. Patients are ill, under increased stress related to their hospitalization and diagnosis, and in an environment not conducive to learning. Ideally, people with diabetes should be taught at a time and place conducive to learning: as an outpatient in a recognized program of diabetes education. For the hospitalized patient, diabetes “survival skills” education is generally a feasible approach to provide sufficient information and training to enable safe care at home. Patients hospitalized because of a crisis related to diabetes management or poor care at home need education to prevent subsequent episodes of hospitalization. An assessment of the need for a home health referral or referral to an outpatient diabetes education program should be part of discharge planning for all patients.

DSME cannot wait until discharge, especially in those new to insulin therapy or in whom the diabetes regimen has been substantially altered during the hospitalization.

It is recommended that the following areas of knowledge be reviewed and addressed prior to hospital discharge:

- Identification of health care provider who will provide diabetes care after discharge
- Level of understanding related to the diagnosis of diabetes, SMBG, and explanation of home blood glucose goals
- Definition, recognition, treatment, and prevention of hyperglycemia and hypoglycemia
- Information on consistent eating patterns
- When and how to take blood glucose-lowering medications including insulin administration (if going home on insulin
- Sick-day management
- Proper use and disposal of needles and syringes

It is important that patients be provided with appropriate durable medical equipment, medication, supplies, and prescriptions at the time of discharge in order to avoid a potentially dangerous hiatus in care. These supplies/prescriptions should include the following:

- Insulin (vials or pens) if needed
- Syringes or pen needles (if needed)
- Oral medications (if needed)
- Blood glucose meter and strips
- Lancets and lancing device
- Urine ketone strips (type 1)
- Glucagon emergency kit (insulin-treated)
- Medical alert application/charm

More expanded diabetes education can be arranged in the community. An outpatient follow-up visit with the primary care provider, endocrinologist, or diabetes educator within 1 month of discharge is advised for all patients having hypoglycemia in the hospital. Clear communication with outpatient providers either directly or via hospital discharge summaries facilitates safe transitions to outpatient care. Providing information regarding the cause or the plan for determining the cause of hyperglycemia, related complications and comorbidities, and recommended treatments can assist outpatient providers as they assume ongoing care.

### B. Diabetes and employment

Any person with diabetes, whether insulin treated or noninsulin treated, should be eligible for any employment for which he/she is otherwise qualified. Employment decisions should never be based on generalizations or stereotypes regarding the effects of diabetes. When questions arise about the medical fitness of a person with diabetes for a particular job, a health care professional with expertise in treating diabetes should perform an individualized assessment. See the ADA position statement on diabetes and employment (492).

### C. Diabetes and driving

A large percentage of people with diabetes in the U.S. and elsewhere seek a license to drive, either for personal or employment purposes. There has been considerable debate whether, and the extent to which, diabetes may be a relevant factor in determining the driver ability and eligibility for a license.

People with diabetes are subject to a great variety of licensing requirements applied by both state and federal jurisdictions, which may lead to loss of employment or significant restrictions on a person’s license. Presence of a medical condition that can lead to significantly impaired consciousness or cognition may lead to drivers being evaluated for fitness to drive. For diabetes, this typically arises when the person has had a hypoglycemic episode behind the wheel, even if this did not lead to a motor vehicle accident. Epidemiological and simulator data suggest that people with insulin-treated diabetes have a small increase in risk of motor vehicle accidents, primarily due to hypoglycemia and decreased awareness of hypoglycemia. This increase (RR 1.12–1.19) is much smaller than the risks associated with teenage male drivers (RR 42), driving at night (RR 142), driving on rural roads compared with urban roads (RR 9.2), and obstructive sleep apnea (RR 2.4), all of which are accepted for unrestricted licensure.

The ADA position statement on diabetes and driving (493) recommends against blanket restrictions based on the diagnosis of diabetes and urges individual assessment by a health care professional knowledgeable in diabetes if restrictions on licensure are being considered. Patients should be evaluated for decreased awareness of hypoglycemia, hypoglycemia episodes while driving, or severe hypoglycemia. Patients with retinopathy or peripheral neuropathy require assessment to determine if those complications interfere with operation of a motor vehicle. Health care professionals should be cognizant of the potential risk of driving with diabetes and counsel their patients about detecting and avoiding hypoglycemia while driving.

### D. Diabetes management in correctional institutions

People with diabetes in correctional facilities should receive care that meets national standards. Because it is estimated that nearly 80,000 inmates have diabetes, correctional institutions should have written policies and procedures for the management of diabetes and for training of medical and correctional staff in diabetes care practices. See the ADA position statement on diabetes management in correctional institutions (494) for further discussion.

### X. STRATEGIES FOR IMPROVING DIABETES CARE

#### Recommendations

- Care should be aligned with components of the Chronic Care Model (CCM) to ensure productive interactions between a prepared proactive
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A patient-centered communication style should be employed that incorporates patient preferences, assesses literacy and numeracy, and addresses cultural barriers to care. (B)

There has been steady improvement in the proportion of diabetic patients achieving recommended levels of A1C, blood pressure, and LDL cholesterol in the last 10 years, both in primary care settings and in endocrinology practices. Mean A1C nationally has declined from 7.82% in 1999–2000 to 7.18% in 2004 based on NHANES data (495). This has been accompanied by improvements in lipids and blood pressure control and led to substantial reductions in end-stage microvascular complications in those with diabetes. Nevertheless in some studies only 57.1% of adults with diagnosed diabetes achieved an A1C of <7%, only 45.5% had a blood pressure <130/80 mmHg, and just 46.5% had a total cholesterol <200 mg/dL, with only 12.2% of people with diabetes achieving all three treatment goals (496). Evidence also suggests that progress in risk factor control may be slowing (497). Certain patient groups, such as patients with complex comorbidities, financial or other social hardships, and/or limited English proficiency, may present particular challenges to goal-based care (498,499). Persistent variation in quality of diabetes care across providers and across practice settings even after adjusting for patient factors indicates that there remains potential for substantial further improvements in diabetes care.

Although numerous interventions to improve adherence to the recommended standards have been implemented, a major barrier to optimal care is a delivery system that too often is fragmented, lacks clinical information capabilities, often duplicates services, and is poorly designed for the coordinated delivery of chronic care. The CCM has been shown in numerous studies to be an effective framework for improving the quality of diabetes care (500). The CCM includes six core elements for the provision of optimal care of patients with chronic disease: 1) delivery system design (moving from a reactive to a proactive care delivery system where planned visits are coordinated through a team based approach), 2) self-management support, 3) decision support (basing care on evidence-based, effective care guidelines), 4) clinical information systems (using registries that can provide patient-specific and population-based support to the care team), 5) community resources and policies (identifying or developing resources to support healthy lifestyles), and 6) health systems (to create a quality-oriented culture). Re-definition of the roles of the clinic staff and promoting self-management on the part of the patient are fundamental to the successful implementation of the CCM (501). Collaborative, multidisciplinary teams are best suited to provide such care for people with chronic conditions such as diabetes and to facilitate patients’ performance of appropriate self-management (163,165,220,502).

NDEP maintains an online resource (www.betterdiabetescare.nih.gov) to help health care professionals design and implement more effective health care delivery systems for those with diabetes. Three specific objectives, with references to literature that outlines practical strategies to achieve each, are outlined below.

Objective 1: Optimize provider and team behavior
The care team should prioritize timely and appropriate intensification of lifestyle and/or pharmaceutical therapy of patients who have not achieved beneficial levels of blood pressure, lipid, or glucose control (503). Strategies such as explicit goal setting with patients (504), identifying and addressing language, numeracy, or cultural barriers to care (505–508), integrating evidence-based guidelines and clinical information tools into the process of care (509–511), and incorporating care management teams including nurses, pharmacists, and other providers (512–515) have each been shown to optimize provider and team behavior and thereby catalyze reduction in A1C, blood pressure, and LDL cholesterol.

Objective 2: Support patient behavior change
Successful diabetes care requires a systematic approach to supporting patients’ behavior change efforts, including a) healthy lifestyle changes (physical activity, healthy eating, nonuse of tobacco, weight management, effective coping), b) disease self-management (medication taking and management; self-monitoring of glucose and blood pressure when clinically appropriate), and c) prevention of diabetes complications (self-monitoring of foot health; active participation in screening for eye, foot, and renal complications; immunizations). High-quality DSME has been shown to improve patient self-management, satisfaction, and glucose control (184,516), as has delivery of ongoing DSMS so that gains achieved during DSME are sustained (134,135,152). National DSME standards call for an integrated approach that includes clinical content and skills, behavioral strategies (goal-setting, problem solving), and addressing emotional concerns in each needed curriculum content area.

Objective 3: Change the system of care
The most successful practices have an institutional priority for providing high quality of care (517). Changes that have been shown to increase quality of diabetes care include basing care on evidence-based guidelines (518), expanding the role of teams and staff (501,519), redesigning the processes of care (520), implementing electronic health record tools (521,522), activating and educating patients (523,524), and identifying and/or developing and engaging community resources and public policy that support healthy lifestyles (525). Recent initiatives such as the Patient-Centered Medical Home show promise to improve outcomes through coordinated primary care and offer new opportunities for team-based chronic disease care (526). Alterations in reimbursement that reward the provision of appropriate and high-quality care rather than visits-based billing (527) and that can accommodate the need to personalize care goals may provide additional incentives to improve diabetes care (528).

It is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of dedicated health care professionals working in an environment where patient-centered high-quality care is a priority.

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Position Statement
Position Statement
Diagnosis and Classification of Diabetes Mellitus

American Diabetes Association

DEFINITION AND DESCRIPTION OF DIABETES MELLITUS—Diabetes is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of different organs, especially the eyes, kidneys, nerves, heart, and blood vessels.

Several pathogenic processes are involved in the development of diabetes. These range from autoimmune destruction of the β-cells of the pancreas with consequent insulin deficiency to abnormalities that result in resistance to insulin action. The basis of the abnormalities in carbohydrate, fat, and protein metabolism in diabetes is deficient action of insulin on target tissues. Deficient insulin action results from inadequate insulin secretion and/or diminished tissue responses to insulin at one or more points in the complex pathways of hormone action. Impairment of insulin secretion and defects in insulin action frequently coexist in the same patient, and it is often unclear which abnormality, if either alone, is the primary cause of the hyperglycemia.

Symptoms of marked hyperglycemia include polyuria, polydipsia, weight loss, sometimes with polyphagia, and blurred vision. Impairment of growth and susceptibility to certain infections may also accompany chronic hyperglycemia. Acute, life-threatening consequences of uncontrolled diabetes are hyperglycemia with ketoacidosis or the nonketotic hyperosmolar syndrome.

Long-term complications of diabetes include retinopathy with potential loss of vision; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers, amputations, and Charcot joints; and autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction. Patients with diabetes have an increased incidence of atherosclerotic cardiovascular, peripheral arterial, and cerebrovascular disease. Hypertension and abnormalities of lipoprotein metabolism are often found in people with diabetes.

The vast majority of cases of diabetes fall into two broad etiopathogenetic categories (discussed in greater detail below). In one category, type 1 diabetes, the cause is an absolute deficiency of insulin secretion. Individuals at increased risk of developing this type of diabetes can often be identified by serological evidence of an autoimmune pathologic process occurring in the pancreatic islets and by genetic markers. In the other, much more prevalent category, type 2 diabetes, the cause is a combination of resistance to insulin action and an inadequate compensatory insulin secretory response. In the latter category, a degree of hyperglycemia sufficient to cause pathologic and functional changes in various target tissues, but without clinical symptoms, may be present for a long period of time before diabetes is detected. During this asymptomatic period, it is possible to demonstrate an abnormality in carbohydrate metabolism by measurement of plasma glucose in the fasting state or after a challenge with an oral glucose load or by A1C.

The degree of hyperglycemia (if any) may change over time, depending on the extent of the underlying disease process (Fig. 1). A disease process may be present but may not have progressed far enough to cause hyperglycemia. The same disease process can cause impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT) without fulfilling the criteria for the diagnosis of diabetes. In some individuals with diabetes, adequate glycemic control can be achieved with weight reduction, exercise, and/or oral glucose-lowering agents. These individuals therefore do not require insulin. Other individuals who have some residual insulin secretion but require exogenous insulin for adequate glycemic control can survive without it. Individuals with extensive β-cell destruction and therefore no residual insulin secretion require insulin for survival. The severity of the metabolic abnormality can progress, regress, or stay the same. Thus, the degree of hyperglycemia reflects the severity of the underlying metabolic process and its treatment more than the nature of the process itself.

CLASSIFICATION OF DIABETES MELLITUS AND OTHER CATEGORIES OF GLUCOSE REGULATION—Assigning a type of diabetes to an individual often depends on the circumstances present at the time of diagnosis, and many diabetic individuals do not easily fit into a single class. For example, a person diagnosed with gestational diabetes mellitus (GDM) may continue to be hyperglycemic after delivery and may be determined to have, in fact, type 2 diabetes. Alternatively, a person who acquires diabetes because of large doses of exogenous steroids may become normoglycemic once the glucocorticoids are discontinued, but then may develop diabetes many years later after recurrent episodes of pancreatitis. Another example would be a person treated with thiazides who develops diabetes years later. Because thiazides in themselves seldom cause severe hyperglycemia, such individuals probably have type 2 diabetes that is exacerbated by the drug. Thus, for the clinician and patient, it is less important to label the particular type of diabetes than it is to understand the pathogenesis of the hyperglycemia and to treat it effectively.

Type 1 diabetes (β-cell destruction, usually leading to absolute insulin deficiency)

Immune-mediated diabetes. This form of diabetes, which accounts for only 5–10% of those with diabetes, previously encompassed by the terms insulin-dependent diabetes or juvenile-onset diabetes, results from a cellular-mediated autoimmune destruction of the β-cells of
the pancreas. Markers of the immune destruction of the β-cell include islet cell autoantibodies, autoantibodies to insulin, autoantibodies to GAD (GAD65), and autoantibodies to the tyrosine phosphatases IA-2 and IA-2β. One and usually more of these autoantibodies are present in 85–90% of individuals when lasting hyperglycemia is initially detected. Also, the disease has strong HLA associations, with linkage to the DQA and DQB genes, and it is influenced by the DRB genes. These HLA-DR/DQ alleles can be either predisposing or protective.

In this form of diabetes, the rate of β-cell destruction is quite variable, being rapid in some individuals (mainly infants and children) and slow in others (mainly adults). Some patients, particularly children and adolescents, may present with ketoacidosis as the first manifestation of the disease. Others have modest fasting hyperglycemia that can rapidly change to severe hyperglycemia and/or ketoacidosis in the presence of infection or other stress. Still others, particularly adults, may retain residual β-cell function sufficient to prevent ketoacidosis for many years; such individuals eventually become dependent on insulin for survival and are at risk for ketoacidosis. At this latter stage of the disease, there is little or no insulin secretion, as manifested by low or undetectable levels of plasma C-peptide. Immune-mediated diabetes commonly occurs in childhood and adolescence, but it can occur at any age, even in the 8th and 9th decades of life.

Autoimmune destruction of β-cells has multiple genetic predispositions and is also related to environmental factors that are still poorly defined. Although patients are rarely obese when they present with this type of diabetes, the presence of obesity is not incompatible with the diagnosis. These patients are also prone to other autoimmune disorders such as Graves' disease, Hashimoto's thyroiditis, Addison's disease, vitiligo, celiac sprue, autoimmune hepatitis, myasthenia gravis, and pernicious anemia.

Idiopathic diabetes. Some forms of type 1 diabetes have no known etiologies. Some of these patients have permanent insulinopenia and are prone to ketoadiposis, but have no evidence of autoimmunity. Although only a minority of patients with type 1 diabetes fall into this category, of those who do, most are of African or Asian ancestry. Individuals with this form of diabetes suffer from episodic ketoadiposis and exhibit varying degrees of insulin deficiency between episodes. This form of diabetes is strongly inherited, lacks immunological evidence for β-cell autoimmunity, and is not HLA associated. An absolute requirement for insulin replacement therapy in affected patients may come and go.

Type 2 diabetes (ranging from predominantly insulin resistance with relative insulin deficiency to predominantly an insulin secretory defect with insulin resistance)

This form of diabetes, which accounts for ~90–95% of those with diabetes, previously referred to as non–insulin-dependent diabetes, type 2 diabetes, or adult-onset diabetes, encompasses individuals who have insulin resistance and usually have relative (rather than absolute) insulin deficiency. At least initially, and often throughout their lifetime, these individuals do not need insulin treatment to survive. There are probably many different causes of this form of diabetes. Although the specific etiologies are not known, autoimmune destruction of β-cells does not occur, and patients do not have any of the other causes of diabetes listed above or below.

Most patients with this form of diabetes are obese, and obesity itself causes some degree of insulin resistance. Patients who are not obese by traditional weight criteria may have an increased percentage of body fat distributed predominantly in the abdominal region. Ketoadiposis seldom occurs spontaneously in this type of diabetes; when seen, it usually arises in association with the stress of another illness such as infection. This form of diabetes frequently goes undiagnosed for many years because the hyperglycemia...
forms result from mutations in other transcription factors, including HNF-4α, HNF-1β, insulin promoter factor (IPF)-1, and NeuroD1.

Diabetes diagnosed in the first 6 months of life has been shown not to be typical autoimmune type 1 diabetes. This so-called neonatal diabetes can either be transient or permanent. The most common genetic defect causing transient disease is a defect on ZAC/HYAMI imprinting, whereas permanent neonatal diabetes is most commonly a defect in the gene encoding the Kir6.2 subunit of the β-cell K<sub>ATP</sub> channel. Diagnosing the latter has implications, since such children can be well managed with sulfonylureas.

Point mutations in mitochondrial DNA have been found to be associated with diabetes and deafness. The most common mutation occurs at position 3,243 in the tRNA leucine gene, leading to an A-to-G transition. An identical lesion occurs in the MELAS syndrome (mitochondrial myopathy, encephalopathy, lactic acidosis, and stroke-like syndrome); however, diabetes is not part of this syndrome, suggesting different phenotypic expressions of this genetic lesion.

Genetic abnormalities that result in the inability to convert proinsulin to insulin have been identified in a few families, and such traits are inherited in an autosomal dominant pattern. The resultant glucose intolerance is mild. Similarly, the production of mutant insulin molecules with resultant impaired receptor binding has also been identified in a few families and is associated with an autosomal inheritance and only mildly impaired or even normal glucose metabolism.

**Genetic defects in insulin action.** There are unusual causes of diabetes that result from genetically determined abnormalities of insulin action. The metabolic abnormalities associated with mutations of the insulin receptor may range from hyperinsulinemia and modest hyperglycemia to severe diabetes. Some individuals with these mutations may have acanthosis nigricans. Women may be virilized and have enlarged, cystic ovaries. In the past, this syndrome was termed type A insulin resistance. Leprechaunism and the Rabson-Mendenhall syndrome are two pediatric syndromes that have mutations in the insulin receptor gene with subsequent alterations in insulin receptor function and extreme insulin resistance. The former has characteristic facial features and is usually fatal in infancy, while the latter is associated with abnormalities of teeth and nails and pineal gland hyperplasia.

Alterations in the structure and function of the insulin receptor cannot be demonstrated in patients with insulin-resistant lipoatrophic diabetes. Therefore, it is assumed that the lesion(s) must reside in the postreceptor signal transduction pathways.

**Diseases of the exocrine pancreas.** Any process that diffusely injures the pancreas can cause diabetes. Acquired processes include pancreatitis, trauma, infection, pancreatic, and pancreatic carcinoma. With the exception of that caused by cancer, damage to the pancreas must be extensive for diabetes to occur; adenocarcinomas that involve only a small portion of the pancreas have been associated with diabetes. This implies a mechanism other than simple reduction in β-cell mass. If extensive enough, cystic fibrosis and hereditary ataxia will also damage β-cells and impair insulin secretion. Fibrocalculous pancreatopathy may be accompanied by abdominal pain radiating to the back and pancreatic calcifications identified on X-ray examination. Pancreatic fibrosis and calcium stones in the exocrine ducts have been found at autopsy.

**Endocrinopathies.** Several hormones (e.g., growth hormone, cortisol, glucagon, epinephrine) antagonize insulin action. Excess amounts of these hormones (e.g., acromegaly, Cushings syndrome, glucagonoma, pheochromocytoma, respectively) can cause diabetes. This generally occurs in individuals with preexisting defects in insulin secretion, and hyperglycemia typically resolves when the hormone excess is resolved.

Somatostatinomas, and aldosteronoma-induced hypokalemia, can cause diabetes, at least in part, by inhibiting insulin secretion. Hyperglycemia generally resolves after successful removal of the tumor.

**Drug- or chemical-induced diabetes.** Many drugs can impair insulin secretion. These drugs may not cause diabetes by themselves, but they may precipitate diabetes in individuals with insulin resistance. In such cases, the classification is uncertain because the sequence or relative importance of β-cell dysfunction and insulin resistance is unknown. Certain toxins such as Vacor (a rat poison) and intravenous pentamidine can permanently destroy pancreatic β-cells. Such drug reactions fortunately are rare. There are also many drugs and hormones that
can impair insulin action. Examples include nicotinic acid and glucocorticoids. Patients receiving α-interferon have been reported to develop diabetes associated with islet cell antibodies and, in certain instances, severe insulin deficiency. The list shown in Table 1 is not all-inclusive, but reflects the more commonly recognized drug-, hormone-, or toxin-induced forms of diabetes.

**Infections.** Certain viruses have been associated with β-cell destruction. Diabetes occurs in patients with congenital rubella, although most of these patients have HLA and immune markers characteristic of type 1 diabetes. In addition, coxsackievirus B, cytomegalovirus, adenovirus, and mumps have been implicated in inducing certain cases of the disease.

**Uncommon forms of immune-mediated diabetes.** In this category, there are two known conditions, and others are likely to occur. The stiff-man syndrome is an autoimmune disorder of the central nervous system characterized by stiffness of the axial muscles with painful spasms. Patients usually have high titers of the GAD autoantibodies, and approximately one-third will develop diabetes.

Anti-insulin receptor antibodies can cause diabetes by binding to the insulin receptor, thereby blocking the binding of insulin to its receptor in target tissues. However, in some cases, these antibodies can act as an insulin agonist after binding to the receptor and can thereby cause hypoglycemia. Anti-insulin receptor antibodies are occasionally found in patients with systemic lupus erythematosus and other autoimmune diseases. As in other states of extreme insulin resistance, patients with anti-insulin receptor antibodies often have acanthosis nigricans. In the past, this syndrome was termed type B insulin resistance.

**Other genetic syndromes sometimes associated with diabetes.** Many genetic syndromes are accompanied by an increased incidence of diabetes. These include the chromosomal abnormalities of Down syndrome, Klinefelter syndrome, and Turner syndrome. Wolfram syndrome is an autosomal recessive disorder characterized by insulin-deficient diabetes and the absence of β-cells at autopsy. Additional manifestations include diabetes insipidus, hypogonadism, optic atrophy, and neural deafness. Other syndromes are listed in Table 1.

**GDM**

For many years, GDM has been defined as any degree of glucose intolerance with

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**Table 1—Etiologic classification of diabetes mellitus**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Type 1 diabetes</td>
<td>β-cell destruction, usually leading to absolute insulin deficiency</td>
<td>A. Immune mediated&lt;br&gt;B. Idiopathic</td>
</tr>
<tr>
<td>II. Type 2 diabetes</td>
<td>May range from predominantly insulin resistance with relative insulin deficiency to a predominantly secretory defect with insulin resistance</td>
<td>A. Genetic defects of β-cell function&lt;br&gt;B. Genetic defects in insulin action&lt;br&gt;C. Diseases of the exocrine pancreas&lt;br&gt;D. Endocrinopathies&lt;br&gt;E. Drug or chemical induced&lt;br&gt;F. Infections&lt;br&gt;G. Uncommon forms of immune-mediated diabetes&lt;br&gt;H. Other genetic syndromes sometimes associated with diabetes&lt;br&gt;I. Gestational diabetes mellitus</td>
</tr>
<tr>
<td>A. Genetic defects of β-cell function</td>
<td>1. MODY 3 (Chromosome 12, HNF-1α)&lt;br&gt;2. MODY 1 (Chromosome 20, HNF-4α)&lt;br&gt;3. MODY 2 (Chromosome 7, glucokinase)&lt;br&gt;4. Other very rare forms of MODY (e.g., MODY 4: Chromosome 13, insulin promoter factor-1; MODY 6: Chromosome 2, NeuroD1; MODY 7: Chromosome 9, carboxyl ester lipase)&lt;br&gt;5. Transient neonatal diabetes (most commonly ZAC/HYAMI imprinting defect on 6q24)&lt;br&gt;6. Permanent neonatal diabetes (most commonly KCNJ11 gene encoding Kir6.2 subunit of β-cell KATP channel)&lt;br&gt;7. Mitochondrial DNA&lt;br&gt;8. Others</td>
<td></td>
</tr>
<tr>
<td>I. Gestational diabetes mellitus</td>
<td>Patients with any form of diabetes may require insulin treatment at some stage of their disease. Such use of insulin does not, of itself, classify the patient.</td>
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</table>
onset or first recognition during pregnancy. Although most cases resolve with delivery, the definition applied whether or not the condition persisted after pregnancy and did not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy. This definition facilitated a uniform strategy for detection and classification of GDM, but its limitations were recognized for many years. As the ongoing epidemic of obesity and diabetes has led to more type 2 diabetes in women of childbearing age, the number of pregnant women with undiagnosed type 2 diabetes has increased.

After deliberations in 2008–2009, the International Association of Diabetes and Pregnancy Study Groups (IADPSG), an international consensus group with representatives from multiple obstetrical and diabetes organizations, including the American Diabetes Association (ADA), recommended that high-risk women found to have diabetes at their initial prenatal visit, using standard criteria (Table 3), receive a diagnosis of overt, not gestational, diabetes. Approximately 7% of all pregnancies (ranging from 1 to 14%, depending on the population studied and the diagnostic tests employed) are complicated by GDM, resulting in more than 200,000 cases annually.

**CATEGORIES OF INCREASED RISK FOR DIABETES**—In 1997 and 2003, the Expert Committee on Diagnosis and Classification of Diabetes Mellitus (1,2) recognized an intermediate group of individuals whose glucose levels do not meet criteria for diabetes, yet are higher than those considered normal. These people were defined as having impaired fasting glucose (IFG) [fasting plasma glucose (FPG) levels 100 mg/dl (5.6 mmol/l) to 125 mg/dl (6.9 mmol/l)], or impaired glucose tolerance (IGT) [2-h values in the oral glucose tolerance test (OGTT) of 140 mg/dl (7.8 mmol/l) to 199 mg/dl (11.0 mmol/l)].

Individuals with IFG and/or IGT have been referred to as having prediabetes, indicating the relatively high risk for the future development of diabetes. IFG and IGT should not be viewed as clinical entities in their own right but rather risk factors for diabetes as well as cardiovascular disease. They can be observed as intermediate stages in any of the disease processes listed in Table 1. IFG and IGT are associated with obesity (especially abdominal or visceral obesity), dyslipidemia with high triglycerides and/or low HDL cholesterol, and hypertension. Structured lifestyle intervention, aimed at increasing physical activity and producing 5–10% loss of body weight, and certain pharmacological agents have been demonstrated to prevent or delay the development of diabetes in people with IGT; the potential impact of such interventions to reduce mortality or the incidence of cardiovascular disease has not been demonstrated to date. It should be noted that the 2003 ADA Expert Committee report reduced the lower FPG cut point to define IFG from 110 mg/dl (6.1 mmol/l) to 100 mg/dl (5.6 mmol/l), in part to ensure that prevalence of IFG was similar to that of IGT. However, the World Health Organization (WHO) and many other diabetes organizations did not adopt this change in the definition of IFG.

As A1C is used more commonly to diagnose diabetes in individuals with risk factors, it will also identify those at higher risk for developing diabetes in the future. When recommending the use of the A1C to diagnose diabetes in its 2009 report, the International Expert Committee (3) stressed the continuum of risk for diabetes with all glycemic measures and did not formally identify an equivalent intermediate category for A1C. The group did note that those with A1C levels above the laboratory “normal” range but below the diagnostic cut point for diabetes (6.0 to <6.5%) are at very high risk of developing diabetes. Indeed, incidence of diabetestes in people with A1C levels in this range is more than 10 times that of people with lower levels (4–7). However, the 6.0 to <6.5% range fails to identify a substantial number of patients who have IFG and/or IGT. Prospective studies indicate that people within the A1C range of 5.5–6.0% have a 5-year cumulative incidence of diabetes that ranges from 12 to 25% (4–7), which is appreciably (three- to eightfold) higher than incidence in the U.S. population as a whole (8). Analyses of nationally representative data from the National Health and Nutrition Examination Survey (NHANES) indicate that the A1C value that most accurately identifies people with IFG or IGT falls between 5.5 and 6.0%. In addition, linear regression analyses of these data indicate that among the nondiabetic adult population, an FPG of 110 mg/dl (6.1 mmol/l) corresponds to an A1C of 5.6%, while an FPG of 100 mg/dl (5.6 mmol/l) corresponds to an A1C of 5.4% (R.T. Ackerman, personal communication). Finally, evidence from the Diabetes Prevention Program (DPP), wherein the mean A1C was 5.9% (SD 0.5%), indicates that preventive interventions are effective in groups of people with A1C levels both below and above 5.9% (9). For these reasons, the most appropriate A1C level above which to initiate preventive interventions is likely to be somewhere in the range of 5.5–6%.

As was the case with FPG and 2-h PG, defining a lower limit of an intermediate category of A1C is somewhat arbitrary, as the risk of diabetes with any measure or surrogate of glycemia is a continuum, extending well into the normal ranges. To maximize equity and efficiency of preventive interventions, such an A1C cut point should balance the costs of “false negatives” (failing to identify those who are going to develop diabetes) against the costs of “false positives” (false identifying and then spending intervention resources on those who were not going to develop diabetes anyway).

As is the case with the glucose measures, several prospective studies that used A1C to predict the progression to diabetes demonstrated a strong, continuous association between A1C and subsequent diabetes. In a systematic review of 44,203 individuals from 16 cohort studies with a follow-up interval averaging 5.6 years (range 2.8–12 years), those with an A1C between 5.5 and 6.0% had a substantially increased risk of diabetes with 5-year incidences ranging from 9 to 25%. An A1C range of 6.0–6.5% had a 5-year risk of developing diabetes between 25 and 50% and relative risk 20 times higher compared with an A1C of 5.0% (10). In a community-based study of black and white adults without diabetes, baseline A1C was a stronger predictor of subsequent diabetes and cardiovascular events than was fasting glucose (11). Other analyses suggest that an A1C of 5.7% is associated with similar diabetes risk to the high-risk participants in the DPP (12). Hence, it is reasonable to consider an A1C range of 5.7–6.4% as identifying individuals with high risk for future diabetes, to whom the term prediabetes may be applied.

Individuals with an A1C of 5.7–6.4% should be informed of their increased risk for diabetes as well as cardiovascular disease and counseled about effective strategies, such as weight loss and physical activity, to lower their risks. As with glucose measurements, the continuum of risk is curvilinear, so that as A1C rises, the risk of diabetes rises disproportionately.
Accordingly, interventions should be most intensive and follow-up should be particularly vigilant for those with A1C levels above 6.0%, who should be considered to be at very high risk. However, just as an individual with a fasting glucose of 98 mg/dl (5.4 mmol/l) may not be at negligible risk for diabetes, individuals with A1C levels below 5.7% may still be at risk, depending on level of A1C and presence of other risk factors, such as obesity and family history.

Table 2 summarizes the categories of increased risk for diabetes. Evaluation of patients at risk should incorporate a global risk factor assessment for both diabetes and cardiovascular disease. Screening for and counseling about risk of diabetes should always be in the pragmatic context of the patient’s comorbidities, life expectancy, personal capacity to engage in lifestyle change, and overall health goals.

**DIAGNOSTIC CRITERIA FOR DIABETES MELLITUS**—For decades, the diagnosis of diabetes has been based on glucose criteria, either the FPG or the 75-g OGTT. In 1997, the first Expert Committee on the Diagnosis and Classification of Diabetes Mellitus revised the diagnostic criteria, using the observed association between FPG levels and prevalence of retinopathy as the key factor with which to identify threshold glucose level. The Committee examined data from three cross-sectional epidemiologic studies that assessed retinopathy with fundus photography or direct ophthalmoscopy and measured glyceremia as FPG, 2-h PG, and A1C. These studies demonstrated glycemic levels below which there was little prevalent retinopathy and above which the prevalence of retinopathy increased in an apparently linear fashion. The deciles of the three measures at which retinopathy began to increase were the same for each measure within each population. Moreover, the glycemic values above which retinopathy increased were similar across the populations. These analyses confirmed the long-standing diagnostic 2-h PG value of ≥200 mg/dl (11.1 mmol/l). However, the older FPG diagnostic cut point of 140 mg/dl (7.8 mmol/l) was noted to identify far fewer individuals with diabetes than the 2-h PG cut point. The FPG diagnostic cut point was reduced to ≥126 mg/dl (7.0 mmol/l).

A1C is a widely used marker of chronic glycemia, reflecting average blood glucose levels over a 2- to 3-month period of time. The test plays a critical role in the management of the patient with diabetes, since it correlates well with both microvascular and, to a lesser extent, macrovascular complications and is widely used as the standard biomarker for the adequacy of glycemic management. Prior Expert Committees have not recommended use of the A1C for diagnosis of diabetes, in part due to lack of standardization of the assay. However, A1C assays are now highly standardized so that their results can be uniformly applied both temporally and across populations. In their recent report (3), an International Expert Committee, after an extensive review of both established and emerging epidemiological evidence, recommended the use of the A1C test to diagnose diabetes, with a threshold of ≥6.5%, and ADA affirms this decision. The diagnostic A1C cut point of 6.5% is associated with an inflection point for retinopathy prevalence, as are the diagnostic thresholds for FPG and 2-h PG (3). The diagnostic test should be performed using a method that is certified by the National Glycohemoglobin Standardization Program (NGSP) and standardized or traceable to the Diabetes Control and Complications Trial reference assay. Point-of-care A1C assays are not sufficiently accurate at this time to use for diagnostic purposes.

There is an inherent logic to using a more chronic versus an acute marker of dysglycemia, particularly since the A1C is already widely familiar to clinicians as a marker of glycemic control. Moreover, the A1C has several advantages to the FPG, including greater convenience, since fasting is not required, evidence to suggest greater preanalytical stability, and less day-to-day perturbations during periods of stress and illness. These advantages, however, must be balanced by greater cost, the limited availability of A1C testing in certain regions of the developing world, and the incomplete correlation between A1C and average glucose in certain individuals. In addition, the A1C can be misleading in patients with certain forms of anemia and hemoglobinopathies, which may also have unique ethnic or geographic distributions. For patients with a hemoglobinopathy but normal red cell turnover, such as sickle cell trait, an A1C assay without interference from abnormal hemoglobins should be used (an updated list is available at http://www.ngsp.org/interf.asp). For conditions with abnormal red cell turnover, such as anemias from hemolysis and iron deficiency, the diagnosis of diabetes must employ glucose criteria exclusively.

The established glucose criteria for the diagnosis of diabetes remain valid. These include the FPG and 2-h PG. Additionally, patients with severe hyperglycemia such as those who present with severe classic hyperglycemic symptoms or hyperglycemic crisis can continue to be diagnosed when a random (or casual) plasma glucose of ≥200 mg/dl (11.1 mmol/l) is found. It is likely that in such cases the health care professional would also measure an A1C test as part of the initial assessment of the severity of the diabetes and that it would (in most cases) be above the diagnostic cut point for diabetes. However, in rapidly evolving diabetes, such as the development of type 1 diabetes in some children, A1C may not be significantly elevated despite frank diabetes.

Just as there is less than 100% concordance between the FPG and 2-h PG tests, there is not full concordance between A1C and either glucose-based test. Analyses of NHANES data indicate that, assuming universal screening of the undiagnosed, the A1C cut point of ≥6.5% identifies one-third fewer cases of undiagnosed diabetes than a fasting glucose cut point of ≥126 mg/dl (7.0 mmol/l) (www.cdc.gov/diabetes/pubs/factsheet11/table1_2.htm). However, in practice, a large portion of the population with type 2 diabetes remains unaware of their condition. Thus, it is conceivable that the lower sensitivity of A1C at the designated cut point will be offset by the test’s greater practicality, and that wider application of a more convenient test (A1C) may actually increase the number of diagnoses made.

Further research is needed to better characterize those patients whose glycemic status might be categorized differently by two different tests (e.g., FPG and

### Table 2—Categories of increased risk for diabetes (prediabetes)*

<table>
<thead>
<tr>
<th>Category</th>
<th>Thresholds</th>
</tr>
</thead>
<tbody>
<tr>
<td>FPG 100 mg/dl (5.6 mmol/l) to 125 mg/dl (6.9 mmol/l)</td>
<td><strong>IFG</strong></td>
</tr>
<tr>
<td>2-h PG in the 75-g OGTT 140 mg/dl (7.8 mmol/l)</td>
<td><strong>IGT</strong></td>
</tr>
<tr>
<td>A1C 5.7–6.4%</td>
<td><strong>IGT</strong></td>
</tr>
</tbody>
</table>

*For all three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at higher ends of the range.

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**Position Statement**

S72   Diabetes Care, Volume 36, Supplement 1, January 2013  care.diabetesjournals.org
A1C), obtained in close temporal approximation. Such discordance may arise from measurement variability, change over time, or because A1C, FPG, and post-challenge glucose each measure different physiological processes. In the setting of an elevated A1C but “nondiabetic” FPG, the likelihood of greater postprandial glucose levels or increased glycation rates for a given degree of hyperglycemia may be present. In the opposite scenario (high FPG yet A1C below the diabetes cut point), augmented hepatic glucose production or reduced glycation rates may be present.

As with most diagnostic tests, a test result diagnostic of diabetes should be repeated to rule out laboratory error, unless the diagnosis is clear on clinical grounds, such as a patient with classic symptoms of hyperglycemia or hyperglycemic crisis. It is preferable that the same test be repeated for confirmation, since there will be a greater likelihood of concurrence in this case. For example, if the A1C is 7.0% and a repeat result is 6.8%, the diagnosis of diabetes is confirmed. However, there are scenarios in which results of two different tests (e.g., FPG and A1C) are available for the same patient. In this situation, if the two different tests are both above the diagnostic thresholds, the diagnosis of diabetes is confirmed.

On the other hand, when two different tests are available in an individual and the results are discordant, the test whose result is above the diagnostic cut point should be repeated, and the diagnosis is made on the basis of the confirmed test. That is, if a patient meets the diabetes criterion of the A1C (two results ≥6.5%) but not the FPG (<126 mg/dl or 7.0 mmol/l), or vice versa, that person should be considered to have diabetes. Admittedly, in most circumstance the “nondiabetic” test is likely to be in a range very close to the threshold that defines diabetes.

Since there is preanalytic and analytic variability of all the tests, it is also possible that when a test whose result was above the diagnostic threshold is repeated, the second value will be below the diagnostic cut point. This is least likely for A1C, somewhat more likely for FPG, and most likely for the 2-h PG. Barring a laboratory error, such patients are likely to have test results near the margins of the threshold for a diagnosis. The healthcare professional might opt to follow the patient closely and repeat the testing in 3–6 months.

The decision about which test to use to assess a specific patient for diabetes should be at the discretion of the healthcare professional, taking into account the availability and practicality of testing an individual patient or groups of patients. Perhaps more important than which diagnostic test is used, is that the testing for diabetes be performed when indicated. There is discouraging evidence indicating that many at-risk patients still do not receive adequate testing and counseling for this increasingly common disease, or for its frequently accompanying cardiovascular risk factors. The current diagnostic criteria for diabetes are summarized in Table 3.

### Diagnosis of GDM

GDM carries risks for the mother and neonate. The Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study (13), a large-scale (~25,000 pregnant women) multinational epidemiologic study, demonstrated that risk of adverse maternal, fetal, and neonatal outcomes continuously increased as a function of maternal glycemia at 24–28 weeks, even within ranges previously considered normal for pregnancy. For most complications, there was no threshold for risk. These results have led to careful reconsideration of the diagnostic criteria for GDM.

After deliberations in 2008–2009, the IADPSG, an international consensus group with representatives from multiple obstetrical and diabetes organizations, including ADA, developed revised recommendations for diagnosing GDM. The group recommended that all women not known to have diabetes undergo a 75-g OGTT at 24–28 weeks of gestation. Additionally, the group developed diagnostic cut points for the fasting, 1-h, and 2-h plasma glucose measurements that conveyed an odds ratio for adverse outcomes of at least 1.75 compared with women with mean glucose levels in the HAPO study. Current screening and diagnostic strategies, based on the IADPSG statement (14), are outlined in Table 4.

These new criteria will significantly increase the prevalence of GDM, primarily because only one abnormal value, not two, is sufficient to make the diagnosis. The ADA recognizes the anticipated significant increase in the incidence of GDM to be diagnosed by these criteria and is sensitive to concerns about the “medicalization” of pregnancies previously categorized as normal. These diagnostic criteria changes are being made in the context of worrisome worldwide increases in obesity and diabetes rates, with the intent of optimizing gestational outcomes for women and their babies.

Admittedly, there are few data from randomized clinical trials regarding therapeuetic interventions in women who will now be diagnosed with GDM based on only one blood glucose value above the specified cut points (in contrast to the older criteria that stipulated at least two

### Table 3—Criteria for the diagnosis of diabetes

<table>
<thead>
<tr>
<th>Criteria for the diagnosis of diabetes</th>
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<tbody>
<tr>
<td>A1C ≥6.5%: The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*</td>
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<tr>
<td>OR</td>
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<tr>
<td>FPG ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.*</td>
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<tr>
<td>OR</td>
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<tr>
<td>2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by the World Health Organization, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*</td>
</tr>
<tr>
<td>OR</td>
</tr>
<tr>
<td>In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dl (11.1 mmol/l).</td>
</tr>
</tbody>
</table>

*In the absence of unequivocal hyperglycemia, criteria 1–3 should be confirmed by repeat testing.

### Table 4—Screening for and diagnosis of GDM

<table>
<thead>
<tr>
<th>Screening for and diagnosis of GDM</th>
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<tbody>
<tr>
<td>Perform a 75-g OGTT, with plasma glucose measurement fasting and at 1 and 2 h, at 24–28 weeks of gestation in women not previously diagnosed with overt diabetes. The OGTT should be performed in the morning after an overnight fast of at least 8 h.</td>
</tr>
<tr>
<td>The diagnosis of GDM is made when any of the following plasma glucose values are exceeded:</td>
</tr>
<tr>
<td>- Fasting: ≥92 mg/dl (5.1 mmol/l)</td>
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<tr>
<td>- 1 h: ≥180 mg/dl (10.0 mmol/l)</td>
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<tr>
<td>- 2 h: ≥153 mg/dl (8.5 mmol/l)</td>
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</tbody>
</table>
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abnormal values). Expected benefits to their pregnancies and offspring is inferred from intervention trials that focused on women with more mild hyperglycemia than identified using older GDM diagnostic criteria and that found modest benefits (15,16). The frequency of their follow-up and blood glucose monitoring is not yet clear but likely to be less intensive than women diagnosed by the older criteria. Additional well-designed clinical studies are needed to determine the optimal intensity of monitoring and treatment of women with GDM diagnosed by the new criteria (that would not have met the prior definition of GDM). It is important to note that 80–90% of women in both of the mild GDM studies (whose glucose values overlapped with the thresholds recommended herein) could be managed with lifestyle therapy alone.

References

Diabetes Care in the School and Day Care Setting

American Diabetes Association

Diabetes is one of the most common chronic diseases of childhood (1). There are ~215,000 individuals <20 years of age with diabetes in the U.S. (2). The majority of these young people attend school and/or some type of day care and need knowledgeable staff to provide a safe school environment. Both parents and the health care team should work together to provide school systems and day care providers with the information necessary to allow children with diabetes to participate fully and safely in the school experience (3,4).

Diabetes and the Law—Federal laws that protect children with diabetes include Section 504 of the Rehabilitation Act of 1973 (5), the Individuals with Disabilities Education Act (originally the Education for All Handicapped Children Act of 1975) (6), and the Americans with Disabilities Act (7). Under these laws, diabetes has been considered to be a disability, and it is illegal for schools and/or day care centers to discriminate against children with disabilities. In addition, any school that receives federal funding or any facility considered open to the public must reasonably accommodate the special needs of children with diabetes. Indeed, federal law requires an individualized assessment of any child with diabetes. The required accommodations should be documented in a written plan developed under the applicable federal law such as a Section 504 Plan or Individualized Education Program (IEP). The needs of a student with diabetes should be provided for within the child’s usual school setting with as little disruption to the school’s and the child’s routine as possible and allowing the child full participation in all school activities (8,9).

Despite these protections, children in the school and day care setting still face discrimination. For example, some day care centers may refuse admission to children with diabetes, and children in the classroom may not be provided the assistance necessary to monitor blood glucose and administer insulin and may be prohibited from eating needed snacks. The American Diabetes Association works to ensure the safe and fair treatment of children with diabetes in the school and day care setting (10–15) (www.diabetes.org/schooldiscrimination).

Diabetes care in schools
Appropriate diabetes care in the school and day care setting is necessary for the child’s immediate safety, long-term well-being, and optimal academic performance. The Diabetes Control and Complications Trial showed a significant link between blood glucose control and later development of diabetes complications, with improved glycemic control decreasing the risk of these complications (16,17). To achieve glycemic control, a child must check blood glucose frequently, monitor food intake, take medications, and engage in regular physical activity. Insulin is usually taken in multiple daily injections or through an infusion pump. Crucial to achieving glycemic control is an understanding of the effects of physical activity, nutrition therapy, and insulin on blood glucose levels.

To facilitate the appropriate care of the student with diabetes, the school nurse as well as other school and day care personnel must have an understanding of diabetes and must be trained in its management and in the treatment of diabetes emergencies (18,19,20,23,36).

Knowledgeable trained personnel are essential if the student is to avoid the immediate health risks of low blood glucose and to achieve the metabolic control required to decrease risks for later development of diabetes complications (3,20). Studies have shown that the majority of school personnel have an inadequate understanding of diabetes (21,22). Consequently, diabetes education must be targeted toward day care providers, teachers, and other school personnel who interact with the child, including school administrators, school nurses, coaches, health aides, bus drivers, secretaries, etc. (3,20). Current recommendations and up-to-date resources regarding appropriate care for children with diabetes in the school are universally available to all school personnel (3,23).

The purpose of this position statement is to provide recommendations for the management of children with diabetes in the school and day care setting.

General Guidelines for the Care of the Child in the School and Day Care Setting

I. Diabetes Medical Management Plan
An individualized Diabetes Medical Management Plan (DMMP) should be developed by the student’s personal diabetes health care team with input from the parent/guardian. Inherent in this process are delineated responsibilities assumed by all parties, including the parent/guardian, the school personnel, and the student (3,24,25). These responsibilities are outlined in this position statement. In addition, the DMMP should be used as the basis for the development of written education plans such as the Section 504 Plan or the IEP. The DMMP should address the specific needs of the child and provide specific instructions for each of the following:

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DOI: 10.2337/dc13-S075
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1. Blood glucose monitoring, including the frequency and circumstances requiring blood glucose checks, and use of continuous glucose monitoring if utilized.
2. Insulin administration (if necessary), including doses/injection times prescribed for specific blood glucose values and for carbohydrate intake, the storage of insulin, and, when appropriate, physician authorization of parent/guardian adjustments to insulin dosage.
3. Meals and snacks, including food content, amounts, and timing.
4. Symptoms and treatment of hypoglycemia (low blood glucose), including the administration of glucagon if recommended by the student’s treating physician.
5. Symptoms and treatment of hyperglycemia (high blood glucose).
6. Checking for ketones and appropriate actions to take for abnormal ketone levels, if requested by the student’s health care provider.
7. Participation in physical activity.
8. Emergency evacuation/school lockdown instructions.

A sample DMMP (http://professional.diabetes.org/DMMP) may be accessed online and customized for each individual student. For detailed information on the symptoms and treatment of hypoglycemia and hyperglycemia, refer to Medical Management of Type 1 Diabetes (26). A brief description of diabetes targeted to school and day care personnel is included in the APPENDIX; it may be helpful to include this information as an introduction to the DMMP.

II. Responsibilities of the various care providers

A. The parent/guardian should provide the school or day care provider with the following:

1. All materials, equipment, insulin, and other medication necessary for diabetes care tasks, including blood glucose monitoring, insulin administration (if needed), and urine or blood ketone monitoring. The parent/guardian is responsible for the maintenance of the blood glucose monitoring equipment (i.e., cleaning and performing controlled testing per the manufacturer’s instructions) and must provide materials necessary to ensure proper disposal of materials. A separate logbook should be kept at school with the diabetes supplies for the staff or student to record blood glucose and ketone results; blood glucose values should be transmitted to the parent/guardian for review as often as requested. Some students maintain a record of blood glucose results in meter memory rather than recording in a logbook, especially if the same meter is used at home and at school.
2. The DMMP completed and signed by the student’s personal diabetes health care team.
3. Supplies to treat hypoglycemia, including a source of glucose and a glucagon emergency kit, if indicated in the DMMP.
5. Emergency phone numbers for the parent/guardian and the diabetes health care team so that the school can contact these individuals with diabetes-related questions and/or during emergencies.
6. Information about the student’s meal/snack schedule. The parent should work with the school during the teacher preparation period before the beginning of the school year or before the student returns to school after diagnosis to coordinate this schedule with that of the other students as closely as possible. For young children, instructions should be given for when food is provided during school parties and other activities.
7. In most locations, and increasingly, a signed release of confidentiality from the health care team so that the school can contact these individuals with diabetes-related questions and/or during emergencies.

B. The school or day care provider should provide the following:

1. Opportunities for the appropriate level of ongoing training and diabetes education for the school nurse.
2. Training for school personnel as follows: level 1 training for all school staff members, which includes a basic overview of diabetes, typical needs of a student with diabetes, recognition of hypoglycemia and hyperglycemia, and who to contact for help; level 2 training for school staff members who have responsibility for a student or students with diabetes, which includes all content from level 1 plus recognition and treatment of hypoglycemia and hyperglycemia and required accommodations for those students; and level 3 training for a small group of school staff members who will perform student-specific routine and emergency care tasks such as blood glucose monitoring, insulin administration, and glucagon administration when a school nurse is not available to perform these tasks and which will include level 1 and 2 training as well.
3. Immediate accessibility to the treatment of hypoglycemia by a knowledgeable adult. The student should remain supervised until appropriate treatment has been administered, and the treatment should be available as close to where the student is as possible.
4. Accessibility to scheduled insulin at times set out in the student’s DMMP as well as immediate accessibility to treatment for hyperglycemia including insulin administration as set out by the student’s DMMP.
5. A location in the school that provides privacy during blood glucose monitoring and insulin administration, if desired by the student and family, or permission for the student to check his or her blood glucose level and take appropriate action to treat hypoglycemia in the classroom or anywhere the student is in conjunction with a school activity, if indicated in the student’s DMMP.
6. School nurse and back-up trained school personnel who can check blood glucose and ketones and administer insulin, glucagon, and other medications as indicated by the student’s DMMP.
7. School nurse and back-up trained school personnel responsible for the student who will know the schedule of the student’s meals and snacks and work with the parent/guardian to coordinate this schedule with that of the other students as closely as possible. This individual will also notify the parent/guardian in advance of any expected changes in the school schedule that affect the student’s meal times or exercise routine and will remind young children of snack times.
Table 1—Resources for teachers, child care providers, parents, and health professionals


*A available in the American Diabetes Association’s Education Discrimination Packet by calling 1-800-DIABETES.

8. Permission for self-sufficient and capable students to carry equipment, supplies, medication, and snacks; to perform diabetes management tasks; and to have cell phone access to reach parent/guardian and health care provider.

9. Permission for the student to see the school nurse and other trained school personnel upon request.

10. Permission for the student to eat a snack anywhere, including the classroom or the school bus, if necessary to prevent or treat hypoglycemia.

11. Permission to miss school without consequences for illness and required medical appointments to monitor the student’s diabetes management. This should be an excused absence with a doctor’s note, if required by usual school policy.

12. Permission for the student to use the restroom and have access to fluids (i.e., water) as necessary.

13. An appropriate location for insulin and/or glucagon storage, if necessary.

14. A plan for the disposal of sharps based upon an agreement with the student’s family, local ordinances, and Universal Precaution Standards.

15. Information on serving size and caloric, carbohydrate, and fat content of foods served in the school (27).

The school nurse should be the key coordinator and provider of care and should coordinate the training of an adequate number of school personnel as specified above and ensure that if the school nurse is not present at least one adult is present who is trained to perform these procedures in a timely manner while the student is at school, on field trips, participating in school-sponsored extracurricular activities, and on transportation provided by the school or day care facility. This is needed in order to enable full participation in school activities (3, 18, 20). These school personnel need not be health care professionals (3, 9, 20, 28, 33, 35).

It is the school’s responsibility to provide appropriate training of an adequate number of school staff on diabetes-related tasks and in the treatment of diabetes emergencies. This training should be provided by the school nurse or another qualified health care professional with expertise in diabetes. Members of the student’s diabetes health care team should provide school personnel and parents/guardians with educational materials from the American Diabetes Association and other sources targeted to school personnel and/or parents. Table 1 includes a listing of appropriate resources.

III. Expectations of the student in diabetes care

Children and youth should be allowed to provide their own diabetes care at school to the extent that is appropriate based on the student’s development and his or her experience with diabetes. The extent of the student’s ability to participate in diabetes care should be agreed upon by the school personnel, the parent/guardian, and the health care team, as necessary. The ages at which children are able to perform self-care tasks are variable and depend on the individual, and a child’s capabilities and willingness to provide self-care should be respected (18).

1. Toddlers and preschool-aged children: unable to perform diabetes tasks independently and will need an adult to provide all aspects of diabetes care. Many of these younger children will have difficulty in recognizing hypoglycemia, so it is important that school personnel are able to recognize and provide prompt treatment. However, children in this age range can usually determine which finger to prick, can choose an injection site, and are generally cooperative.

2. Elementary school-aged children: depending on the length of diagnosis and level of maturity, may be able to perform their own blood glucose checks, but usually will require supervision. Older elementary school-aged children are generally beginning to self-administer insulin with supervision and understand the effect of insulin, physical activity, and nutrition on blood glucose levels. Unless the child has hypoglycemic unawareness, he or she should usually be able to let an adult know when experiencing hypoglycemia.

3. Middle school– and high school-aged children: usually able to provide self-care depending on the length of...
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Diagnosis and level of maturity but will always need help when experiencing severe hypoglycemia. Independence in older children should be encouraged to enable the child to make his or her decisions about his or her own care.

Students’ competence and capability for performing diabetes-related tasks are set out in the DMMP and then adapted to the school setting by the school health team and the parent/guardian. At all ages, individuals with diabetes may require help to perform a blood glucose check when the blood glucose is low. In addition, many individuals require a reminder to eat or drink during hypoglycemia and should not be left unsupervised until such treatment has taken place and the blood glucose value has returned to the normal range. Ultimately, each person with diabetes becomes responsible for all aspects of routine care, and it is important for school personnel to facilitate a student in reaching this goal. However, regardless of a student’s ability to provide self-care, help will always be needed in the event of a diabetes emergency.

MONITORING BLOOD GLUCOSE IN THE CLASSROOM—It is best for a student with diabetes to monitor blood glucose levels and respond to the results as quickly and conveniently as possible. This is important to avoid medical problems being worsened by a delay in monitoring and treatment and to minimize educational problems caused by missing instruction in the classroom. Accordingly, as stated earlier, a student should be permitted to monitor his or her blood glucose level and take appropriate action to treat hypoglycemia and hyperglycemia in the classroom or anywhere the student is in conjunction with a school activity, if preferred by the student and indicated in the student’s DMMP (3,24). However, some students desire privacy for blood glucose monitoring and other diabetes care tasks, and this preference should also be accommodated.

In summary, with proper planning and the education and training of school personnel, children and youth with diabetes can fully participate in the school experience. To this end, the family, the health care team, and the school should work together to ensure a safe learning environment.

APPENDIX

Background information on diabetes for school personnel

Diabetes is a serious, chronic disease that impairs the body’s ability to use food. Insulin, a hormone produced by the pancreas, helps the body convert food into energy. In people with diabetes, either the pancreas does not make insulin or the body cannot use insulin properly. Without insulin, the body’s main energy source—glucose—cannot be used as fuel. Rather, glucose builds up in the blood. Over many years, high blood glucose levels can cause damage to the eyes, kidneys, nerves, heart, and blood vessels.

The majority of school-aged youth with diabetes have type 1 diabetes. People with type 1 diabetes do not produce insulin and must receive insulin through either injections or an insulin pump. Insulin taken in this manner does not cure diabetes and may cause the student’s blood glucose level to become dangerously low. Type 2 diabetes, the most common form of the disease, typically affecting obese adults, has been shown to be increasing in youth. This may be due to the increase in obesity and decrease in physical activity in young people. Students with type 2 diabetes may be able to control their disease through diet and exercise alone or may require oral medications and/or insulin injections. All people with type 1 and type 2 diabetes must carefully balance food, medications, and activity level to keep blood glucose levels as close to normal as possible.

Low blood glucose (hypoglycemia) is the most common immediate health problem for students with diabetes. It occurs when the body gets too much insulin, too little food, a delayed meal, or more than the usual amount of exercise. Symptoms of mild to moderate hypoglycemia include tremors, sweating, light-headedness, irritability, confusion, and drowsiness. In younger children other symptoms may include inattention, falling asleep at inappropriate times, unexplained behavior, and temper tantrums. A student with this degree of hypoglycemia will need to ingest carbohydrates promptly and may require assistance. Severe hypoglycemia, which is rare, may lead to unconsciousness and convulsions and can be life-threatening if not treated promptly with glucagon as per the student’s DMMP (18,24,29,30,31).

High blood glucose (hyperglycemia) occurs when the body gets too little insulin, too much food, or too little exercise; it may also be caused by stress or an illness such as a cold. The most common symptoms of hyperglycemia are thirst, frequent urination, and blurry vision. If untreated over a period of days, hyperglycemia and insufficient insulin can lead to a serious condition called diabetic ketoacidosis (DKA), which is characterized by nausea, vomiting, and a high level of ketones in the blood and urine. For students using insulin infusion pumps, lack of insulin supply may lead to DKA more rapidly. DKA can be life-threatening and thus requires immediate medical attention (32).

Acknowledgments—The American Diabetes Association thanks the members of the Health Care Professional Volunteer Writing Group for this updated statement: William Clarke, MD; Larry C. Deeb, MD; Paula Jameson, MSN, ARNP, CDE; Francine Kaufman, MD; Georgette Klingensmith, MD; Desmond Schatz, MD; Janet H. Silverstein, MD; and Linda M. Simmerino, RN, PhD, CDE.

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11. Calvin Davis and ADA v. LaPetite Academy, Inc. Case no. CV97-0083-PHX-SMM (USCD Arizona 1997)
12. Agreement, Loudoun County Public Schools (VA) and the Office for Civil Rights, United States Department of Education (Complaint nos. 11-99-1003, 11-99-1064, 11-99-1069, 1999)
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Diabetes and Driving

American Diabetes Association

Of the nearly 19 million people in the U.S. with diagnosed diabetes (1), a large percentage will seek or currently hold a license to drive. For many, a driver’s license is essential to work; taking care of family; securing access to public and private facilities, services, and institutions; interacting with friends; attending classes; and/or performing many other functions of daily life. Indeed, in many communities and areas of the U.S. the use of an automobile is the only (or the only feasible or affordable) means of transportation available.

There has been considerable debate whether, and the extent to which, diabetes may be a relevant factor in determining driver ability and eligibility for a license. This position statement addresses such issues in light of current scientific and medical evidence.

Sometimes people with a strong interest in road safety, including motor vehicle administrators, pedestrians, drivers, other road users, and employers, associate all diabetes with unsafe driving when in fact most people with diabetes safely operate motor vehicles without creating any meaningful risk of injury to themselves or others. When legitimate questions arise about the medical fitness of a person with diabetes to drive, an individual assessment of that person’s diabetes management—with particular emphasis on demonstrated ability to detect and appropriately treat potential hypoglycemia—is necessary in order to determine any appropriate restrictions. The diagnosis of diabetes is not sufficient to make any judgments about individual driver capacity.

This document provides an overview of existing licensing rules for people with diabetes, addresses the factors that impact driving for this population, and identifies general guidelines for assessing driver fitness and determining appropriate licensing restrictions.

Licensing Requirements—People with diabetes are currently subject to a variety of licensing requirements and restrictions. These licensing decisions occur at several points and involve different levels and types of review, depending on the type of driving. Some states and local jurisdictions impose no special requirements for people with diabetes. Other jurisdictions ask drivers with diabetes various questions about their condition, including their management regimen and whether they have experienced any diabetes-related problems that could affect their ability to safely operate a motor vehicle. In some instances, answers to these questions result in restrictions being placed on a person’s license, including restrictions on the type of vehicle they may operate and/or where they may operate that vehicle. In addition, the rules for operating a commercial motor vehicle, and for obtaining related license endorsements (such as rules restricting operation of a school bus or transport of passengers or hazardous materials) are quite different and in many ways more cumbersome for people with diabetes, especially those who use insulin.

With the exception of commercial driving in interstate commerce (Interstate commercial driving is defined as trade, traffic or transportation in the United States between a place in a state and a place outside of such a state, between two places in a state through another state or a place outside of the United States, or between two places in a state as part of trade, traffic or transportation originating or terminating outside the state or the United States [2]), which is subject to uniform federal regulation, both private and commercial driving are subject to rules determined by individual states. These rules vary widely, with each state taking its own approach to determining medical fitness to drive and the issuance of licenses. How diabetes is identified, which people are medically evaluated, and what restrictions are placed on people who have experienced hypoglycemia or other problems related to diabetes all vary from state to state.

States identify drivers with diabetes in a number of ways. In at least 23 states, drivers are either asked directly if they have diabetes or are otherwise required to self-identify if they have diabetes. In other states drivers are asked some variation of a question about whether they have a condition that is likely to cause altered perception or loss of consciousness while driving. In most states, when the answer to either question is yes, the driver is required to submit to a medical evaluation before he or she will be issued a license.

Medical evaluation
Drivers whose medical conditions can lead to significantly impaired consciousness are evaluated for their fitness to continue to drive. For people with diabetes, this typically occurs when a person has experienced hypoglycemia (3) behind the wheel, even if this did not result in a motor vehicle accident. In some states this occurs as a result of a policy to evaluate all people with diabetes, even if there has been no triggering event. It can also occur when a person experiences severe hypoglycemia while not driving and a physician reports the episode to the licensing authority. In a handful of states, such reporting by physicians is mandatory. In most other states physicians are permitted to make reports but are given discretion to determine when such reports are necessary. Some states specify that physicians may voluntarily report those patients who pose an imminent threat to public safety because they are driving against medical advice. Physicians and others required to make reports to the licensing authority are usually provided with immunity from civil and criminal actions resulting from the report.

When licensing authorities learn that a driver has experienced an episode of hypoglycemia that potentially affected the ability to drive, that driver is referred for a medical evaluation and in many cases will lose driving privileges for a period of time until cleared by the licensing authority. This period can range from 3 to 6 months or longer. Some state laws allow for waivers of the rules when the episode is a one-time event not likely to recur, for
example because of a change in medication
or episodes that occur only during sleep.

Medical evaluation procedures vary
and range from a simple confirmation of
the person’s diabetes from a physician to a
more elaborate process involving a state
medical advisory board, hearings, and
presentation and assessment of medical
evidence. Some states convene medical
advisory boards with nurses and physi-
cians of different specialties who review
and make recommendations concerning
the licensing of people with diabetes and
other medical conditions. In other states,
licensing decisions are made by admin-
istrative staff with little or no medical
training and with little or no review by a
medical review board or by a physician
or physicians with any relevant expertise
concerning medical conditions presented
by individual applicants.

The medical evaluation process for
commercial drivers occurs at predeter-
mimed intervals, typically every 2 years.
Unlike noncommercial licenses, these
regular evaluations are not linked to
episodes of severe hypoglycemia but are
part of an ongoing fitness evaluation for
jobs requiring commercial driving. The fed-
eral government has no diabetes-specific
restrictions for individuals who manage
their disease with diet, exercise, and/or
oral medication. It offers an exemption
program for insulin-using interstate com-
mercial drivers and issues medical certifi-
cates to qualified drivers. Factors in the
federal commercial driving medical evalu-
ation include a review of diabetes history,
medications, hospitalizations, blood glu-
cose history, and tests for various com-
lications and an assessment of driver
understanding of diabetes and willingness
to monitor their condition.

**SCIENCE OF DIABETES AND
DRIVING**—Hypoglycemia indicating
an impaired ability to drive, retinopathy
or cataract formation impairing the vision
needed to operate a motor vehicle, and
neuropathy affecting the ability to feel foot
pedals can each impact driving safety (4). How-
ever, the incidence of these conditions
is not sufficiently extensive to justify re-
striction of driving privileges for all drivers
with diabetes. Driving mishaps related to
diabetes are relatively infrequent for most
drivers with diabetes and occur at a lower
rate than mishaps of many other drivers
with conditions that affect driving perform-
ance and that are tolerated by society.

However, just as there are some pa-

tients with conditions that increase their
risk of incurring driving mishaps, such as
unstable coronary heart disease, obstruc-
tive sleep apnea, epilepsy, Parkinson’s
disease, or alcohol and substance abuse,
there are also some drivers with diabetes
that have a higher risk for driving mis-
haps. The challenges are to identify high-
risk individuals and develop measures to
assist them to lower their risk for driving
mishaps.

**Understanding the risk of diabetes
and driving**

In a recent Scottish study, only 62% of
health care professionals suggested that
insulin-treated drivers should test their
blood glucose before driving; 13% of health
care professionals thought it safe to drive
with blood glucose <72 mg/dL (4 mmol/L),
and 8% did not know that impaired aware-
ness of hypoglycemia might be a contrain-
dication to driving (5). It is important that
health care professionals be knowledgeable
and take the lead in discussing risk reduc-
tion for their patients at risk for hypoglyce-
emia. In a large international study, nearly
half of drivers with type 1 diabetes and
three-quarters of those with type 2 diabetes
had never discussed driving guidelines with
their physician (8).

A meta-analysis of 15 studies sug-
gested that the relative risk of having a
motor vehicle accident for people with
diabetes as a whole, i.e., without differen-
tiating those with a significant risk from
those with little or no risk, as compared
with the general population ranges be-
 tween 1.126 and 1.19, a 12–19% in-
creased risk (6). Some published studies
indicated that drivers with type 1 diabetes
have a slightly higher risk, with a relative
risk ratio of ~2 (7,8,9), but this was not
confirmed by other studies (10). Two stud-
ies even suggested that there is no increased
risk associated with insulin-treated dia-
betes (11,12), but the methodologies used
have been criticized (13).

This increased risk of collisions must
be interpreted in the light of society’s tol-
erance of other and much higher–risk
conditions. For example, 16-year-old
males have 42 times more collisions than
35- to 45-year-old women. If the heaviest
car collides with the lightest car, the driver
of the latter is 20 times more likely to be
cilled than the driver of the former. The
most dangerous rural highways are 9.2
times more dangerous than the safest urban
highways. Driving at 1:00 A.M. on Sunday is
142 times more dangerous than driving at
11:00 A.M. (7). Drivers with attention deficit
hyperactivity disorder have a relative risk
data from one study, 51% of respondents
thought it was safe to drive even when blood glucose was <70
mg/dL (3.9 mmol/L) (31).

While significant hyperglycemia may
impair cognitive, motor, and perceptual
functioning (32–35), there is only one re-
port suggesting extreme hyperglycemia
can impact driving safety (36). Thus,
Position Statement

Efforts to equate hyperglycemia with driving impairment are currently not scientifically justified.

**Individual differences**

Eighty percent of episodes of severe hypoglycemia affect about 20% of people with type 1 diabetes (37–39). Available data suggest that a small subgroup of drivers with type 1 diabetes account for the majority of hypoglycemia-related collisions (9, 30, 40). When 452 drivers with type 1 diabetes were followed prospectively for a year, baseline reports of prior episodes of mild symptomatic hypoglycemia while driving or severe hypoglycemia while driving, hypoglycemia-related driving mishaps, or hypoglycemia-related collisions were associated with a higher risk of driving mishaps in the following 12 months by 3, 6, 6, and 20%, respectively. Risk increased exponentially with additional reported episodes: If individuals had two episodes of severe hypoglycemia in the preceding 12 months their risk increased to 12%, and two collisions in the previous 2 years increased their risk by 40%. The strongest predictors involved a history of hypoglycemia while driving (21). Laboratory studies that compared drivers with type 1 diabetes who had no history of hypoglycemia-related driving mishap in the past year to those who had more than one mishap found that those with a history of mishaps: 1) drove significantly worse during progressive mild hypoglycemia (70–50 mg/dL, 3.9–2.8 mmol/L) but drove equally well when blood glucose was normal (euglycemia); 2) had a lower epinephrine response while driving during hypoglycemia; 3) were more insulin sensitive, and 4) demonstrated greater difficulties in working memory and information processing speed during euglycemia and hypoglycemia (24, 40, 41). Thus, a history of mishaps should be used as a basis for identifying insulin-managed drivers with elevated risk of future mishaps. Such individuals are appropriately subjected to additional screening requirements.

Four studies have demonstrated that Blood Glucose Awareness Training (BGAT) reduces the occurrence of collisions and moving vehicle violations while improving judgment about whether to drive while hypoglycemic (42–45). BGAT is an 8-week psycho-educational training program designed to assist individuals with type 1 diabetes to better anticipate, prevent, recognize, and treat extreme blood glucose events. This intervention can be effectively delivered over the internet (46). Diabetes Driving (diabetesdriving.com), a program funded by the National Institutes of Health, is another internet-based tool to help assess the risk of driving mishaps and assist high-risk drivers to avoid hypoglycemia while driving and to better detect and manage hypoglycemia if it occurs while driving.

**RECOMMENDATIONS**

**Identifying and evaluating diabetes in drivers**

Individuals whose diabetes poses a significantly elevated risk to safe driving must be identified and evaluated prior to getting behind the wheel. Because people with diabetes are diverse in terms of the nature of their condition, the symptoms they experience, and the measures they take to manage their diabetes, it is important that identification and evaluation processes be appropriate, individualized, and based not solely on a diagnosis of diabetes but rather on concrete evidence of actual risk. Laws that require all people with diabetes (or all people with insulin-treated diabetes) to be medically evaluated as a condition of licensure are ill advised because they combine people with diabetes into one group rather than identifying those drivers who may be at increased risk due to potential difficulties in avoiding hypoglycemia or the presence of complications. In addition, the logistics of registering and evaluating millions of people with diabetes who wish to drive presents an enormous administrative and fiscal burden to licensing agencies. States that require drivers to identify diabetes should limit the identification to reports of diabetes-related problems.

To identify potentially at-risk drivers, a short questionnaire can be used to find those drivers who may require further evaluation. The questionnaire should ask whether the driver has, within the past 12 months, lost consciousness due to hypoglycemia, experienced hypoglycemia that required intervention from another person to treat or that interfered with driving, or experienced hypoglycemia that developed without warning. The questionnaire should also query about loss of visual acuity or peripheral vision and loss of feeling in the right foot. Inasmuch as obstructive sleep apnea is more common in people with type 2 diabetes than in the nondiabetic population, patients should be queried about falling asleep during the day. Any positive answer should trigger an evaluation to determine whether restrictions on the license or mechanical modifications to the vehicle (e.g., hand controls for people with an insensate foot) are necessary to ensure public safety. It is ill-advised to determine risk for driving mishaps based on a driver’s glycated hemoglobin because episodic transitions into hypoglycemia, not average blood glucose, increases risk of driving mishaps.

Evaluation of drivers with diabetes must include an assessment by the treating physician or another diabetes specialist who can review recent diabetes history and provide to the licensing agency a recommendation about whether the driver has a condition that impairs his or her ability to safely operate a motor vehicle. The treating physician or another physician who is knowledgeable about diabetes is the best source of information concerning the driver’s diabetes management and history. The input of such a physician is essential to assess a person’s diabetes management and determine whether operation of a motor vehicle is safe and practicable. If questions arise concerning the safe driving ability of a person with chronic complications of diabetes (e.g., retinopathy or neuropathy), the individual should be referred to a specialist with expertise in evaluating the diabetes-related problem for specific recommendations.

Physicians should be requested to provide the following information: 1) whether the driver has had an episode of severe hypoglycemia requiring intervention from another person within the previous 2 years (and when this happened); 2) whether there was an explanation for the hypoglycemia; 3) whether the driver is at increased risk of severe hypoglycemia; 4) whether the driver has the ability to recognize incipient hypoglycemia and knows how to take appropriate corrective action; 5) whether the driver provides evidence of sufficient self-monitoring of blood glucose; 6) whether the driver has any diabetes-related complications affecting safe driving that need further assessment; and 7) whether the driver has a good understanding of diabetes and its treatment, has been educated on the avoidance of hypoglycemia while driving, and is willing to follow a suggested treatment plan.

When evaluating a driver with a history of severe hypoglycemia, impaired hypoglycemia awareness, or a diabetes-related motor vehicle accident, it is necessary to
investigate the reasons for the hypoglycemia and to determine whether it is a function of the driver’s treatment regimen or lifestyle, a psychological reaction to the management of their diabetes, or the normal course of diabetes. Appropriate clinical interventions should be instituted.

**Licensing decisions following evaluation**

Drivers with diabetes should only have a license suspended or restricted if doing so is the only practical way to address an established safety risk. Licensing decisions should reflect deference to the professional judgment of the evaluating physician with regard to diabetes, while also balancing the licensing agency’s need to keep the roads and the public safe. States should have medical advisory boards whose role is to assess potential driving risks based on continually updated medical information, to ensure that licensing agency staff is prepared to handle diabetes licensing issues, and to make recommendations relevant to individual drivers. State medical advisory boards should have representation by health care professionals with expertise in treating diabetes, in addition to the information provided by the driver’s treating physician, prior to making licensing decisions for people with diabetes. Where the medical advisory board does not have a permanent member with expertise in diabetes, such an expert should be consulted in cases involving restrictions on a driver with diabetes.

As discussed above, a history of hypoglycemia does not mean an individual cannot be a safe driver. Rather, when there is evidence of a history of severe hypoglycemia, an appropriate evaluation should be undertaken to determine the cause of the low blood glucose, the circumstances of the episode, whether it was an isolated incident, whether adjustment to the insulin regimen may mitigate the risk, and the likelihood of such an episode recurring. It is important that licensing decisions take into consideration contributory factors that may mitigate a potential risk, and that licensing agencies do not adopt a “one strike” approach to licensing people with diabetes. Drivers with diabetes must be individually assessed to determine whether their diabetes poses a safety risk. The mere fact that a person’s diabetes has come to the attention of the licensing agency—whether by a report or because of an accident—should not itself predetermine a licensing decision.

Generally, severe hypoglycemia that occurs during sleep should not disqualify a person from driving. Hypoglycemia that occurs while the person is not driving should be examined to determine if it is indicative of a larger problem or an event that is not likely to recur while the person is behind the wheel of a car (e.g., hypoglycemia that occurs during an intense bout of exercise). Some episodes of severe hypoglycemia can be explained and corrected with the assistance of a diabetes health care professional, e.g., episodes that occur because of a change in medication. However, recurrent episodes of severe hypoglycemia, defined as two or more episodes in a year, may indicate that a person is not able to safely operate a motor vehicle.

States whose licensing rules lead to a suspension of a driver’s license following an episode of hypoglycemia should allow for waiver of these rules when the hypoglycemia can be explained and addressed by the treating physician and is not likely to recur. For example, waivers may be appropriate following hypoglycemia that happens as a result of a change in medication during or concurrent with illness or pregnancy. Licensing agencies may request documentation from the physician attesting that the patient meets the conditions for a waiver (which may include, among other requirements, education on diabetes management and avoidance of hypoglycemia).

Drivers with a suspended license because of factors related to diabetes should be eligible to have their driver’s license reinstated following a sufficient period of time (usually no more than 6 months) upon advice from the treating physician that the driver has made appropriate adjustments and is adhering to a regimen that has resulted in correction of the problems that led to the license suspension. Following reinstatement of driving privileges, periodic follow-up evaluation is necessary to ensure that the person remains safely able to operate a motor vehicle.

People who experience progressive impairment of their awareness of hypoglycemia should consult a health care provider to determine whether it is safe to continue driving with proper measures to avoid disruptive hypoglycemia (such as testing blood glucose before driving and at regular intervals in the course of a journey lasting more than 30–60 min). If the driver is able to make adjustments to improve awareness or prevent disruptive hypoglycemia while driving, there should not be license restrictions. Continuous glucose monitoring may also be beneficial, particularly when noting the direction of the glucose trend. If this technology is used, the person using the device needs to appreciate that any action taken (e.g., additional carbohydrate consumption) needs to be based on a blood glucose measurement.

The determination of which disqualified drivers should be reevaluated and when this should be done should be made on an individual basis considering factors such as the circumstances of the disqualifying event and changes in medication and behavior that have been implemented by the driver. When an assessment determines that the driver should be evaluated at some point in the future, the driver’s physician should be consulted to determine the length of the reevaluation period. A driver with diabetes should not be kept in an endless cycle of reevaluation if there is no longer a significantly elevated safety risk.

The determination of medical fitness to drive should be a clinical one, weighing the various factors noted above. Decisions about whether licensing restrictions are necessary to ensure safety of the traveling public are ultimately determined by the licensing agency, taking into account the clinical determination of medical fitness.

**Physician reporting**

Although the concept behind mandatory physician reporting laws is to keep roads safe by eliminating unacceptable risk from impaired driving, such laws have the unintended consequence of discouraging people with diabetes from discussing their condition frankly with a physician when there is a problem that needs correction due to fear of losing their license. Patients who are not candid with their physicians are likely to receive inferior treatment and therefore may experience complications that present a driving risk. In addition to the negative effect that mandatory reporting has on the physician-patient relationship, there is no evidence that mandatory physician reporting reduces the crash rate or improves public safety (47).

Physicians should be permitted to exercise professional judgment in deciding whether and when to report a patient to the licensing agency for review of driving privileges. States that allow physicians to make such reports should focus on whether the driver’s mental or physical condition impairs the patient’s ability to exercise safe control over a motor vehicle.
Position Statement

Reports based solely on a diagnosis of diabetes, or tied to a characterization that the driver has a condition involving lapses of consciousness, are too broad and do not adequately measure individual risk. Ultimately, reports must be left to the discretion of the physician, using professional judgment about whether the patient poses a safety risk. Further, in order to protect the physician-patient relationship and ensure the open and honest communication that ultimately promotes safety, it is important that physicians be immunized from liability, both for making reports and not making reports.

Patient education and clinical interventions

It is important that health care professionals be knowledgeable and take the lead in discussing risk reduction for their patients at risk for disruptive hypoglycemia. This starts with health care professionals being conversant with safe practices, particularly for those patients at increased risk for diabetes-related incidents. Perhaps the most important aspect of encouraging people with diabetes to be safe drivers is for health care professionals who treat diabetic drivers to provide education about driving with diabetes and potential risks associated with patients’ treatment regimens. When that regimen includes the possibility of hypoglycemia, education should include instruction on avoiding and responding to hypoglycemia, discussion about the patient’s vulnerability for driving mishaps, and ongoing learning to ensure that patients have knowledge of when it is and not safe for them to drive. For example, the risks of driving under the influence of alcohol are well known, but the delayed hypoglycemic effects of even moderate alcohol intake are not, and alcohol exacerbates the cognitive impairment associated with hypoglycemia (48). Inasmuch as hypoglycemia can be mistaken for intoxication, and both increase the risk of motor vehicle accidents, patients should be counseled to test glucose more frequently for several hours after moderate alcohol intake. When a patient has complications of diabetes, it is important for the physician to discuss with the driver the effect of those complications, if any, on driving ability.

Physicians and other health care professionals who treat people with diabetes should regularly discuss the risk of driving with low blood glucose with their patients. Clinical visits should include review of blood glucose logs and questions to the patient about symptoms associated with high or low blood glucose levels and what the patient did to treat those levels. Allowing health care professionals to exercise professional judgment about the information they learn in these patient conversations will encourage candid sharing of information and lead to improved patient health and road safety.

Clinical interventions in response to hypoglycemia vary by individual but may include strategies for the frequency and timing of blood glucose monitoring, medication dosage changes, and establishing more conservative glucose targets if there is a history of severe hypoglycemia. Certain people who have a history of severe hypoglycemia may be encouraged by their health care provider to use continuous glucose monitoring systems that enable them to detect a trend toward hypoglycemia before glucose levels fall to a level that will affect safe driving.

Of note, special care should be taken to prevent hypoglycemia while operating any vehicle in drivers with type 1 diabetes and in those with type 2 diabetes who are at risk for developing hypoglycemia. They should be instructed to always check blood glucose before getting behind the wheel and at regular intervals while driving for periods of 1 h or greater. Consideration should be given to factors that may predict a fall in blood glucose, including time of insulin administration, timing of the last meal or food ingestion, and exercise type, duration, intensity, and timing. Low blood glucose values should be treated immediately and appropriately, and the driver should not drive until blood glucose is in a safely acceptable range, usually after 30–60 min because of delayed recovery of cognitive function.

People with diabetes who are at risk for disruptive hypoglycemia should be counseled to: 1) always carry a blood glucose meter and appropriate snacks, including a quick-acting source of sugar (such as juice, nondiet soda, hard candy, or dextrose tablets) as well as snacks with complex carbohydrate, fat, and protein (e.g., cheese crackers), in their vehicle; 2) never begin an extended drive with low normal blood glucose (e.g., 70–90 mg/dL) without prophylactic carbohydrate consumption to avoid a fall in blood glucose during the drive; 3) stop the vehicle as soon as any of the symptoms of low blood glucose are experienced and measure and treat the blood glucose level; and 4) not resume driving until their blood glucose and cognition have recovered.

CONCLUSION

In summary, people with diabetes should be assessed individually, taking into account each individual’s medical history as well as the potential related risks associated with driving.

Acknowledgments—The American Diabetes Association thanks the members of the writing group for developing this statement: Daniel Lorber, MD, FACP, CDE (Chair); John Anderson, MD, Sherene Arent, JD, Daniel J. Cox, PhD, ABPP; Brian M. Frier, BSc, MD, FRCP, FRCPG; Michael A. Greene, JD; John W. Griffin, Jr., JD, Gary Gross, JD; Katie Hathaway, JD; Irl Hirsch, MD; Daniel B. Kohrmann, JD, David G. Marrero, PhD; Thomas J. Songer, PhD; and Alan L. Yatvin, JD.

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Diabetes Management in Correctional Institutions

American Diabetes Association

At any given time, over 2 million people are incarcerated in prisons and jails in the U.S. (1). It is estimated that nearly 80,000 of these inmates have diabetes, a prevalence of 4.8% (2). In addition, many more people pass through the corrections system in a given year. In 1998 alone, over 11 million people were released from prison to the community (1). The current estimated prevalence of diabetes in correctional institutions is somewhat lower than the overall U.S. prevalence of diabetes, perhaps because the incarcerated population is younger than the general population. The prevalence of diabetes and its related comorbidities and complications, however, will continue to increase in the prison population as current sentencing guidelines continue to increase the number of aging prisoners and the incidence of diabetes in young people continues to increase.

People with diabetes in correctional facilities should receive care that meets national standards. Correctional institutions have unique circumstances that need to be considered so that all standards of care may be achieved (3). Correctional institutions should have written policies and procedures for the management of diabetes and for training of medical and correctional staff in diabetes care practices. These policies must take into consideration issues such as security needs, transfer from one facility to another, and access to medical personnel and equipment, so that all appropriate levels of care are provided. Ideally, these policies should encourage or at least allow patients to self-manage their diabetes. Ultimately, diabetes management is dependent upon having access to needed medical personnel and equipment. Ongoing diabetes therapy is important in order to reduce the risk of later complications, including cardiovascular events, visual loss, renal failure, and amputation. Early identification and intervention for people with diabetes is also likely to reduce short-term risks for acute complications requiring transfer out of the facility, thus improving security.

This document provides a general set of guidelines for diabetes care in correctional institutions. It is not designed to be a diabetes management manual. More detailed information on the management of diabetes and related disorders can be found in the American Diabetes Association (ADA) Clinical Practice Recommendations, published each year in January as the first supplement to Diabetes Care, as well as the “Standards of Medical Care in Diabetes” (4) contained therein. This discussion will focus on those areas where the care of people with diabetes in correctional facilities may differ, and specific recommendations are made at the end of each section.

INTAKE MEDICAL ASSESSMENT

Reception screening

Reception screening should emphasize patient safety. In particular, rapid identification of all insulin-treated persons with diabetes is essential in order to identify those at highest risk for hypoglycemia and diabetic ketoacidosis (DKA). All insulin-treated patients should have a capillary blood glucose (CBG) determination within 1–2 h of arrival. Signs and symptoms of hypoglycemia can often be confused with intoxication or withdrawal from drugs or alcohol. Individuals with diabetes exhibiting signs and symptoms consistent with hypoglycemia, particularly altered mental status, agitation, combativeness, and diaphoresis, should have finger-stick blood glucose levels measured immediately.

Intake screening

Patients with a diagnosis of diabetes should have a complete medical history and physical examination by a licensed health care provider with prescriptive authority in a timely manner. If one is not available on site, one should be consulted by those performing reception screening. The purposes of this history and physical examination are to determine the type of diabetes, current therapy, alcohol use, and behavioral health issues, as well as to screen for the presence of diabetes-related complications. The evaluation should review the previous treatment and the past history of both glycemic control and diabetes complications. It is essential that medication and medical nutrition therapy (MNT) be continued without interruption upon entry into the correctional system, as a hiatus in either medication or appropriate nutrition may lead to either severe hypoglycemia or hyperglycemia that can rapidly progress to irreversible complications, even death.

Intake physical examination and laboratory

All potential elements of the initial medical evaluation are included in Table 7 of the ADA’s “Standards of Medical Care in Diabetes,” referred to hereafter as the “Standards of Care” (4). The essential components of the initial history and physical examination are detailed in Fig. 1. Referrals should be made immediately if the patient with diabetes is pregnant.

Recommendations

• Patients with a diagnosis of diabetes should have a complete medical history and undergo an intake physical examination by a licensed health professional in a timely manner. (E)

• Insulin-treated patients should have a CBG determination within 1–2 h of arrival. (E)

• Medications and MNT should be continued without interruption upon entry into the correctional environment. (E)

SCREENING FOR DIABETES—

Consistent with the ADA Standards of Care, patients should be evaluated for diabetes risk factors at the intake physical and at appropriate times thereafter. Those who are at high risk should be considered for blood glucose screening. If pregnant, a risk assessment for gestational diabetes

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mellitus (GDM) should be undertaken at the first prenatal visit. Patients with clinical characteristics consistent with a high risk for GDM should undergo glucose testing as soon as possible. High-risk women not found to have GDM at the initial screening and average-risk women should be tested between 24 and 28 weeks of gestation. For more detailed information on screening for both type 2 and gestational diabetes, see the ADA Position Statement "Screening for Type 2 Diabetes" (5) and the Standards of Care (4).

**MANAGEMENT PLAN**—Glycemic control is fundamental to the management of diabetes. A management plan to achieve normal or near-normal glycemia with an A1C goal of <7% should be developed for diabetes management at the time of initial medical evaluation. Goals should be individualized (4), and less stringent treatment goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, elderly adults, and individuals with co-morbid conditions (4). This plan should be documented in the patient’s record and communicated to all persons involved in his/her care, including security staff. Table 1, taken from the ADA Standards of Care, provides a summary of recommendations for setting glycemic control goals for adults with diabetes.

People with diabetes should ideally receive medical care from a physician-coordinated team. Such teams include, but are not limited to, physicians, nurses, dietitians, and mental health professionals with expertise and a special interest in diabetes. It is essential in this collaborative and integrated team approach that individuals with diabetes assume as active a role in their care as possible. Diabetes self-management education is an integral component of care. Patient self-management should be emphasized, and the plan should encourage the involvement of the patient in problem solving as much as possible.

It is helpful to house insulin-treated patients in a common unit, if this is possible, safe, and consistent with providing access to other programs at the correctional institution. Common housing not only can facilitate mealtimes and medication administration, but also potentially provides an opportunity for diabetes self-management education to be reinforced by fellow patients.

**NUTRITION AND FOOD SERVICES**—Nutrition counseling and menu planning are an integral part of the multidisciplinary approach to diabetes management in correctional facilities. A combination of education, interdisciplinary communication, and monitoring food intake aids patients in understanding their medical nutritional needs and can facilitate diabetes control during and after incarceration.

Nutrition counseling for patients with diabetes is considered an essential component of diabetes self-management. People with diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of MNT for persons with diabetes.

Educating the patient, individually or in a group setting, about how carbohydrates and food choices directly affect diabetes control is the first step in facilitating self-management. This education enables the patient to identify better food choices and understand the impact of dietary changes on glycemic control.

**Figure 1**—Essential components of the initial history and physical examination. Alb/Cr ratio, albumin-to-creatinine ratio; ALT, alanine aminotransferase; AST, aspartate aminotransferase.
**Position Statement**

**Table 1—Summary of recommendations for glycemic, blood pressure, and lipid control for most adults with diabetes**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Target Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C</td>
<td>&lt;7.0%*</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>&lt;140/80 mmHg†</td>
</tr>
<tr>
<td>Lipids</td>
<td>&lt;100 mg/dL</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>(&lt;2.6 mmol/L)†‡</td>
</tr>
</tbody>
</table>

*More or less stringent glycemic goals may be appropriate for individual patients. Goals should be individualized based on duration of diabetes, age/life expectancy, comorbid conditions, known CVD or advanced microvascular complications, hypoglycemia unawareness, individual and patient considerations.

†Based on patient characteristics and response to therapy, lower SBP targets may be appropriate. In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dL (1.8 mmol/L), using a high dose of a statin, is an option.

selections from those available in the dining hall and commissary. Such an approach is more realistic in a facility where the patient has the opportunity to make food choices.

The easiest and most cost-effective means to facilitate good outcomes in patients with diabetes is instituting a heart-healthy diet as the master menu (6). There should be consistent carbohydrate content at each meal, as well as a means to identify the carbohydrate content of each food selection. Providing carbohydrate content of food selections and/or providing education in assessing carbohydrate content enables patients to meet the requirements of their individual MNT goals. Commissaries should also help in dietary management by offering healthy choices and listing the carbohydrate content of foods.

The use of insulin or oral medications may necessitate snacks in order to avoid hypoglycemia. These snacks are a part of such patients’ medical treatment plans and should be prescribed by medical staff. Timing of meals and snacks must be coordinated with medication administration as needed to minimize the risk of hypoglycemia, as discussed more fully in the MEDICATION section of this document. For further information, see the ADA Position Statement “Nutrition Recommendations and Interventions for Diabetes” (7).

**Urgent and Emergency Issues**—All patients must have access to prompt treatment of hypo- and hyperglycemia. Correctional staff should be trained in the recognition and treatment of hypo- and hyperglycemia, and appropriate staff should be trained to administer glucagon. After such emergency care, patients should be referred for appropri-ate medical care to minimize risk of future decompensation.

Institutions should implement a policy requiring staff to notify a physician of all CBG results outside of a specified range, as determined by the treating physician (e.g., <50 or >350 mg/dL).

**Hypoglycemia**

Severe hypoglycemia in a person with diabetes may be the result of intercurrent illness, missed or inadequate medication, or corticosteroid therapy. Correctional institutions should have systems in place to identify and refer to medical staff all patients with consistently elevated blood glucose as well as intercurrent illness.

The stress of illness in those with type 1 diabetes frequently aggravates glycemic control and necessitates more frequent monitoring of blood glucose (e.g., every 4–6 h). Marked hyperglycemia requires temporary adjustment of the treatment program and, if accompanied by ketosis, interaction with the diabetes care team. Adequate fluid and caloric intake must be ensured. Nausea or vomiting accompanied with hyperglycemia may indicate DKA, a life-threatening condition that requires immediate medical care to prevent complications and death. Correctional institutions should identify patients with type 1 diabetes who are at risk for DKA, particularly those with a prior history of frequent episodes of DKA. For further information see “Hyperglycemic Crisis in Diabetes” (8).

**Hypoglycemia**

Hypoglycemia is defined as a blood glucose level <70 mg/dL. Severe hypoglyce-mia is a medical emergency defined as hypoglycemia requiring assistance of a third party and is often associated with mental status changes that may include confusion, incoherence, combativeness, somnolence, lethargy, seizures, or coma. Signs and symptoms of severe hypoglycemia can be confused with intoxication or withdrawal. Individuals with diabetes exhibiting signs and symptoms consistent with hypoglycemia, particularly altered mental status, agitation, and diaphoresis, should have their CBG levels checked immediately.

Security staff who supervise patients at risk for hypoglycemia (i.e., those on insulin or oral hypoglycemic agents) should be educated in the emergency response protocol for recognition and treatment of hypoglycemia. Every attempt should be made to document CBG before treatment. Patients must have immediate access to glucose tablets or other glucose-containing foods. Hypoglycemia can generally be treated by the patient with oral carbohydrates. If the patient cannot be relied on to keep hypoglycemia treatment on his/her person, staff members should have ready access to glucose tablets or equivalent. In general, 15–20 g oral glucose will be adequate to treat hypoglycemic events. CBG and treatment should be repeated at 15-min intervals until blood glucose levels return to normal (>70 mg/dL).

Staff should have glucagon for intramuscular injection or glucose for intravenous infusion available to treat severe hypoglycemia without requiring transport of the hypoglycemic patient to an outside facility. Any episode of severe hypoglycemia or recurrent episodes of mild to moderate hypoglycemia require reevaluation of the diabetes management plan by the medical staff. In certain cases of unexplained or recurrent severe hypoglycemia, it may be appropriate to admit the patient to the medical unit for observation and stabilization of diabetes management.

Correctional institutions should have systems in place to identify the patients at greater risk for hypoglycemia (i.e., those on insulin or sulfonylurea therapy) and to ensure the early detection and treatment of hypoglycemia. If possible, patients at greater risk of severe hypoglycemia (e.g., those with a prior episode of severe hypoglycemia) may be housed in units closer to the medical unit in order to minimize delay in treatment.

**Recommendations**

- Train correctional staff in the recognition, treatment, and appropriate referral for hypo- and hyperglycemia. (E)
- Train appropriate staff to administer glucagon. (E)
- Train staff to recognize symptoms and signs of serious metabolic decompensation, and immediately refer the patient for appropriate medical care. (E)
- Institutions should implement a policy requiring staff to notify a physician of all CBG results outside of a specified range, as determined by the treating physician (e.g., <50 or >350 mg/dL). (E)
- Identify patients with type 1 diabetes who are at high risk for DKA. (E)

**Medication**—Formularies should provide access to usual and customary S88 Diabetes Care, volume 36, Supplement 1, January 2013 care.diabetesjournals.org
oral medications and insulins necessary to treat diabetes and related conditions. While not every brand name of insulin and oral medication needs to be available, individual patient care requires access to short-, medium-, and long-acting insulins and the various classes of oral medications (e.g., insulin secretagogues, biguanides, α-glucosidase inhibitors, and thiazolidinediones) necessary for current diabetes management.

Patients at all levels of custody should have access to medication at dosing frequencies that are consistent with their treatment plan and medical direction. Feasible and consistent with security concerns, patients on multiple doses of short-acting oral medications should be placed in a “keep on person” program. In other situations, patients should be permitted to self-inject insulin when consistent with security needs. Medical department nurses should determine whether patients have the necessary skill and responsible behavior to be allowed self-administration and the degree of supervision necessary. When needed, this skill should be a part of patient education. Reasonable syringe control systems should be established.

In the past, the recommendation that regular insulin be injected 30–45 min before meals presented a significant problem when “lock downs” or other disruptions to the normal schedule of meals and medications occurred. The use of multiple-dose insulin regimens using rapid-acting analogs can decrease the disruption caused by such changes in schedule. Correctional institutions should have systems in place to ensure that rapid-acting insulin analogs and oral agents are given immediately before meals if this is part of the patient’s medical plan. It should be noted however that even modest delays in meal consumption with these agents can be associated with hypoglycemia. If consistent access to food within 10 min cannot be ensured, rapid-acting insulin analogs and oral agents are approved for administration during or immediately after meals. Should circumstances arise that delay patient access to regular meals following medication administration, policies and procedures must be implemented to ensure the patient receives appropriate nutrition to prevent hypoglycemia.

Both continuous subcutaneous insulin infusion and multiple daily insulin injection therapy (consisting of three or more injections a day) can be effective means of implementing intensive diabetes management with the goal of achieving near-normal levels of blood glucose (9). While the use of these modalities may be difficult in correctional institutions, every effort should be made to continue multiple daily insulin injection or continuous subcutaneous insulin infusion in people who were using this therapy before incarceration or to institute these therapies as indicated in order to achieve blood glucose targets.

It is essential that transport of patients from jails or prisons to off-site appointments, such as medical visits or court appearances, does not cause significant disruption in medication or meal timing. Correctional institutions and police lock-ups should implement policies and procedures to diminish the risk of hypo- and hyperglycemia by, for example, providing carry-along meals and medication for patients traveling to off-site appointments or changing the insulin regimen for that day. The availability of prefilled insulin “pens” provides an alternative for off-site insulin delivery.

Recommendations

- Formularies should provide access to usual and customary oral medications and insulins to treat diabetes and related conditions. (E)
- Patients should have access to medication at dosing frequencies that are consistent with their treatment plan and medical direction. (E)
- Correctional institutions and police lock-ups should implement policies and procedures to diminish the risk of hypo- and hyperglycemia during off-site travel (e.g., court appearances). (E)
- Foot care: Recommendations for foot care for patients with diabetes and no history of an open foot lesion are described in the ADA Standards of Care. A comprehensive foot examination is recommended annually for all patients with diabetes to identify risk factors predictive of ulcers and amputations. Persons with an insensate foot, an open foot lesion, or a history of such a lesion should be referred for evaluation by an appropriate licensed health professional (e.g., podiatrist or vascular surgeon). Special shoes should be provided as recommended by licensed health professionals to aid healing of foot lesions and to prevent development of new lesions.
- Retinopathy: Annual retinal examinations by a licensed eye care professional should be performed for all patients with diabetes, as recommended in the ADA Standards of Care. Visual changes that cannot be accounted for by acute changes in glycemic control require prompt evaluation by an eye care professional.
- Nephropathy: An annual spot urine test for determination of microalbumin-to-creatinine ratio should be performed. The use of ACE inhibitors or angiotensin receptor blockers is recommended for all patients with albuminuria. Blood pressure should be controlled to <140/80 mmHg.

Cardiac: Patients with type 2 diabetes are at a particularly high risk of coronary artery disease. Cardiovascular disease (CVD) risk factor management is of demonstrated benefit in reducing this complication in patients with diabetes. Blood pressure should be measured at every routine diabetes visit. In adult patients, test for lipid disorders at least annually and as needed to achieve goals with treatment. Use aspirin therapy (75–162 mg/day) in all adult patients with diabetes and cardiovascular risk factors or known macrovascular disease. Current national standards for adults with diabetes call for treatment of lipids to goals of LDL ≤100, HDL >40, triglycerides <150 mg/dL, and blood pressure to a level of <140/80 mmHg.

Routine Screening for and Management of Diabetes Complications—All patients with a diagnosis of diabetes should receive routine screening for diabetes-related complications, as detailed in the ADA Standards of Care (4). Interval chronic disease clinics for persons with diabetes provide an efficient mechanism to monitor patients for complications of diabetes. In this way, appropriate referrals to consultant specialists, such as optometrists/ophthalmologists, nephrologists, and cardiologists, can be made on an as-needed basis and interval laboratory testing can be done.

The following complications should be considered:

- MONITORING/TESTS OF GLYCEMIA—Monitoring of CBG is a strategy that allows caregivers and people with diabetes to evaluate diabetes management regimens. The frequency of monitoring will vary by patients’ glycemic control and diabetes regimens. Patients
with type 1 diabetes are at risk for hypoglycemia and should have their CBG monitored three or more times daily. Patients with type 2 diabetes on insulin need to monitor at least once daily and more frequently based on their medical plan. Patients treated with oral agents should have CBG monitored with sufficient frequency to facilitate the goals of glycemic control, assuming that there is a program for medical review of these data on an ongoing basis to drive changes in medications. Patients whose diabetes is poorly controlled or whose therapy is changing should have more frequent monitoring. Unexplained hyperglycemia in a patient with type 1 diabetes may suggest impending DKA, and monitoring of ketones should therefore be performed.

Glycated hemoglobin (A1C) is a measure of long-term (2- to 3-month) glycemic control. Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control) and quarterly in patients whose therapy has changed or who are not meeting glycemic goals.

Discrepancies between CBG monitoring results and A1C may indicate a hemoglobinopathy, hemolysis, or need for evaluation of CBG monitoring technique and equipment or initiation of more frequent CBG monitoring to identify when glycemic excursions are occurring and which facet of the diabetes regimen is changing.

In the correctional setting, policies and procedures need to be developed and implemented regarding CBG monitoring that address the following:

- infection control
- education of staff and patients
- proper choice of meter
- disposal of testing lancets
- quality control programs
- access to health services
- size of the blood sample
- patient performance skills
- documentation and interpretation of test results
- availability of test results for the health care provider (10)

**Recommendations**

- In the correctional setting, policies and procedures need to be developed and implemented to enable CBG monitoring to occur at the frequency necessitated by the individual patient’s glycemic control and diabetes regimen. (E)
- A1C should be checked every 3–6 months. (E)

**SELF-MANAGEMENT EDUCATION**—Self-management education is the cornerstone of treatment for all people with diabetes. The health staff must advocate for patients to participate in self-management as much as possible. Individuals with diabetes who learn self-management skills and make lifestyle changes can more effectively manage their diabetes and avoid or delay complications associated with diabetes. In the development of a diabetes self-management education program in the correctional environment, the unique circumstances of the patient should be considered while still providing, to the greatest extent possible, the elements of the “National Standards for Diabetes Self-Management Education and Support” (11). A staged approach may be used depending on the needs assessment and the length of incarceration. Table 2 sets out the major components of diabetes self-management education. Survival skills should be addressed as soon as possible; other aspects of education may be provided as part of an ongoing education program.

Ideally, self-management education is coordinated by a certified diabetes educator who works with the facility to develop policies, procedures, and protocols to ensure that nationally recognized education guidelines are implemented. The educator is also able to identify patients who need diabetes self-management education, including an assessment of the patients’ medical, social, and diabetes histories; diabetes knowledge, skills, and behaviors; and readiness to change.

**STAFF EDUCATION**—Policies and procedures should be implemented to ensure that the health care staff has adequate knowledge and skills to direct the management and education of persons with diabetes. The health care staff needs to be involved in the development of the correctional officers’ training program. The staff education program should be at a lay level. Training should be offered at least biannually, and the curriculum should cover the following:

- what diabetes is
- signs and symptoms of diabetes
- risk factors
- signs and symptoms of, and emergency response to, hypo- and hyperglycemia
- glucose monitoring
- medications
- exercise
- nutrition issues including timing of meals and access to snacks

**Recommendations**

- Include diabetes in correctional staff education programs. (E)

**ALCOHOL AND DRUGS**—Patients with diabetes who are withdrawing from drugs and alcohol need special consideration. This issue particularly affects initial police custody and jails. At an intake facility, proper identification and assessment of these patients are critical. The presence of diabetes may complicate detoxification. Patients in need of complicated detoxification should be referred to a facility equipped to deal with high-risk detoxification. Patients with diabetes should be educated in the risks involved with smoking. All inmates should be advised not to smoke. Assistance in smoking cessation should be provided as practical.

**TRANSFER AND DISCHARGE**—Patients in jails may be housed for a short period of time before being transferred or released, and it is not unusual for patients in prison to be transferred within the system several times during their incarceration. One of the many challenges that health care providers face working in the correctional system is how to best collect and communicate important health care information in a timely manner when a patient is in initial police custody, is jailed short term, or is transferred from facility to facility. The importance of this communication becomes critical when the patient has a chronic illness such as diabetes.

Transferring a patient with diabetes from one correctional facility to another requires a coordinated effort. To facilitate a thorough review of medical information and completion of a transfer summary, it is critical for custody personnel to provide medical staff with sufficient notice before movement of the patient.

Before the transfer, the health care staff should review the patient’s medical record and complete a medical transfer summary that includes the patient’s
Survival skills
- hypoglycemia
- sick day management
- medication
- monitoring
- foot care

Table 2—Major components of diabetes self-management education

<table>
<thead>
<tr>
<th>Survival skills</th>
<th>Daily management issues</th>
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<tbody>
<tr>
<td>• hypoglycemia</td>
<td>• disease process</td>
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<tr>
<td>• sick day management</td>
<td>• nutritional management</td>
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<td>• medication</td>
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<td>• foot care</td>
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<td>• acute complications</td>
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<td>• risk reduction</td>
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<td>• goal setting/problem solving</td>
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<td>• psychosocial adjustment</td>
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<td>• preconception care/pregnancy/gestational diabetes management</td>
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</table>

current health care issues. At a minimum, the summary should include the following:

- the patient’s current medication schedule and dosages
- the date and time of the last medication administration
- any recent monitoring results (e.g., CBG and A1C)
- other factors that indicate a need for immediate treatment or management at the receiving facility (e.g., recent episodes of hypoglycemia, history of severe hypoglycemia or frequent DKA, concurrent illnesses, presence of diabetes complications)
- information on scheduled treatment/appointments if the receiving facility is responsible for transporting the patient to that appointment
- name and telephone/fax number of a contact person at the transferring facility who can provide additional information, if needed

The medical transfer summary, which acts as a quick medical reference for the receiving facility, should be transferred along with the patient. To supplement the flow of information and to increase the probability that medications are correctly identified at the receiving institution, sending institutions are encouraged to provide each patient with a medication card to be carried by the patient that contains information concerning diagnoses, medication names, dosages, and frequency. Diabetes supplies, including diabetes medication, should accompany the patient.

The sending facility must be mindful of the transfer time in order to provide the patient with medication and food if needed. The transfer summary or medical record should be reviewed by a health care provider upon arrival at the receiving institution.

Planning for patients’ discharge from prisons should include instruction in the long-term complications of diabetes, the necessary lifestyle changes and examinations required to prevent these complications, and, if possible, where patients may obtain regular follow-up medical care. A quarterly meeting to educate patients with upcoming discharges about community resources can be valuable. Inviting community agencies to speak at these meetings and/or provide written materials can help strengthen the community link for patients discharging from correctional facilities.

Discharge planning for the patients with diabetes should begin 1 month before discharge. During this time, application for appropriate entitlements should be initiated. Any gaps in the patient’s knowledge of diabetes care need to be identified and addressed. It is helpful if the patient is given a directory or list of community resources and if an appointment for follow-up care with a community provider is made. A supply of medication adequate to last until the first postrelease medical appointment should be provided to the patient upon release. The patient should be provided with a written summary of his/her current health care issues, including medications and doses, recent A1C values, etc.

Recommendations
- For all interinstitutional transfers, complete a medical transfer summary to be transferred with the patient. (E)
- Diabetes supplies and medication should accompany the patient during transfer. (E)
- Begin discharge planning with adequate lead time to insure continuity of care and facilitate entry into community diabetes care. (E)

SHARING OF MEDICAL INFORMATION AND RECORDS—Practical considerations may prohibit obtaining medical records from providers who treated the patient before arrest. Intake facilities should implement policies that 1) define the circumstances under which prior medical records are obtained (e.g., for patients who have an extensive history of treatment for complications); 2) identify person(s) responsible for contacting the prior provider; and 3) establish procedures for tracking requests.

Facilities that use outside medical providers should implement policies and procedures for ensuring that key information (e.g., test results, diagnoses, physicians’ orders, appointment dates) is received from the provider and incorporated into the patient’s medical chart after each outside appointment. The procedure should include, at a minimum, a means to highlight when key information has not been received and designation of a person responsible for contacting the outside provider for this information.

All medical charts should contain CBG test results in a specified, readily accessible section and should be reviewed on a regular basis.

CHILDREN AND ADOLESCENTS WITH DIABETES—Children and adolescents with diabetes present special problems in disease management, even outside the setting of a correctional institution. Children and adolescents with diabetes should have initial and follow-up care with physicians who are experienced in their care. Confinement increases the difficulty in managing diabetes in children and adolescents, as it does in adults with diabetes. Correctional authorities also have different legal obligations for children and adolescents.

Nutrition and activity
Growing children and adolescents have greater caloric/nutritional needs than adults. The provision of an adequate amount of calories and nutrients for adolescents is critical to maintaining good nutritional status. Physical activity should be provided at the same time each day. If increased physical activity occurs, additional CBG monitoring is necessary and additional carbohydrate snacks may be required.

Position Statement
Medical management and follow-up

Children and adolescents who are incarcerated for extended periods should have follow-up visits at least every 3 months with individuals who are experienced in the care of children and adolescents with diabetes. Thyroid function tests and fasting lipid and microalbumin measurements should be performed according to recognized standards for children and adolescents (12) in order to monitor for autoimmune thyroid disease and complications and comorbidities of diabetes.

Children and adolescents with diabetes exhibiting unusual behavior should have their CBG checked at that time. Because children and adolescents are reported to have higher rates of nocturnal hypoglycemia (13), consideration should be given regarding the use of episodic overnight blood glucose monitoring in these patients. In particular, this should be considered in children and adolescents who have recently had their overnight insulin dose changed.

Pregnancy

Pregnancy in a woman with diabetes is by definition a high-risk pregnancy. Every effort should be made to ensure that treatment of the pregnant woman with diabetes meets accepted standards (14,15). It should be noted that glycemic standards are more stringent, the details of dietary management are more complex and exacting, insulin is the only antidiabetic agent approved for use in pregnancy, and a number of medications used in the management of diabetic comorbidities are known to be teratogenic and must be discontinued in the setting of pregnancy.

Summary and Key Points

People with diabetes should receive care that meets national standards. Being incarcerated does not change these standards. Patients must have access to medication and nutrition needed to manage their disease. In patients who do not meet treatment targets, medical and behavioral plans should be adjusted by health care professionals in collaboration with the prison staff. It is critical for correctional institutions to identify particularly high-risk patients in need of more intensive evaluation and therapy, including pregnant women, patients with advanced complications, a history of repeated severe hypoglycemia, or recurrent DKA.

A comprehensive, multidisciplinary approach to the care of people with diabetes can be an effective mechanism to improve overall health and delay or prevent the acute and chronic complications of this disease.

Acknowledgments

The following members of the American Diabetes Association/National Commission on Correctional Health Care Joint Working Group on Diabetes Guidelines for Correctional Institutions contributed to the revision of this document: Daniel L. Lorber, MD, FACP, CDE (chair); R. Scott Chavez, MPA, PA-C, Joanne Dorman, RN, CDE, CCHP-A; Lynda K. Fisher, MD; Stephanie Gerken, RD, CDE; Linda B. Haas, CDE, RN; Joan V. Hill, CDE, RD; David Kendall, MD; Michael Puisis, DO; Kathy Salomone, CDE, MSW, APRN; Ronald M. Shansky, MD, MPH; and Barbara Waken, RD, LD.

References

Diabetes and Employment

American Diabetes Association

As of 2010, nearly 26 million Americans have diabetes (1), most of whom are or wish to be participating members of the workforce. Diabetes usually has no impact on an individual’s ability to do a particular job, and indeed an employer may not even know that a given employee has diabetes. In 1984, the American Diabetes Association adopted the following position on employment:

Any person with diabetes, whether insulin [treated] or non-insulin [treated], should be eligible for any employment for which he/she is otherwise qualified.

Questions are sometimes raised by employers about the safety and effectiveness of individuals with diabetes in a given job. When such questions are legitimately raised, a person with diabetes should be individually assessed to determine whether or not that person can safely and effectively perform the particular duties of the job in question. This document provides a general set of guidelines for evaluating individuals with diabetes for employment, including how an assessment should be performed and what changes (accommodations) in the workplace may be needed for an individual with diabetes.

I. EVALUATING INDIVIDUALS WITH DIABETES FOR EMPLOYMENT—It was once common practice to restrict individuals with diabetes from certain jobs or classes of employment solely because of the diagnosis of diabetes or the use of insulin, without regard to an individual’s abilities or circumstances. Such “blanket bans” are medically inappropriate and ignore the many advancements in diabetes management that range from the types of medications used to the tools used to administer them and to monitor blood glucose levels.

Employment decisions should not be based on generalizations or stereotypes regarding the effects of diabetes. The impact of diabetes and its management varies widely among individuals. Therefore, a proper assessment of individual candidates for employment or current employees must take this variability into account.

In addition, federal and state laws require employers to make decisions that are based on assessment of the circumstances and capabilities of the individual with diabetes for the particular job in question (2,3). Application of blanket policies to individuals with diabetes results in people with diabetes being denied employment for which they are well qualified and fully capable of performing effectively and safely. It should be noted that, as a result of amendments to the Americans with Disabilities Act, which became effective on 1 January 2009, all persons with diabetes are considered to have a “disability” within the meaning of that law. This is because, among other reasons, diabetes constitutes a substantial limitation on endocrine system functioning—the Act was amended to extend its coverage to persons with a substantial limitation in, among other things, a major bodily function, such as the endocrine system. Therefore, persons with diabetes are protected from discrimination in employment and other areas. The amendments overturned a series of Supreme Court decisions that had severely narrowed who was covered by the law and resulted in many people with diabetes and other chronic illnesses being denied protection from discrimination.

The involvement of the diabetes health care professionals is the best qualified health professional to assume this responsibility (4). The individual’s treating physician is generally the health care professional with the best knowledge of an individual’s diabetes. Thus, even when the employer utilizes its own physician to perform the evaluation, the opinions of the treating physician and other health care professionals with clinical expertise in diabetes should be sought out and carefully considered. In situations where there is disagreement between the opinion of the employee’s treating physician and that of the employer’s physician, the evaluation should be handed over to an independent health care professional with significant clinical expertise in diabetes.

Individual assessment

A medical evaluation of an individual with diabetes may occur only in limited circumstances (3). Employers may not inquire about an individual’s health status—directly or indirectly and regardless of the type of job—before making a job offer, but may require a medical examination or make a medical inquiry once an offer of employment has been extended and before the individual begins the job.
The job offer may be conditioned on the results of the medical inquiry or examination. An employer may withdraw an offer from an applicant with diabetes only if it becomes clear that he or she cannot do the essential functions of the job or would pose a direct threat (i.e., a significant risk of substantial harm) to health or safety and such threat could not be eliminated with an accommodation (a workplace change that enables a worker with a disability to safely and effectively perform job duties). Another situation in which a medical evaluation is permissible is when a problem potentially related to the employee’s diabetes arises on the job and such problem could affect job performance and/or safety. In this situation, a physician may be asked to evaluate the employee’s fitness to remain on the job and/or his or her ability to safely perform the job.

Employers also may obtain medical information about an employee when the employee has requested an accommodation and his or her disability or need for accommodation is not obvious. An employer should not rely on a medical evaluation to deny an employment opportunity to an individual with diabetes unless it is conducted by a health care professional with expertise in diabetes and based on sufficient and appropriate medical data. The information sought and assessed must be properly limited to data relevant to the individual’s diabetes and job performance (3). The data needed will vary depending on the type of job and the reason for the evaluation, but an evaluation should never be made based on one piece of data, such as a single blood glucose result or A1C result. Since diabetes is a chronic disease in which health status and management requirements naturally change over time, it is inappropriate—and medically unnecessary—for examiners to collect all past laboratory values or information regarding office visits whether or not related to diabetes. Only medical information relevant to evaluating an individual’s current capacity for safe performance of the particular job at issue should be collected. For example, in some circumstances a review of an individual’s hypoglycemia history may be relevant to the evaluation and should be collected.

Information about the individual’s diabetes management (such as the current treatment regimen, medications, and blood glucose logs), job duties, and work environment are all relevant factors to be considered. Only health care professionals tasked with such evaluations should have access to employee medical information, and this information must be kept separate from personnel records (3).

Screening guidelines
A number of screening guidelines for evaluating individuals with diabetes in various types of high risk jobs have been developed in recent years. Examples include the American College of Occupational and Environmental Medicine’s National Consensus Guideline for the Medical Evaluation of Law Enforcement Officers, the National Fire Protection Association’s Standard on Comprehensive Occupational Medical Program for Fire Departments, the U.S. Department of Transportation’s Federal Motor Carrier Safety Administration’s Diabetes Exemption Program, and the U.S. Marshall Service and Federal Occupational Health Law Enforcement Program Diabetes Protocol.

Such guidelines and protocols can be useful tools in making decisions about individual candidates or employees if they are used in an objective way and based on the latest scientific knowledge about diabetes and its management. These protocols should be regularly reevaluated and updated to reflect changes in diabetes knowledge and evidence and should be developed and reviewed by health care professionals with significant experience in diabetes and its treatment. Individuals who do not meet the standards set forth in such protocols should be given the opportunity to demonstrate exceptional circumstances that would justify deviating from the guidelines. Such guidelines or protocols are not absolute criteria but rather the framework for a thorough individualized assessment.

Recommendations
- People with diabetes should be individually considered for employment based on the requirements of the specific job and the individual’s medical condition, treatment regimen, and medical history. (E)
- When questions arise about the medical fitness of a person with diabetes for a particular job, a health care professional with expertise in treating diabetes should perform an individualized assessment; input from the treating physician should always be included. (E)
- Employment evaluations should be based on sufficient and appropriate medical data and should never be made based solely on one piece of data. (E)
- Screening guidelines and protocols can be useful tools in making decisions about employment if they are used in an objective way and based on the latest scientific knowledge about diabetes and its management. (E)

II. EVALUATING THE SAFETY RISK OF EMPLOYEES WITH DIABETES—Employers who deny job opportunities because they perceive all people with diabetes to be a safety risk do so based on misconceptions, misinformation, or a lack of current information about diabetes. The following guidelines provide information for evaluating an individual with diabetes who works or seeks to work in what may be considered a safety-sensitive position.

Safety concerns
The first step in evaluating safety concerns is to determine whether the concerns are reasonable in light of the job duties the individual must perform. For most types of employment (such as jobs in an office, retail, or food service environment) there is no reason to believe that the individual’s diabetes will put employees or the public at risk. In other types of employment (such as jobs where the individual must carry a firearm or operate dangerous machinery) the safety concern is whether the employee will become suddenly disoriented or incapacitated. Such episodes, which are usually due to severely low blood glucose (hypoglycemia), occur only in people receiving certain treatments such as insulin or secretagogues such as sulfonylureas and even then occur infrequently. Workplace accommodations can be made that are minimal yet effective in helping the individual to manage his or her diabetes on the job and avoid severe hypoglycemia.

Hypoglycemia
Hypoglycemia is defined as a blood glucose level <70 mg/dL (4.6). It is a potential side effect of some diabetes treatments, including insulin and sulfonylureas. It can usually be effectively self-treated by ingestion of glucose (carbohydrate) and is not often associated with loss of consciousness or a seizure. Severe hypoglycemia, requiring the assistance of another person, is a medical emergency.
Symptoms of severe hypoglycemia may include confusion or, rarely, seizure or loss of consciousness (6). Most individuals with diabetes never experience an episode of severe hypoglycemia because either they are not on medication that causes it or they recognize the early warning signs and can quickly self-treat the problem by drinking or eating. Also, with self-monitoring of blood glucose levels, most people with diabetes can manage their condition in such a manner that there is minimal risk of incapacitation from hypoglycemia because mildly low glucose levels can be easily detected and treated (4,7).

A single episode of severe hypoglycemia should not per se disqualify an individual from employment. Rather, an appropriate evaluation should be undertaken by a health care professional with expertise in diabetes to determine the cause of the low blood glucose, the circumstances of the episode, whether it was an isolated incident, whether adjustment to the insulin regimen may mitigate this risk, and the likelihood of such an episode happening again. Some episodes of severe hypoglycemia can be explained and corrected with the assistance of a diabetes health care professional.

However, recurrent episodes of severe hypoglycemia may indicate that an individual may in fact not be able to safely perform a job, particularly jobs or tasks involving significant risk of harm to employees or the public, especially when these episodes cannot be explained. The person's medical history and details of any history of severe hypoglycemia should be examined closely to determine whether it is likely that such episodes will recur on the job. In all cases, job duties should be carefully examined to determine whether there are ways to minimize the risk of severe hypoglycemia (such as adjustment of the insulin regimen or providing additional breaks to check blood glucose levels).

Hyperglycemia
In contrast to hypoglycemia, high blood glucose levels (hyperglycemia) can cause long-term complications over years or decades but does not normally lead to any adverse effect on job performance. The symptoms of hyperglycemia generally develop over hours or days and do not occur suddenly. Therefore, hyperglycemia does not pose an immediate risk of sudden incapacitation. While over years or decades, high blood glucose may cause long-term complications to the nerves (neuropathy), eyes (retinopathy), kidneys (nephropathy), or heart, not all individuals with diabetes develop these long-term complications. Such complications become relevant in employment decisions only when they are established and interfere with the performance of the actual job being considered. Evaluations should not be based on speculation as to what might occur in the future. Job evaluations should take high blood glucose levels into account only if they have already caused long-term complications such as visual impairment that interfere with performance of the specific job.

Aspects of a safety assessment
When an individual with diabetes is assessed for safety risk there are several aspects that must be considered.

Blood glucose test results. A single blood glucose test result only gives information about an individual’s blood glucose level at one particular point in time. Because blood glucose levels fluctuate throughout the day (this is also true for people without diabetes), one test result is of no use in assessing the overall health of a person with diabetes. The results of a series of self-monitored blood glucose measurements over a period of time, however, can give valuable information about an individual’s diabetes health. Blood glucose records should be assessed by a health care professional with expertise in diabetes (7).

History of severe hypoglycemia. Often, a key factor in assessing employment safety and risk is documentation of incidents of severe hypoglycemia. An individual who has managed his or her diabetes over an extended period of time without experiencing severe hypoglycemia is unlikely to experience this condition in the future. Conversely, multiple incidents of severe hypoglycemia may in some situations disqualify for high-risk occupations. However, the circumstances of each incident should be examined, as some incidents can be explained due to changes in insulin dosage, illness, or other factors and thus will be unlikely to recur or have already been addressed by the individual through changes to his or her diabetes treatment regimen or education.

Hypoglycemia unawareness. Some individuals over time lose the ability to recognize the early warning signs of hypoglycemia. These individuals are at increased risk for a sudden episode of severe hypoglycemia. Some of these individuals may be able to lessen this risk with careful changes to their diabetes management regimen (for example, more frequent blood glucose testing or frequent meals).

Presence of diabetes-related complications. Chronic complications that may result from long-term diabetes involve the blood vessels and nerves. These complications may involve nerve (neuropathy), eye (retinopathy), kidney (nephropathy), and heart disease. In turn, these problems can lead to amputation, blindness or other vision problems, including vision loss, kidney failure, stroke, or heart attack. As these complications could potentially affect job performance and safety, such complications should be evaluated by a specialist in the specific area related to the complication. If complications are not present, their possible future development should not be addressed, both because of laws prohibiting such consideration and because with medical monitoring and therapies, long-term complications can now often be avoided or delayed. Thus, many people with diabetes never develop any of these complications, and those that do generally develop them over a period of years.

Inappropriate assessments
The following tools and terms do not accurately reflect the current state of diabetes treatment and should be avoided in an assessment of whether an individual with diabetes is able to safely and effectively perform a particular job.

Urine glucose tests. Urine glucose results are no longer considered to be an appropriate and accurate methodology for assessing diabetes control (8). Before the mid-1970s, urine glucose tests were the best available method of monitoring blood glucose levels. However, the urine test is not a reliable or accurate indicator of blood glucose levels and is a poor measure of the individual’s current health status. Blood glucose monitoring is a more accurate and timely means to measure glycemic control. Urine glucose tests should never be used to evaluate the employability of a person with diabetes.

A1C and estimated average glucose. Hemoglobin A1C (A1C) test results reflect average glycemia over several months and correlate with mean plasma glucose levels (4). Estimated average glucose (eAG) is directly related to A1C and also provides an individual with an estimate of average blood glucose over a period of time, but it uses the same values and units that are observed when using a
Recommendations

- Evaluating the safety risk of employees with diabetes includes determining whether the concerns are reasonable in light of the job duties the individual must perform. (E)
- Most people with diabetes can manage their condition in such a manner that there is no or minimal risk of incapacitation from hypoglycemia at work. A single episode of severe hypoglycemia should not per se disqualify an individual from employment, but an individual with recurrent episodes of severe hypoglycemia may be unable to safely perform certain jobs, especially when those episodes cannot be explained. (E)
- Hyperglycemia does not pose an immediate risk of sudden incapacitation on the job, and long-term complications are relevant in employment decisions only when they are established and interfere with the performance of the actual job being considered. (E)
- Proper safety assessments should include review of blood glucose test results, history of severe hypoglycemia, presence of hypoglycemia unawareness, and presence of diabetes-related complications and should not include urine glucose or A1C/eAG tests or be based on a general assessment of level of control. (E)

III. ACCOMMODATING EMPLOYEES WITH DIABETES—Individuals with diabetes may need certain changes or accommodations on the job in order to perform their work responsibilities effectively and safely. Federal and state laws require the provision of “reasonable accommodations” to help an employee with diabetes to perform the essential functions of the job. (3). Additional laws provide for leave for an employee to deal with his or her medical needs or those of a family member (9). Although there are some typical accommodations that many people with diabetes use, the need for accommodations must be assessed on an individualized basis (2).

Accommodating daily diabetes management needs

Many of the accommodations that employees with diabetes need on a day-to-day basis are those that allow them to manage their diabetes in the workplace as they would elsewhere. They are usually simple accommodations, can be provided without any cost to the employer, and should cause little or no disruption in the workplace. Most employers are required to provide accommodations unless those accommodations would create an undue burden (3). Some accommodations that may be needed include the following.

Testing blood glucose. Breaks may be needed to allow an individual to test blood glucose levels when needed. Such checks only take minutes to complete. Some individuals use continuous glucose monitors but will still need an opportunity to check blood glucose with a meter. Blood glucose can be checked wherever the employee is without putting other employees at risk, and employers should not limit where employees with diabetes are permitted to manage their diabetes. Some employees may prefer to have a private location for testing or other diabetes care tasks that should be provided whenever feasible.

Administering insulin. Employees may need short breaks during the workday to administer insulin when it is needed. Insulin can be safely administered wherever the employee happens to be. The employee may also need a place to store insulin and other supplies if work conditions (such as extreme temperatures) prevent the supplies from being carried on the person (10).

Food and drink. Employees may need access to food and/or beverages during the workday. This is particularly important in the event that the employee needs to quickly respond to low blood glucose levels or maintain hydration if glucose levels are high. Employees should be permitted to consume food or beverages as needed at their desk or work station (except in an extremely rare situation in which this would pose a hazard and create a safety issue, and if this is the case, an alternative site should be provided).

Leave. Employees may need leave or a flexible work schedule to accommodate medical appointments or other diabetes care needs. Occasionally, employees may need to miss work due to unanticipated events (severe hypoglycemic episode) or illness.

Work schedules. Certain types of work schedules, such as rotating or split shifts, can make it especially difficult for some individuals to manage diabetes effectively.

Accommodating complications of diabetes

In addition to accommodating the day-to-day management of diabetes in the workplace, for some individuals it is also necessary to seek modifications for long-term diabetes-related complications. Such people can remain productive employees if appropriate accommodations are implemented.

For example, an employee with diabetic retinopathy or other vision impairments may benefit from using a big screen computer or other visual aids, while an employee with nerve pain may benefit from reduced walking distances or having the ability to sit down on the job. Individuals with kidney problems may need to have flexibility to take time off work for dialysis treatment.

It is impossible to provide an exhaustive list of potential accommodations. The key message in accommodating an employee with diabetes is to ensure that
accommodations are tailored to the individual and effective in helping the individual perform his or her job. Input from health care professionals who specialize in the particular complication, or from vocational rehabilitation specialists or organizations, may help identify appropriate accommodations.

Recommendations

- Individuals with diabetes may need accommodations on the job in order to perform their work responsibilities effectively and safely; these include accommodating daily diabetes needs and, when present, the complications of diabetes. All such accommodations must be tailored to the individual and effective in helping the individual perform his or her job. (E)

CONCLUSION

Individuals with diabetes can and do serve as highly productive members of the workforce. While not every individual with diabetes will be qualified for, nor can perform, every available job, reasonable accommodations can readily be made that allow the vast majority of people with diabetes to effectively perform the vast majority of jobs. The therapies for, and effects of, diabetes vary greatly from person to person, so employers must consider each person’s capacities and needs on an individual basis. People with diabetes should always be evaluated individually with the assistance of experienced diabetes health care professionals. The requirements of the specific job and the individual’s ability to perform that job, with or without reasonable accommodations, always need to be considered.

Acknowledgments—The American Diabetes Association thanks the members of the volunteer writing group for this updated statement: John E. Anderson, MD; Michael A. Greene, JD; John W. Griffin, Jr., JD; Daniel B. Kohrman, JD; Daniel Lorber, MD, FACP, CDE; Christopher D. Saudek, MD; Desmond Schatz, MD; and Linda Siminerio, RN, PhD, CDE.

References


Diabetes is a chronic disease that affects nearly 26 million Americans (1) and is characterized by serious, costly, and often fatal complications. The total cost of diagnosed diabetes in the U.S. in 2007 was estimated to be $174 billion (2). To prevent or delay costly diabetes complications and to enable people with diabetes to lead healthy, productive lives, appropriate medical care based on current standards of practice, self-management education, and medication and supplies must be available to everyone with diabetes. This article is based on technical reviews titled “Diabetes Self-Management Education” (3) and “National Standards for Diabetes Self-Management Education Programs” (4).

The goal of medical care for people with diabetes is to optimize glycemic control and minimize complications. The Diabetes Control and Complications Trial (DCCT) demonstrated that treatment that maintains blood glucose levels near normal in type 1 diabetes delays the onset and reduces the progression of microvascular complications. The UK Prospective Diabetes Study (UKPDS) documented that optimal glycemic control can also benefit most individuals with type 2 diabetes. To achieve optimal glucose control, the person with diabetes must be able to access health care providers who have expertise in the field of diabetes. Treatment plans must also include self-management training and tools, regular and timely laboratory evaluations, medical nutrition therapy, appropriately prescribed medication(s), and regular self-monitoring of blood glucose levels. The American Diabetes Association position statement “Standards of Medical Care in Diabetes” outlines appropriate medical care for people with diabetes (5).

An integral component of diabetes care is self-management education (inpatient and/or outpatient) delivered by an interdisciplinary team. Self-management training helps people with diabetes adjust their daily regimen to improve glycemic control. Diabetes self-management education teaches individuals with diabetes to assess the interplay among medical nutrition therapy, physical activity, emotional/physical stress, and medications, and then to respond appropriately and continually to those factors to achieve and maintain optimal glucose control.

Today, self-management education is understood to be such a critical part of diabetes care that medical treatment of diabetes without systematic self-management education is regarded as inadequate. The National Standards for Diabetes Self-Management Education and Support establish specific criteria against which diabetes education programs can be measured, and a quality assurance program has been developed and subsequently revised (6).

Treatments and therapies that improve glycemic control and reduce the complications of diabetes will also significantly reduce health care costs (7,8). Numerous studies have demonstrated that self-management education leads to reductions in the costs associated with all types of diabetes. Participants in self-management education programs have been found to have decreased lower-extremity amputation rates, reduced medication costs, and fewer emergency room visits and hospitalizations.

To achieve optimal glycemic control, thus achieving long-term reduction in health care costs, individuals with diabetes must have access to the integral components of diabetes care, such as health care visits, diabetes supplies, self-management education, and diabetes medications. As such, insurers must reimburse for diabetes-related medical treatment as well as for self-management education programs that have met accepted standards, such as the American Diabetes Association’s National Standards for Diabetes Self-Management Education and Support. Furthermore, third-party payers must also reimburse for medications and supplies related to the daily care of diabetes. These same standards should also apply to organizations that purchase health care benefits for their members or employees, as well as managed care organizations that provide services to participants.

It is recognized that the use of formularies, prior authorization, competitive bidding, and related provisions (hereafter referred to as “controls”) can manage provider practices and costs to the potential benefit of payors and patients. Social Security Act Title XIX, section 1927, states that excluded medications should not have “a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcomes of such treatment of such population.” A variety of laws, regulations, and executive orders also provide guidance on the use of such controls to oversee the purchase and use of durable medical equipment (hereafter referred to as “equipment”) and single-use medical supplies (hereafter referred to as “supplies”) associated with the management of diabetes.

Certain principles should guide the creation and enforcement of controls in order to insure that they meet the comprehensive medical needs of people living with diabetes. A wide array of medications and supplies are correlated with improved glycemic outcomes and a reduction in the risk of diabetes-related complications. Because no single diabetes treatment regimen is appropriate for all people with diabetes, providers and patients should have access to a broad array of medications and supplies to develop an effective treatment modality.
However, the Association also recognizes that there may be a number of medications and/or supplies within any given class. As such, any controls should ensure that all classes of antidiabetic agents with unique mechanisms of action are available to facilitate achieving glycemic goals to reduce the risk of complications. Similar issues operate in the management of lipid disorders, hypertension, and other cardiovascular risk factors, as well as for other diabetes complications. Furthermore, any controls should ensure that all classes of equipment and supplies designed for use with such equipment are available to facilitate achieving glycemic goals to reduce the risk of complications. It is important to note that medical advances are rapidly changing the landscape of diabetes medications and supplies. To ensure that patients with diabetes have access to beneficial updates in treatment modalities, systems of controls must employ efficient mechanisms through which to introduce and approve new products.

Though it can seem appropriate for controls to restrict certain items in chronic disease management, particularly with a complex disorder such as diabetes, it should be recognized that adherence is a major barrier to achieving targets. Any controls should take into account the huge mental and physical burden that intensive disease management exerts upon patients with diabetes. Protections should ensure that patients with diabetes can readily comply with therapy in the widely variable circumstances encountered in daily life. These protections should guarantee access to an acceptable range and all classes of antidiabetic medications, equipment, and supplies. Furthermore, fair and reasonable appeals processes should ensure that diabetic patients and their medical care practitioners can obtain medications, equipment, and supplies that are not contained within existing controls.

Diabetes management needs individualization in order for patients to reach glycemic targets. Because there is diversity in the manifestations of the disease and in the impact of other medical conditions upon diabetes, it is common that practitioners will need to uniquely tailor treatment for their patients. To reach diabetes treatment goals, practitioners should have access to all classes of antidiabetic medications, equipment, and supplies without undue controls. Without appropriate safeguards, these controls could constitute an obstruction of effective care.

The value of self-management education and provision of diabetes supplies has been acknowledged by the passage of the Balanced Budget Act of 1997 (9) and by stated medical policy on both diabetes education and medical nutrition therapy.

References
National Standards for Diabetes Self-Management Education and Support

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By the most recent estimates, 18.8 million people in the U.S. have been diagnosed with diabetes and an additional 7 million are believed to be living with undiagnosed diabetes. At the same time, 79 million people are estimated to have blood glucose levels in the range of prediabetes or categories of increased risk for diabetes. Thus, more than 100 million Americans are at risk for developing the devastating complications of diabetes (1).

Diabetes self-management education (DSME) is a critical element of care for all people with diabetes and those at risk for developing the disease. It is necessary in order to prevent or delay the complications of diabetes (2–6) and has elements related to lifestyle changes that are also essential for individuals with prediabetes as part of efforts to prevent the disease (7,8).

The National Standards for Diabetes Self-Management Education are designed to define quality DSME and support and to assist diabetes educators in providing evidence-based education and self-management support. The Standards are applicable to educators in solo practice as well as those in large multicare center programs—and everyone in between. There are many good models for the provision of diabetes education and support. The Standards do not endorse any one approach, but rather seek to delineate the commonalities among effective and excellent self-management education strategies. These are the standards used in the field for recognition and accreditation. They also serve as a guide for non-accredited and nonrecognized providers and programs.

Because of the dynamic nature of health care and diabetes-related research, the Standards are reviewed and revised approximately every 5 years by key stakeholders and experts within the diabetes education community. In the fall of 2011, a Task Force was jointly convened by the American Association of Diabetes Educators (AADE) and the American Diabetes Association (ADA). Members of the Task Force included experts from the areas of public health, underserved populations including rural primary care and other rural health services, individual practices, large urban specialty practices, and urban hospitals. They also included individuals with diabetes, diabetes researchers, certified diabetes educators, registered nurses, registered dietitians, physicians, pharmacists, and a psychologist. The Task Force was charged with reviewing the current National Standards for Diabetes Self-Management Education for their appropriateness, relevance, and scientific basis and updating them based on the available evidence and expert consensus.

The Task Force made the decision to change the name of the Standards from the National Standards for Diabetes Self-Management Education to the National Standards for Diabetes Self-Management Education and Support. This name change is intended to codify the significance of ongoing support for people with diabetes and those at risk for developing the disease, particularly to encourage behavior change, the maintenance of healthy diabetes-related behaviors, and to address psychosocial concerns. Given that self-management does not stop when a patient leaves the educator’s office, self-management support must be an ongoing process.

Although the term “diabetes” is used predominantly, the Standards should also be understood to apply to the education and support of people with prediabetes. Currently, there are significant barriers to the provision of education and support to those with prediabetes. And yet, the strategies for supporting successful behavior change and the healthy behaviors recommended for people with prediabetes are largely identical to those for
individuals with diabetes. As barriers to care are overcome, providers of DSME and diabetes self-management support (DSMS), given their training and experience, are particularly well equipped to assist individuals with prediabetes in developing and maintaining behaviors that can prevent or delay the onset of diabetes.

Many people with diabetes have or are at risk for developing comorbidities, including both diabetes-related complications and conditions (e.g., heart disease, lipid abnormalities, nerve damage, hypertension, and depression) and other medical problems that may interfere with self-care (e.g., emphysema, arthritis, and alcoholism). In addition, the diagnosis, progression, and daily work of managing the disease can take a major emotional toll on people with diabetes that makes self-care even more difficult (9). The Standards encourage providers of DSME and DSMS to address the entire panorama of each participant’s clinical profile. Regular communication among the members of participant’s health care teams is essential to ensure high-quality, effective education and support for people with diabetes and prediabetes.

In the course of its work on the Standards, the Task Force identified areas in which there is currently an insufficient amount of research. In particular, there are three areas in which the Task Force recommends additional research:

1. What is the influence of organizational structure on the effectiveness of the provision of DSME and DSMS?
2. What is the impact of using a structured curriculum in DSME?
3. What training should be required for those community, lay, or peer workers without training in health or diabetes who are to participate in the provision of DSME and to provide DSMS?

Finally, the Standards emphasize that the person with diabetes is at the center of the entire diabetes education and support process. It is the individuals with diabetes who do the hard work of managing their condition, day in and day out. The educator’s role, first and foremost, is to make that work easier (10).

DEFINITIONS
DSME: The ongoing process of facilitating the knowledge, skill, and ability necessary for prediabetes and diabetes self-care. This process incorporates the needs, goals, and life experiences of the person with diabetes or prediabetes and is guided by evidence-based standards. The overall objectives of DSME are to support informed decision making, self-care behaviors, problem solving, and active collaboration with the health care team and to improve clinical outcomes, health status, and quality of life.

DSMS: Activities that assist the person with prediabetes or diabetes in implementing and sustaining the behaviors needed to manage his or her condition on an ongoing basis beyond or outside of formal self-management training. The type of support provided can be behavioral, educational, psychosocial, or clinical (11–15).

STANDARD 1
Internal structure
The providers(s) of DSME will document an organizational structure, mission statement, and goals. For those providers working within a larger organization, that organization will recognize and support quality DSME as an integral component of diabetes care.

Documentation of an organizational structure, mission statement, and goals can lead to efficient and effective provision of DSME and DSMS. In the business literature, case studies and case report investigations of successful management strategies emphasize the importance of clear goals and objectives, defined relationships and roles, and managerial support. Business and health policy experts and organizations emphasize written commitments, policies, support, and the importance of outcomes reporting to maintain ongoing support or commitment (16,17).

Documentation of an organizational structure that delineates channels of communication and represents institutional commitment to the educational entity is critical for success. According to The Joint Commission, this type of documentation is equally important for both small and large health care organizations (18). Health care and business experts overwhelmingly agree that documentation of the process of providing services is a critical factor in clear communication and provides a solid basis from which to deliver quality diabetes education. In 2010, The Joint Commission published the Disease-Specific Care Certification Manual, which outlines standards and performance measurements for chronic care programs and disease management services, including “Supporting Self-Management” (18).

STANDARD 2
External input
The provider(s) of DSME will seek ongoing input from external stakeholders and experts in order to promote program quality.

For both individual and group providers of DSME and DSMS, external input is vital to maintaining an up-to-date, effective program. Broad participation of community stakeholders, including individuals with diabetes, health professionals, and community interest groups, will increase the program’s knowledge of the local population and allow the provider to better serve the community. Often, but not always, this external input is best achieved by the establishment of a formal advisory board. The DSME and DSMS provider(s) must have a documented plan for seeking outside input and acting on it.

The goal of external input and discussion in the program planning process is to foster ideas that will enhance the quality of the DSME and/or DSMS being provided, while building bridges to key stakeholders (19). The result is effective, dynamic DSME that is patient centered, more responsive to consumer-identified needs and the needs of the community, more culturally relevant, and more appealing to consumers (17,19,20).

STANDARD 3
Access
The provider(s) of DSME will determine who to serve, how best to deliver diabetes education to that population, and what resources can provide ongoing support for that population.

Currently, the majority of people with diabetes and prediabetes do not receive any structured diabetes education (19,20). While there are many barriers to DSME, one crucial issue is access (21). Providers of DSME can help address this issue by:

- Clarifying the specific population to be served. Understanding the community, service area, or regional demographics is crucial to ensuring that as many people as possible are being reached, including those who do not frequently attend clinical appointments (9,17,22–24).
- Determining that population’s self-management education and support
needs. Different individuals, their families, and communities need different types of education and support (25). The provider(s) of DSME and DSMS needs to work to ensure that the necessary education alternatives are available (25–27). This means understanding the population’s demographic characteristics, such as ethnic/cultural background, sex, age, as well as levels of formal education, literacy, and numeracy (28–31). It may also entail identifying resources outside of the provider’s practice that can assist in the ongoing support of the participant.

- Identifying access issues and working to overcome them. It is essential to determine factors that prevent individuals with diabetes from receiving self-management education and support. The assessment process includes the identification of these barriers to access (32–34). These barriers may include the socioeconomic or cultural factors mentioned above, as well as, for example, health insurance shortfalls and the lack of encouragement from other health providers to seek diabetes education (35,36).

### STANDARD 4

**Program coordination**

A coordinator will be designated to oversee the DSME program. The coordinator will have oversight responsibility for the planning, implementation, and evaluation of education services.

Coordination is essential to ensure that quality diabetes self-management education and support is delivered through an organized, systematic process (37,38). As the field of DSME continues to evolve, the coordinator plays a pivotal role in ensuring accountability and continuity in the education program (39–41). The coordinator’s role may be viewed as that of coordinating the program (or education process) and/or as supporting the coordination of the many aspects of self-management in the continuum of diabetes and related conditions when feasible (42–49). This oversight includes designing an education program or service that helps the participant access needed resources and assists him or her in navigating the health care system (37,50–55).

The individual serving as the coordinator will have knowledge of the lifelong process of managing a chronic disease and facilitating behavior change, in addition to experience with program and/or clinical management (56–59). In some cases, particularly in solo or other small practices, the coordinator may also provide DSME and/ or DSMS.

### STANDARD 5

**Instructional staff**

One or more instructors will provide DSME and, when applicable, DSMS. At least one of the instructors responsible for designing and planning DSME and DSMS will be a registered nurse, registered dietitian, or pharmacist with training and experience pertinent to DSME, or another professional with certification in diabetes care and education, such as a CDE or BC-ADM. Other health workers can contribute to DSME and provide DSMS with appropriate training in diabetes and with supervision and support.

Historically, nurses and dietitians were the main providers of diabetes education (3,4,60–64). In recent years, the role of the diabetes educator has expanded to other disciplines, particularly pharmacists (65–67). Reviews comparing the effectiveness of different disciplines for education have not identified clear differences in the quality of services delivered by different professionals (3–5). However, the literature favors the registered nurse, registered dietitian, and pharmacist serving both as the key primary instructors for diabetes education and as members of the multidisciplinary team responsible for designing the curriculum and assisting in the delivery of DSME (1–7,68). Expert consensus supports the need for specialized diabetes and educational training beyond academic preparation for the primary instructors on the diabetes team (69–72). Professionals serving as instructors must document appropriate continuing education or comparable activities to ensure their continuing competence to serve in their instructional, training, and oversight roles (73).

Reflecting the evolving health care environment, a number of studies have endorsed a multidisciplinary team approach to diabetes care, education, and support. The disciplines that may be involved include, but are not limited to, physicians, psychologists and other mental health specialists, physical activity specialists (including physical therapists, occupational therapists, and exercise physiologists), optometrists, and podiatrists (68,74,75). More recently, health educators (e.g., Certified Health Education Specialists and Certified Medical Assistants), case managers, lay health and community workers (76–83), and peer counselors or educators (84,85) have been shown to contribute effectively as part of the DSME team and in providing DSMS. While DSME and DSMS are often provided within the framework of a collaborative and integrated team approach, it is crucial that the individual with diabetes is viewed as central to the team and that he or she takes an active role.

Certification as a diabetes educator (CDE) by the National Certification Board for Diabetes Educators (NCBDE) is one way a health professional can demonstrate mastery of a specific body of knowledge, and this certification has become an accepted credential in the diabetes community (86). An additional credential that indicates specialized training beyond basic preparation is board certification in Advanced Diabetes Management (BC-ADM) offered by the AADE, which is available for nurses, dietitians, pharmacists, physicians, and physician assistants (68,74,87).

Individuals who serve as lay health and community workers and peer counselors or educators may contribute to the provision of DSME instruction and provide DSMS if they have received training in diabetes management, the teaching of self-management skills, group facilitation, and emotional support. For these individuals, a system must be in place that ensures supervision of the services they provide by a diabetes educator or other health care professional and professional back-up to address clinical problems or questions beyond their training (88–90).

For services outside the expertise of any provider(s) of DSME and DSMS, a mechanism must be in place to ensure that the individual with diabetes is connected with appropriately trained and credentialed providers.

### STANDARD 6

**Curriculum**

A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes, will serve as the framework for the provision of DSME. The needs of the individual participant will determine which parts of the curriculum will be provided to that individual.

Individuals with prediabetes and diabetes and their families and caregivers have much to learn to become effective self-managers of their condition. DSME
can provide this education via an up-to-date, evidence-based, and flexible curricu-
ulum (8,91).

The curriculum is a coordinated set of courses and educational experiences. It also specifies learning outcomes and effective teaching strategies (92,93). The curriculum must be dynamic and reflect current evidence and practice guidelines (93–97). Recent education research endorses the inclusion of practical problem-solving approaches, collaborative care, psychosocial issues, behavior change, and strategies to sustain self-management efforts (12,13,19,74,86,98–101).

The following core topics are commonly part of the curriculum taught in comprehensive programs that have demonstrated successful outcomes (2,3,5,91,102–104):

- Describing the diabetes disease process and treatment options
- Incorporating nutritional management into lifestyle
- Incorporating physical activity into lifestyle
- Using medication(s) safely and for maximum therapeutic effectiveness
- Monitoring blood glucose and other parameters and interpreting and using the results for self-management decision making
- Preventing, detecting, and treating acute complications
- Preventing, detecting, and treating chronic complications
- Developing personal strategies to address psychosocial issues and concerns
- Developing personal strategies to promote health and behavior change

While the content areas listed above provide a solid outline for a diabetes education and support curriculum, it is crucial that the content be tailored to match each individual’s needs and be adapted as necessary for age, type of diabetes (including prediabetes and diabetics in pregnancy), cultural factors, health literacy and numeracy, and comorbidities (14,105–108). The content areas will be able to be adapted for all practice settings.

Approaches to education that are interactive and patient centered have been shown to be effective (12,13,109–112). Also crucial is the development of action-oriented behavioral goals and objectives (12–14,113). Creative, patient-centered, experience-based delivery methods—beyond the mere acquisition of knowledge—are effective for supporting informed decision making and meaningful behavior change and addressing psychosocial concerns (114,115).

**STANDARD 7**

**Individualization**

The diabetes self-management, education, and support needs of each participant will be assessed by one or more instructors. The participant and instructor(s) will then together develop an individualized education and support plan focused on behavior change.

Research has demonstrated the importance of individualizing diabetes education to each participant’s needs (116). The assessment process is used to identify what those needs are and to facilitate the selection of appropriate educational and behavioral interventions and self-management support strategies, guided by evidence (2,63,116–118). The assessment must garner information about the individual’s medical history, age, cultural influences, health beliefs and attitudes, diabetes knowledge, diabetes self-management skills and behaviors, emotional response to diabetes, readiness to learn, literacy level (including health literacy and numeracy), physical limitations, family support, and financial status (11,106,108,117,119–128). The education and support plan that the participant and instructor(s) develop will be rooted in evidence-based approaches to effective health communication and education while taking into consideration participant barriers, abilities, and expectations. The instructor will use clear health communication principles, avoiding jargon, making information culturally relevant, using language- and literacy-appropriate education materials, and using interpreter services when indicated (107,129–131). Evidence-based communication strategies such as collaborative goal setting, motivational interviewing, cognitive behavior change strategies, problem solving, self-efficacy enhancement, and relapse prevention strategies are also effective (101,132–134). Periodic reassessment can determine whether there is need for additional or different interventions and future reassessment (6,72,134–137). A variety of assessment modalities, including telephone follow-up and other information technologies (e.g., Web based, text messaging, or automated phone calls), may augment face-to-face assessments (72,87,138–141).

The assessment and education plan, intervention, and outcomes will be documented in the education/health record. Documentation of participant encounters will guide the education process, provide evidence of communication among instructional staff and other members of the participant’s health care team, prevent duplication of services, and demonstrate adherence to guidelines (117,135,142,143). Providing information to other members of the participant’s health care team through documentation of educational objectives and personal behavioral goals increases the likelihood that all the members will work in collaboration (86,143). Evidence suggests that the development of standardized procedures for documentation, training health professionals to document appropriately, and the use of structured standardized forms based on current practice guidelines can improve documentation and may ultimately improve quality of care (135,143–145).

**STANDARD 8**

**Ongoing support**

The participant and instructor(s) will together develop a personalized follow-up plan for ongoing self-management support. The participant’s outcomes and goals and the plan for ongoing self-management support will be communicated to other members of the health care team.

While DSME is necessary and effective, it does not in itself guarantee a lifetime of effective diabetes self-care (113). Initial improvements in participants’ metabolic and other outcomes have been found to diminish after approximately 6 months (3). To sustain the level of self-management needed to effectively manage prediabetes and diabetes over the long term, most participants need ongoing DSMS (15).

The type of support provided can be behavioral, educational, psychosocial, or clinical (11–14). A variety of strategies are available for providing DSMS both within and outside the DSME organization. Some patients benefit from working with a nurse case manager (6,86,146). Case management for DSMS can include reminders about needed follow-up care and tests, medication management, education, behavioral goal setting, psychosocial support, and connection to community resources.

The effectiveness of providing DSMS through disease management programs, trained peers and community health workers, community-based programs, information technology, ongoing education, support groups, and medical nutrition
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therapy has also been established (7–11,86,88–90,142,147–150).

While the primary responsibility for diabetes education belongs to the provider(s) of DSME, participants benefit by receiving reinforcement of content and behavioral goals from their entire health care team (135). Additionally, many patients receive DSMS through their primary care provider. Thus, communication among the team regarding the patient’s educational outcomes, goals, and DSMS plan is essential to ensure that people with diabetes receive support that meets their needs and is reinforced and consistent among the health care team members.

Because self-management takes place in patients’ daily lives and not in clinical or educational settings, patients will be assisted to formulate a plan to find community-based resources that may support their ongoing diabetes self-management. Ideally, DSME and DSMS providers will work with participants to identify such services and, when possible, track those that have been effective with patients, while communicating with providers of community-based resources in order to better integrate them into patients’ overall care and ongoing support.

STANDARD 9

Patient progress
The provider(s) of DSME and DSMS will monitor whether participants are achieving their personal diabetes self-management goals and other outcome(s) as a way to evaluate the effectiveness of the educational intervention(s), using appropriate measurement techniques.

Effective diabetes self-management can be a significant contributor to long-term, positive health outcomes. The provider(s) of DSME and DSMS will assess each participant’s personal self-management goals and his or her progress toward those goals (151,152).

The AANIE Outcome Standards for Diabetes Education specify behavior change as the key outcome and provide a useful framework for assessment and documentation. The AANIE7 lists seven essential factors: physical activity, healthy eating, taking medication, monitoring blood glucose, diabetes self-care-related problem solving, reducing risks of acute and chronic complications, and psychosocial aspects of living with diabetes (93,153,154). Differences in behaviors, health beliefs, and culture as well as their emotional response to diabetes can have a significant impact on how participants understand their illness and engage in self-management. DSME providers who account for these differences when collaborating with participants on the design of personalized DSME or DSMS programs can improve participant outcomes (147,148).

Assessments of participant outcomes must occur at appropriate intervals. The interval depends on the nature of the outcome itself and the time frame specified based on the participant’s personal goals. For some areas, the indicators, measures, and time frames will be based on guidelines from professional organizations or government agencies.

STANDARD 10

Quality improvement
The provider(s) of DSME will measure the effectiveness of the education and support and look for ways to improve any identified gaps in services or service quality using a systematic review of process and outcome data.

Diabetes education must be responsive to advances in knowledge, treatment strategies, education strategies, and psychosocial interventions, as well as consumer trends and the changing health care environment. By measuring and monitoring both process and outcome data on an ongoing basis, providers of DSME can identify areas of improvement and make adjustments in participant engagement strategies and program offerings accordingly.

The Institute for Healthcare Improvement suggests three fundamental questions that should be answered by an improvement process (149):

- What are we trying to accomplish?
- How will we know a change is an improvement?
- What changes can we make that will result in an improvement?

Once areas for improvement are identified, the DSME provider must designate timelines and important milestones including data collection, analysis, and presentation of results (150). Measuring both processes and outcomes helps to ensure that change is successful without causing additional problems in the system. Outcome measures indicate the result of a process (i.e., whether changes are actually leading to improvement), while process measures provide information about what caused those results (144,150). Process measures are often targeted to those processes that typically impact the most important outcomes.

Acknowledgments—No potential conflicts of interest relevant to this article were reported.

The Task Force acknowledges Paulina Duker, ADA Staff Facilitator; Leslie Kolb, AABE Staff Facilitator; Karen Fitzner, PhD, meeting facilitator (FH Consultants, Chicago, Illinois); and Sara Sklaroff for technical writing assistance.

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## Professional Practice Committee for the 2013 Clinical Practice Recommendations

Committee members disclosed the following financial or other conflicts of interest covering the period 1 November 2011–31 October 2012.

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<tr>
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<th>Employment</th>
<th>Research grant</th>
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*≥$10,000 per year from company to individual; #grant or contract is to university or other employer.
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A systematic review provides a scientific rationale for a position statement and undergoes critical peer review before submission to the Professional Practice Committee for approval. Effective January 2010, technical reports were replaced with systematic reviews, for which a priori search and inclusion/exclusion criteria are developed and published. Listed below are recent reviews.

**Macronutrients, Food Groups, and Eating Patterns in the Management of Diabetes: A Systematic Review of the Literature, 2010**

**Cost-Effectiveness of Interventions to Prevent and Control Diabetes Mellitus: A Systematic Review**
Rui Li, Ping Zhang, Lawrence E. Barker, Farah M. Chowdhury, and Xuanping Zhang
*Diabetes Care* 33:1872–1894, 2010
Effective January 2010, prior reports of the types listed below were renamed "consensus reports." Listed below are recent consensus reports.

**EXPERT COMMITTEE REPORTS**

  - *Diabetes Care* 32:1327–1334, 2009

**CONSENSUS REPORTS**

- Diabetes in Older Adults
  - M. Sue Kirkman, Vanessa Jones Briscoe, Nathaniel Clark, Hermes Florez, Linda B. Haas, Jeffrey B. Halter, Elbert S. Huang, Mary T. Korytkowski, Medha N. Munshi, Peggy Soule Odegard, Richard E. Pratley, and Carrie S. Swift
  - *Diabetes Care* 35:2650–2664, 2012

- The Charcot Foot in Diabetes
  - Lee C. Rogers, Robert G. Frykberg, David G. Armstrong, Andrew J.M. Boulton, Michael Edmonds, Georges Ha Van, Agnes Hartemann, Frances Game, William Jeffcoat, Alexandra Jirkovska, Edward Jude, Stephan Morbach, William B. Morrison, Michael Pinzur, Dario Pitocco, Lee Sanders, Dan K. Wukich, and Luigi Uccioli
  - *Diabetes Care* 34:2123–2129, 2011

- Diabetes and Cancer
  - Edward Giovannucci, David M. Harlan, Michael C. Archer, Richard M. Bergenstal, Susan M. Gapstur, Laurel A. Habel, Michael Pollak, Judith G. Regensteiner, and Douglas Yee
  - *Diabetes Care* 33:1674–1685, 2010

American Association of Clinical Endocrinologists and American Diabetes Association Consensus Statement on Inpatient Glycemic Control
- Etie S. Moghissi, Mary T. Korytkowski, Monica DiNardo, Daniel Einhorn, Richard Hellman, Irl B. Hirsch, Silvio E. Inzucchi, Faramarz Ismail-Beigi, M. Sue Kirkman, and Guillermo E. Umpierrez

Hyperglycemic Crises in Adult Patients With Diabetes
- Abbas E. Kitabchi, Guillermo E. Umpierrez, John M. Miles, and Joseph N. Fisher
  - *Diabetes Care* 32:1335–1343, 2009

How Do We Define Cure of Diabetes?
  - *Diabetes Care* 32:2133–2135, 2009

Lipoprotein Management in Patients With Cardiometabolic Risk: Consensus Statement From the American Diabetes Association and the American College of Cardiology Foundation
- John D. Brunzell, Michael Davidson, Curt D. Furberg, Ronald B. Goldberg, Barbara V. Howard, James H. Stein, and Joseph L. Witzum

Managing Preexisting Diabetes for Pregnancy: Summary of Evidence and Consensus Recommendations for Care

Influence of Race, Ethnicity, and Culture on Childhood Obesity: Implications for Prevention and Treatment: A Consensus Statement of Shaping America’s Health and the Obesity Society
- Sonia Caprio, Stephen R. Daniels, Adam Drewnowski, Francine R. Kaufman, Lawrence A. Palinkas, Arlan L. Rosenbloom, and Jeffrey B. Schwimmer

Screening for Coronary Artery Disease in Patients With Diabetes
- Jeroen J. Bax, Lawrence H. Young, Robert L. Frye, Robert O. Bonow, Helmut O. Steinberg, and Eugene J. Barrett
Position Statements

A position statement is an official point of view or belief of the ADA. Position statements are issued on scientific or medical issues related to diabetes. They may be authored or unauthored and are published in ADA journals and other scientific/publications as appropriate. Position statements must be reviewed and approved by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors. ADA position statements are typically based on a technical review or other review of published literature. They are reviewed on an annual basis and updated as needed. In addition to those published in this supplement, listed below are recent position statements.

Diabetes Management at Camps for Children With Diabetes
American Diabetes Association
Diabetes Care 35 (Suppl. 1):S72–S75, 2012

Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach. Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)
Silvio E. Inzucchi, Richard M. Bergenstal, John B. Buse, Michaela Diamant, Ele Ferrannini, Michael Nauck, Anne L. Peters, Apostolos Tsapas, Richard Wender, and David R. Matthews
Diabetes Care 35:1364–1379, 2012

Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus
David B. Sacks, Mark Arnold, George L. Bakris, David E. Bruns, Andrea Rita Horvath, M. Sue Kirkman, Ake Lernmark, Boyd E. Metzger, and David M. Nathan
Diabetes Care 34:e61–e99, 2011

Diabetes Care for Emerging Adults: Recommendations for Transition From Pediatric to Adult Diabetes Care Systems. A Position Statement of the American Diabetes Association, With Representation by the American College of Osteopathic Family Physicians, the American Academy of Pediatrics, the American Association of Clinical Endocrinologists, the American Osteopathic Association, the Centers for Disease Control and Prevention, Children with Diabetes, The Endocrine Society, the International Society for Pediatric and Adolescent Diabetes, Juvenile Diabetes Research Foundation International, the National Diabetes Education Program, and the Pediatric Endocrine Society (formerly Lawson Wilkins Pediatric Endocrine Society)
Anne Peters, Lori Laffel, and the American Diabetes Association Transitions Working Group
Diabetes Care 34:2477–2485, 2011

Michael Pignone, Mark J. Alberts, John A. Colwell, Mary Cushman, Silvio E. Inzucchi, Debabrata Mukherjee, Robert S. Rosenson, Craig D. Williams, Peter W. Wilson, and M. Sue Kirkman
Diabetes Care 33:1395–1402, 2010

Exercise and Type 2 Diabetes. The American College of Sports Medicine and the American Diabetes Association: Joint Position Statement
Sheri R. Colberg, Ronald J. Sigal, Bo Fernhall, Judith G. Regensteiner, Bryan J. Blissmer, Richard R. Rubin, Lisa Chasan-Taber, Ann L. Albright, and Barry Braun
Diabetes Care 33:e147–e167, 2010

Clinical Care Guidelines for Cystic Fibrosis–Related Diabetes: A Position Statement of the American Diabetes Association and a Clinical Practice Guideline of the Cystic Fibrosis Foundation, Endorsed by the Pediatric Endocrine Society
Antoinette Moran, Carol Brunzell, Richard C. Cohen, Marcia Katz, Bruce C. Marshall, Gary Onady, Karen A. Robinson, Kathryn A. Sabadosa, Arlene Stecenko, Bonnie Slovis, and the CFRD Guidelines Committee
Diabetes Care 33:2697–2708, 2010

Jay S. Skyler, Richard Bergenstal, Robert O. Bonow, John Buse, Prakash Deedwania, Edwin A.M. Gale, Barbara V. Howard, M. Sue Kirkman, Mikhail Kosiborod, Peter Reaven, and Robert S. Sherwin
Diabetes Care 32:187–192, 2009

Nutrition Recommendations and Interventions for Diabetes: A Position Statement of the American Diabetes Association
American Diabetes Association
Diabetes Care 31 (Suppl. 1):S61–S78, 2008
A scientific statement is a scholarly synopsis of a topic related to diabetes, which may or may not contain clinical or research recommendations. Any recommendations included represent the official point of view or belief of the ADA. Work Group Reports and Task Force Reports fall into this category. Scientific statements must be reviewed and approved by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors. Listed below are recent scientific statements.

**Nonnutritive Sweeteners: Current Use and Health Perspectives. A Scientific Statement From the American Heart Association and the American Diabetes Association**
Christopher Gardner, Judith Wylie-Rosett, Samuel S. Gidding, Lyn M. Steffen, Rachel K. Johnson, Diane Reader, and Alice H. Lichtenstein, on behalf of the American Heart Association Nutrition Committee of the Council on Nutrition, Physical Activity and Metabolism, Council on Arteriosclerosis, Thrombosis and Vascular Biology, Council on Cardiovascular Disease in the Young, and the American Diabetes Association
Diabetes Care 35:1798–1808, 2012

**Comprehensive Foot Examination and Risk Assessment: A Report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, With Endorsement by the American Association of Clinical Endocrinologists**
Andrew J.M. Boulton, David G. Armstrong, Stephen F. Albert, Robert G. Frykberg, Richard Hellman, M. Sue Kirkman, Lawrence A. Lavery, Joseph W. LeMaster, Joseph L. Mills, Sr., Michael J. Mueller, Peter Sheehan, and Dane K. Wukich
Diabetes Care 31:1679–1685, 2008

The Disaster Response Task Force
Diabetes Care 30:2395–2398, 2007